

Decision Modeling to Estimate the Impact of Gastric Bypass Surgery on Life Expectancy for the Treatment of Morbid Obesity

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Objective: To create a decision analytic model to estimate the balance between treatment risks and benefits for patients with morbid obesity.

Design: Decision analytic Markov state transition model with multiple logistic regression models as inputs. Data from the 2005 National Inpatient Survey were used to calculate in-hospital mortality risk associated with bariatric surgery and then adjusted for 30-day mortality. To calculate excess mortality associated with obesity, we used the 1991-1996 National Health Interview Survey linked to the National Death Index. Bariatric surgery was assumed to influence mortality only through its impact on the excess mortality associated with obesity, and the efficacy of surgery was estimated from a recent large observational trial.

Intervention: Gastric bypass surgery.

Main Outcome Measure: Life expectancy.

Results: Our base case, a 42-year-old woman with a body mass index of 45, gained an additional 2.95 years of life expectancy with bariatric surgery. No surgical treatment was favored in our base case when the 30-day surgical mortality exceeded 9.5% (baseline 30-day mortality, 0.2%) or when the efficacy of bariatric surgery for reducing mortality decreased to 2% or less (baseline efficacy, 53%).

Conclusions: The optimal decision for individual patients varies based on the balance of risk between perioperative mortality, excess annual mortality risk associated with increasing body mass index, and the efficacy of surgery; however, for the average morbidly obese patient, gastric bypass improves life expectancy.

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MORBID OBESITY CONTINUES to be a growing problem in the United States, affecting 5.1% of the population,¹ with an associated increase in direct health care costs of more than \$11 billion.² Available evidence indicates that dietary, behavioral, and drug treatment options frequently fail to result in sustained, clinically meaningful weight loss in patients with morbid obesity.³⁻⁵ Given the increasing prevalence of morbid obesity and the lack of viable alternative treatments, the annual demand for bariatric surgery has increased dramatically during the past 12 years from 16 800 cases⁶ in 1992 to an estimated 205 000 cases⁷ in 2007.

While no large-scale randomized controlled trials have compared bariatric surgery with intensive medical management for the morbidly obese, there is evidence from large controlled clinical trials and numerous case series that bariatric surgery is currently the only effective therapy for promoting clinically significant weight loss and improving obesity-associated conditions

among adults with a body mass index (BMI) of 40 or higher (calculated as weight in kilograms divided by height in meters squared).⁸⁻¹² Bariatric surgery has also been shown to be cost-effective compared with nonoperative weight loss interventions.¹³

Several retrospective cohort studies and 1 prospective study suggest that bariatric surgery also improves survival.^{12,14-16} In the largest study to date, Adams and colleagues¹⁴ matched 7925 subjects who had gastric bypass with 7925 controls identified through the Bureau of Motor Vehicles in Utah. After a mean follow-up of 7.1 years, adjusted mortality had decreased by 40% in the group who underwent surgery.

However, bariatric surgery is not without risk. The 30-day mortality rate following bariatric surgery has been reported to range from 0% to 2%,^{8,17} but the risk for select subgroups of patients may be much higher.¹⁸⁻²⁰ One retrospective cohort study in 16 155 people who underwent bariatric surgery found that the mortality rate at 1 year was 4.6% and that mortality rates were greater for those aged 65 years or older compared with younger people at

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1 year.¹⁸ In a case series of 1067 patients, patients older than 55 years of age had a 3-fold increase in mortality.²⁰

While bariatric surgery has been proven to be efficacious and cost-effective in reducing obesity and obesity-associated conditions, clinical trials have not clearly identified characteristics of the ideal surgical candidate. One must consider tradeoffs between early surgical risk and long-term efficacy. Clearly, when surgical risk is low and life expectancy following surgery is long, the decision to have bariatric surgery may be straightforward. However, when the surgical risk is higher and the patient has less time to realize the benefits of weight loss, the decision to have bariatric surgery is more difficult. Morbidly obese patients considering bariatric surgery would benefit from a better understanding of the uncertainties associated with the procedure and its impact on weight loss. Therefore, our goal was to better characterize obesity-related mortality and the risks of bariatric surgery and then create a decision analytic model to estimate the balance between treatment risks and benefits for patients with morbid obesity across a variety of clinical scenarios.

METHODS

We developed a decision analytic Markov state transition model to evaluate 2 clinical strategies in morbidly obese patients: bariatric surgery vs no surgical treatment. We chose to model only gastric bypass, because it is the most common procedure for morbid obesity in the United States, accounting for more than 65% of cases.¹⁹ The decision model was constructed using Decision Maker,²¹ and all other analyses were conducted using SAS, version 9.1 (SAS Institute Inc, Cary, North Carolina).

For our base case analyses, we chose a 42-year-old woman with a BMI of 45 and a 44-year-old man with a BMI of 45, since they could be considered average morbidly obese surgical patients. We also performed analyses for a series of BMI, age, and sex categories.

DECISION MODEL STRUCTURE

The model incorporates a 30-day cycle length and a life-long time horizon. Prior to entering the Markov simulation, patients in the bariatric surgery branch face the 30-day risk of surgery-related mortality. During the first month of the simulation, all patients enter either a postoperative state or a nonsurgical morbidly obese state. During each monthly cycle, patients face a mortality risk that is based on their BMI, surgical status, age, and sex. Outcomes are evaluated using non-quality-adjusted life-years, because long-term data on changes in quality of life are not currently available for these populations.

ASSUMPTIONS

Major simplifying assumptions included assuming that bariatric surgery influences mortality only through its impact on the excess mortality associated with obesity and for the subjects not receiving surgery, that BMI category did not change over time. We explored these assumptions through sensitivity analyses.

MODEL INPUTS

Mortality Due to Obesity

Age-, sex-, and BMI-specific risk of death was calculated using 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, un-institutionalized US population. Mortality follow-up was performed through December 31, 2002, and is based on a probabilistic match with each NHIS participant.

We combined the data sets from 1991 through 1996, and the resulting data set was then weighted to be a nationally representative sample. We used this data set to develop a multivariable logistic regression model that predicts 5-year mortality based on age, sex, and BMI. Because we were most interested in fitting the model to the subset of the population that was overweight or obese, we limited the analysis to subjects with a BMI greater than 25.

The logistic regression model was used to estimate the excess mortality associated with obesity. We calculated the annual death rate for specific examples and compared them with the average weight-, age-, and sex-matched death rate to derive the excess annual mortality associated with BMI. We used a BMI of 26 as the referent, as this was the average BMI in the NHIS data set between 1991 and 1996. In the decision model, we added the excess mortality rate associated with obesity to the calculated mortality rates for an average weight population based on age and sex.

Bariatric Surgery Risk

A second logistic regression model was developed to calculate the in-hospital mortality risk associated with bariatric surgery using data from the 2005 National Inpatient Survey. The National Inpatient Survey is an administrative data set and does not contain height or weight information, so we included only age and sex as variables in the final model. Because in-hospital mortality has been shown¹⁵ to underestimate 30-day mortality by a factor of 2 to 3, we adjusted upwards the probability of death calculated using the logistic regression model by a factor of 3.0. This is a conservative estimate that biases the model against gastric bypass surgery. We explored this factor in sensitivity analyses.

Efficacy of Bariatric Surgery

To determine the impact of surgery on survival, we used a retrospective cohort study of gastric bypass with matched controls published by Adams et al.¹⁴ We calculated the efficacy of surgery from this 7-year study correcting for age and sex by calculating the average survival rate for the surgical and nonsurgical arms of the study. We then subtracted the expected survival for an age- and sex-matched cohort using life tables. Comparing the resultant differences between the surgical group and nonsurgical group yields the effect of surgery on the mortality associated with obesity.

In the model, the mortality risk reduction resulting from surgery was multiplied by the excess mortality rate associated with obesity. In this way, surgery could only impact mortality associated with obesity and not improve survival beyond that of the normal-weight population.

RESULTS

More than 399 000 subjects from the NHIS data set were included in the final calculation of excess mortality from obesity. The average age was 44.6 years, and 46% of the sample was male. The median BMI was 26. The final multivariable logistic regression model predicting mortality based on age, sex, and BMI incorporated 7 terms: BMI,

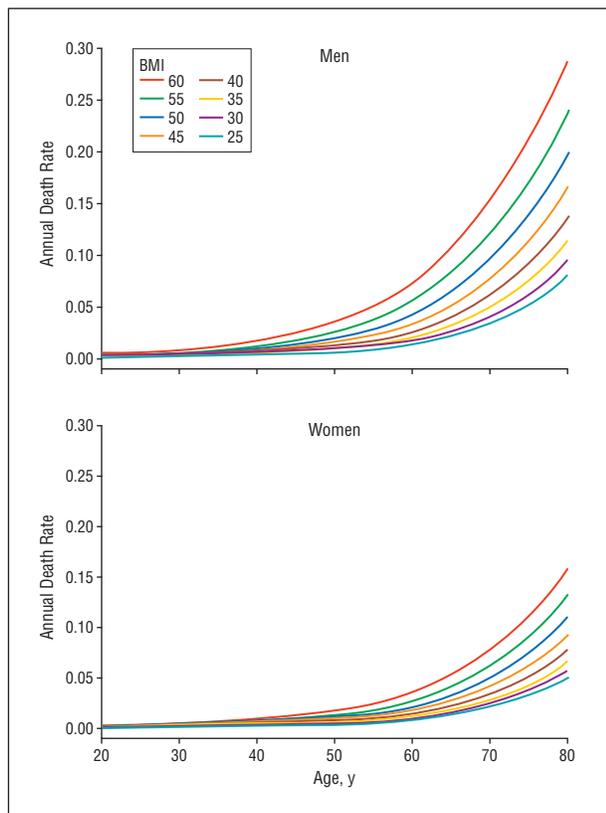


Figure 1. Annual predicted death rate by age, sex, and body mass index (BMI), calculated as weight in kilograms divided by height in meters squared.

BMI², age, age², sex, sex × BMI, and age × sex. The fit to the data was good (Hosmer-Lemeshow goodness-of-fit, $P > .05$; c statistic, 0.83). Model estimates of annual death rates, stratified by sex, are presented in **Figure 1**.

We included 23 281 subjects from the National Inpatient Survey data set to calculate in-hospital mortality of patients who underwent bariatric surgery. Overall, 0.13% of patients died during their hospitalization in 2005. The results of the logistic regression model predicting in-hospital mortality are presented in **Figure 2**, adjusted for 30-day mortality. Male patients and older patients had higher 30-day mortality from bariatric surgery.

MODEL CALIBRATION AND VALIDATION

To evaluate the model calibration, we compared predicted outcomes from our model with the control group described in the study by Adams et al.¹⁴ Because the control arm of their study is only used in the calculation of the efficacy term for the decision model and is not used in the nonsurgical arm of the decision model, using the results of the decision model in the nonsurgical arm provides an unbiased comparison. The control group in this study consisted of 7925 subjects with an average age of 39 years, 84% of whom were female. During an average follow-up of 7.1 years, 4.1% of the control group died. Using these input parameters, our model predicted that 4.16% would die at 7.1 years without gastric bypass surgery.

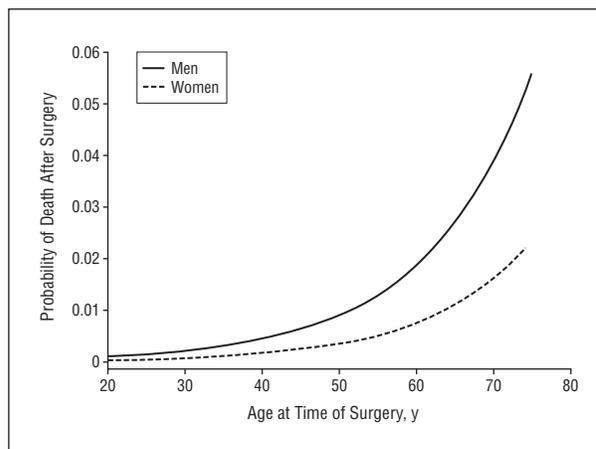


Figure 2. Thirty-day predicted probability of death after bariatric surgery for men and women by age.

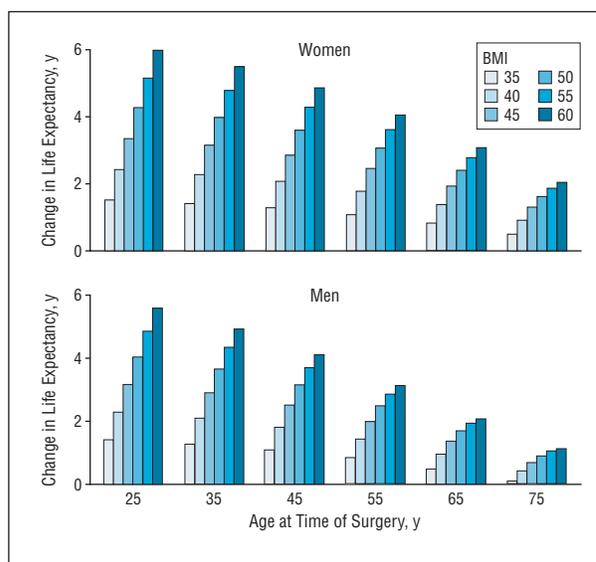


Figure 3. Change in life expectancy with bariatric surgery for men and women at different ages and body mass indexes (BMIs), calculated as weight in kilograms divided by height in meters squared.

MARKOV MODEL RESULTS

In our base case analysis for an average 42-year-old woman with a BMI of 45, bariatric surgery resulted in a gain of 2.95 years of life expectancy (35.03 vs 32.08 years). No surgical treatment was the preferred strategy in our base case when 30-day surgical mortality exceeded 9.5% (baseline 30-day mortality, 0.2%) or when the efficacy of bariatric surgery decreased to 2% or less (baseline efficacy, 53%).

Additional sensitivity analyses revealed that younger women with higher BMIs gained the most life expectancy from bariatric surgery (**Figure 3**). For women with a BMI of 45, surgery results in a gain of at least 1 year of life expectancy until age 80 years. Women with a BMI of 40 gain at least 1 year of life expectancy until age 74 years, while women with a BMI of 35 gain less than 1 year after age 60 years.

A 44-year-old man with a BMI of 45 would gain 2.57 additional years of life (26.82 vs 24.25 years). No surgical treatment was preferred when the 30-day surgical mor-

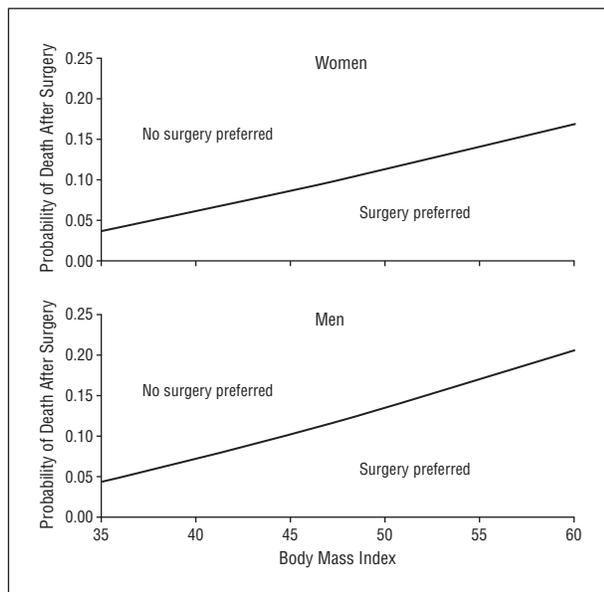


Figure 4. Two-way sensitivity analysis for 30-day probability of death after surgery for women at age 42 years and men at age 44 years. In the region to the lower right, below the line, where the probability of death is low and body mass index (calculated as weight in kilograms divided by height in meters squared) is higher, bariatric surgery is preferred. To the upper left, when the probability of death is higher and the body mass index is lower, no surgery is the preferred strategy. The line indicates the threshold between the surgery and no surgery strategies.

tality exceeded 8.6% (baseline 30-day mortality, 0.55%) or when the efficacy of bariatric surgery decreased to 3% or less (baseline efficacy, 53%).

As with women, younger men with higher BMIs gained the most life expectancy after bariatric surgery; however, the gain was slightly less for men of all ages and BMI subgroups (Figure 3). Men with a BMI of 45 gain at least 1 year of life expectancy until age 72 years. Men with a BMI of 40 gain at least 1 year of life expectancy until age 66 years, while men with a BMI of 35 gain less than 1 year after age 50 years.

Because variability in surgical mortality may be due to both institutional (eg, surgical centers) and individual patient characteristics, we examined this parameter closely. As expected, when the 30-day risk of dying from surgery is higher than average, the expected benefit of bariatric surgery is lower. However, the model is only sensitive to this parameter when the treatment decision is a close call (Figure 4).

There may be additional obesity-related comorbid conditions (eg, diabetes and hypertension) that impact survival; therefore, in any BMI category, some patients may have a higher or lower annual mortality risk. In sensitivity analyses examining this parameter, bariatric surgery becomes more attractive as the mortality of obesity-associated conditions increases. This is particularly evident in subgroups in which the benefit is small (eg, older age and lower BMI).

The efficacy of surgery may also vary across patient groups.¹⁴ Therefore, we examined the impact of changes in surgical efficacy across subgroups, including BMI and sex. Outcomes for men and older patients were more sensitive to this parameter (Figure 5).

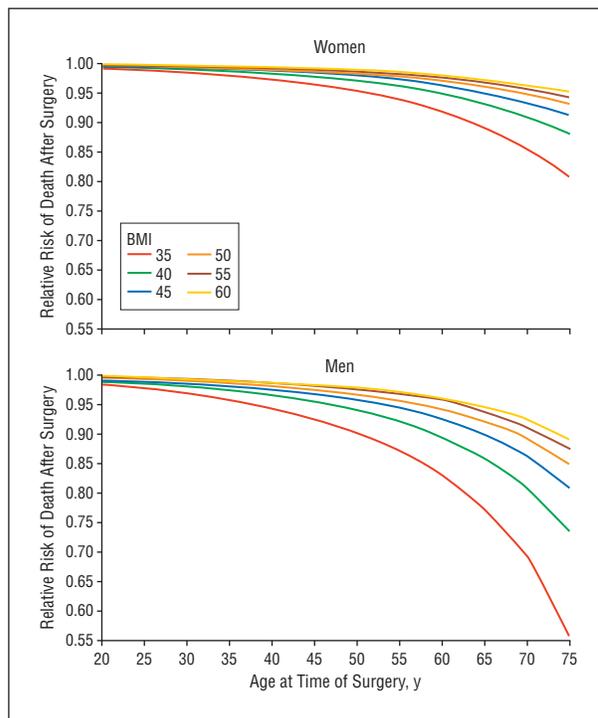


Figure 5. Three-way sensitivity analysis for the impact of surgery on the relative risk of death (1-efficacy) at varying ages and body mass indexes (BMIs), calculated as weight in kilograms divided by height in meters squared, by sex. The areas below the lines are where surgery is the preferred strategy. For higher relative risks of death (or lower efficacies), above the lines, no surgery is preferred. For example, for a 45-year-old woman with a BMI of 40, when the relative risk of death after surgery is greater than 0.98 (efficacy of surgery is less than 0.02), no surgical treatment is the preferred strategy. When the relative risk of death after surgery is less than 0.98 (efficacy of surgery is greater than 0.02), bariatric surgery is the strategy with the greatest gain in life expectancy.

Some studies²² have suggested that bariatric surgery may be beneficial for patients with a BMI between 30 and 35. Therefore, we performed exploratory analyses for patients with a BMI in this range (Figure 6). In these sub-analyses, women benefit from bariatric surgery. However, the benefit from surgery is very sensitive to the model parameters. For instance, a 42-year-old women with a BMI of 32 gains 0.8 years of life expectancy, but if the 30-day surgical mortality exceeds 2.4% (baseline 30-day mortality, 0.2%), surgery is no longer favored. Recognizing that the efficacy of surgery may be lower in this subgroup, we performed a sensitivity analysis on efficacy within this BMI range. We found that, as efficacy decreases, the benefit of surgery decreases for all ages, though, for a 42-year-old woman with a BMI of 32, surgery remains favored until the efficacy is below 4%. We found similar results for men, but the benefits of bariatric surgery were less.

COMMENT

We developed a decision analytic model to evaluate the decision to have gastric bypass surgery for the treatment of morbid obesity. The optimal decision for individual patients varies depending on the balance of risks between perioperative mortality, excess annual mortal-

ity associated with increasing BMI, and the efficacy of surgery; however, for the average morbidly obese patient, gastric bypass surgery increases life expectancy. Younger patients have lower surgical risk and more time over which to realize the benefits of surgery. For older patients, the gain is smaller, and for some, gastric bypass surgery will decrease life expectancy.

The results of our base case are similar to the results of a previously published decision analysis by Pope and colleagues.²¹ Their analysis found that a 40-year-old woman with a BMI of 40 would gain 2.6 years of life expectancy with bariatric surgery and that the absolute life expectancy benefit is similar across age groups. However, we found that the absolute gain in life expectancy is inversely correlated with age.

There are 3 major differences between the 2 models that lead to somewhat different conclusions. First, the model by Pope and colleagues assumed that the increase in life expectancy was due to changes in BMI after surgery, placing the patient in a new BMI category with a lower mortality rate; while in our model, we made no assumptions about weight loss, rather, we used an efficacy term derived from a large prospective cohort study. Second, Pope and colleagues estimated the additional mortality associated with obesity by using a large prospective cancer trial and were unable to adjust for the effect of age on mortality. By using NHIS, we were able to use a nationally representative sample fully adjusted for age, sex, and BMI across a broader continuum. Finally, the surgical mortality risk used by Pope and colleagues was based on case series and explored in sensitivity analyses. The surgical risk in our model is based on a logistic regression model derived from the National Inpatient Survey that takes into account patient age and sex. These 3 factors allow our model to better examine a wide range of patient-specific scenarios and BMI categories.

There are several limitations to our analysis. Because the data set from the National Inpatient Survey is derived from administrative data, it does not include clinical variables, such as BMI, that may be important predictors of surgical mortality. However, the National Inpatient Survey data set provides the best nationally representative sample of surgical mortality, and until more complete data sets become available, the most generalizable estimates of surgical mortality. A number of obesity-associated conditions may increase operative mortality and conversely may increase the benefits following successful surgery. However, data capturing this level of detail do not currently exist. When such data become available, models like ours will be able to make even more specific recommendations.

The data used to determine the efficacy of surgery, from the study by Adams et al,¹⁴ is from a single state, Utah, and is not from a randomized controlled trial. While these data are not nationally representative and involve selection bias, it is the largest study to date demonstrating the efficacy of gastric bypass surgery.

Another limitation of our analysis is that we did not model long-term complications following surgery, including the need for surgical revision. However, by using efficacy data published by Adams and colleagues, we in-

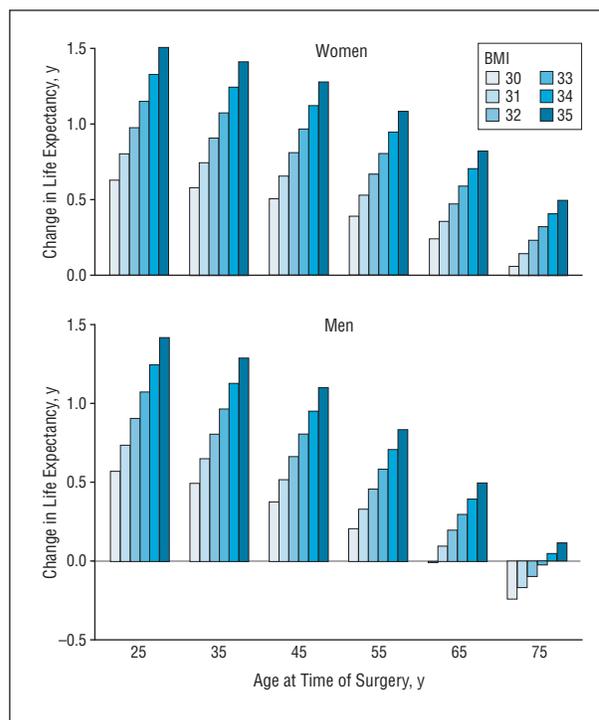


Figure 6. Sensitivity analysis exploring effect of bariatric surgery on patients with lower body mass indexes (BMIs), calculated as weight in kilograms divided by height in meters squared, between 30 and 35.

directly accounted for long-term mortality due to surgery. The most common complications, anastomotic stricture, marginal ulcer, and internal hernia, are rarely fatal and therefore have limited impact on life expectancy.

Because data describing longitudinal changes in quality of life over time owing to changes in body weight are not yet available, we chose to use life expectancy alone as our outcome metric. Gastric bypass surgery has been shown to improve quality of life in the short-term.²³ Until there are studies demonstrating the durability and stability of the quality of life improvements using preference-based utilities suitable for use in a decision analysis, incorporating quality of life adjustments would bias the results of the model toward favoring gastric bypass.

We did not explicitly model deaths due to accident or suicide, though it has been reported that patients having bariatric surgery may be at increased risk of these events.¹⁴ However, we included these deaths in the determination of the efficacy and thus biased the model further against bariatric surgery by systematically underestimating the effect of surgery on obesity-related mortality.

It is likely that certain subgroups of patients with high mortality due to obesity-associated conditions but with a BMI of less than 35 may benefit from gastric bypass. Our sensitivity analyses demonstrated that, for women in particular, there are subgroups of patients with a BMI between 30 and 35 whose survival would improve with surgery. Further research needs to explore the benefit of bariatric surgery in subgroups of patients who may benefit outside of the current guidelines.

The decision analysis presented here is a step forward in understanding optimal patient selection but also

highlights some of the areas for which better data are needed. Understanding more about how efficacy of bariatric surgery varies based on patient characteristics is an important next step because the data necessary to accurately model these outcomes are not currently available. For example, there are currently data on the impact of bariatric surgery on the resolution of diabetes,²⁴ but there are no data on the stability of this resolution over time or how this affects long-term mortality. Likewise, it would not be accurate to stratify operative mortality by obesity-associated condition in the decision analysis without including long-term mortality projections. Including pre-surgical duration of obesity-associated conditions may also be important, especially in patients with diabetes mellitus. The presence of microvascular or macrovascular complications prior to surgery may impact both surgical risk and the efficacy of surgery.

In conclusion, while not all patients are guaranteed a good outcome, our model indicates that gastric bypass increases life expectancy for most patient subgroups; however, for those at high surgical risk or in whom efficacy of surgery is likely to be low, benefit will be minimal. We believe results of this analysis can be used to better inform both patients' and physicians' decisions regarding gastric bypass surgery.

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