Cost-Effectiveness of Roux-en-Y Gastric Bypass in Type 2 Diabetes Patients

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Objective: To assess the cost-effectiveness of Roux-en-Y gastric bypass for treating type 2 diabetes mellitus (T2DM) in the United States compared with standard medical management, using clinical data from a prospective observational study conducted at an academic medical center.

Study Design: Our study used a predictive health economic model (the CORE Diabetes Model) to project the long-term costs and clinical effectiveness of Roux-en-Y gastric bypass as a treatment for T2DM using the prospective observational study as the basis for our clinical effectiveness assumptions.

Methods: The CORE Diabetes Model used Monte Carlo simulation with tracker variables to estimate the lifetime costs and clinical outcomes of Roux-en-Y gastric bypass compared with standard medical management of obese T2DM patients. Sensitivity analyses were performed on key clinical assumptions, discount rates, and shorter time horizons.

Results: The base-case scenario yielded an incremental cost-effectiveness ratio (ICER) of $21,973 per quality-adjusted life-year (QALY) gained. In sensitivity analyses, shortening the time horizon to 5 and 10 years and excluding the negative impact of increased body mass index on the patient's quality of life had the greatest adverse impact on the ICERs (ie, higher cost per QALY).

Conclusions: Under base-case assumptions, Roux-en-Y gastric bypass is cost-effective in the treatment of T2DM in the United States with an ICER below $50,000 per QALY gained. Sensitivity analyses indicated that bariatric surgery is not cost-effective over shorter time horizons, or if the negative quality-of-life impact of increased body mass index is ignored.

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For author information and disclosures, see end of text.

Obesity is a major independent risk factor for type 2 diabetes mellitus (T2DM), an effect thought to occur through increased insulin resistance of cells.[1] Nearly one-third of the nonpregnant adult population (age ≥20 years) in the United States is obese (defined as having a body mass index [BMI] ≥30 kg/m^2),[2] and about one-quarter of obese persons have T2DM.[3] Conversely, about 8% of the US population has T2DM,[4] and more than half of the patients with diabetes (both type 1 and type 2) are obese.[5] Together, these 2 conditions impose an enormous burden on patients, caregivers, and society as a whole. The total cost of obesity has been estimated at $155 billion, including $60 billion in direct medical costs (adjusted to 2007 price levels from an estimate for 1998)[6] and $95 billion in indirect costs (lost productivity, again adjusted to 2007 price levels from an estimate for 1995).[7] Similarly, the total cost of T2DM in 2007 was an estimated $174 billion, including $116 billion in direct medical costs and $58 billion in indirect costs.[4]

In recent years, bariatric surgery—mainly gastric bypass, usually the Roux-en-Y type, but also adjustable gastric banding, and vertical banded gastroplasty—has increasingly become recognized as a highly effective alternative for achieving major weight reduction for obese patients.[8,9] Moreover, recent studies have demonstrated that patients with diabetes who have undergone bariatric surgery also experienced major reductions in blood glucose levels, some sufficient to suggest remission of diabetes mellitus.[8-10] However, bariatric surgery is not without its own risks, including some potentially serious complications,[11] and the procedure itself is expensive[12]; consequently, candidates for bariatric surgery must be carefully screened. Practice guidelines suggest that bariatric surgery should be considered only for patients with a BMI ≥40 kg/m^2 (35 kg/m^2 if the patient has major comorbidities such as T2DM) after failure of a 1-year course of well-conducted medical treatment.[13,14]

Previous studies have demonstrated the cost-effectiveness of bariatric surgery, but most have included nondiabetic obese patients in their study populations.[15-17] Our study used an established health economic model and prospective observational data from an academic medical center in the United States to assess the long-term cost-effectiveness and clinical outcomes

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Take-Away Points

A predictive health economic model (the CORE Diabetes Model) was used to project the long-term costs and clinical effectiveness of bariatric surgery as a treatment for type 2 diabetes mellitus.

- Our study demonstrated that compared with medical management, the Roux-en-Y gastric bypass procedure is cost-effective under very conservative assumptions for procedure costs and complication rates/costs, using procedure-related and follow-up data from the University of Minnesota.
- Results for the analysis were robust under most scenarios observed, with the exception of shorter time horizons or when the quality-of-life impact of losing weight was removed.

of bariatric surgery compared with standard medical management of T2DM.

METHODS

The CORE Diabetes Model

The CORE Diabetes Model (CDM) has been described and validated in 2 separate publications and is consistent with recently published American Diabetes Association modeling guidelines and principles.[18-20] The CDM is designed to predict the development and progression of type 1 or type 2 diabetes over long time horizons (≥5 years) using the best published clinical and epidemiologic data available. The model has a standard Markov structure, combined with Monte Carlo simulation and tracker variables, which allows for the development and progression of multiple complications within an individual patient, while at the same time overcoming the memory-free properties of basic Markov models. The CDM design includes 16 submodels that simulate diabetes-related complications and nonspecific mortality.[19] Transition probabilities and risk adjustments for the CDM were derived from published resources and have been detailed in previous reports.[19] The CDM was validated through 66 separate analyses, including both second-order and third-order validation exercises and is fully detailed elsewhere.[20]

Effectiveness of Bariatric Surgery

Data on the effectiveness of bariatric surgery were drawn from a prospective observational study conducted at an academic medical center in the United States (Minnesota cohort; unpublished data, University of Minnesota Medical Center, Minneapolis). From January 2001 through May 2007, 2223 consecutive patients underwent Roux-en-Y gastric bypass surgery, of whom 567 (25.5%) had previously been diagnosed with either T2DM or prediabetes. Several clinical end points were measured at varying times before and after surgery (minimum duration of follow-up was 11 months, maximum was 80 months). These included BMI, glycosylated hemoglobin (A1C), lipid parameters (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides), systolic blood pressure, and use of medications for diabetes (both oral and insulin), hypertension (angiotensin-converting enzyme inhibitors and angiotensin receptor blockers), and dyslipidemia (statins), as well as aspirin for prevention of cardiovascular disease (CVD). Of the 567 bariatric surgery patients with T2DM, 204 (36.0%) had complete data on all end points needed for simulation of future clinical and economic outcomes (unpublished data, University of Minnesota Medical Center). We performed additional analyses for those with follow-up data available (n = 204) compared with those Roux-en-Y gastric bypass patients without end-point follow-up data (n = 363). Compared with the patients who had follow-up data available, the patients without follow-up end-point data (n = 363) were younger (46.6 vs 50.1 years, P <.001), had higher baseline low-density lipoprotein cholesterol (107.2 vs 96.9 mg/dL, P <.001), and had a shorter preoperative duration of T2DM (72.5 vs 104.5 months, P <.001) (unpublished data, University of Minnesota Medical Center). The sex, preoperative BMI and weight, A1C, and systolic blood pressure were similar between the 2 groups of patients with T2DM or prediabetes who had Roux-en-Y gastric bypass (unpublished data, University of Minnesota Medical Center).

The Minnesota cohort demographic and baseline clinical characteristics, plus other data used in the standard "US medical management of diabetes" arm of the CDM (drawn from the literature on diabetes and obesity, as summarized elsewhere[19]), were used in both the bariatric surgery cohort and the medical management cohort (Table 1). Changes from before and after surgery on the clinical measures listed above constituted the impact of surgery in the bariatric surgery cohort (**eAppendix A** available at **www.ajmc.com**). Changes in the control cohort over time on those same measures were based on standard algorithms derived from the literature on diabetes and its complications, and summarized elsewhere.[19] For modeling purposes, we made no assumption with respect to weight gain after Roux-en-Y gastric bypass because of lack of data and assumed this value to be zero. We assumed that A1C and systolic blood pressure values would increase based on values obtained from the United Kingdom Prospective Diabetes Study (UKPDS),[19] while lipid values would increase along the same curve observed in the Framingham Heart Study.[19]

Patient Characteristics

Patients in the bariatric surgery observational study were relatively young (mean age 50.1 years, with only 11.8% over

Table 1. Baseline Characteristics of the Bariatric Surgery and Control Cohorts

Characteristic	Baseline Value	Reference
Patient demographics		
Mean age, y	50.1	Unpublished data[a]
Mean duration of diabetes, y	8.7	Unpublished data[a]
Percent male	22.1	Unpublished data[a]
Risk factors		
Body mass index, kg/m^2	48.4	Unpublished data[a]
A1C, mean %	7.7	Unpublished data[a]
Systolic blood pressure, mm Hg	137.2	Unpublished data[a]
Total cholesterol, mg/dL	176.3	Unpublished data[a]
Low-density lipoprotein cholesterol, mg/dL	96.9	Unpublished data[a]
High-density lipoprotein cholesterol, mg/dL	41.6	Unpublished data[a]
Triglycerides, mg/dL	205.9	Unpublished data[a]
Race/ethnicity, %		
Caucasian	83.5	Unpublished data[a]
African American	13.5	Unpublished data[a]
Hispanic	3.0	Unpublished data[a]
Cardiovascular disease, %		
Stroke	8.4	21
Angina pectoris	11.2	21
Myocardial infarction	15.0	21
Congestive heart failure	11.8	22
Atrial fibrillation	0.75	23
Left ventricular hypertrophy detected by electrocardiogram	4.2	24
Peripheral vascular disease	14.0	25
Renal disease, %		
Microalbuminuria	28.2	26
Gross proteinuria	7.6	26
End-stage renal disease	0.4	26
Retinopathy, %		
Background diabetic retinopathy	39.0	21
Proliferative diabetic retinopathy	3.0	21
Other complications, %		
Peripheral neuropathy	40.0	27
Foot ulcer	10.5	28
Amputation	2.6	28
Cataract	14.0	21
Macular edema	4.0	21
Severe vision loss	2.2	21
Patient management of type 2 diabetes, %		
Taking oral antidiabetic medications	81.9	Unpublished data[a]
Taking insulin	51.5	Unpublished data[a]
Taking aspirin	50.0	Unpublished data[a]
Taking ACEI/ARB	64.2	Unpublished data[a]
Taking statins	63.7	Unpublished data[a]
Screened for retinopathy (assumed to be treated with laser if detected)	74.0	25
Screened for renal disease (assumed to be treated with ACEI or ARB if detected)	55.0	25
Screened for foot disease	87.0	25

A1C indicates glycosylated hemoglobin; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.
[a]Unpublished data are from the University of Minnesota Medical Center, Minneapolis.

■ **Table 2.** Direct Medical Costs of Bariatric Surgery and Medical Management of Diabetes, 2007 Dollars

Description of Event or State	Cost per Event or State, $	Reference
Bariatric surgery		
Initial surgery and follow-up	24,289	30, 31
Major reoperation (early)	38,960	11, 30-32
Moderate reoperation (early)	23,851	11, 30-32
Major reoperation (late)	42,896	11, 30-32
Moderate reoperation (late)	14,736	11, 30-32
Any complication (weighted average)	14,663	See the text[a]
Type 2 diabetes mellitus complications for all		
Myocardial infarction, year of event	38,783	33
Myocardial infarction, each subsequent year	2144	33
Angina, year of onset	7694	33
Angina, each subsequent year	1987	33
Congestive heart failure, year of onset	3332	33
Congestive heart failure, each subsequent year	3332	33
Stroke, year of event	51,360	33
Stroke, each subsequent year	17,141	33
Peripheral vascular disease, onset	4878	34
End-stage renal disease	47,299	33
Retinal photocoagulation	864	33
Severe vision loss/blindness, year of onset	4186	33
Severe vision loss/blindness, subsequent years	4184	33
Cataract extraction	2751	34
Neuropathy, onset	422	33
Uninfected ulcer	2206	35
Infected ulcer	3975	35
Gangrene	7601	35
Amputation, year of event	34,468	33
Postamputation prosthesis	1239	33
Ketoacidosis event	13,892	33
Major hypoglycemic event	1234	36
Aspirin (annual)	24	32
Statin (simvastatin 10 mg/day) (annual)	982	32
Angiotensin-converting enzyme inhibitor (captopril 25 mg 3 times daily) (annual)	442	37
Screening for retinopathy	85	33
Screening for microalbuminuria	19	33
Screening for gross proteinuria	28	33
Nonstandard ulcer treatment (becaplermin gel 0.1%)	2085	38

[a]"Costs and Utilities for Bariatric Surgery and Medical Management of Diabetes" in the Methods section.

age 60 years), predominantly female (77.9%), and Caucasian (83.5%) (Table 1). On average, they had been diagnosed with T2DM or prediabetes for 104 months (8.7 years) and were followed for a mean of 27.6 months (2.3 years). Their baseline BMI scores were high (mean 48.4, with only 12.8% having a BMI <40), but their baseline scores on other key end points were not as high as those of patients in other studies of T2DM (mean A1C of 7.7%, mean systolic blood pressure of

137.2 mm Hg, and mean low-density lipoprotein cholesterol of 96.9 mg/dL).

Adverse Effects of Bariatric Surgery and Complications of Diabetes

Although some data on the incidence of various adverse effects of bariatric surgery were available in these observational data, more comprehensive data were available from previously published studies of bariatric surgery (eAppendix B available at **www.ajmc.com**).[11,29] Although the patient populations in those studies included nondiabetic obese patients, the complications of bariatric surgery may not differ substantially between diabetic and nondiabetic patients.

Costs and Utilities for Bariatric Surgery and Medical Management of Diabetes

The analysis assumed a third-party payer perspective. Direct medical costs (**Table 2**) and health-state utilities (**eAppendix C** available at **www.ajmc.com**) for estimating quality-adjusted life-years (QALYs) for events and states associated with medical management of diabetes in the CDM were drawn from T2DM studies previously detailed elsewhere.[19] The increase in overall utility for decreasing BMI associated with bariatric surgery for T2DM patients came from the Cost of Diabetes in Europe–type 2 (CODE-2) study.[39] The coefficient for each unit decrease in BMI increases the overall utility score by 0.003813 and was based on the CODE-2 study from Europe.[39]

Costs associated with bariatric surgery were derived from previously published studies,[30-32,40] as were health-state utilities associated with bariatric surgery.[41,42] In those studies, cost and utility/disutility estimates were reported separately for early onset (eg, within 30 days of surgery) and late onset (more than 30 days and up to 1 year after surgery) for each complication of bariatric surgery. However, the structure of the CDM required that a single estimate be entered for the cost and the utility of *any* such complication. Accordingly, a weighted average of the "early" estimate and the "late" estimate for the cost and utility for each complication was computed by multiplying the risk of each early and late complication (see eAppendix B)[11] by the cost estimate for each early and late complication to arrive at a single cost for any complication, and a cumulative risk for any complication. These composite estimates for each complication were then further averaged across all complications. The resulting composite estimates are detailed in Table 2 (cost) and in eAppendix C. All cost figures were inflated to 2007 dollars using the Consumer Price Index for All Urban Consumers,[43] which yields a more conservative estimate than the Medical Care component of the same index.

Time Horizon and Discounting

The model was run over a 35-year period, consistent with current guidelines, which recommend that the time horizon be sufficient to capture the development of long-range disease complications.[18,44] Costs and clinical outcomes were both discounted at 3% per annum, also in accordance with published US recommendations.[44]

Sensitivity Analyses

Exploratory simulations were run on shorter time horizons of 5 and 10 years and annual discount rates of 0% and 6%. Additional sensitivity analyses were performed on the following clinical and economic parameters: using the actual costs associated with bariatric surgery at the site that provided the clinical data on bariatric surgery, as this estimate was much lower than the published national data we used in the base case; excluding the negative impact of increased BMI on the patient's quality of life; excluding the effects of lipid parameters; weight gain[45] after bariatric surgery; reducing the effect of bariatric surgery on A1C levels by 25%; decreasing the A1C decay from 0.15% per year from UKPDS to 0.016% per year over the first 6 years and returning to the default diabetes decay rate of 0.15% per year thereafter; and decreasing the overall complication rate for bariatric surgery by 25% (from 22.6% to 16.9%) and 50% (from 22.6% to 11.3%).

Bootstrapping

A nonparametric bootstrapping technique was used to explore uncertainty in clinical and cost outcomes for the CDM simulations.[46] In summary, each transition probability used in the CDM was simulated by applying first-order Monte Carlo simulation techniques to provide a point estimate for each parameter to be used in the second-order Monte Carlo simulation technique.[19] The resampling method was then applied to each parameter estimate obtained in the first-order Monte Carlo results with costs and outcomes calculated for 1000 theoretical patients, with each patient going through the model 1000 times. The mean costs and outcomes then were calculated from these simulations. The percentages of joint distributions falling within a preconceived cost-effectiveness range were calculated and the data plotted into a scatter plot and cost-effectiveness acceptability curve. This basic procedure was performed on the base-case simulation and repeated for all sensitivity analyses.

RESULTS

Life Expectancy and Quality-Adjusted Life-Years

The base-case analysis showed that compared with medical management of T2DM, bariatric surgery improved life expec-

Table 3. Summary Results for the Base-Case Analysis[a]

35-Year Time Horizon	Mean (SD) Bariatric Surgery	Mean (SD) Medical Management	Difference
Life expectancy, y	11.536 (0.424)	10.870 (0.187)	+0.666 (0.460)
Quality-adjusted life expectancy, y	6.782 (0.479)	5.883 (0.105)	+0.899 (0.493)
Total costs (2007 dollars)	83,482 (3191)	63,722 (2296)	+19,760 (3861)
Management	9117	11,621	–2504
Cardiovascular disease	34,811	37,824	–3013
Renal	3592	4539	–947
Eye	3769	3963	–194
Ulcer/neuropathy/amputation	5915	5776	+139
Surgery	23,131	0	+23,131
Incremental cost per life-year gained (2007 dollars)	—	—	29,676
Incremental cost per QALY gained (2007 dollars)	—	—	21,973

QALY indicates quality-adjusted life-year.
[a]Costs and clinical outcomes were discounted at 3% annually.

tancy, both unadjusted and adjusted for patient quality of life (Table 3). The mean discounted life expectancy for bariatric surgery was 11.54 years, compared with 10.87 years for medical management of T2DM, representing an increase of 0.67 year. Undiscounted life expectancy for bariatric surgery was 15.94 years, compared with 14.66 years for medical management of T2DM. In terms of discounted QALYs, the mean for bariatric surgery was 6.78, compared with 5.88 for medical management of diabetes, representing an increase of 0.90 QALY.

Direct Medical Costs and Cost-Effectiveness

The survival improvements with bariatric surgery compared with standard medical management of diabetes were achieved at increased direct medical costs, but at an acceptable level of cost-effectiveness (Table 3). Mean lifetime direct medical costs for bariatric surgery were $83,482 per patient, compared with $63,722 per patient for medical management of diabetes, representing an increase of $19,760. The highest costs in both cohorts were those associated with CVD, which were higher for the medical-management cohort ($37,824) than for the bariatric surgery cohort ($34,811) and represented an 8% decrease in CVD-related costs. Indeed, costs were higher in the medical-management cohort than in the bariatric surgery cohort for all components except those associated with diabetic foot ulcer ($5776 vs $5915). The resulting overall incremental cost-effectiveness ratio (ICER) for bariatric surgery was $29,676 per life-year gained and $21,973 per QALY, well under the standard and perhaps stricter guideline for cost-effectiveness in the United States of $50,000.[44,47]

The incremental cost-effectiveness scatter plot displays the difference in mean costs plotted against the difference in mean life expectancy between bariatric surgery and standard medical management of T2DM for 1000 patients (eAppendix D available at **www.ajmc.com**). The majority of points in this scatter plot are in the upper-right quadrant, indicating that bariatric surgery was both more costly and more effective than standard medical management. When the scatter plot was converted into cost-effectiveness acceptability curves (Figure), bariatric surgery had a 74% probability of being cost-effective at or below $50,000 per life-year gained and an 84% probability of being cost-effective at or below $50,000 per QALY compared with medical management, using the base-case assumptions.

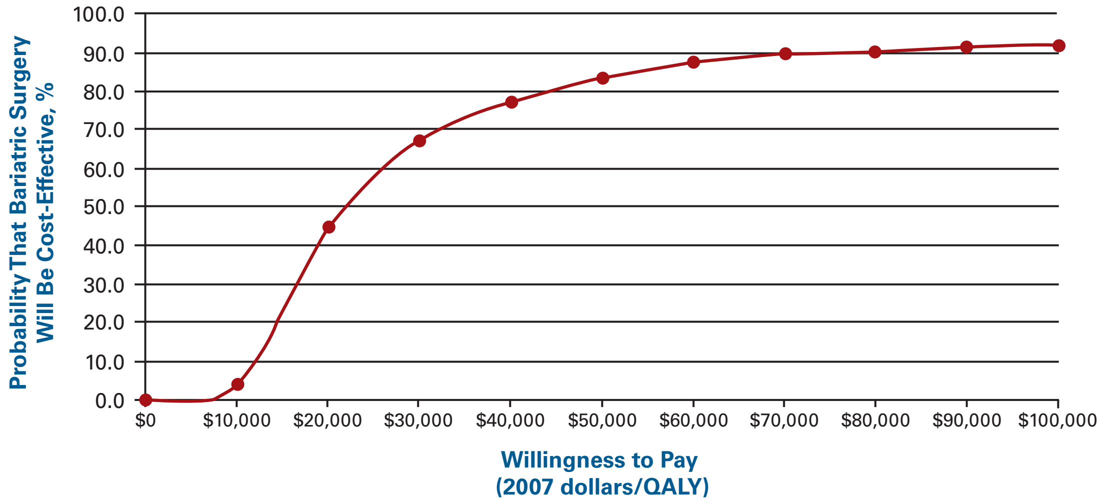
Sensitivity Analyses

Sensitivity analyses using the shorter time horizon of 10 years had the greatest impact on the cost-effectiveness of bariatric surgery compared with standard medical management of T2DM, yielding a much higher ICER of $122,001 per QALY (Table 4). Using the even shorter time horizon of 5 years resulted in a *loss* of 0.042 QALY (presumably due to the short-term effects of surgery, not yet offset by its long-term benefits), and a subsequent dominated strategy. The only other sensitivity analysis that increased the ICER above the US standard guideline[44,47] of cost-effectiveness ($50,000 per QALY) was exclusion of the negative impact of increased BMI on the patient's quality of life, yielding an ICER of $69,313 per QALY, demonstrating the sensitivity and impact of weight loss on an obese T2DM patient's overall well-being.

DISCUSSION

The results of our study suggest that bariatric surgery can

■ **Figure.** Base-Case Analysis Acceptability Curve for Bariatric Surgery Compared With Standard Medical Management for 1000 Patients With Type 2 Diabetes[a]



QALY indicates quality-adjusted life-year.
[a]The acceptability curves show how likely it is that bariatric surgery will be cost-effective for any particular willingness-to-pay level. With a willingness to pay of $50,000 per life-year or QALY gained, there is a 73.7% probability (based on life-year gained [line not shown]) or an 83.7% probability (based on QALY gained) that bariatric surgery will be cost-effective compared with medical management.

lead to positive clinical impacts on T2DM at a reasonable additional cost, relative to standard medical management. These positive clinical effects of bariatric surgery could mean a lower incidence of long-term diabetic complications, reduced long-term treatment costs, and improved QALYs for T2DM patients in the United States. These results were robust over a wide range of clinical and economic assumptions, including discount rates, reduced effects on A1C, lipid effects, and weight gain[45] after Roux-en-Y gastric bypass. The ICERs for the base-case and most sensitivity analyses fell below $50,000 per life-year gained, a level that may be considered cost-effective in the United States.[44,47] Only shorter time horizons (5 and 10 years) and exclusion of the impact of increased BMI on the patient's quality of life yielded ICERs above that level.

Limitations

The chief limitation of the study is the lack of clinical data directly comparing bariatric surgery with standard medical management of diabetes as we assumed that medically managed patients would stay at the same baseline parameters as the bariatric surgery cohort and worsen over time along standard clinical paradigms available from the literature and programmed into the CDM (eg, UKPDS). Furthermore, the clinical data on the effects of bariatric surgery on diabetes-related end points were drawn from only 1 academic medical center in the United States. The CDM utilizes data from credible sources to calculate epidemiologic risk functions. However, many of the inputs for our analysis came from the University of Minnesota triple end-point study (unpublished data, University of Minnesota Medical Center, Minneapolis), potentially limiting full generalizability. These facts may diminish the potential contribution of risk factors for which available data are currently sparse. Our analysis also excluded the potential added costs of skin reduction surgery, skin infections, and other complications because of lack of data on these outcomes and accompanying costs.

Inclusion of only those patients with complete data on all parameters needed for the model may have biased the study results in favor of the active treatment (here, bariatric surgery), similar to using only completers in clinical trials rather than all randomized or treated patients (intention to treat). In both cases, the included patients may be more likely to respond favorably to the study treatment.

The University of Minnesota triple end-point study did not collect complete information on the costs of surgical adverse events and Roux-en-Y gastric bypass surgery costs. Therefore, we utilized published literature to address this data gap. Also, Roux-en-Y gastric bypass complications and costs were assumed to occur only in the first year after surgery, consistent with the published literature.[11] Reanalysis of the University of Minnesota cohort found a crude Roux-en-Y gastric bypass complication rate of 12.7% (26/204) up to 30 days postoperatively for any complication related or not to Roux-en-Y gastric bypass, increasing to 25.0% (51/204) at 90 days, which is consistent with the published data we used for these rates (22.9% overall complication rate) in our analysis.[11]

Table 4. Sensitivity Analyses

Altered Parameter	Mean (SD) QALYs Gained	Mean (SD) Incremental Cost (2007 dollars)	Incremental Cost per QALY Gained (2007 dollars)
Base case	0.899 (0.493)	19,760 (3861)	21,973
Costs at bariatric surgery site	0.899 (0.493)	10,486 (3860)	11,660
No BMI adjustment for QALY	0.285 (0.342)	19,760 (3861)	69,313
Time horizon 5 y	−0.042 (0.096)	23,924 (1360)	Dominated
Time horizon 10 y	0.175 (0.187)	21,314 (2468)	122,001
No lipid effects	0.805 (0.474)	20,291 (3780)	25,219
BMI increased in patients over 10 y (3.322 kg/m^2 total increase divided evenly over 10 y)[44]	0.753 (0.497)	19,263 (3747)	25,588
25% less effect on A1C	0.823 (0.496)	20,064 (3924)	24,378
0.016% A1C decay rate for the first 6 y, then 0.15%/y	0.924 (0.496)	19,381 (3829)	20,968
25% decrease in complication rate for bariatric surgery	0.905 (0.497)	18,759 (3898)	20,279
50% decrease in complication rate for bariatric surgery	0.906 (0.496)	17,997 (3878)	19,858
Discount rate 0%	1.329 (0.710)	19,211 (5602)	14,452
Discount rate 6%	0.684 (0.394)	20,177 (2912)	29,515

A1C indicates glycosylated hemoglobin; BMI, body mass index; QALY, quality-adjusted life-year.

Our analysis may underestimate the cost-effectiveness of weight reduction in patients with T2DM by leaving out the positive effects of weight loss on other comorbid conditions not directly assessed by the CDM. Gilmer and colleagues[48] found that CVD, hypertension, and depression more strongly predicted future costs than reductions in A1C for adults with diabetes, suggesting that efforts to improve glycemic control, CVD, hypertension, and depression may have a more substantial financial impact on diabetes than efforts to improve only glycemic control. Our results did not include the potential ameliorating effects on depression in T2DM for patients undergoing bariatric surgery, thereby making the procedure potentially more cost-effective, as our analysis focused primarily on direct medical complications of T2DM.

Lastly and perhaps most importantly, we based all of our modeling results on continuation of a 2.3-year observational study, which in T2DM is a very short period of follow-up. Future studies designed to follow Roux-en-Y gastric bypass patients longer will help bridge the gap between what is known and our modeled outcomes.

CONCLUSIONS

This study has demonstrated that under our base-case assumptions, bariatric surgery provides good value for the money compared with standard medical management of T2DM, with an ICER of $21,973 per QALY gained. When assumptions were varied in sensitivity analyses (reduced effects on A1C, exclusion of lipid effects, lower and higher discount rates, and lower costs of treatment as observed at the medical center where bariatric surgery was performed), the ICERs remained under $50,000 per QALY in most cases. Only when the time horizon was greatly reduced and the quality-of-life impact of increased BMI was excluded did the ICERs exceed that standard guideline. These results can provide managed care formularies and other healthcare payers with important information on the economic value of bariatric surgery in treating T2DM in the United States.

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Authorship Information: Concept and design (CDK, MEM); acquisition of data (SI, TS); analysis and interpretation of data (CDK, TS, MEM); drafting of the manuscript (CDK, MEM); critical revision of the manuscript for important intellectual content (SI, CDK, TS, MEM); statistical analysis (CDK, TS, MEM); provision of study materials or patients (SI); obtaining funding (MEM); and administrative, technical, or logistic support (TS, MEM).

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