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Impact of bariatric surgery on life expectancy in severely obese patients with diabetes: A Decision analysis

Daniel P. Schauer, MD, MSc¹, David E. Arterburn, MD, MPH², Edward H. Livingston, MD³, Karen J. Coleman, Ph.D.⁴, Steve Sidney, MD, MPH⁵, David Fisher, MD⁵, Patrick O'Connor, MD, MA, MPH⁶, David Fischer, MD⁷, and Mark H. Eckman, MD, MS¹

¹Division of General Internal Medicine and Center for Clinical Effectiveness, University of Cincinnati, Cincinnati, OH

²Group Health Center for Health Studies, Seattle, WA

³Department of Gastrointestinal and Endocrine Surgery, University of Texas Southwestern School of Medicine, Dallas, TX

⁴Kaiser Permanente Southern California, Pasadena, CA

⁵Kaiser Permanente Northern California, Oakland, CA

⁶Health Partners Institute for Education and Research, Minneapolis, MN

⁷Division of General Surgery, University of Cincinnati Medical Center, Cincinnati, OH

Abstract

Objective—To create a decision analytic model to estimate the balance between treatment risks and benefits for severely obese patients with diabetes.

Summary Background Data—Bariatric surgery leads to many desirable metabolic changes, but long-term impact of bariatric surgery on life expectancy in patients with diabetes has not yet been quantified.

Methods—We developed a Markov state transition model with multiple Cox proportional hazards models and logistic regression models as inputs to compare bariatric surgery versus no surgical treatment for severely obese diabetic patients. The model is informed by data from three large cohorts: 1) 159,000 severely obese diabetic patients (4,185 had bariatric surgery) from 3 HMO Research Network sites, 2) 23,000 subjects from the Nationwide Inpatient Sample (NIS), and 3) 18,000 subjects from the National Health Interview Survey linked to the National Death Index.

Results—In our main analyses, we found that a 45 year-old female with diabetes and a BMI of 45 kg/m² gained an additional 6.7 years of life expectancy with bariatric surgery (38.4 years with surgery vs. 31.7 without). Sensitivity analyses revealed that the gain in life expectancy decreased with increasing BMI, until a BMI of 62 kg/m² is reached, at which point nonsurgical treatment

Address correspondence to: Daniel P. Schauer, M.D., M.Sc., Division of General Internal Medicine, University of Cincinnati, PO Box 670535, Cincinnati, OH 45267-0535, Phone (513) 558-2048, Fax (513) 558-2744, Daniel.Schauer@uc.edu.

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was associated with greater life expectancy. Similar results were seen for both men and women in all age groups.

Conclusions—For most severely obese patients with diabetes, bariatric surgery appears to improve life expectancy; however, surgery may reduce life expectancy for the super obese with BMIs over 62 kg/m².

Introduction

The prevalence of obesity and diabetes continue to increase in the United States^{1, 2} Obesity and diabetes are closely linked and severe obesity increases the risk of diabetes more than 7-fold³. It is well established that bariatric surgery is an effective treatment for obesity,⁴ and numerous studies have documented that bariatric surgical procedures have profound effects on glycemic control among patients with diabetes,⁵⁻¹⁴ is cost-effective in patients with diabetes,^{15, 16} and may improve survival^{17, 18}.

However, bariatric surgery is not without risk. The 30-day mortality rate following bariatric surgery has been reported to range from 0.08 to 0.22%,¹⁹ but the risk for some subgroups of patients may be much higher²⁰⁻²². In a case series of 1,067 patients having open gastric bypass, those older than 55 years of age had a 3-fold increase in perioperative mortality²².

Policy makers, patients and clinicians would benefit from a better understanding of the balance between these risks and benefits and the long-term impact of bariatric surgery on life expectancy for severely obese patients with diabetes. Our goal was to create a decision analytic model to estimate the balance between treatment risks and benefits for severely obese patients with diabetes and to generate patient-specific predictions of expected lifetime gains (or losses) in survival following surgery.

Methods

We developed a decision-analytic Markov state transition model²³ to evaluate two common treatment strategies in severely obese patients with diabetes: bariatric surgery versus nonsurgical treatment. A Markov state transition model consists of a set of specific health states that are mutually exclusive and collectively exhaustive with transition probabilities that define the probability of traveling from one state to another during each cycle. The decision model was constructed using Decision Maker® version 2010.9.1 (New Brunswick, NJ), and all other analyses were conducted using SAS version 9.3 (Cary, NC).

For our main analyses, or base cases, we used the characteristics of “average” surgical patients: a 45 year-old female with diabetes and a body mass index (BMI) of 45 kg/m² and a 45 year-old male with diabetes and a BMI of 45 kg/m². We ran the Markov model for our base cases and then reran a series of Markov models using variations in BMI, age and gender categories with three more obesity associated conditions: hypertension, coronary artery disease and congestive heart failure.

Decision Model Structure

The basic model structure is similar to a model we published previously²⁴. The model incorporates a 30-day cycle length and a lifelong time horizon. Prior to entering the Markov simulation, patients undergoing bariatric surgery face a 30-day risk of surgery-related mortality. During the first monthly cycle of the simulation, all patients enter either a post-operative state or a non-surgical severely obese state; both of these account for the presence of any obesity associated conditions. During each monthly cycle patients face a mortality risk that is based upon their BMI, surgical status, age, gender and obesity-associated health conditions. The main study outcome, life expectancy, is quantified using non-quality adjusted life years because long-term, disease specific data on changes in quality of life are not currently available for these populations.

Assumptions

Because long-term data are lacking for several aspects of our model, we made several simplifying assumptions in our base case analyses and explored the impact of these assumptions in sensitivity analyses. For subjects not receiving surgery, we assumed that BMI category does not change over time. This assumption is supported by a five-year follow-up study of severely obese patients who did not get surgery²⁵. We also assumed that the efficacy of surgery observed in the datasets was durable over time. Finally, we assumed that patients did not develop new obesity-associated conditions after the start of the model.

Model Inputs

Efficacy of Bariatric Surgery

To determine the impact of surgery on survival, we used data from three sites in the HMO Research Network: Kaiser Permanente Southern California, Kaiser Permanente Northern California, and HealthPartners in Minnesota. The Institutional Review Board at each institution approved the use of the data for this model. This dataset contains adult patients with diabetes who had bariatric surgery, 96% of which was gastric bypass, as well as non-surgical patients with diabetes and a BMI greater than 35 kg/m² obtained from the three sites between 2005 and 2008 with mortality follow-up through January 1, 2009. We excluded patients with diabetes associated with pregnancy unless they met inclusion criteria for diabetes outside of the pregnancy time period. We excluded surgical cases that were associated with gastrointestinal malignancies. The baseline date for inclusion in the cohort was the first date that patients were older than 18 years, had a BMI greater than or equal to 35 kg/m² and met at least one of our seven inclusion criteria for diabetes¹². Obesity-associated conditions were determined using ICD-9 codes identified in the year prior to baseline.

Missing BMI data in the surgical cohort (1,082 subjects) were imputed using a multiple imputation method²⁶. We explored the impact of including or not including imputation of missing BMI data in sensitivity analyses and present both results. Since the purpose of the decision model was to create a predictive model to provide estimates based on patient-specific clinical parameters, we estimated a multivariable Cox proportional hazards model in

this cohort that included age, gender, BMI, and the presence or absence of obesity associated conditions as possible predictors of survival. We included surgery as a time varying covariate and tested the assumption of constant proportional hazards over time. Interaction terms were included if significant. The survival hazard function associated with bariatric surgery was found to not be proportional over time so we allowed the hazard ratio for surgery to vary over time. Because of concerns about making direct comparisons between surgical and nonsurgical patients using all patients in our observational cohort, we also developed predictive models using a propensity score matched sample as described by Austin and colleagues²⁶. Results were qualitatively similar; however, we present both sets of results.

Bariatric Surgery Risk

To calculate in-hospital mortality risk associated with bariatric surgery, we developed a logistic regression model using data from the 2004 through 2007 Nationwide Inpatient Sample (NIS). NIS is an administrative dataset that includes in-hospital mortality but does not contain height or weight information. Cases were identified using DRG #288 and ICD-9-CM codes for bariatric surgical procedures (4431, 4438, 4439, 4468, 4389 and 4495). The final model was limited to diabetic patients and included age, gender and the presence or absence of coronary artery disease and congestive heart failure. Because in-hospital mortality has been shown to underestimate 30-day mortality by a factor of 2 to 3,²⁷ we adjusted upwards the probability of death calculated using the logistic regression model by a factor of 3.0. This factor was explored in sensitivity analyses.

Model Calibration

Since a commercially insured population of obese patients might underestimate mortality in the general population, we calibrated our model using data from the publicly available National Health Interview Survey (NHIS) linked to the National Death Index. The NHIS is a nationally representative yearly survey conducted by the National Center for Health Statistics to gauge the health of the civilian non-institutionalized U.S. population. Mortality follow-up was through December 31, 2006 and is based on a probabilistic match with each NHIS participant.

We used the NHIS dataset from 2002 to develop a multivariable logistic regression model to predict 4-year mortality based upon age, gender, BMI and obesity associated conditions. We included all subjects with a BMI > 25 kg/m². Variables that were significant at P < 0.10 in univariate models were considered for inclusion in the multivariable model and selected for the final model if they remained significant at P < 0.05. Results of this model were compared to the results of the Cox proportional hazards model that predicts mortality in the HMO Research Network dataset. The decision model was then calibrated to reflect the baseline mortality from the nationally representative NHIS data.

Sensitivity Analyses

To determine the impact of each variable on the model results, we performed standard one-way deterministic sensitivity analyses for all parameters in the model. Since the decision model includes inputs from several different data sources including mortality predictions

from regression and survival models, we conducted a probabilistic sensitivity analysis to yield distributions of outcomes as results. We used log normal distributions to describe the output from the Cox proportional hazards models and logistic regression models for specific sets of covariates²⁸. We performed 10,000 second order Monte Carlo simulations for a 45 year old female with diabetes and no other obesity associated conditions at seven different BMIs for a total of 70,000 simulations. We then calculated distributions describing gain or loss of life expectancy between bariatric surgery and no surgery to establish the 95% confidence intervals for our model predictions.

Results

Focusing initially on the HMO Research Network databases, 158,948 patients with diabetes were included in the final analysis of which 4,185 had bariatric surgery. There were significant differences between the two groups of patients (Table 1). Patients having surgery were significantly younger, had a higher BMI and had fewer obesity-associated conditions. After matching on the propensity to have bariatric surgery, the groups were very similar with BMI being the only significant difference between the two. The median follow-up time for the cohort was 2 years, with maximum follow-up time of 4 years.

The hazard ratios for the risk of death after bariatric surgery in the Cox proportional hazards model adjusted for age, gender, BMI, hypertension, coronary artery disease and congestive heart failure with imputed BMIs are presented in Figure 1. There was also a significant interaction between bariatric surgery and BMI, with patients having higher BMIs gaining smaller survival benefits. The pseudo R^2 for the model was 0.74²⁹. Sensitivity analyses comparing a cohort matched on propensity score with and without imputation yielded similar results (Figure 2).

Perioperative Mortality

In our calculations of in-hospital mortality following bariatric surgery from the NIS dataset, we included 23,186 subjects with diabetes. Overall 0.12% of patients died during their hospitalization between 2004 and 2007. Results of the logistic regression model for in-hospital mortality were adjusted to predict 30-day mortality. Discrimination and model fit were good, (Hosmer-Lemeshow goodness-of-fit p-value = 0.1073, c statistic 0.55).

Model Calibration

To calibrate the model, 18,947 subjects were included from the 2002 NHIS dataset in the calculation of the baseline mortality rate. The average age was 44.6 years and 54% of the sample was female. The final multivariable logistic regression model predicting mortality incorporated 10 terms based upon age, gender, BMI, and the presence or absence of diabetes mellitus, hypertension, coronary artery disease or congestive heart failure. Discrimination and model fit were good, (Hosmer-Lemeshow goodness-of-fit p-value = 0.4175, c statistic 0.847). It was found that the models derived from the HMORN dataset estimated lower mortality rates compared to the nationally representative NHIS dataset. For example, for a 40 year old female with a BMI of 45 kg/m² the model based on the HMORN dataset estimated a life expectancy of 37.4 years versus 32.6 years using the NHIS model.

Therefore, we adjusted the baseline mortality rates in the decision model as a function of the models from the NHIS dataset to be reflective of a nationally representative sample.

Markov Model Results

We estimated that our base case patient, a 45 year-old female with diabetes and a BMI of 45 kg/m², and no history of hypertension, coronary artery disease or congestive heart failure, would gain 6.7 additional years of life expectancy with bariatric surgery (38.4 years with surgery vs. 31.7 without surgery). Surgery was no longer favored in our base case when 30-day surgical mortality exceeded 18% (baseline risk was 0.2%). A 45 year-old female with a BMI of 45 kg/m² and hypertension, coronary artery disease and congestive heart failure would be expected to have much shorter life expectancy than a patient without these conditions but would still gain 6.7 additional years of life expectancy (22.3 years with surgery vs. 15.6 years without surgery).

For males, the results were similar. A 45 year-old male with diabetes and a BMI of 45 kg/m², and no history of hypertension, coronary artery disease or congestive heart failure, also gained an additional 6.5 years of life expectancy with bariatric surgery (33.7 years with surgery vs. 27.2 without surgery). Surgery was no longer favored when 30-day surgical mortality exceeded 18.9% (baseline risk was 0.49%). A 45 year-old male with a BMI of 45 kg/m² and hypertension, coronary artery disease and congestive heart failure would gain 5.4 years of life expectancy (17.0 years with surgery vs. 11.6 years without surgery).

Additional obesity associated conditions did not change the magnitude of the effect of surgery by much but did change the relative effect. For example, in our base case, a 45 year old female with a BMI of 45 kg/m², the absolute gain in life expectancy was 6.7 years with surgery and the relative gain was 21%. For a similar subject with hypertension, coronary artery disease and congestive heart failure, the absolute gain in life expectancy was 6.7 years with surgery but the relative gain was 43%. Bariatric surgery was the preferred strategy for all combinations of obesity associated conditions for BMI's below 60 kg/m² and no longer resulted in life expectancy gains above a threshold in the 60-65 kg/m² range. A similar pattern was observed for men.

Sensitivity Analyses

Sensitivity analyses revealed that the gain in life expectancy decreased with increasing BMI, until a BMI of 62 kg/m² was reached, at which point nonsurgical treatment was expected to yield greater life expectancy than bariatric surgery (Figure 2). Similar results were seen for both men and women in all age groups. With the addition of hypertension, coronary artery disease and congestive heart failure, the BMI threshold at which bariatric surgery was no longer favored decreased slightly.

Using models that had no imputed data did not change the results of the decision analysis. Models with no imputed data had slightly larger gains and losses in life expectancy but the BMI threshold at which bariatric surgery was no longer preferred remained 62 kg/m².

We assumed that the effect of bariatric surgery on survival would be life-long. We explored this assumption in sensitivity analyses and found that, while the magnitude of the benefit

would change with a shorter duration of benefit, the overall decision to have bariatric surgery is not impacted in most cases. For example, our base case would only gain 0.14 additional years of life expectancy if the effect of surgery was stopped at four years. The threshold for BMI at which bariatric surgery is the preferred treatment strategy decreases as the duration of benefit decreases. Similar results were seen for men and women and across all age groups.

Probabilistic sensitivity analyses provide additional insight into the impact of parameter uncertainty and enable us to calculate a distribution of expected results. These are presented in Figure 3 for a 45 year-old female with diabetes across a range of BMI values. The 95% confidence intervals start to include no change in life expectancy at BMI values above 50 kg/m².

Discussion

For most severely obese diabetic patients, bariatric surgery increases life expectancy; however, in our model, surgery results in a loss of life expectancy for those with extremely high BMIs over 60 kg/m². Changes in life expectancy are similar across ages and the presence or absence of obesity-associated conditions but depend on the baseline BMI. While there is uncertainty in the predictions, the 95% confidence intervals do not cross zero at BMI values in the range of 35 to 50 kg/m² for a 45 year old woman with diabetes and no other obesity associated conditions. At BMI's over 50 kg/m², the confidence intervals include zero, making the decision to choose bariatric surgery or no surgery less certain.

We found that the survival benefit afforded by bariatric surgery was very different in the first year compared to the following years after which it stabilized. This is likely due to the risk of complications in the first year after surgery and the time it takes to realize the benefits of weight loss and diabetes resolution. This has far reaching implications when modeling the efficacy of bariatric surgery. Other studies that have failed to find a significant reduction in mortality following bariatric surgery may have done so because they modeled the impact of bariatric surgery as a constant proportional hazard where it is assumed that the hazard ratio does not change over time³⁰. Furthermore, our sensitivity analyses examining the impact of varying assumptions for the durability of the survival benefit afforded by bariatric surgery highlight the importance that future long-term outcome studies focus on this issue.

Several other studies have looked at survival after bariatric surgery but none have focused on patients with diabetes. Adams and colleagues performed a retrospective analysis comparing patients with gastric bypass to a matched control group from the Utah Department of Motor Vehicles¹⁷. They reported that overall survival was improved following bariatric surgery and that the greatest reduction in mortality was for the subgroup of patients with a BMI greater than or equal to 45 kg/m². However, the Adams' analysis did not control for the presence of diabetes. It is likely, that patients with diabetes respond differently to bariatric surgery than patients without diabetes. The Swedish Obese Subjects study had a relatively low prevalence of diabetes and did not stratify by BMI when reporting results of their survival analysis¹⁸. A third study by Christou and colleagues demonstrated a

reduction in the relative risk of death by 89%³¹. However, this study excluded patients with preexisting diabetes and the controls were only matched on age and gender.

A previous decision analysis published by the authors of the current study reported that higher BMIs were associated with larger increases in life expectancy after bariatric surgery²⁴. While these results appear to be conflicting, the previous analysis was based upon the data published by Adams and colleagues¹⁷ and did not adjust for obesity-associated conditions including diabetes. The current results suggest that bariatric surgery potentially has a different mechanism of benefit in those with diabetes versus those without diabetes and stratifying by diabetes is important.

The declining benefit of bariatric surgery as BMI increases may have several causes. Patients with higher BMIs may have had diabetes for a longer duration and thus may be less likely to have resolution of their diabetes following bariatric surgery resulting in less potential benefit from surgery. Similarly, patients with higher BMI's are more likely to have complications after the perioperative period that potentially lead to death that are not explicitly captured in our model³⁰. Alternatively, resolution of diabetes may be dependent upon reaching a BMI threshold such that patients with a higher pre-operative BMI don't lose enough weight to drop below that threshold. Indeed, preliminary studies on diabetes resolution following bariatric surgery suggest a non-significant trend towards patients with higher BMIs being less likely to have resolution of diabetes following surgery¹².

There are several limitations to the current study. Only 2.7% of the surgical cases had a BMI greater than or equal to 60 kg/m². This resulted in wider confidence intervals and less certainty in the estimates for patients with elevated BMI's. While the model has not incorporated quality of life, adding patient-specific quality of life would likely increase the gain afforded by bariatric surgery due to resolution or improvements in obesity-related conditions. Further research needs to be done to determine the change in quality of life following bariatric surgery for severely obese patients with diabetes. Another limitation of this study is that none of the surgical patients had a BMI of less than 35. Recent evidence has demonstrated that bariatric surgery is more effective than medical management in these patients,^{13, 32} so understanding the impact of bariatric surgery on their survival is an important future research question.

There are also several limitations of the modeling process used. We did not explicitly model complications of surgery but the mortality impact of early and late complications was captured in the overall mortality estimates. The model for in-hospital mortality that utilizes the NIS data had a poor c-statistic due to few in-hospital deaths; however, as the sensitivity analyses demonstrated, in-hospital mortality had little effect on the results. There is also likely persistent observation bias in the model predictions as the propensity scores only account for bias in the observed predictors. The efficacy of surgery was assumed to be constant after the four years of follow-up available. This was explored in sensitivity analyses and found to impact only the magnitude of the gain or loss in life expectancy. Cross sectional data was used to make longitudinal predictions which is similar to the methods used to construct life tables³³. Finally, the model structure is not varied in sensitivity analyses; this may under estimate the actual variability.

For most patients with diabetes and a BMI greater than 35 kg/m², bariatric surgery increases life expectancy. However, this gain in life expectancy decreases as BMI increases and ultimately results in a net loss with extremely high BMIs at which point no surgery is the preferred strategy. However, it is possible that diabetic patients with a BMI over 60 may reap benefits from surgery which we did not model, such as improved quality of life and reduced burden of obesity associated diseases. Further research is needed to determine the mechanisms driving this interaction.

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Figure 1.

Hazard ratios for death following bariatric surgery by time interval compared with non-surgical treatment. The fully adjusted Cox proportional hazards model are the dark lines. The light gray lines are for the matched analysis. In both models, the hazard ratios are below one for lower BMIs and go up as the BMI goes up.

Figure 2.

Changes in life expectancy by BMI for 3 different age groups of patients. The benefit of gastric bypass decreases as the BMI increases for all age groups for both women and men.

Figure 3.
Probabilistic sensitivity analysis for a 45 year-old woman across a range of BMIs.

Characteristics of the cohort

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