

**Bariatric Surgery for Severe Obesity:
Determinants of Use and Economic Impact**

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**A dissertation
submitted in partial fulfillment of the
requirements for the degree of**

Doctor of Philosophy

University of Washington

2013

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Program Authorized to Offer Degree:

**Pharmaceutical Outcomes Research and Policy Program
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Abstract

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Objectives: Obesity in the U.S. population is a major public health problem with important clinical and economic implications. Bariatric surgery is currently the most effective long-term weight loss treatment for morbid obesity but less than 2% of the potentially eligible population has undergone the procedure. Our aims were to: 1) determine the patient characteristics associated with receiving a bariatric procedure among eligible patients; 2) identify patient characteristics that could be used as predictors of resource use and costs in severely obese patients with and without bariatric surgery; and 3) estimate and project the differences in long-term costs and outcomes across different clinically defined populations undergoing bariatric surgery compared to non-surgical approaches, refining a previously developed cost-effectiveness model.

Methods: We used electronic medical records from members of Group Health Cooperative, based in Washington State to identify severely obese individuals, eligible for bariatric surgery, from 2004 to 2010. The probability of undergoing bariatric surgery was assessed using multivariate logistic regression adjusting for demographic and clinical characteristics, as well as patterns of practice. To determine the predictors of costs, we used generalized

linear models for both groups with similar adjustment variables. We created a propensity score matched cohort based on specific characteristics previously identified at the date of surgery and the assigned index date for those who did not have surgery. Finally, we used these data to update a previously developed cost-effectiveness model to re-estimate the cost-effectiveness of bariatric surgery compared to non-surgical interventions.

Results: A total of 48,166 subjects were identified as eligible for bariatric surgery. Only 1,129 had bariatric surgery. The characteristics associated with having a bariatric procedure were: having insurance coverage for the procedure (OR=5.61; 4.71-6.68), higher body mass index (BMI) (1.10; 1.09-1.11), and older age (1.00; 1.00-1.01). The presence of comorbidities was associated with higher odds of having surgery. Examining comorbidities individually, only coronary heart disease was not associated with the surgery (0.96; 0.74-1.26). These characteristics changed over time, showing time trends towards increasing numbers of older adults and subjects with lower BMI having the procedure in the recent years. For costs, total annual costs were higher prior to surgery in the bariatric surgery group but decreased more (in absolute and relative terms) after the surgery compared to the non-surgical group. The total health care costs post-surgery for both groups were primarily driven by inpatient costs. The presence of comorbid conditions was associated with greater annual total costs in both groups. Major cardiovascular risk factors, such as coronary heart disease, hypertension, diabetes, and a higher comorbidity index, were associated with the highest increase in mean annual total costs. Despite being more expensive, bariatric surgery is cost-effective due to the impact on weight loss, which is associated with improved life expectancy and quality of life after the procedure. The incremental cost-effectiveness ratio of the bariatric surgery is sensitive to the presence of multiple comorbidities, mainly due to the reduction in the differences in the lifetime costs between surgical and non-surgical interventions for patients with multiple comorbidities.

Conclusions: There are demographic, clinical, and insurance differences among subjects eligible for bariatric surgery that receive and do not receive the surgery. The presence of specific comorbid conditions increases the probability of surgery and is associated with higher total costs in this population. The cost-effectiveness of these procedures also depends on the presence of specific comorbid conditions. Understanding these differences could better inform the decisions that patients, clinicians, payers and policy-makers face in addressing the problem of increasing population obesity.

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Chapter 1: Who is getting bariatric surgery?

Background

Obesity is a significant problem worldwide (1). Recent data suggests that, in the U.S., almost two-thirds of the population is overweight (2), defined as a body mass index (BMI) 25 kg/m^2 and over, and half of these are obese, BMI 30 kg/m^2 or greater (2, 3). Severe obesity, defined as BMI $>40 \text{ kg/m}^2$, has been reported to be present in 5.7% of the adult population in the U.S., accounting for more than 15 million people (3), and continues to be the fastest growing obesity group by BMI category (3-5). Obesity is associated with multiple chronic conditions such as diabetes mellitus, hypertension, dyslipidemia, coronary heart disease, sleep apnea, asthma, gastroesophageal reflux, fatty liver disease, and osteomuscular injuries leading to back pain and arthritis (6-9). Additionally, several types of cancers, such as esophageal, gallbladder, colorectal, and kidney, are often reported in association with obesity (9), as well as a higher risk of endometrial and breast cancer in postmenopausal women who are overweight or obese (8, 10-11). The impact of obesity in terms of reducing life expectancy, decreasing the quality of life and increasing healthcare expenditures has been widely reported and continues to grow in the US and the rest of the world (10-13).

Treatment for obesity ranges from life style modifications, such as diet and exercise, to pharmacotherapy, and to surgical interventions with varying degrees of invasiveness. The effectiveness, safety, and costs of these interventions also vary. Life style modifications in different levels of intensity and in multiple combinations have demonstrated low to moderate effectiveness for long term weight loss (14,15). There are few effective pharmaceutical products labeled for morbid obesity. Their studies report higher short term weight loss compared to life style modifications or placebo, but there is no solid evidence for their long term effectiveness, and when therapy is stopped, patients usually regain most of their lost weight back in the following years.(16). Surgical

interventions to treat severe obesity, known as bariatric procedures, have shown better long term efficacy in reducing weight and improving comorbid conditions compared to non-surgical interventions (17-22). These positive effects and the development of minimally invasive surgical techniques have resulted, according to the US Agency for Healthcare Research and Quality (AHRQ), in an increase in bariatric surgery by nine-fold for the period 1998-2004 (23). In the U.S., as in most parts of the world, the Roux-in-Y Gastric Bypass (RYGB) is the most common bariatric procedure (24-26), accounting for almost 80% of the total number of procedures (26). In a 2009 study with 4,776 patients undergoing first time or primary bariatric procedures, the most common procedure was RYGB in 3,412 (71.4%) cases (27), and according to the American Society for Metabolic and Bariatric Surgery, in a six-year period (2003-2009), the number of RYGB procedures more than doubled to a significant 220,000 surgeries per year (28). RYGB can be performed through an open abdominal approach (ORYGB) or with a less invasive laparoscopic technique (LRYGB) (29). Because of the improved recovery time, decreased pain and relative safety of LRYGB, it is rapidly replacing the ORYGB as the procedure of choice (30). The most troubling side effects of these procedures are anastomotic leak, strictures or marginal ulcers (33-33). In relatively rare instances, medical or surgical complications can lead to death (approximately 0.5%) in the 30 days after the surgery (36); however, severe complications occur in less than 2% of the patients undergoing these procedures (18, 22, 26). Although the safety of these procedures continues to improve, the costs remain high (37).

According to previous reports, the disparity in health care access and delivery of bariatric surgery is mainly associated with insurance status and socioeconomic characteristics, but many other factors could be affecting this association (38, 39). Our aim for the current study was to examine the differences in the clinical characteristics among eligible patients who received and do not received the bariatric procedure in a single large, integrated health insurance and care delivery system in the Pacific Northwest. We hypothesized that patients with specific characteristics were may be more likely to receive a surgical intervention for obesity than others. To our knowledge, this assessment has not previously been performed in the US, and could better inform whether the characteristics of patients receiving the surgery are representative of the overall eligible population. These

results could be used to address barriers to bariatric surgery access and help to guide providers and policy makers to establish policies to improve access and delivery of these effective interventions to the patients who are likely to benefit from them.

Methods:

Design

A longitudinal cohort of adults with severe obesity who were potentially eligible for bariatric surgery were identified and followed between 2004 and 2010.

Data Sources

We used data from members of Group Health Cooperative (GHC) in Washington State. GHC is a healthcare system that integrates care and coverage serving approximately 620,000 Washington State residents. Compared to the area population, the population from GHC includes fewer persons with high and low incomes, but is generally representative with regard to age, gender, and ethnicity. The Electronic Medical Record (EMR) and administrative, clinical, and laboratory data were used to identify the subjects potentially eligible for the study. Additionally, GHC data systems allow serial tracking patient body height and weight within the EMR, which is a very important variable for obesity evaluations and is often missing in other large administrative datasets.

Population

Based on the recommendations for eligibility for bariatric surgery of the National Institute of Health (NIH) guidelines for the identification, evaluation, and treatment of overweight and obesity (40), we identified adult subjects with BMI of 35 kg/m² or higher. For those subjects with BMI between 35 and 40 kg/m², we additionally identified the International Classification of Diseases, version 9 (ICD-9-CM) codes for relevant comorbidities that established eligibility for surgery: diabetes, hypertension, dyslipidemia, sleep apnea, gastroesophageal reflux disease, osteoarthritis, metabolic syndrome, or depression. Subjects with BMI equal or higher than 40 kg/m² were included regardless of the presence or not of comorbidities. For all subjects, we excluded those who were pregnant or lactating or had other relative contraindications to bariatric surgery, such as dementia, psychosis, disabling neurologic disorders, HIV, cancer, inflammatory bowel disease,

cirrhosis, dialysis, or current substance abuse and other related conditions. These diagnoses were defined based on their respective ICD-9 codes (Figure 1; Appendix 1).

Subjects' demographic and clinical characteristics were assessed, as well as the information about insurance status and coverage. Participants in GHC can belong to Medicare, Medicaid, the Basic Health Plan (a state-supported plan for low-income residents), the state government employees plan, federal workers, and/or individually-purchased plans. These different health plans may offer different types of coverage for bariatric procedures: some will cover the procedures and others do not. We identified coverage for bariatric surgery and the enrollment periods when this specific coverage was available for each patient as a separate variable in our analysis to explore its effect of the likelihood of receiving bariatric surgery. Specific comorbidities considered as independent major cardiovascular risk factors, such as diabetes mellitus, hypertension, dyslipidemia, and coronary heart disease, were identified using ICD-9-CM codes. Other comorbidities and health status reports were assessed using a comorbidity index. Specifically, we used Quan's enhanced version of the Charlson comorbidity index which has been reported to match or outperform the original Deyo and Elixhauser ICD-9-CM coding algorithms in predicting in-hospital mortality (41). For the bariatric surgical interventions, we identified the patients undergoing these procedures using ICD-9-CM and CPT codes (full list available at request). The specific type of bariatric surgery and the dates of the procedure were identified as used as the index date for the surgical patients.

Statistical Analysis

When assessing access and use of health services, including surgical interventions like bariatric surgery in this case, it is recommended to take into account both societal and individual determinants that could help to explain key patterns and trends in the use of health resources. Following these principles, we adapted the conceptual framework of the behavioral model for health care utilization from Andersen-Newman (42,43). Based on this adapted model, we hypothesized that the access and use of healthcare resources associated with bariatric surgery would depend on: (1) the predisposition of the individual to use services (predisposing factors: age and gender); (2) the member's ability to secure services

(enabling characteristics: insurance status and coverage for the procedure); and (3) the member's illness level (need for health care: comorbidities, health status, and BMI). We identified variables relevant to each of these categories for our analysis.

The data were de-identified in accordance with the Health Insurance Portability and Accountability Act's definition of a limited dataset. The Office of Research Subjects from the University of Washington and GHC deemed the study to be exempt from federal regulations because the research activities were considered to be of minimal risk to patients.

Since the outcome of interest was the ability to obtain or not obtain a bariatric procedure, we developed a multivariate logistic regression model to determine the characteristics that differed between the eligible subjects who had bariatric surgery and those who did not undergo the procedure between 2004 and 2010. For all subjects, we considered the available information prior to their date of surgery, particularly regarding the comorbidities. As the trends in the adoption of bariatric surgery and obesity may also play a role in the observed changes, we also performed additional analysis at annual intervals to assess potential differences or trends in the use of the surgery during the period of analysis. All analyses were conducted using STATA Version 12.1, StataCorp. 2011. College Station, TX: StataCorp LP.

Results

We identified a total of 48,166 adult subjects with a reported BMI higher than 35 kg/m² from GHC electronic databases between 2004 and 2010; and among those, 29,679 were identified as eligible for bariatric surgery based on the eligibility criteria outlined above and consistent with the recommendations from the National Institute of Health (40). The most common reasons for excluding patients from the cohort were the lack of additional comorbidities in the group of subjects with BMI between 35 and 40 kg/m² and the presence of comorbidities described above as exclusion criteria to be eligible for bariatric procedures. Among the eligible population, 17,071 (57%) had a health plan with bariatric surgery coverage during the follow up; and there was a slightly higher proportion of females, the mean age was 49 (SD: 12.3) years old, and the mean BMI was 40 (SD: 7.2) kg/m². Overall, hypertension was the most common major cardiovascular risk factor reported in this subpopulation, found in 45% of the subjects, followed by dyslipidemia and diabetes mellitus, both present in almost a quarter of the patients in this cohort. A smaller proportion of patients were identified with coronary heart disease. The mean comorbidity index was 0.34 (SD: 0.65) and only 4.8% of the patients had an index of 2 or greater. A total of 1,129 (3.8%) subjects were identified as having a bariatric procedure during this time period.

In the initial unadjusted analysis, comparing patient characteristics across those who did and did not have bariatric surgery, we found significant differences between the two groups. Patients who underwent bariatric surgery were more likely to be female, have a higher BMI, and have insurance coverage for the procedure. We also found significant differences in comorbidities between the two groups, with the patients who underwent bariatric surgery having a higher likelihood of having diabetes, hypertension, or dyslipidemia, as well as a higher score on Quan's comorbidity index. Age was marginally associated with the likelihood of receiving bariatric surgery, and we did not find significant differences by the presence coronary heart disease (Table 1).

The multivariate adjusted logistic regression analysis showed that having coverage for bariatric surgery had the strongest association with undergoing the procedure, increasing the odds of surgery by more than 5 times. Being female and having a higher BMI were also associated with the procedure. Greater comorbidities on the Quan's index were found to also increase the probability of having the procedure; however, coronary heart disease was not significantly different between the two groups (see Table 2). When the analysis was restricted to the subpopulation of the 17,071 subjects with bariatric surgery coverage, the results were similar.

Considering the distribution of the surgical procedures over time, in addition to the potential changes in the prevalence of obesity and increasing number of bariatric surgeries in this time period, we performed additional analysis to adjust for time trends between 2004 and 2010. The surgical cohort revealed significant changes over time, both in the characteristics of the population eligible for surgery and the characteristics of the subjects undergoing surgery. The odds associated with having bariatric surgery increased over time during the study period as a reflection of the distribution of the proportion of patients undergoing bariatric surgery every year. Almost half of the patients who had bariatric surgery had the procedure in the last 3 years of the study period. The population eligible for surgery showed an increase in the proportion of young adults (from 16 to 22%), females (from 58 to 62%), and higher mean BMI (from 38.3 to 41 Kg/m²). For the subjects undergoing surgery, we identified a different trend with an increased number of older patients with lower BMIs receiving surgical interventions (See Figure 2a and 2b).

Discussion

In this long-term analysis of a population-based cohort of severely obese patients who were eligible for bariatric surgery, having insurance coverage for the procedure was the single characteristic most strongly associated with having bariatric surgery. Being female, having higher BMI, diabetes, or hypertension, or dyslipidemia, or having a greater overall burden of comorbidities were each also associated with a higher odds of undergoing surgery independent of bariatric insurance coverage. These results seem to be consistent with the recommendations for bariatric surgery which promotes the use of bariatric surgery for patients with specific comorbidities unless a patient has a specific contraindication for the procedure (40).

Previous studies, using the same NIH eligibility criteria, and based on the information of the population who participated in the National Health and Nutrition Examination Survey (NHANES) (2, 3), have reported the proportion of eligible patients for bariatric procedures in the United States; using the number of bariatric surgeries performed in the U.S. during the same period, the authors estimated the proportion of eligible patients who had undergone the procedure to be approximately 0.5% of the total potential eligible population (39). This proportion is much lower than what we found in our results, where 3.8% of the subjects in our cohort underwent bariatric surgery. These differences can be explained by the selection of the population in each study. We selected our cohort from patients with information in the EMRs and other administrative databases from GHC. We included only those subjects who seek any type of healthcare for any reason. On the other hand, in the report previously described, the authors included subjects from the general population and not from within a specific health care plan or system.

In 2004, Livingston and Ko (44), identified 5.3 million patients eligible for bariatric surgery— based on the NIH guidelines using a national health survey—and demonstrated disparities by race and insurance type between the population eligible for bariatric surgery and those receiving bariatric surgery. More recently, Martin et al. reported significant socio-economic differences among subjects receiving bariatric surgery and those

who did not (47). According to them, more than 22 million people in the US were eligible for bariatric surgery in 2006, but fewer than 88,000 bariatric procedures were performed during the same year. Most of these procedures were performed in white female patients, those with greater median incomes, and those with private insurance. Important limitations of the analysis conducted by Martin et al., was using two different datasets with different samples and types of information (NHANES and Nationwide Inpatient Sample—NIS) to try to estimate the population eligible for bariatric surgery and the lack of some key clinical characteristics of the patients, particularly in the group of patients who did not receive the procedure. Our analysis of GHC data included demographic and clinical characteristics of potentially eligible subjects for bariatric surgery, including BMI, and showed an increased probability of having bariatric surgery for subjects with the obesity-related comorbidities highlighted by the NIH guidelines.

Our analysis has limitations that should be considered to put these results in context. Our population was selected from the group of members of GHC who have sought medical care for any reason and who have the required information in their EMRs. This population is not necessarily representative of the general population because there was a proportion of patients who did not seek any medical attention regularly. At the same time, another potential source of bias in our analysis is the fact that subjects seeking and undergoing bariatric surgery could have had better screening and higher detection of comorbidities as a result of the required pre-surgical assessment and could explain in part the differences in comorbidities between the patients who underwent surgery and those who did not. We focused on comorbid conditions considered as major cardiovascular risk factors as the main contributors of mortality and complications in this population and used the comorbidity indices as a proxy for a measure of severity of multiple comorbid conditions beyond the ones that we examined individually recognizing that this approach has its own limitations.

The duration of obesity and other comorbidities is difficult to ascertain given the information available through the EMRs and the restrictions on the periods available from 2004 to 2010. These same limitations prevented us from performing a time-to-surgery analysis. Additional information that has been reported to influence access to bariatric

surgery such as level of education, household income, and race were not available in our dataset to be able to consider them in our analysis.

The recent uptake of bariatric surgery and the increased number of procedures at GHC is, in part, explained by the increased availability of surgeons who perform these procedures in their network, but can also be a reflection of the changes in practice across the U.S. in the same period with an increased number of bariatric procedures (23, 24) and perhaps increased level of acceptance from patients to pursue bariatric surgery. The evolution of the bariatric procedures from open abdominal surgeries to minimally invasive procedures and to safer interventions may also explain the changes in the characteristics of patients undergoing the procedure over time, with increasing number of surgical procedures among older adults and those with BM in the lower ranges of the eligibility.

These results clearly highlight the differences in the population of patients undergoing bariatric surgery and those who are eligible for the procedure but do not undergo surgery. Since the eligible population differs from the population undergoing the procedure, any projection or extrapolation of the benefits or harms associated with these procedures is not necessarily applicable to the entire eligible population. Identifying these differences can help to determine the real potential of surgical interventions at a population level.

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Figures and Tables

Figure 1. Identification and distribution of subjects

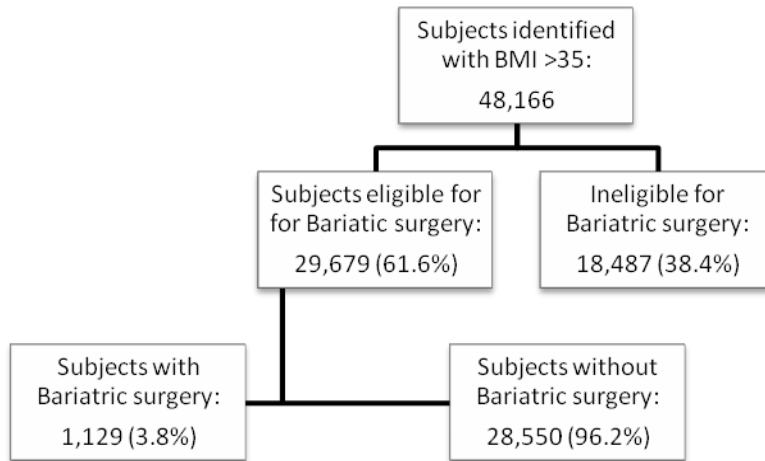
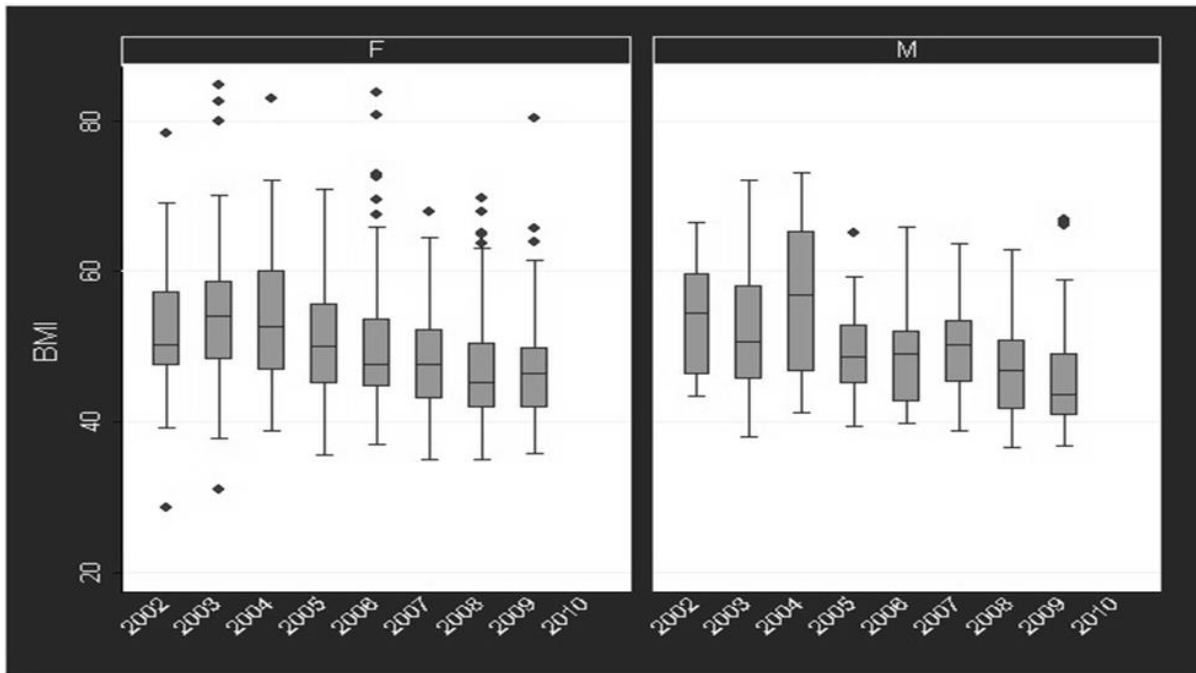
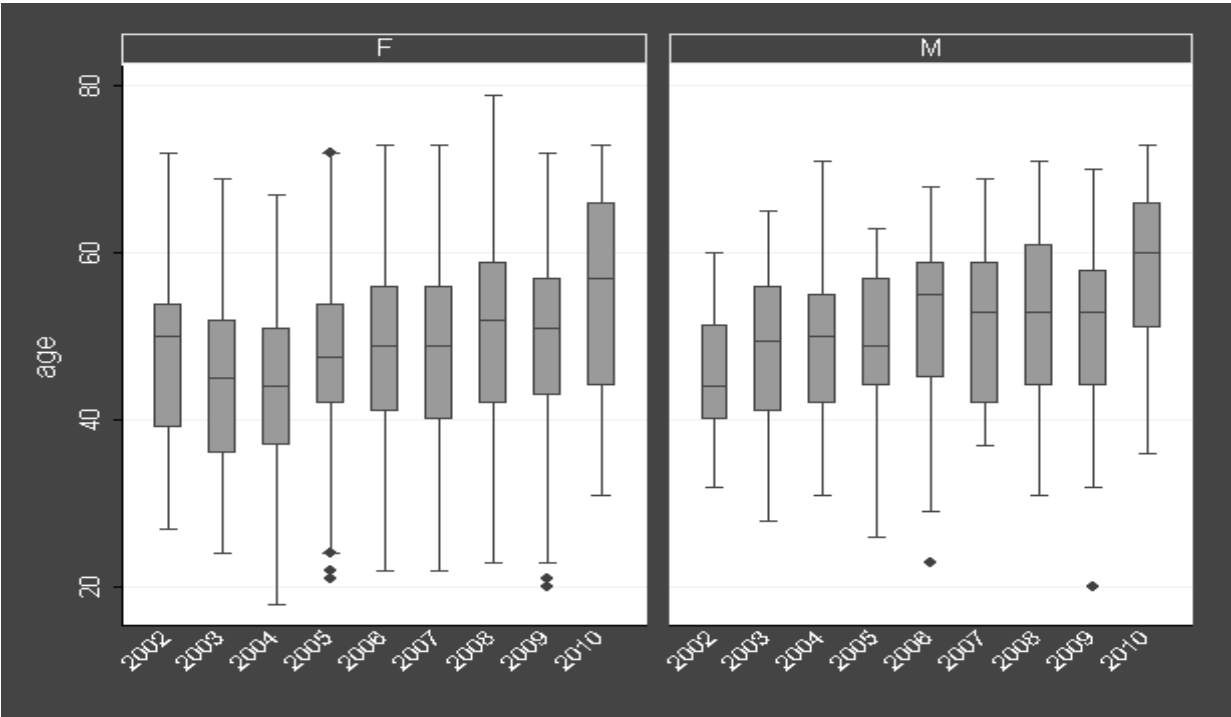


Figure 2. BMI distribution in subjects receiving bariatric surgery by year



M= Male; F=Female; BMI=Body Mass Index

Figure 3. Age distribution in subjects receiving bariatric surgery by year



M= Male; F=Female

Table 1. Unadjusted comparison of characteristics of the patients eligible for bariatric surgery, by those who did and did not undergo surgery, 2004 to 2010 in Group Health Cooperative

	No Bariatric Surgery	Bariatric Surgery	P value
N	28,550	1,129	
Age (SD)	49.7 (13.0)	49.6 (10.7)	0.66
% Female	53.5%	80.3%	<0.001
Mean BMI (SD)	39.5 (6.9)	45.0 (9.5)	<0.001
Coverage for Bariatric Surgery (rider)	56.5%	84.4%	<0.001
Diabetes Mellitus	24.3%	40.7%	<0.001
Hypertension	44.5%	58.5%	<0.001
Dyslipidemia	25.6%	30.2%	<0.001
Coronary Heart Disease	7.1%	7.0%	0.885
Charlson Comorbidity Index (CCI) (Mean)	0.33 (0.64)	0.37 (0.67)	0.049
CCI =0	72.8%	70.7%	0.058
CCI=1	22.8%	23.6%	
CCI>2	4.4%	5.8%	

SD: Standard Deviation

BMI: Body Mass Index

CCI: Charlson Comorbidity Index (Quan's modification)

Table 2. Multivariate logistic regression: multivariable adjusted odds ratio for having bariatric surgery.

	OR	95% CI		P value
Male Gender	0.20	0.17	0.24	<0.001
Coverage for surgery	5.61	4.71	6.68	<0.001
Age	1.00	1.00	1.01	0.048
Diabetes	2.03	1.77	2.35	<0.001
Hypertension	1.92	1.66	2.22	<0.001
Coronary Heart Disease	0.96	0.74	1.26	0.783
Dyslipidemia	1.38	1.19	1.61	<0.001
CCI=0	Ref.			
CCI = 1	1.23	1.05	1.44	0.007
CCI => 2	1.29	0.96	1.72	0.084
BMI (kg/m ²)	1.10	1.09	1.11	<0.001

CCI: Charlson Comorbidity Index (Quan's modification)

BMI: Body Mass Index

Table 3. Multivariable adjusted odds ratios (OR) for having bariatric surgery adjusted by year of surgery.

	OR	95% CI		P value
Male Gender	0.23	0.20	0.28	<0.001
Coverage for surgery	6.14	5.13	7.34	<0.001
Age	1.01	1.01	1.02	<0.001
Diabetes	2.20	1.90	2.56	<0.001
Hypertension	1.69	1.46	1.97	<0.001
Coronary Heart Disease	1.05	0.79	1.39	0.738
Dyslipidemia	1.07	0.92	1.26	0.382
CCI=0	Ref.			
CCI = 1	1.21	1.03	1.42	0.018
CCI => 2	0.97	0.72	1.32	0.865
BMI (kg/m²)	1.11	1.11	1.12	<0.001
2004	Ref.			
2005	0.74	0.57	0.96	0.025
2006	1.44	1.11	1.88	0.006
2007	2.89	2.24	3.73	<0.001
2008	6.70	5.24	8.56	<0.001
2009	10.83	8.43	13.92	<0.001

CCI: Charlson Comorbidity Index (Quan's modification)

BMI: Body Mass Index

Chapter 2: Costs Associated with Bariatric Surgery

Background

Obesity is growing more rapidly in the highest body mass index (BMI) categories. The growth of the prevalence of severe obesity, defined as BMI ≥ 40 kg/m², was twice that of the growth in mild obesity (BMI 30–34.9 kg/m²) in the United States in the past decade [1]. Compared to normal weight adults, those with increased weight also have greater risk of comorbidities, in particular those associated with metabolic and cardiovascular risk factors, such as diabetes mellitus type 2, hypertension and dyslipidemia [2-4]. The presence of comorbid conditions in severely obese subjects has been reported to be associated with increased resource use and healthcare expenditures compared to normal weight subjects [5-11]. An estimated \$147 billion is spent due to obesity and obesity-related medical care in the US [12]. It has been reported that 25 to 64% of these costs are financed by the public sector via Medicare and Medicaid, which affects both the federal and state budgets [13]. Due to the increasing prevalence of severe obesity, healthcare payers and policymakers are interested in estimating the healthcare costs associated with this condition and its comorbidities. Additionally, rigorous economic evaluations need to assess the effect of obesity interventions on specific comorbidities, which could better inform clinical guidelines, health policies, and coverage decisions.

Bariatric surgery in severe obesity produces sustained weight loss and improvement in many obesity-related conditions, particularly for diabetes mellitus where sustained reductions in HbA1c have been consistently reported early after the procedure and may last for several years in some patients [14]. These benefits have promoted the support from some scientific societies to promote the use of bariatric surgery in patients with diabetes mellitus and lower levels of obesity. Some studies reflect these benefits through reductions in costs and resource utilization following bariatric surgery, and particularly through a reduction of direct medical costs and prescription drug use compared to the periods prior to

the surgery [15-19]. More recent analyses have compared the costs of patients undergoing bariatric surgery with non-surgical controls in selected populations showing decreasing costs with surgery but not necessarily savings compared to non-surgical groups [20,21]. Few of these analyses have focused on the relative contribution of specific comorbidities to the total costs or have compared the costs and resource use associated with specific comorbidities to provide more targeted evidence for the potential cost impact of bariatric surgery. Understanding costs and utilization in these subpopulations is very important because if bariatric surgery substantially reduces the use of health care resources and overall medical costs beyond the costs of the procedure, it may be cost saving overall for the U.S. health care system. Additionally, identifying the specific subgroups with greater potential cost savings could help to inform decisions for coverage policies and clinical guidelines.

The objective of this study was to examine the long-term health care utilization and costs, in a cohort of patients of Group Health Cooperative, an integrated health plan and care delivery system in the Pacific Northwest, with BMI > 35kg/m² who were eligible for bariatric surgery from 2004 to 2010. We sought to assess the utilization and costs before and after surgery and compare these results to a cohort of patients eligible for bariatric surgery in the same time period that did not undergo the procedure. We performed these analyses to estimate the relative contribution of specific comorbidities to total costs, pharmacy costs, inpatient costs, and outpatient costs before and after surgery or the assigned index date for those not undergoing surgery.

Methods:

Design:

This was a cohort study of patients who underwent bariatric surgery and patients with BMI equal or greater than 35 kg/m² who were eligible for bariatric surgery but did not undergo the procedure during the follow-up. We assessed the utilization and costs before and after bariatric surgery, or before and after a specific index date in the non-surgical cohort. The index date, for the non-surgical patients, was defined by the closest date of a medical visit one year after being identified as potentially eligible for bariatric surgery between 2004 and 2010. This period of one year after being identified as eligible for bariatric surgery was chosen based on the fact that most patients who undergo bariatric surgery must undergo a screening process that could take from 3 to 6 months or even up to year before getting the surgery.

Data:

We obtained data from electronic medical records (EMRs) from 2004 to 2010 from members of Group Health Cooperative (GHC). GHC is a healthcare system that integrates care and coverage serving approximately 620,000 Washington State residents. Compared to the area population, the population from GHC includes fewer persons with high and low incomes, but is generally representative with regard to age, gender, and ethnicity. The EMR and the integrated administrative data systems from GHC were used to identify the subjects potentially eligible for the study using administrative, clinical, and laboratory data. Additionally, GHC data systems allow tracking of patient height and weights within the EMR, which is a very important variable for obesity evaluations and is often missing in other large administrative datasets. The data included enrollment files, benefits information to determine medical and pharmacy coverage, and inpatient, outpatient, and pharmacy claims records containing International Classification of Disease-9 Clinical Modification (ICD-9 CM) codes, Common Procedural Terminology codes, prescription National Drug Codes, and costs.

The GHC Cost Accounting Database records all health services provided or paid for by GHC and assigns a cost of production based on actual operating budgets (rather than charges). Data from this system have been used in previous studies. Previous works also indicates that about 95% of all allopathic medical care used by adults is received through linked facilities at GHC and has been captured in the automated clinical and administrative databases.

Age, sex, and number of months of medical and pharmacy coverage were measured using enrollment data. The data were de-identified in accordance with the Health Insurance Portability and Accountability Act's definition of a limited dataset. The Human Subjects Division (HSD) from the University of Washington and GHC deemed the study to be exempt from federal regulations because the research activities were considered to be of minimal risk to patients.

Health Resource Use and Costs:

Costs were determined using the information directly provided by GHC for total annual costs for each patient. In addition to total costs, we identified subcategories based on type of service: (1) inpatient, which includes both inpatient facility and physician costs; (2) outpatient, physician and other independent professional services provided in an office setting; (3) pharmacy costs, based on paid prescriptions filled or reimbursed by GHC. Costs were calculated annually for the year of the surgery as well as for the years before and after the surgery. Similar periods were defined to calculate annual costs for the non-surgical group, who were assigned an index date equivalent to the date of surgery as described above. All the information available from 2004 to 2010 on each eligible patient was extracted. For example, a patient who had bariatric surgery in 2009 could provide information since 2006, 3 years before surgery but only 1 year of data after surgery. Other patients from the non-surgical cohort that was identified in 2007, and the index date was set for 2008, could provide information on 2 years of data after that initial index date and 3 years of information prior to that date. For health resource use and costs analysis, we performed descriptive analysis to identify the trends and distribution of the data. Means,

medians, ranges, maximum and minimum values for annual costs and annual resource use were identified, as well as other measures of dispersion and central tendency. Influential outliers, defined as extreme values above the 99th percentile or below the 1st percentile were examined individually for plausibility and consistency. To determine resource use and medical expenditures for each group (surgical and non-surgical), we performed separate analysis for each cohort. The first set of analysis used multivariable regression models adjusted by age, gender, initial BMI, diabetes mellitus, coronary heart disease (CHD), hypertension, dyslipidemia, and year. Health status and other chronic conditions were considered by estimating a comorbidity index. We used the Quan's version of the Charlson's Comorbidity Index (CCI) as describe in Chapter 1 [24]. All cost data were adjusted to 2010 dollars using the Consumer Price Index (CPI) obtained from the Bureau of Labor Statistics. No discount was applied to the cost calculations. To account for the skewed distribution of annual costs we used a Generalized Linear Model (GLM) with a gamma distribution and a log link [25]. The link function was validated using a Box-Cox regression and the outcome distribution was validated using the Modified Park Test. Annual medical costs were calculated transforming these coefficients into dollars. These models were replicated for each one of the subcategories of costs described above: (1) inpatient; (2) outpatient; (3) pharmacy costs.

To adjust for right censoring, we used the Lin method [26] to specify time periods of 1 year in each analysis, and weighted the costs calculating the probability of censoring in every period for death or disenrollment based on the information available in the dataset for each patient.

In the previous chapter, we described the main differences identified between the subjects who underwent bariatric surgery and those who did not, despite meeting the eligibility criteria. In order to make better comparisons between these two groups of patients and reduce measured bias and selection, we also performed another set of analysis using propensity score matching (PSM) to compare costs and resource use before and after surgery or index date in both groups.

Propensity Score Matching:

PSM is a class of multivariate methods used to construct samples that have similar distributions on many covariates between intervention and control groups. This matching is the observational study analog of randomization in experiments, but is far less complete as it can only balance the distribution of observed covariates, whereas randomization balances the distribution of all covariates, both observed and unobserved[27]. An important feature of propensity score matching is that it can be easily combined with model-based regression adjustments or with matching on a subset of special prognostic covariates or combinations of prognostic covariates that have been identified as being especially predictive of the outcome variables [28]. We estimated a propensity score for each subject during the year of the bariatric surgery or the index year for the non-surgical cohort. The propensity score was calculated for every individual based on the following variables, identified in the previous chapter: gender, age and BMI at index, diabetes mellitus, hypertension, dyslipidemia, coronary heart disease, and a comorbid conditions index (CCI). Using each individual score from the subjects in the surgical group, we identified the closest match in the non-surgical group using the greedy algorithm to create a new cohort of 1:1 matched subjects.

All analyses were conducted using STATA Version 12.1, StataCorp. 2011. College Station, TX: StataCorp LP.

Results:

Our study sample included 29,679 individuals eligible for bariatric surgery; and of those, 1,129 had bariatric surgery during follow-up. There were significant differences between these groups at the moment of surgery or the predetermined index date for those who did not undergo surgery. In the surgical group, most patients were female, had higher BMI, and had higher prevalence of diabetes, or hypertension, or dyslipidemia, had greater overall burden of comorbidities, or had a higher likelihood of coverage for the procedure, as described previously in Chapter 1. For both groups, the highest number of subjects available with complete information was available in the index periods (year of surgery or predetermined index date for the comparison group). Before and after this period, the number of subjects available in both groups decreased significantly due to the design of the cohorts and the changes in the number of surgical procedures in the later years in the surgery cohort.

Almost all patients (~98%), in both groups had costs reported in every year during the follow up. The surgery group shows the highest mean annual costs during the year of the surgery (\$33,510), which is explained by the high cost of the procedure and by the potential costs of complications after the surgery in the first year, when they are most common. In comparison the non-surgical group had less variation in total costs, with higher mean total costs in the years prior to the index date. In both groups, we identified large ranges of annual total costs between the minimum and maximum costs in every year with several influential outliers (table 1). Interestingly, the maximum values reported were consistently higher in the non-surgical group. We also observed a decrease in mean total costs in the post-surgery period compared with the pre-surgery period in those patients who had bariatric surgery (total mean annual costs before surgery were \$9,697 vs. \$7,343 total mean annual costs after surgery). This trend was similar in the non-surgical group, having lower mean annual costs after index compared to the period before index (total mean annual costs before surgery: \$7,387 vs. average mean annual costs after surgery: \$4,642). In both groups, the main drivers of costs were the costs associated with inpatient stays. Mean

annual inpatient and outpatient costs were also higher in the year prior to surgery compared to the mean annual costs in the non-surgical group. The median annual total costs were much lower than the mean annual costs for both groups in every year (table 1).

After calculating the propensity score for each individual at the year of surgery or the predefined index date for the non-surgical group, a 1:1 matched cohort was created to compare the annual costs both groups examining the costs before and after the surgery or index date, and the costs associated with specific comorbid conditions. The comparison of the demographic and clinical characteristics in the two cohorts did not reveal any statistical difference at baseline (table 2). A total of 1,065 subjects in each group were matched. The distribution of the subjects with information available before and after the procedure or the predefined index date was similar to the entire sample with fewer observations every subsequent year before and after the procedure or the index date. The mean annual total costs, in the propensity-matched cohort per year from index, showed consistency with the results from the entire non-matched sample despite having a smaller sample size (table 3).

We developed two multivariate predictive models for total annual cost. The first one included all the information before and after the surgery or the prespecified index date; and a second one was developed using only the information after the surgical intervention or the pre-specified index date for the comparison group. In each of the analyses the presence of comorbid conditions showed a significant increase in the estimates of annual total cost (tables 4 and 5). The regression model that focused on the years after index had a better fit and higher C statistic than the model using all the years, before and after. Nevertheless, in both models, individual comorbidities, at the moment of surgery or during the index period for the comparison group, such as CHD, hypertension and diabetes showed the highest increase in mean total costs. Dyslipidemia was associated with a moderate increase in costs in the surgical group, but it was not significant in the non-surgical group. Higher CCI was associated with a substantial increase in mean annual cost compared to having a CCI of 0 in both groups. BMI at index was not significantly associated with mean annual costs in either of the two cohorts.

Patients undergoing bariatric surgery consistently showed higher annual mean total costs estimates in the pre-surgical period compared with the post-surgical period (Figure 1). The trend in these annual total costs seems to show a constant decrease over time after surgery compared to the initial costs prior to surgery. As expected, the highest total annual costs, in this bariatric surgery cohort, are attributed to the year of the surgical procedure. In comparison with the pre-surgical period, the total annual costs were lower in the post-surgery period and remained relatively flat over the time of follow-up. In the cohort of patients without surgery, a similar trend in total annual costs was shown. The total annual costs, on average, were higher prior to the predefined index date compared to the periods after the surgery.

As expected, the main driver of total annual costs in both groups was inpatient costs. Similar to the total costs, inpatient costs were higher prior to the surgery, being the highest during the year of surgery and decreasing after the procedure for the surgical cohort. For the nonsurgical cohort, inpatient costs were, on average, higher prior to the prespecified index date compared to the period after the index date.

Similarly, estimates of the mean annual outpatient costs for both cohorts followed the same trends as the total and inpatient costs but the values were smaller in magnitude. For the surgical cohort, proportionally this is where the highest relative difference was seen in the periods before and after the surgery. The odds of having any pharmacy costs were lower in the post-surgery period compared with the pre-surgery period. However, among those beneficiaries who had any pharmacy costs, the ratios of costs were higher in first year post-surgery compared with the pre-surgery period. For the non-surgical cohort, these differences were not as remarkable but still followed the same general trend of higher utilization and costs in the period after the index date compared to the period prior to index.

In all of the multivariate regression analyses performed in both groups, there was consistency reporting higher total costs, in patients with CHD, hypertension, diabetes, and a higher CCI.

Discussion

This study examined the impact of bariatric surgery on health care costs and utilization among adults who had bariatric surgery and those who were eligible for bariatric surgery but did not undergo the procedure. For up to six years after having bariatric surgery, individuals having bariatric surgery were observed to have a slight, but statistically significant decrease their total annual health care expenditures compared to their total annual expenditures prior to the surgery. A similar decreasing trend in cost is seen in the non-surgical group but not in the same magnitude of the difference. In both groups, these costs are mainly driven by inpatient costs. These costs mainly include hospitalizations and additional surgical procedures. Outpatient costs and other costs, including mostly prescriptions for pharmaceutical products, seem to follow the same pattern but in different magnitudes. Lower pharmacy costs in the post-surgery period among patients who received bariatric surgery compared to the group who did not receive the surgery might reflect individuals in this group coming off their medications more quickly than individuals who do not receive the procedure. Although the change in total annual costs from pre-surgery to post-surgery was greater among the group receiving bariatric surgery, when comparing the total annual costs between the 2 groups in the post-surgical period, no significant differences were noted.

This study is consistent with recent reports of cohorts of obese patients with and without surgery in specific populations in different US settings [20,21] and contradicts previous research showing significant savings for cohorts of patients undergoing bariatric surgery. Although greater cost reductions are achieved in the surgical group, comparing the pre-surgical and post-surgical periods, these reductions in costs do not seem to compensate the additional costs during the year of the surgery in the early post-surgical period. Previous research has reported that bariatric surgery is cost-saving and can provide a short-term return on investment; i.e., to achieve savings at least equivalent to the expenses related to the intervention as early as in the first three to five years after the procedure.[Citations] Our results cannot support those findings. Differences between our results and earlier studies could be due to the relatively small number of adjustable gastric banding surgeries in our

cohort (<10%), which have lower cost, and the potential effect of the preventive programs in GHC that may improve the health of their patients and decrease the cost of these patients beyond other populations in the US.

The analysis of costs in patients with specific comorbidities, consistently reported that patients with diabetes, coronary heart disease, hypertension and multiple chronic conditions (represented by a CCI > 2) had higher costs in both groups—surgical and non-surgical. The fact that BMI at index or at surgery was not a significant predictor of costs could be explained, in part, by the way the cohorts were created with a prespecified BMI cut-off, moderating the effect of BMI compared to a non-selected population. In any case, the relationship between BMI and costs, at least in these cohorts was not as strong as that with comorbidities, as previously described. The mean total costs for both groups showed a decreasing trend, which is similar to other studies [20,21], but could also be a reflection of the adjustment made using the CPI to inflate the costs to 2010 dollars. Removing the adjustment by CPI, total mean annual costs also showed a less pronounced decreased trend for both groups (Appendix 3).

The highest relative difference in costs was in outpatient costs and pharmacy costs, which had a steeper decline in the surgical group in the post-surgical period compared to the pre-surgical period and also compared to the non-surgical group in the same period post-index date. This finding is consistent with previous reports [20,21]. It is expected that individuals who received the surgery could benefit from the procedure by reducing weight, and resolving some comorbidities, more specifically diabetes, which could lead to reduced clinical encounters and fewer medications in immediate period after surgery. These benefits are not necessarily expected in the non-surgical group and are not shown in our analysis.

There are some limitations to this study, which suggest that it may be prudent to focus on the observed trends of utilization across time rather than the absolute costs values. Only a portion of the sample had data for all years and the majority had information in the year of the surgery or the index year for the non-surgical group. Therefore, the predictive ability of the models is decreasing over time before and after the procedure or the index date.

Another limitation of this analysis is the lack of other very relevant costs, in addition to the costs identified in this study, such as the out-of-pocket costs or the costs incurred by lost productivity, including presenteeism and absenteeism, which may affect employers' decisions regarding the coverage of bariatric surgery. Recent research suggests that the annual cost attributable to obesity among full-time employees was \$73.1 billion in 2008 [12]. Our finding that bariatric surgery is not cost-saving in the short term among eligible adults may discourage employer interest in providing this coverage. However, a reduction or elimination of weight-related comorbidities, improved quality of life, and improved mobility as a result of surgery may make this a valuable procedure in this population of patients beyond the costs.

Although we unfortunately lack race/ethnicity data on our study sample, previous research suggests that privately insured, middle-aged, white women primarily utilize bariatric surgery, so our sample may not be a representative of all individuals who are eligible for bariatric surgery. Individual subject-level data indicating characteristics such as income, education, or other health risk factors (e.g., alcohol consumption, smoking) were also not available. Therefore, it was not possible to adjust for any differences between samples related to these variables. Additional research is also needed to understand differences in cost and utilization by these demographic characteristics.

On the other hand, the fact that we used a cohort that reflects healthcare utilization in contemporary practice rather than under clinical trial conditions can be considered as strength of this analysis. Data for both samples were sourced from identical time periods; therefore, clinical and pricing contexts were directly comparable. At the same time, observational studies, such as this one are more prone to confounding and selection bias in particular. A common approach and our choice for this study, to reduce these biases is to perform propensity score matching to create a balanced and comparable cohort of surgical and non-surgical patients. But, this method also has known limitations. For example, the method is limited to study the effects of the matching variables on the outcome and assumes that all relevant covariates have been measured, which in most cases is not possible.

The therapeutic categories with the greatest excess healthcare costs in the severely obese observed by this study align with the diseases with the highest obesity-related relative risks for morbidity. These included type 2 diabetes (diabetes drugs costs were higher), cardiovascular disease (lipid-modifying drugs costs were higher; antihypertensive agents drug costs were higher). Previous studies report that costs for the severely obese are 65% to 113% higher relative to healthy-weight samples. Costs are unlikely to be directly comparable across studies due to different inclusion criteria (i.e., inclusion of one or more of pharmaceutical, inpatient, and outpatient costs), healthcare settings, and analytical methods. Nevertheless, there is a consistent relationship reported across these studies for far greater healthcare costs in the severely obese with multiple comorbidities.

An important issue in undertaking economic evaluation of new therapies is to ascertain the degree to which the costs of the therapy can be offset by reductions in the future use of healthcare services and pharmaceuticals. Results from this study can be utilized to inform more sensitive cost-effectiveness analysis of obesity interventions, particularly those targeting severe obesity or be combined with prevalence data to estimate the economic burden of obesity.

This severely obese sample was a cohort seeking and subsequently receiving bariatric surgery. Their follow up information was limited to one or two years for most patients and few had up to 6 years of follow up limiting the opportunity to establish a full cost-offset. Therefore, the generalizability of results to the entire population of severely obese is uncertain. This study found that annual healthcare costs in severely obese subjects before receiving bariatric surgery were higher than the equivalent costs relative to the comparison group. The excess costs attributable to severe obesity would have been even higher if the comparator group had been a healthy-weight sample. Cost differences were largely driven by greater annual healthcare costs relating to treating diabetes, cardiovascular disease, and other comorbidities in the severely obese subjects.

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Tables and figures

Table 1. Description of unadjusted total annual costs from index year by cohort

	Year from Index	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6
No surgery	N	3668	7260	13860	17955	21084	24286	28369	12320	5638	2939	1548	767	188
	min	0	0	0	0	0	0	0	0	0	0	0	0	0
	mean	8,318	9,504	9,058	8,280	7,538	7,078	5,821	5,693	5,239	5,500	5,321	4,682	4,493
	max	332,116	861,346	616,003	738,734	590,978	1,183,001	541,802	530,540	237,193	232,610	229,791	99,832	76,486
	p25	1,649	1,672	1,550	1,404	1,316	1,211	1,067	950	956	902	925	884	823
	p50	3,428	3,521	3,433	3,070	2,941	2,706	2,284	2,233	2,223	2,118	2,193	2,025	2,209
	p75	7,731	8,649	8,136	7,500	7,007	6,494	5,306	5,434	5,269	5,039	4,789	4,598	4,919
	p99	82,988	89,795	89,053	86,144	74,979	71,366	56,827	57,608	49,703	60,093	48,994	41,002	46,118
Surgery	N	199	263	353	467	648	914	1128	1040	839	667	474	246	43
	Min	103	67			20		1,016		17				327
	Mean	9,967	9,125	9,115	9,892	10,367	9,405	33,510	8,578	7,964	7,471	6,715	6,987	5,701
	Max	135,174	101,119	219,753	155,760	175,405	231,712	425,673	168,336	254,889	137,602	93,730	94,765	29,218

p25	1,665	1,747	1,525	1,587	1,808	2,099	23,068	2,820	1,832	1,723	1,558	1,597	1,277
p50	4,593	4,601	3,724	4,155	4,537	4,328	30,223	5,318	3,801	3,684	3,437	3,306	3,024
p75	12,109	10,873	9,750	11,992	13,395	10,125	38,207	10,520	8,862	8,268	7,880	8,528	8,195
p99	118,817	69,232	84,834	79,597	58,012	76,564	120,149	45,256	57,789	67,714	52,949	53,610	29,218

Table 2. Propensity Score Matched comparison of characteristics of the patients eligible for bariatric surgery, by those who did and did not undergo surgery, 2004 to 2010 in Group Health Cooperative.

	No Surgery	Surgery	P value
N	1,065	1,065	
Age (SD)	49.2(13.0)	49.6 (10.7)	NS
% Female	81.1%	80.3%	NS
Mean BMI (SD)	45.1 (6.9)	44.4 (8.1)	NS
Coverage for Bariatric Surgery (rider)	82.6%	85.0%	NS
Diabetes Mellitus	30.2%	31.7%	NS
Hypertension	37.0%	39.6%	NS
Dyslipidemia	18.7%	19.7%	NS
Coronary Heart Disease	4.6%	5.2%	NS
Comorbidity Index (CI) (Mean)	0.24 (0.6)	0.26 (0.7)	NS
CI=0	71.2%	70.9%	NS
CI=1	23.4%	24.0%	
CI>2	5.4%	5.1%	

SD: Standard Deviation

CI: Comorbidity Index

NS: Not Significant

Table 3. Propensity Score Matched Annual Total Costs by Group and Year from Index

	Year from Index	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6
No surgery	N	46	127	319	515	808	1,077	1,529	856	586	410	302	191	55
	min	408	199	105	91			105						
	mean	6,615	8,204	8,456	8,108	6,887	6,051	5,736	5,369	4,391	5,076	4,576	4,369	4,0741
	max	39,736	89,354	219,664	188,837	151,469	217,381	481,109	118,360	44,654	63,060	84,900	99,832	46,118
	p25	1,177	1,446	1,549	1,292	1,347	1,187	1,053	768	672	738	685	745	489
	p50	2,919	3,216	3,429	3,062	2,714	2,672	2,207	2,052	1,824	1,999	1,860	1,715	2,169
	p75	6,516	8,569	8,390	8,282	6,266	6,103	4,993	5,276	4,836	4,981	4,400	4,547	4,431
	p99	39,736	82,753	95,865	71,812	63,352	52,072	53,816	49,141	35,243	41,806	38,258	71,079	46,118
Surgery	N	197	254	340	451	622	871	1,064	982	780	607	425	215	34
	Min	103	67			20		1,027		17				327
	Mean	10,036	9,202	9,079	9,920	10,501	9,444	33,735	8,624	7,735	7,617	6,865	7,155	6,062
	Max	135,174	101,119	219,753	155,760	175,405	231,712	425,673	168,336	126,893	137,062	93,730	94,765	29,218
	p25	1,665	1,773	1,551	1,603	18,18	2,107	23,386	2,824	1,822	1,783	1,529	1,451	1,747
	p50	4,712	4,854	3,765	4,155	4,641	4,352	30,443	5,302	3,851	3,733	3,5000	3,276	3,278
	p75	12,109	10,898	9,753	12,083	13,455	10,125	38,207	10,427	8,844	8,284	7,934	8,492	8,342

p99	118,817	69,232	84,834	79,597	58,012	82,440	124,760	45,947	57,789	67,714	52,949	53,610	29,218
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Table 4. Adjusted Model for the Propensity Matched Group using Generalized Linear Models

	Surgery				No Surgery			
	Coef.	P Value	95% Conf. Interval		Coef.	P Value	95% Conf. Interval	
Constant	27205	0.000	24091	30318	4747	0.000	2794	6701
Age at Index	46	0.000	23	69	-11	0.318	-32	10
Hypertension	1818	0.000	1184	2451	1701	0.000	1033	2369
Coronary Heart Disease	7003	0.000	4326	9679	7005	0.000	3124	10886
Diabetes	1357	0.000	718	1996	1651	0.000	917	2386
Dyslipidemia	928	0.027	105	1751	90	0.807	-633	814
Quan's Charlson Comorbidity Index								
0	Ref.							
1	3366	0.000	2446	4286	2889	0.000	1801	3977
2	10195	0.000	7110	13280	13647	0.000	7308	19985
BMI at Index	-5	0.695	-30	20	-15	0.268	-42	12
Years to index								
-6	-23053	0.000	-25950	-20155	-1208	0.418	-4130	1714
-5	-22589	0.000	-25429	-19749	-411	0.713	-2595	1774
-4	-23021	0.000	-25770	-20272	257	0.741	-1263	1777

-3	-21181	0.000	-23966	-18396	697	0.292	-600	1995
-2	-20708	0.000	-23456	-17960	536	0.316	-511	1582
-1	-22448	0.000	-25103	-19793	-175	0.690	-1035	685
Index Year	Ref.							
1	-23689	0.000	-26318	-21060	-325	0.473	-1211	562
2	-24965	0.000	-27582	-22347	-1271	0.003	-2100	-442
3	-24587	0.000	-27232	-21942	-769	0.159	-1837	300
4	-24900	0.000	-27565	-22236	-1468	0.004	-2465	-471
5	-24462	0.000	-27234	-21691	-1302	0.053	-2623	18
6	-26414	0.000	-29640	-23188	-1614	0.081	-3425	197

Table 5. Estimated Adjusted Total Annual Costs by Surgery Group

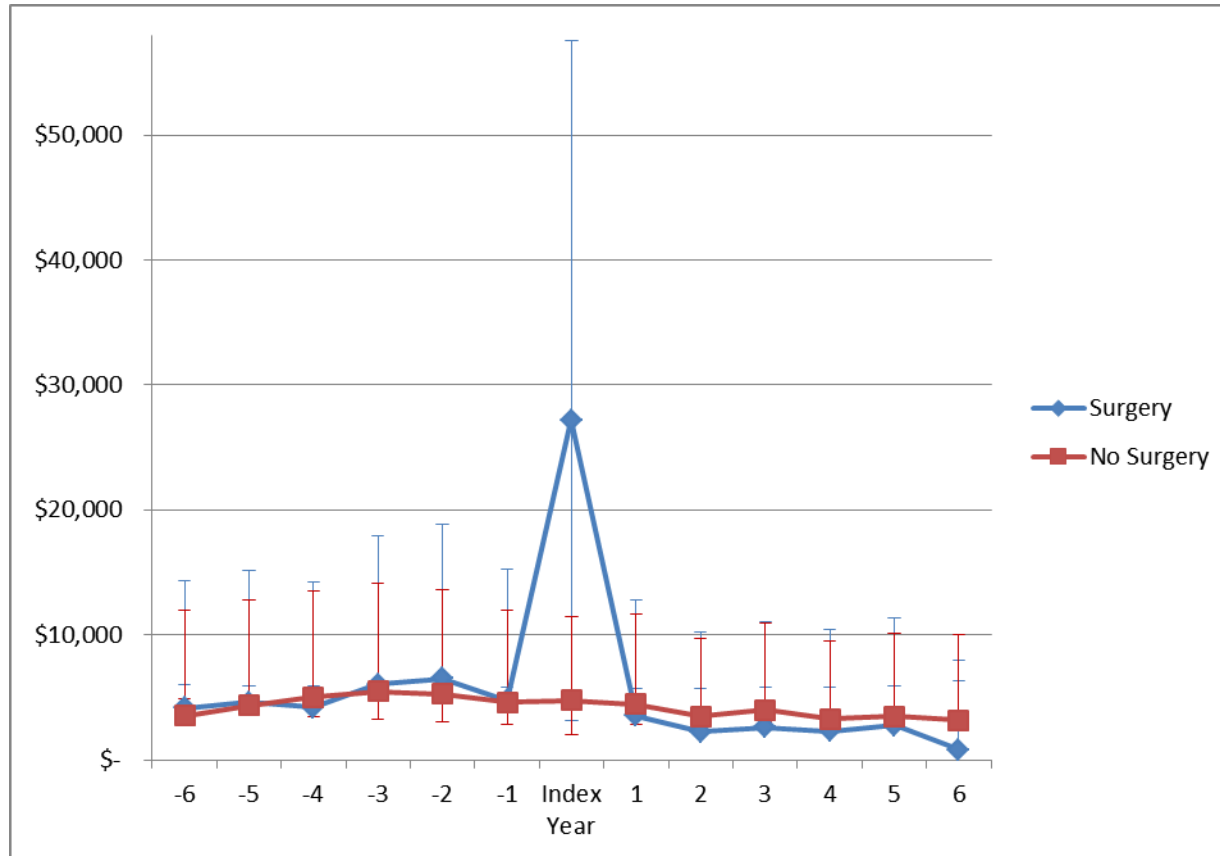
Mean Total Costs	No Surgery					Surgery				
	Exp. Coef.	P value	Coef.	[95% Conf. Interval]		Exp. Coef.	P value	Coef.	[95% Conf. Interval]	
Gender	(656.73)	0.01	-0.20	-0.35	-0.05	(972.48)	<0.001	-0.18	-0.26	-0.09
Age at index	0.82	0.925	0.00	0.00	0.00	36.08	<0.001	0.01	0.00	0.01
Hypertension	1,444.10	<0.001	0.33	0.21	0.46	1,502.71	<0.001	0.23	0.15	0.30
CHD	4,529.19	<0.001	0.81	0.52	1.10	3,597.71	<0.001	0.47	0.33	0.62
Diabetes	1,485.43	<0.001	0.34	0.21	0.48	1,003.45	<0.001	0.16	0.08	0.23
Dyslipidemia	(52.83)	0.853	-0.01	-0.17	0.14	563.70	0.041	0.09	0.00	0.18
CCI										
1	2,652.45	<0.001	0.55	0.39	0.70	2,600.53	<0.001	0.36	0.28	0.45
2	9,794.83	<0.001	1.31	1.00	1.62	7,305.08	<0.001	0.80	0.65	0.95
BMI	(1.73)	0.873	0.00	-0.01	0.01	9.08	0.412	0.00	0.00	0.01

CDH: Coronary Heart Disease

CCI: Charlson's Comorbidity Index

BMI: Body Mass Index

Figure 1. Adjusted Mean Annual Total Costs by surgery.



Chapter 3: Cost-Effectiveness of Bariatric Surgery: A Revised Estimate

Background

As we have previously described, obesity is an important health care issue in the United States and around the globe, not only from a public health standpoint [1,2] but also from an economic perspective [3-5]. Significant and sustained weight loss in patients with severe obesity has only been achieved with surgical interventions which additionally, offer the potential for improving, or in some cases resolving associated conditions, such as diabetes [6,7]. Unfortunately, specific patient characteristics, insurance status, and the high costs of these procedures, as described in Chapters 1 and 2, may limit access to treatment.

Given the increasing number of patients with morbid obesity and the greater availability of bariatric centers in the U.S., it is important for patients, payers, and policymakers to understand the long-term cost-effectiveness of these approaches. Previous studies, including our own modeled analysis, showed that bariatric procedures are generally cost-effective, ranging from \$1,206 to \$27,802, in 2010 US dollars, per additional quality-adjusted life years (QALY) gained compared to non-surgical interventions [8-25] (table 1). However, many of these studies used different assumptions about the population, the durability of the effect of the procedure, in terms of weight loss as well as in the resolution of comorbid conditions. Most studies that have informed these economic analyses on bariatric surgery have had a short follow-up with limited long-term data available, and even less for newer procedures, making it very difficult to assess with precision the long-term benefits and harms associated with these procedures. Another common methodological challenge is the selection of a control or reference group that would be comparable to the group of patients undergoing these procedures.

Given our previous experience developing the Bariatric Outcomes Obesity Model (BOOM) model [25], the aim of this analysis was to revise our earlier estimates of cost-effectiveness based on information obtained from the analyses of the GHC cohort described

in the previous chapters. Unfortunately, this model could not incorporate or predict the impact of surgical intervention on patients with specific conditions, such as diabetes, hypertension, coronary heart disease, dyslipidemia or combined comorbidity scores, relying only on BMI, age and gender to drive the predictions. As it was previously described, most patients who have undergone a bariatric procedure or are eligible for bariatric surgery have a high prevalence of chronic comorbid conditions, particularly major cardiovascular risk factors, such as diabetes, hypertension, coronary heart disease, and dyslipidemia. Based on our previous analysis in Chapter 2, patients with severe obesity in association with these conditions consistently have higher total annual costs compared to patients with severe obesity without these conditions.

Methods

We used the information from two propensity-matched cohorts of patients from GHC, a bariatric surgery cohort and a non-surgical cohort of patients eligible for bariatric surgery, as described previously in Chapters 1 and 2. We followed the same methodological approach and basic modeling structure from BOOM [28] and updated the statistical models to incorporate these major cardiovascular risk factors. The lifetime cost-effectiveness model has two integrated sub-models. First, a decision analytic sub-model represents the first five years after a bariatric procedure, and estimates the direct medical costs and outcomes using a deterministic approach. This initial sub-model was modified and updated substantially to include the impact of specific comorbidities on costs and outcomes, given the information provided in the previous two chapters. Second, the integrated natural history sub-model was used to project costs and outcomes for the lifetime of the subject because data pertaining to costs and outcomes associated with bariatric surgery beyond five years are limited. This second sub-model remained largely unchanged, except in the first five years for the non-surgical cohort where similar changes regarding the specific impact of comorbidities were included.

Following the original model, we estimated the lifetime direct medical costs and outcomes associated with three bariatric procedures: Open Roux-in –Y Gastric Bypass (ORYGB), Laparoscopic Roux-in –Y Gastric Bypass (LYRGB), and Laparoscopic Adjustable Gastric Banding (LAGB) compared with non-surgical care using the information provided from GHC and described previously. The original integrated simulation model for individuals eligible for bariatric surgery was primarily based on BMI and BMI changes to estimate costs and outcomes. The basic structure of the model did not change, but the statistical models now incorporate the specific contribution of each one of the conditions previously described beyond BMI changes. The simulation was based on two integrated sub-models: 1) a decision-analytic model, to model the first five years post-surgery and estimate the cost-effectiveness of the three surgical procedures; and 2) a “natural history” BMI-driven simulation model that projects the long-term costs, and quality of life changes for the non-surgical control population as well as the surgical

population beyond the fifth year following surgery. This original two-part model was comprised of a number of interconnected regression equations to forecast expected lifetime changes in BMI, life expectancy, costs, and patient quality of life after each intervention or non-surgical approach.

All analyses were performed by following the original, baseline settings from the model, using the payer perspective and assuming a standard discount rate of 3% for costs and quality-adjusted life expectancy (QALYs). The model was updated in Microsoft Excel based on the original model (Microsoft Corporation, Redmond, WA USA).

Improvements in the Decision-Analytic Model

The decision analytic sub-model was updated using the demographic and clinical information available from the propensity scored matched cohort described in Chapter 2. This sub-model was developed to simulate each surgical procedure and estimate changes in BMI, costs, and quality-adjusted life expectancy from the time of procedure to five years post-surgery, comparing the impact of surgical procedures to non-surgical care. Unlike the original BOOM report, that used the Medicare claims database (2004-2008) to directly estimate rates, in the first 30 days after each procedure, for all-cause mortality and complications; we used the GHC data to be consistent with the rest of the inputs and to estimate the direct medical costs. The definitions for complications and extended length of stay were maintained from the original report and continued to be used to identify subjects with increased health resource use over the first five years after each procedure but now adding specific comorbidities instead of only age, BMI and gender. The annual changes in BMI associated with two of the three procedures from the GHC database were validated with the systematic review of literature by Picot et al [23].

The estimation of utilities, from the same systematic review and cost-effectiveness analysis from the United Kingdom [23], was unchanged in the model since we did not have that information available directly from patients in our dataset. The estimation of annual direct medical costs in the first five years post-surgery used the same model described for

the propensity-matched cohort in Chapter 2, using a generalized linear model (GLM) with a log link function and gamma distribution. Adjustment variables in the GLM cost model included the same original parameters and the addition of the specific comorbidities: diabetes, hypertension, dyslipidemia, coronary heart disease, and a comorbidity index, as described in the previous chapters.

Updates to the Natural History Model

Except for the estimation of costs in the first five years of this sub-model, the original structure and calculations of the natural history model were unchanged. This natural history sub-model model was mainly driven by our previously published annual estimates of BMI change conditional on survival and did not consider specific comorbidities [26]. Using longitudinal data from patients with BMI ≥ 35 enrolled in GHC between 2004 and 2010, this sub-model predicts BMI changes over time given starting age, baseline BMI, and gender [27].

Mortality estimates and life tables informing the sub-models to estimate life years and life expectancy were not changed in the model. Life expectancy was also based on BMI, age, and gender and did not include comorbidities due to the lack of long-term information on a similar cohort to inform this analysis. The National Health Interview Survey between 1997 and 2000, linked to the National Death Index with mortality follow-up through December 31, 2005, was used to estimate the survival model in the original model, and this remained unchanged.

Estimation of health utilities were not changed from the original model due to lack of information in this specific population. Data from the Medical Expenditure Panel Survey (MEPS) between 2000 and 2006, were used to estimate utilities in the original model.

The estimation of total costs in this natural history sub-model did not change after the first five years. A two-part model was developed to estimate the annual medical costs and to address the high proportion of zero costs in the MEPS dataset [28,29]. Adjustment

variables in the utility and cost models included only BMI, age, and gender, as described in the original model.

Scenario Analysis

For this new analysis, we tried to replicate the original base case of our BOOM model, a 53 year-old female with a baseline BMI of 44 kg/m². Then we examined three different clinical scenarios to estimate the cost-effectiveness of the different types of bariatric procedures in patients with different combinations of major cardiovascular risk factors and comorbidities and severe obesity. The scenarios were divided into: 1) Low risk: subjects with severe obesity and only one comorbidity; in this case, hypertension was chosen, as it was the most commonly reported comorbidity in our sample; 2) Moderate risk: subjects with severe obesity and two comorbidities. The combination included hypertension and diabetes, or 3) High risk: subjects with severe obesity and three or more comorbid conditions. For this scenario, we included diabetes, hypertension, dyslipidemia, and a comorbidity index of 2 or higher.

Results

Decision Analysis: five-year model

In this updated model, the total annual costs in the first five years post-surgery were higher for ORYGB, followed by LRYGB, and LAGB. This trend was maintained across all the scenarios with important changes in the magnitude of the costs as the number and combination of comorbidities was increased. The five-year costs of non-surgical subjects in the low-risk scenario were almost one quarter of the total costs in the high-risk scenario (\$30,618 vs. \$125,486), but in both cases the total costs were still lower than any of the surgical interventions (table 2). In this short-term model, ORYGB and LRYGB had higher five-year QALY values and reached lower BMI measurements five years after the procedure. The non-surgical group had the lowest QALY value and the highest BMI after 5 years compared to the surgical interventions. BMI changes and QALY estimates were the same across scenarios.

Having the non-surgical intervention as the reference group for comparison, the calculated five-year incremental cost-effectiveness ratio (ICER) for the three surgical interventions ranged from \$19,589 to \$32,951 per QALY gained in the low-risk scenario; and from \$2,502 to \$44,768 per QALY gained in the high-risk scenario. These differences in ICERs are mainly driven by the cost difference between interventions in each scenario.

Lifetime Analysis

In every scenario, the non-surgical cohort had lower lifetime direct medical costs compared to the surgical interventions but the magnitude of the differences between the interventions was lower when the scenario was a higher risk patient subgroup (table 3). Consistently, all surgical interventions were associated with longer life expectancy compared with the non-surgical cohort and yielded both greater life years and QALYs.

The incremental cost-effectiveness ratios (ICERs) for surgical procedures compared to no surgery ranged from \$1,597 to \$18,241 per QALY gained in the high-risk scenario and

\$7,803 to \$13,319 per QALY gained in the low-risk scenario. In the moderate- and high-risk scenarios, LAGB had the lowest ICER compared to the other surgical interventions; while in the low-risk scenario, LRYGB had the lowest ICER among the surgical interventions.

Under the commonly cited willingness-to-pay (WTP) threshold of \$100,000 per QALY gained, each surgical procedure would be cost-effective compared to no surgery for severe obesity. Even under a stricter WTP threshold of \$50,000 per QALY gained, these interventions remain cost-effective. Results were sensitive to the presence of comorbid conditions expressed in the three different scenarios and particularly affected the estimation of total direct medical costs.

Discussion

The number of patients undergoing bariatric surgery continues to grow in the US but still represents only a small portion of the population of patients who are eligible for the procedure: less than 2% of eligible subjects are having bariatric surgery [38]. Multiple studies have shown the short-term health benefits of these procedures but long-term outcomes data for newer procedures is still lacking. The perception of high costs associated with these interventions continues to be a barrier to access and to more consistent reimbursement policies for bariatric surgery. Following our initial work in the assessment and development of a comprehensive model to estimate the cost-effectiveness of the most common bariatric surgical approaches compared to a non-surgical cohort, we have incorporated additional variables and statistical parameters that were previously identified, as important contributors, to the impact of surgical interventions on costs and health outcomes in severely obese patients. Adding comorbid conditions to a previously BMI-driven model could provide more meaningful information to patients, payers, and policymakers to help them make decision that is more clinically and patient-centered focus.

Many of the components of the model remain the same. The basic structure of the model and the background statistical engines that provide the estimations for mortality, life expectancy, and utilities were unchanged in these updates. The main changes occurred in the estimation of costs for the decision analysis sub-model that, which focuses on the surgical interventions and the first five years in the natural history model for the non-surgical group. These changes were informed by the analysis using a propensity-matched cohort from GHC, previously described in Chapters 1 and 2.

We first replicated the original base case analysis for the BOOM model and added three scenarios of combinations of comorbidities and major cardiovascular risk factors. We found each of the bariatric procedures analyzed is cost-effective compared to non-surgical approaches for patients eligible for bariatric surgery, assuming a willingness-to-pay (WTP) threshold of \$100,000 or even \$50,000 per QALY gained. Despite being cost-effective,

under all the different scenarios, the surgical procedures remained more costly than the non-surgical alternatives. The cost-effectiveness of these interventions is driven by the benefits provided through increased life expectancy and improved quality of life. This is still a controversial topic since other studies [12,20] have reported some surgical interventions for obesity to be cost-saving but more recent analysis have reported no difference or higher costs for patients undergoing surgery, at least in the short term [30,31].

Previous studies have reported the cost-effectiveness of bariatric surgery compared to no surgical intervention [8-25] but none, to our knowledge, has incorporated all the major cardiovascular risk factors in their analysis. These updated cost-effectiveness estimates, incorporating the three scenarios combining multiple conditions and levels of risk, fall within the range of ICERs that have been reported in the literature, including our original model (Table 1), and vary based on the level of risk associated with the presence of more comorbidities which is in line with clinical perception and the evidence on the epidemiology and costs of these risk factors in other populations. Other studies have focused only on diabetic patients showing a more pronounced effect of surgery in costs and outcomes, particularly due to the remission of the condition in a high proportion of subjects. We limited our improvements to the cost estimation due to the lack of specific information on outcomes that incorporates these conditions for a severely obese population. Having detailed information of the impact of bariatric surgery on each one of the major cardiovascular risk factors in the long term and the potential differential effect in the quality of life on patients with these conditions could improve the estimation of this new model.

The advantage of using information from GHC is that it may be a better reflection of clinical practice, but currently, it has less information on newer procedures including AGB, which accounted for approximately 10% of the total number of patients undergoing bariatric surgery. Furthermore, none of these patients had more than three years of follow-up in our dataset, limiting our power to project costs and outcomes specific to this or other procedures. We attempted to replicate the base case of the original model as it was published, but it may not be the best reflection of the average patient in this population

from GHC, who is younger and with lower BMI. The results of the estimates would vary slightly, but the policy recommendation and the cost-effectiveness of these procedures would be maintained given that despite the variation, the incremental cost-effectiveness ratio would still be considered under the thresholds commonly used as references in the US (\$50,000 or \$100,000 per QALY gained).

The ICER estimates for bariatric surgical procedures appear to be cost-effective under all modeled scenarios. Current clinical trends toward better immediate post-surgical outcomes (i.e., lower mortality and fewer complications), new procedures, techniques, devices, and long-term management are likely to make surgical options even more cost-effective. These results suggest that surgical procedures to treat severe obesity have higher lifetime direct medical costs, but the improvement in quality of life and life expectancy yields a favorable ICER for these three surgical procedures compared to non-surgical interventions. Depending upon the specific willingness to fund QALY gains, by usual standards, bariatric surgery is likely to be cost-effective compared to no surgery. Additional data over a longer duration of follow-up measuring the impact of bariatric surgery on specific comorbidities is needed to improve the precision of these estimates.

Acknowledgements

This work was possible thanks to the Bariatric Outcomes and Obesity Modeling (BOOM) Project team, which is a multidisciplinary research collaboration investigating obesity health services. Collaborators of BOOM include: Franklin Skip Carr and Larry Belenke (Ventura Healthcare Systems LLC); David Flum MD MPH (co-PI), Andrew Wright MD, Rebecca Petersen MD, Steve Kwon, MD, Allison Devlin Rhodes MS, Kara E. MacLeod MPH, MA, Rebecca Gaston Symons, MPH, Andy Louie, Erin Machinchick, Katrina Golub MPH, Hao He PhD (Surgical Outcomes Research Center, University of Washington); Sean D. Sullivan PhD (co-PI), Louis Garrison PhD, Rafael Alfonso MD, MS, Bruce Wang PhD, Edwin Wong PhD, (Pharmaceutical Outcomes Research and Policy Program, University of Washington); David Arterburn MD, MPH (Group Health Research Institute, Group Health); and Louis Martin MD MS (Samaritan Physicians).

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Tables and Figures

Table 1. Review of Base-case incremental costs per QALY gained in studies using QALYs as outcome measure

Study	Type of intervention	Costs per QALY gained (2010 \$US)	Decision analytic type ^a	Study time horizon (years)
Ackroyd et al.[50]	Surgical	1206	2.1	5
McEwen et al.[56]	Surgical	1560	2.1	Lifetime
Keating et al.[54]	Surgical	2683	2.3	Lifetime
Hoerger et al.[57]	Surgical	7800	2.3	Lifetime
Jensen and Flum[49]	Surgical	8208	2.2	Lifetime
Clegg et al.[13]	Surgical	9357	2.5	20
Campbell et al.[55]	Surgical	9760	2.3	Lifetime
BOOM	Surgical	10,033	3	Lifetime
Salem et al.[52]	Surgical	16 909	2.2	Lifetime
Ikramuddin et al.[53]	Surgical	23 060	3.3	Lifetime
Craig and Tseng[48]	Surgical	24 950	2.2	Lifetime
van Mastrigt et al.[51]	Surgical	27 802	1	1

a Numbers in this column refer to the classification in the notes Type 2.1 Mathematical application; 2.2 Decision tree model; 2.3 Markov model; 2.4 Patient-level simulation; 2.5 Unclear; Performed alongside a clinical trial or observational study with modelling used to predict impacts after the trial period; Type 3: Mixed methods 3.1 Mathematical application

3.2 Decision tree model; 3.3 Markov model; 3.4 Patient-level simulation; 3.5 Unclear

Table 2. Results of the 5-year simulation for the base case (53 year old Female with BMI 44 kg/m², using GHC data

Intervention:	BMI	Costs	QALYs	5-year ICER
Low Risk Scenario				
Lap RYGB	32.12	\$ 51,407	4.30	\$ 19,589
Lap Band	35.20	\$ 47,919	4.21	\$ 17,685
Open RYGB	32.12	\$ 65,246	4.28	\$ 32,951
Non-Surgical	42.75	\$ 30,618	3.23	Ref
High Risk Scenario				
Lap RYGB	32.12	\$ 138,142	4.30	\$ 11,926
Lap Band	35.20	\$ 127,933	4.21	\$ 2,502
Open RYGB	32.12	\$ 172,532	4.28	\$ 44,768
Non-Surgical	42.75	\$ 125,486	3.23	Ref

Lap RYGB: Laparoscopic Roux-Y Gastric Bypass

Open RYGB: Open Roux-Y Gastric Bypass

Table 3. Results of the lifetime simulation for the base case (53 year old Female with BMI 44 kg/m², using GHC data

Lifetime Outcomes				
Intervention	Non-surgical	LRYGB	LAGB	ORYGB
Highest risk (all comobidities)				
Direct Medical Costs	\$ 287,028	\$ 298,664	\$ 290,473	\$ 333,053
QALY	11.46	13.99	13.61	13.98
Expected Age of Death	78	81	81	81
ICER	Ref.	4,593	1,597	18,241
Intermediate Risk (Diabetes +CCI=1)				
Direct Medical Costs	\$ 220,489	\$ 235,623	\$ 232,231	\$ 255,297
QALY	11.46	13.99	13.61	13.98
Expected Age of Death	78	81	81	81
ICER	Ref.	5,974	5,443	13,796
Lower risk (minimal CC)				
Direct Medical Costs	\$ 192,160	\$ 211,928	\$ 210,459	\$ 225,767
QALY	11.46	13.99	13.61	13.98
Expected Age of Death	78	81	81	81
ICER	Ref.	7,803	8,483	13,319

QALY: Quality Adjusted Life-Years
 ICER: Incremental Cost-Effectiveness Ratio