WEIGHING IN ON BARIATRIC SURGERY: INVESTIGATION OF THE LONG-TERM EFFECTIVENESS AMONG MEDICAID BENEFICIARIES

By

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ABSTRACT OF THE DISSERTATION

Weighing in on bariatric surgery: Investigation of the long-term effectiveness among Medicaid beneficiaries

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Obesity is one of the leading causes of preventable disease and death in the United States. Obesity treatment is critical for mitigating the detrimental effects of obesity on early disability, disease burden, and quality of life. In the general population, bariatric surgery is well documented as the most effective obesity treatment that facilitates important sustained weight loss, remission of associated comorbidities, and improved quality of life. Access to bariatric surgery among Medicaid beneficiaries—a population with a disproportionately high burden of obesity—is limited and the effectiveness of surgery in this population is controversial. Investigation of bariatric surgery outcomes among Medicaid patients is a critical step in informing appropriate obesity treatment guidelines for low-income patient populations with severe obesity. This dissertation aimed to evaluate the long-term success of bariatric surgical care in Medicaid beneficiaries, compared to commercially insured patients by 1) systematically summarizing the existing evidence, 2) assessing long-term weight loss and regain patterns, and 3) determining the changes to comorbidity prevalence over time. Chapter 1 is a brief introduction to obesity and bariatric surgery. Chapter 2 presents results of a systematic review, which suggested some heterogeneity

between groups in short-term outcomes with little evidence available on long-term outcomes. Study findings reported in Chapter 3 and 4 utilized data from the Longitudinal Assessment of Bariatric Surgery (LABS) study, a multi-center national prospective cohort of 2,458 patients receiving bariatric surgery and followed over five years. Chapter 3 demonstrates that Medicaid patients lose a substantial amount of weight and experienced minimal weight regain through 5-years post-operatively, levels which were similar to commercially insured patients. Chapter 4 indicates that Medicaid patients have substantially higher prevalence of comorbid disease than commercially insured patients at baseline but experience important and sustained reductions in the disease prevalence after receipt of bariatric surgery. Lastly, Chapter 5 includes a discussion of the implications of the new long-term evidence provided in this study, which confirms the effectiveness and long-term durability of bariatric surgery among Medicaid patients. Increasing the number and availability of specialty providers, eliminating unjustified pre-operative requirements, and universal coverage of bariatric surgery by state Medicaid programs are critical steps in providing equitable access to this lifesaving procedure.

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Chapter 1: Introduction and Background

1.1 The burden and consequences of obesity in the United States

In 2013, the American Medical Association officially recognized obesity—a complex, multifactorial, and chronic condition—as a disease (1). Obesity is most simply defined as excess body weight for height and is frequently divided into three body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) categories: Class I: BMI 30 to <35 kg/m^2; Class II: BMI 35 to <40 kg/m^2; and Class III BMI ≥40 kg/m^2 (2). Since 1960, the prevalence of adult obesity has nearly tripled, increasing from 13% in 1960-1962 to 39.8% in 2015-2016; indicating that more than 1 in 3 adults in the United States (U.S.) have obesity (3, 4). In 2013-2014, an estimated 1 in 13 adults were considered to have class III obesity (7.7%) (5). The prevalence of obesity further varies substantially by sex, socioeconomic status, and race/ethnicity. It is higher among women, those with a lower socioeconomic status, individuals of Hispanic origin, and non-Hispanic black adults (6). For example, in 2011-2014, the age-adjusted prevalence of obesity was 38.3% among women versus 34.3% among men; 34.5% among non-Hispanic white adults versus 48.1% among non-Hispanic black adults and 42.5% among Hispanic adults; and, among women, lower in the highest income group (29.7%) compared to the lowest income group (45.2%) (6).

Obesity is associated with a myriad of serious comorbid conditions, including but not limited to hypertension, dyslipidemia, Type 2 diabetes mellitus (diabetes), coronary heart disease, stroke, asthma osteoarthritis, sleep apnea, respiratory problems, and certain cancers (2). Obesity increases the odds of developing type 2 diabetes by seven-fold, the risk of hypertension by five-fold, and the risk of coronary heart disease by three-fold (7). Obesity also has negative impacts on mental health and health-related quality of life (2, 3, 8, 9). Finally, obesity is independently associated with increased risk of all-cause and cardiovascular disease mortality (1, 2).

Obesity and obesity related diseases not only increase morbidity and reduce life expectancy but drastically increase societal economic burden through direct and indirect costs. In the U.S., there is a clear link between the rising prevalence of obesity and increases in direct medical spending; chronic diseases like cancer, diabetes, and obesity are primary drivers of health care spending, disability, and death (10, 11). In 2008, the U.S. spent approximately 147 billion dollars treating obesity and obesity-related diseases (1). Per capita medical spending for individuals with obesity is $1,429 higher per year, or approximately 42 percent higher, than those who are normal weight (11, 12). Currently, although pharmaceutical, medical and surgical interventions exist for the treatment of obesity, the majority of these costs stem from treating the diseases that obesity promotes, such as diabetes and hypertension (11).

The indirect costs of obesity, including absenteeism (absence from work because of health issues), presenteeism (not being productive while on the job), and disability, are estimated to be several times higher than direct medical spending (13-15). Absenteeism and presenteeism both increase with increasing BMI, representing a substantial loss in productivity (14). A less productive workforce could lead to substantially increased production costs and in general a less competitive workforce (13). In 2012, approximately 9.3% of absenteeism was attributable to obesity, an estimated economic loss of $8.65 billion in productive work time (13, 14). In regards to disability, obesity can increase disability payments and disability insurance premiums (16). Burkhauser and Cawley observed the probability of receiving disability income increased by 6.9% and 5.6% for men and women with obesity, respectively, as compared to individuals of normal weight (17).

Although commercial payers bear the majority of obesity-related medical expenses, obesity health care resources impose substantial costs onto individual states (18). Medicaid enrolls a population with the highest prevalence of obesity- and obesity-related chronic conditions. Consequently, approximately 11% of adult Medicaid expenditures are attributable to obesity (18, 19). In 2013, an estimated $69 billion in medical costs was attributed to severe obesity and related conditions; an estimated $18 billion was spent on 64.2 million commercially insured adults, while an estimated $8 billion was spent on just 12.2 million Medicaid beneficiaries (**Figure 1.1**) (12, 20, 21).

1.2 The determinants of obesity

At the most basic understanding, obesity is a result of long-term weight gain caused by a lack of energy balance, where *energy intake*, or the amount of energy or calories one gets from food and drinks, exceeds *energy expenditure*, or the amount of energy the body uses for things like breathing, digesting, and being physically active (22). There are a multitude of individual-level risk factors for being out of energy balance, including diet, sedentary behaviors, genetics, family history, health conditions, certain medical treatments, emotional contributors, age, pregnancy, and lack of sleep (2, 22). These individual level risk factors are further influenced by multiple levels of socioenvironmental risk, including at the interpersonal level (e.g., family, social networks), community level (e.g., schools, workplaces), and governmental level (e.g., state or national legislation) (2, 23, 24). Then, as a result of social and economic changes at the systems level—economic growth, easy availability of inexpensive, energy-dense, palatable foods, industrialization, and mechanized transportation—the U.S. obesogenic environment further promotes obesity (25). The complex interactions between the environment, socioeconomic factors, personal behaviors, and genetics make completely understanding obesity, including best practices for prevention and treatment, increasingly difficult.

1.3 Current obesity prevention and treatment practices in the U.S.

Slowing the current obesity epidemic will require a systems-oriented, multi-level framework encompassing research that focuses on adopting policies and creating environments that support healthier lifestyle choices (24, 26). Prevention approaches that are informed by an ecological framework, emphasizing the importance of social, environment, and policy contexts as personal behavior influences, are important (27). Many of the common individual level prevention strategies include encouraging healthy food choices, limiting portion sizes, decreasing screen time, and increasing physical activity. Current strategies at the community level include efforts to increase the availability of affordable healthy food and beverages, encourage breastfeeding, encourage physical activity, limit sedentary activity among children and youth, and create safer neighborhoods and communities that promote walkability (26).

While prevention is of utmost importance, the medical treatment and management of the millions of individuals already affected by obesity is necessary and equally challenging (7). It is widely recognized that obesity is typically irreversible without medical treatment, including lifestyle intervention, pharmacotherapy, or surgical treatment (7). In 2012, the American Heart Association (AHA), American College of Cardiology (ACA), and The Obesity Society (TOS) collaboratively published rigorous evidence-based obesity treatment guidelines (**Figure 1.2**). These guidelines recommend comprehensive lifestyle intervention as the first line of treatment, and as a second step either 1) add pharmacotherapy as an adjunct to the lifestyle intervention or 2) referral to a bariatric surgeon (1).

The effectiveness of medical treatment for obesity varies by treatment type. Lifestyle interventions (combination of diet, physical activity, and behavioral modification therapy) demonstrate moderate and variable amounts of short-term weight loss (5% to 10% of initial weight) and are greater than those produced by usual care (1). In the long-term, lifestyle interventions are variable and associated with a gradual weight regain of 1 to 2 kg/year on average, relative to the weight loss achieved in the first year (1). Adding pharmacotherapy as an adjunct to comprehensive lifestyle interventions is demonstrated to increase the likelihood of achieving clinically-meaningful weight loss (3-9% of initial weight) at 1-year, compared to placebo, although the response varies by drug type (28).

Additionally, while weight loss following the introduction of pharmacotherapy produces greater improvement in many cardiometabolic risk factors compared to placebo, no obesity medication has been demonstrated to reduce cardiovascular morbidity or mortality (28). For patients who have not responded to behavioral treatment (with or without pharmacotherapy), bariatric surgery is the best available treatment evidenced to produce a consistent and sustained weight loss of more than 15% of initial body weight. As compared to bariatric surgery, both lifestyle interventions and the use of pharmacotherapy are considerably less effective in the long-term on improving outcomes, including comorbidity remission and survival (1).

1.4 Bariatric procedure types, risks, and benefits

In 1991, the National Institutes of Health (NIH) released a consensus statement endorsing the use of bariatric surgery for the treatment of severe obesity (class II or class III obesity) (29). The statement also established the patient selection criteria, where a patient must have 1) BMI ≥ 40 kg/m^2 or 2) BMI 35-40 kg/m^2 with a high-risk comorbid condition (e.g., sleep apnea, hypertension, diabetes) to be eligible for surgery (29). Currently, there are four primary variations of bariatric surgery in use: vertical sleeve gastrectomy (VSG), Roux-en-Y Gastric Bypass (RYGB), adjustable gastric band (AGB), and biliopancreatic diversion with duodenal switch (BPD/DS). The mechanisms through which these procedures induce weight loss are under ongoing investigation but are believed to be dominated by complex changes to neuroendocrine signaling (30, 31).

Since the NIH's 1991 statement on bariatric surgery, the evidence base supporting the surgical treatment of severe obesity among the general patient population has grown. The most recent observational research suggests that 75% of patients undergoing RYGB maintain at least 20% weight loss, and 50% of LAGB patients maintain at least 16% weight loss through 7 years post-operatively (32). At 5 years post-operatively, recent clinical trial evidence suggests patients undergoing VSG maintain slightly less overall weight loss as compared to RYGB patients, but for both surgery types, mean percent weight loss still exceeded 25% (33, 34). In addition to substantial and durable weight loss, bariatric surgery induces long-term remission of comorbidities, including diabetes, dyslipidemia, and hypertension (32, 35-37), improved functional capacity and quality of life (38-40), and lower all-cause mortality (41-43).

Although surgical complications were a serious concern in the past, safety has been improved in bariatric surgical practice. Based on data from 109 hospitals from 7/2007 to 9/2010, mortality and complications following bariatric surgery are exceedingly low; mortality within 30 days occurs in 0.11% of VSG patients, 0.05% of LAGB patients, and 0.14% in RYGB patients. 30-day re-admissions occur in 5.61% of VSG patients, 1.44% of LAGB patients, and 5.91% of RYGB patients; 30-day reoperation/intervention occurs in 2.95% of VSG patients, 0.92% of LAGB patients, and 5.02% of RYGB patients (44, 45). The health risks from obesity far outweigh the risks associated with bariatric surgery.

1.5 Utilization, costs, and coverage of bariatric surgery

Coinciding with the improvements in safety and established long-term effectiveness of bariatric surgery, the utilization of surgery has drastically increased over the past two decades, including an observed tenfold increase from 1993 to 2008 (46-48). Historically, the RYGB has been considered the “gold standard” surgery, inducing the most substantial long-term weight loss with the best long-term maintenance of the initial weight loss (49). Consequently, the RYGB has been the most commonly performed bariatric procedure type for years. However, in recent years, VSG has been performed at increasing frequency while the use of RYGB has decreased slightly and the use of LAGB has markedly decreased (**Table 1.1**) (50). Surprisingly, despite the steady increase in the use of bariatric surgery and its evidenced effectiveness in treating severe obesity, surgery is achieved as a treatment option for only 1% of all eligible patients in a given year (estimated number of patients with class III obesity) (50).

The cost and insurer coverage of bariatric procedures likely play an important role in the relatively low utilization of bariatric surgery amongst eligible patients. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) estimates on average surgery can cost between $15,000 and $25,000, largely dependent upon the procedure type and absent complications (51). Although the initial cost of the operation is high, compared to pharmaceutical treatments, lifestyle interventions, and the cost of treating obesity-related diseases, evidence supports the use of bariatric surgery as a long-term cost saving operation (52-55). For example, one study found that after investing $17,000-26,000 for bariatric surgery, the third-party payer would recoup that cost within 4 years of an open bariatric procedure and only in 2 years following a laparoscopic surgery as a result of the reduction in prescription drug costs, physician visits costs, and hospital costs (53).

Today, bariatric surgery is covered to varying extents by commercial insurance companies and state Medicaid programs, each of whom can set additional patient eligibility criteria beyond the standard NIH requirements. Requirements depend on the coverage type but may include the use of only accredited facilities, demonstrating failed attempts at weight loss via nonsurgical weight loss treatments, and undergoing psychological evaluations (51, 56).

The most recent evaluation of Medicaid coverage revealed that 47 state Medicaid programs, in addition to the District of Columbia, cover bariatric surgery to some extent (**Figure 1.3**). Of these, 36 require prior authorization and 37 require criteria other than BMI to determine eligibility; three state Medicaid programs (Montana, Ohio, Mississippi) specifically exclude coverage of bariatric surgery (57). Compared to other obesity treatments, bariatric surgery is consistently covered by state Medicaid programs, whereas, only 14 state Medicaid programs cover pharmacotherapy treatments (57).

1.6 Disparities in the utilization of bariatric surgery

It is important to recognize that insurance coverage or general access to bariatric surgery does not necessarily equate to utilization. In fact, the pattern of utilization is not uniform across patient populations. Livingston et al and Martin et al reported a substantial mismatch between the eligible patients and those patients who receive bariatric surgery on the basis of several sociodemographic characteristics (58, 59). Generally, for those who undergo surgery there is an underrepresentation of men, those with lower incomes, those with lower educational levels, those of nonwhite race, those living in rural areas, and the underinsured (58-60). Specifically, one pooled estimate suggested of the more than 8.8 million bariatric eligible patients with government insurance, only 29,300 patients received bariatric surgery (60). The disparity in receipt of the most effective treatment for obesity is likely related to multiple factors including the structure of the health care system, procedure cost, reimbursement levels, surgical outcomes believed to be poor, and personal barriers and constraints (e.g., time off work, transportation to clinic). Gaining a better understanding of these populations and their outcomes following bariatric surgery is essential to developing an impartial approach to the provision of bariatric surgery to patients (61).

1.7 Significance and need for the current research

The prevalence of Class III obesity is rising faster than any other degree of obesity, with 7.7% of Americans currently affected; effective obesity treatment is critical for mitigating the numerous adverse effects of severe obesity. For the general patient population, bariatric surgery is the most effective treatment for substantial and sustained weight loss, remission of comorbidities, and increased long-term survival. As a result, the utilization of bariatric surgery has increased rapidly over the last several decades. However, the increased utilization is not equal across patient groups on the basis of various sociodemographic characteristics (59).

Specifically, Medicaid beneficiaries receive bariatric surgery less often than any other insurance group despite recent expansions to surgery eligibility and comprising the largest proportion of surgery-eligible patients (61). Although it is possible that Medicaid patients may not experience the same long-term benefits as other groups, research testing hypotheses related to bariatric surgery outcomes among sub-groups is limited (62, 63). Furthermore, the recently published obesity treatment guidelines specifically highlight the need for research characterizing patient populations whom are most likely to benefit from bariatric surgery on the basis of sociodemographic and clinical characteristics. Further investigation of bariatric surgery effectiveness among Medicaid patients is therefore warranted and remains a critical step in informing appropriate obesity treatment guidelines and reducing obesity-related health disparities for low-income patient populations.

The proposed study determined the comparative impacts of bariatric surgery in Medicaid versus commercially insured patients. We systematically evaluated the existing evidence of surgery outcomes among Medicaid and commercially insured patients to establish the current state of the evidence from which to build upon. We leveraged a unique multicenter geographically diverse longitudinal cohort (Longitudinal Assessment of Bariatric Surgery; **LABS**) of 2,458 bariatric surgery patients followed over five years with high levels of follow-up to evaluate long-term weight loss and regain and comorbidity risk. Study findings on sub-group specific weight loss and weight regain patterns are a first step toward guiding clinical strategies for tailoring post-operative care according to a patient's risk and timing of weight regain. Findings on differences in comorbidity risk across groups are paramount for optimizing clinical strategies to provide therapies and monitoring critical to each subgroup.

Ch.	***Purpose***	***Contribution to new knowledge***
2	Systematically evaluate and summarize the current evidence base on bariatric surgery outcomes in Medicaid patients compared to commercially insured patients.	Findings provide a summary of the current evidence base, highlight specific knowledge gaps, and provide a thorough discussion of future directions for this field.
3	Determine if weight loss and regain over a 5-year period after bariatric surgery differs between Medicaid beneficiaries and commercially insured patients.	Findings fill in a major gap in the evidence base with respect to the long-term durability of weight loss following bariatric surgery among Medicaid patients.
4	Determine if the prevalence of risk of four common comorbidities differ between Medicaid and commercially insured patients 5-years following bariatric surgery.	Findings provide an objective evaluation of changes in comorbidity prevalence and risk over 5 years following bariatric surgery among Medicaid patients.

While the primary public health focus for reducing the socioeconomic disparities in obesity has focused on prevention, effective treatments are a potentially important, yet understudied component. Appropriate and tailored treatment strategies are needed for those suffering with severe obesity to improve health, longevity, and quality of life. This study takes the first steps in evaluating obesity treatments for patient sub-groups.

Institutional Review Board exemption was obtained from Oregon Health & Science University for this project, additional information related to the provision of human subjects' protection is detailed in **Appendix A**.

Table 1.1 Total number of bariatric procedures, 2011-2015 (50)

Year	2011	2012	2013	2014	2015
Total	158,000	173,000	179,000	193,000	196,000
RYGB	36.7%	37.5%	34.2%	26.8%	23.1%
LAGB	35.4%	20.2%	14.0%	9.5%	5.7%
VSG	17.8%	33.0%	42.1%	51.7%	53.8%
BDP/DS	0.9%	1.0%	1.0%	0.4%	0.6%

Figure 1.1 Coverage for obesity treatments and medical expenditures in 2013 attributable to severe obesity, by state and payer (12)

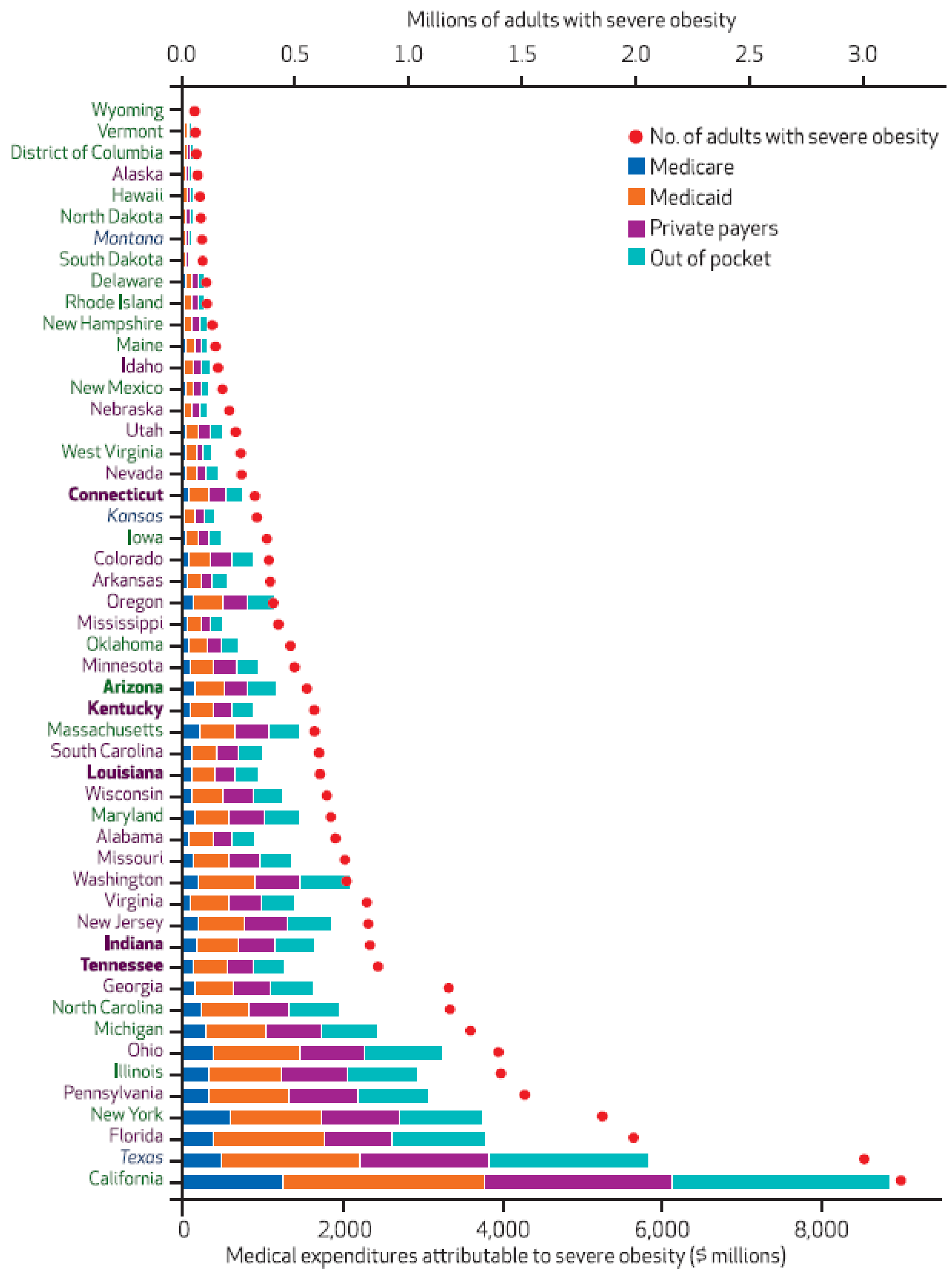


Figure 1.2 Treatment algorithm—Chronic Disease Management for Primary Care of Patients with Overweight and Obesity (1)

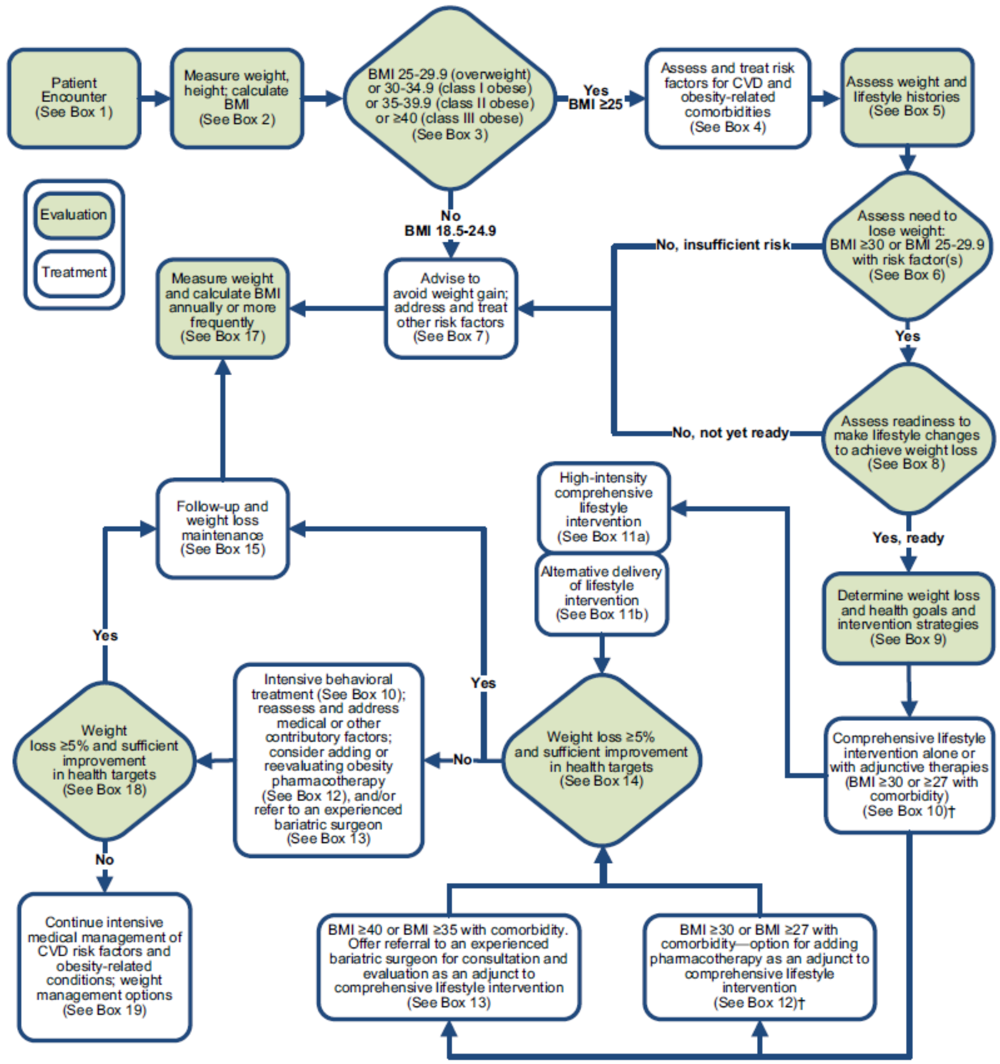
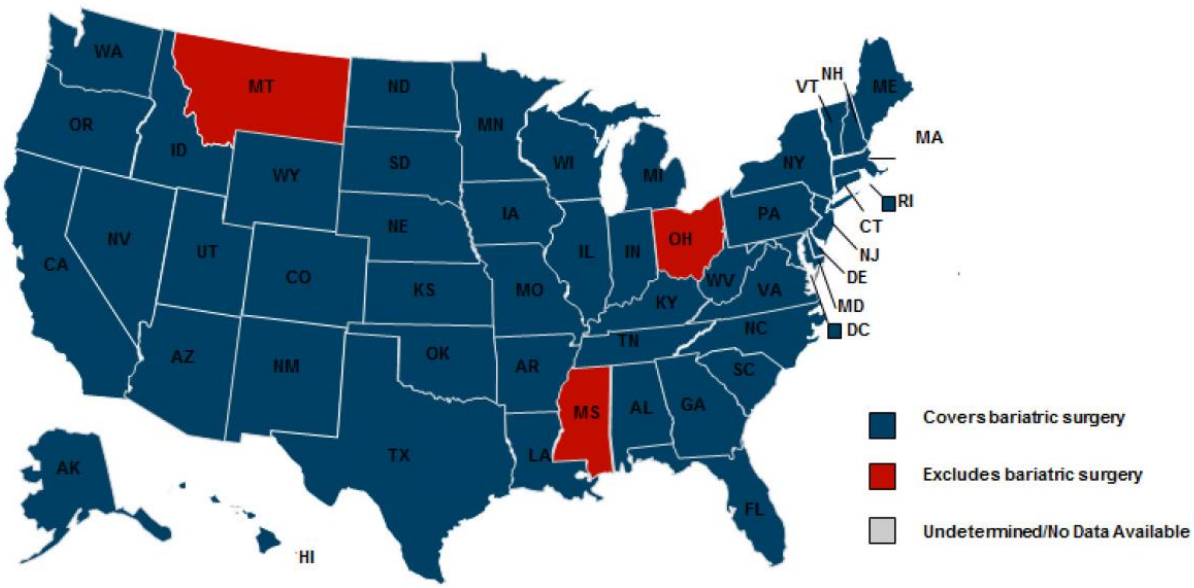


Figure 1.3 State Medicaid Coverage for Bariatric Surgery (57)



Chapter 2: Weighing in on bariatric surgery: effectiveness among Medicaid beneficiaries—limited evidence and future research needs

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Author Contributions: ET, JBH, and CLN contributed to the study design, data analysis, data interpretation, and manuscript preparation. SBA contributed to the data analysis and manuscript preparation. BMW contributed to the study design, data interpretation, and manuscript preparation. ET is the guarantor of this work, and as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the analysis. JBH supervised all aspects of the study. An abstract of this study was presented at Obesity Week 2016 in New Orleans, LA on November 3, 2016.

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2.1 Abstract

In the general population, bariatric surgery is well documented as the most effective obesity treatment for sustained weight loss and remission of comorbidities. Characterization of patient populations most likely to benefit from surgical intervention is needed, but heterogeneity of treatment effects across payer groups has not been reviewed. We conducted a systematic review of published studies focusing on bariatric surgery outcomes among Medicaid beneficiaries. Using PubMed and Scopus, we searched for studies that quantitatively compared clinical or social bariatric surgery outcomes for United States adult Medicaid recipients to commercially insured patients. Of the 568 titles reviewed, 21 met inclusion criteria. Weight loss and remission of comorbidities at one or two years post-operatively were similar between groups, despite differences in baseline health status. Short-term healthcare utilization and mortality outcomes were worse in Medicaid recipients, for instance, Medicaid patients had an average length of stay that was 2 days longer and experienced 3 more deaths in the first post-operative year. Critical research gaps in the evidence base needed to improve treatment guidelines for Medicaid patients undergoing bariatric surgery include understanding of the causes of the baseline health differences and how these differences contribute to post-operative outcomes.

2.2 Introduction

In the United States, obesity and its cardiometabolic sequelae are among the leading causes of preventable disease and death (64). Obesity prevalence has plateaued at 30% in the U.S. adult population, but is as high as 58% in adult African American women, and severe obesity (class II and III) continues to rise (59, 65, 66). In the U.S., obesity burden falls disproportionately on racial-ethnic minorities and low-income patients (67, 68). Substantial implications for the health of the U.S. population stem from the biomedical, psychosocial, and economic consequences of obesity (1).

Treatment of severe obesity is critical for mitigating the detrimental effects of obesity on early disability, disease burden, unemployment, and quality of life (QOL). While lifestyle and pharmaceutical interventions induce small levels of initial weight loss, maintaining long-term weight loss is difficult and improvement in morbidity and mortality is inconsistent (28, 69). For the general patient population with severe obesity, bariatric surgery is the most effective treatment for substantial and sustained weight loss (70, 71). Benefits of bariatric surgery also include remission of comorbidities, improved psychosocial function, and decreased levels of work impairment (70, 72-74).

The utilization of bariatric surgery has increased rapidly over the last several decades, raising pressing questions about sub-groups of patients that are most responsive to surgical intervention (46, 75, 76). In particular, the recently published obesity treatment guidelines highlight the need for research characterizing those patient populations (e.g., on basis of race/ethnicity, psychosocial/behavioral characteristics, or degree/duration of obesity) who are most likely to benefit from surgical intervention (1). One understudied population are adults with Medicaid, 58% of whom are racial/ethnic minorities and 72% live below the federal poverty level (19, 77). Adults with Medicaid also have the highest prevalence of obesity-related chronic conditions, are more likely to be in poor to fair health, and to be limited or unable to work as compared to privately insured or the uninsured (19). As a result, approximately 11% of adult Medicaid expenditures are spent on treating obesity and related conditions (78, 79).

In recent years, while Medicaid and surgery eligibility has expanded, the proportion of Medicaid beneficiaries undergoing bariatric surgery—the most effective treatment for severe obesity—remains lower than any other insurance group (19, 58, 59, 79, 80). The literature with respect to bariatric surgical outcomes among the Medicaid population has not been systematically reviewed to date. Notably, bariatric surgery among Medicaid patient populations may be critical for improving health among those with the highest burden of obesity (58, 59). To summarize current evidence, we conducted a systematic review of published studies on bariatric surgery outcomes among Medicaid beneficiaries.

Key Question

Are outcomes following bariatric surgery different for Medicaid patients, compared to those patients with commercial insurance?

2.3 Methods

Eligibility

We searched Medline (via PubMed) and Scopus databases for English-language literature studies that were conducted in the United States and published between January 1, 2000 and June 1st, 2017. We limited to studies published after 2000 because bariatric surgical risks and practices have changed dramatically in recent years. The search strategy combined medical subject headings (MeSH terms) and plain text searches for bariatric surgery (e.g., MeSH: bariatric surgery), Medicaid (e.g., MeSH: Medicaid; poverty; Centers of Medicare and Medicaid Services) and outcomes (e.g., MeSH: treatment outcomes; outcome assessment) (**Appendix B**). Reference lists of the included papers were additionally searched. The population, interventions, study eligibility criteria are described in **Appendix C**.

Review of Candidate Papers

Two independent reviewers reviewed the title or abstract of all studies identified by the literature search. Studies that 1) met inclusion criteria or 2) the title, abstract, or description didn’t provide sufficient information for exclusion were selected for full-text review. Any discrepancy was resolved by a third reviewer. This process was repeated for reviewing the references of the included papers.

Data Extraction

For papers that met inclusion criteria, two independent reviewers abstracted study information into a predefined template that included the following domains: study characteristics, participant characteristics, exposure and covariates, outcome(s), analytic method, missing data, results, and control of confounding variables (**Appendix D**).

Quality Assessment

Two independent reviewers assessed the quality of all included studies. Any discrepancy was resolved by a third reviewer. A modified version of the NIH Quality Assessment Tool for Observational Cohort and Cross-sectional studies (**Appendix D**) was employed (81). All studies, regardless of quality level, were included due to the small body of literature.

Data Synthesis

We conducted a qualitative data synthesis of all papers that met inclusion criteria. Due to the heterogeneity in body of literature, we were unable to complete a quantitative synthesis of the data.

2.4 Results

Study selection

PubMed and Scopus searches identified 289 unique articles (**Figure 2.1**). Of these, 244 were excluded based on review of the title or abstract, leaving 45 articles for full text review; 17 met inclusion criteria. Review of reference lists of the included papers yielded an additional 4 articles, for a total of 21 articles. Primary reasons for exclusions included no insurance groups, no quantitative comparison between insurance groups, or the combination of Medicaid with another insurance group.

Study characteristics

Six studies were retrospective reviews of electronic medical records (EMR) conducted at 1-2 centers and 15 studies were retrospective reviews of billing or claims databases (**Table 2.1**). The duration of follow-up ranged from hospital discharge to 15 years; follow-up was a year or less in 16 studies, and 2 or more years in five studies. The majority of the included studies examined mortality (n=9), weight loss (n=7) or remission of comorbidities (n=6). Other outcomes included healthcare utilization (n=7) such as length of hospital stay and total charges, and post-operative complications (n=5).

Weight loss

All seven studies reporting on weight outcomes observed substantial weight reduction in all insurance groups (82-88). Reported outcome variables included percent of excess weight lost, difference in weight or BMI between time points, and weight loss classified as sub-optimal (**Table 2.2**). Medicaid recipients had a higher pre-operative BMI or weight in all but one study, 4 of which reached statistical significance. Medicaid beneficiaries' average pre-operative BMI ranged from 1 to 9 BMI units higher than commercially insured patients.

Despite these baseline differences, four of the seven studies reported similar proportions of weight lost at follow-up among Medicaid and commercially insured patients (85-87, 89). Three studies reported lesser weight loss in Medicaid recipients. In the first two, Medicaid recipients lost a significantly lower percent of total excess body weight at follow-up (65.6% non-Medicaid vs. 50.7% Medicaid (83); 64.6% non-Medicaid vs. 53.8% Medicaid (84)). In the third study, Medicaid recipients were twice as likely to have sub-optimal weight loss, defined as failure to lose at least 40% of excess body weight by 1 year following surgery; however, this finding was not statistically significant (95% CI: 0.7, 3.2) (88).

Comorbidities

Six studies examined obesity-related comorbidities, most commonly Type II Diabetes Mellitus (DM), hypertension, hyperlipidemia, or obstructive sleep apnea (**Table 2.3**) (82-86, 90). Four of the six studies reported baseline prevalence of comorbidities, all but one of which observed greater prevalence of pre-operative comorbid conditions in Medicaid beneficiaries. Akin to weight loss outcomes, the three studies that reported on remission of comorbidities reported the proportion in remission at follow-up was similar among Medicaid and commercially insured patients. For example, resolution of DM among commercial and Medicaid patients, respectively, was 63.3% vs. 76.9% (83), 48.7% vs. 66.7% (84), and, among those not on insulin, 72.8% vs. 69.5% (86). Only Hayes et al reported their results reached statistical significance. Contrary to other studies, Chen et al reported that Medicaid patients had lower prevalence of several comorbidities at baseline and at follow-up, and higher resolution of hypertension, hyperlipidemia, and DM; however, these were not statistically significant differences and did not account for baseline differences. Similarly, Gomez et al reported superior dyslipidemia and alcohol use outcomes at follow-up in Medicaid recipients (85).

Mortality

Nine studies reported on mortality; four studies examined in-hospital mortality, while five examined all-cause mortality over study periods ranging from 90-days to 15-years post-operatively (**Table 2.4**) (82-84, 90-95). Six of the 9 studies observed statistically significant differences in mortality between the groups, all higher among the Medicaid recipients. However, mortality was relatively rare among both patient groups. For example, Funk et al reported one death (1.1%) among commercially insured patients versus one (3.3%) among Medicaid patients over two years, while Chen et al reported no deaths among either group within 90-days of surgery (83). Poulouse et al estimated that the odds of in-hospital mortality for a Medicaid patient was four times the odds for a commercially insured patient (95% CI: 1.2, 13.0).

Healthcare Utilization

Health care utilization measures (**Table 2.5**) included hospital admissions/discharges (7 studies), emergency room visits (3 studies), length of hospital stay (LOS) (6 studies), and total charges (2 studies) (82-84, 86, 87, 90, 96-99). Post-operative healthcare utilization measures tended to be higher in Medicaid beneficiaries compared to commercially insured patients, although no comparisons were made to pre-operative utilization. The odds of 30-day hospital readmission was nearly threefold higher among Medicaid beneficiaries as compared to commercially insured patients (OR: 2.8, 95% CI: 1.2, 7.0) (87). Similarly, emergency room visits (OR: 3.2, 95% CI: 1.1, 9.1) (96) and total charges ($6,000 greater: $24,243 vs. $30,165) (90) were higher among Medicaid beneficiaries.

Complications

Five studies reported on post-operative complications, four of which examined in-hospital complications while the other examined complications occurring within 90 days of surgery (**Table 2.6**) (83, 100-103). All five studies reported no statistically significant differences between the insurance groups with regard to the occurrence of post-operative complications.

Quality of included studies

On average, the majority of the included studies only met 5 to 7 of the 11 quality measures included in our modified version of the NIH Quality Assessment Tool. The first and most common quality concern was the inadequate or lack of control of confounding variables. Most notably, the studies utilizing claims databases (N=13) do not have access to data on body weight or BMI and other important disease severity measures at any pre- or post-operative time point; consequently, this precluded these studies from adjusting for baseline differences and other major confounding factors in their analyses. Additionally, 6 studies conducted bivariate comparisons without adjustment for confounding. Second, for the 6 studies that utilized EMR data but did not select their sample based on available follow-up, all but one study had loss to follow-up after baseline that was greater than 20%. Lastly, the lack of detail into how the analytic samples were constructed (N=6), including the description and application of the inclusion/exclusion criteria, makes it difficult to discern the validity and generalizability of these studies findings.

2.5 Discussion

This review suggests that the majority of bariatric surgery patients experience substantial weight loss and remission of obesity-related disease regardless of insurance status. The majority of studies report that Medicaid beneficiaries achieve similar proportions of weight loss and remission of comorbid disease. However, higher body weight and a greater number of comorbid conditions persist post-operatively among Medicaid beneficiaries. Mortality and healthcare utilization measures also tended to be worse among Medicaid recipients, but these studies were vulnerable to bias related to baseline differences, which in part may stem from limited access to treatment. Although the body of literature suggests bariatric surgery is effective among Medicaid patients in short-term weight loss and remission of comorbidities, concern regarding the increased incidence of mortality and healthcare utilization remains. We discuss potential reasons for the current findings, identify the limitations to this body of evidence, and highlight future research needs.

Pre-operative health differences

The majority of studies reported a difference in baseline health status between payer groups, one that often persisted through follow-up. Recognizing the potential root causes for these baseline differences is paramount to guiding decisions about the benefits of bariatric surgery in Medicaid patients. Medicaid's income-related eligibility criteria and the strong association between poverty, poor health, and disability is one contributor to poorer health in Medicaid beneficiaries, compared to commercially insured patients (80). However, the contribution of poverty to poor pre-surgical health may be modifiable by reducing barriers to treatment by providing coverage and an adequate number of specialty providers.

First, in most patient populations, cost can be a barrier to receiving care; this is more pronounced amongst Medicaid beneficiaries than commercially insured patients (80, 104, 105). Compared to commercially insured patients, Medicaid beneficiaries are more likely to delay seeking medical treatment or not seek care at all due to cost of treatment (104, 105). The lack of or delay in medical treatment for obesity can increase the degree of obesity and the number and severity of related comorbidities, contributing to an elevated complexity of pre-operative disease.

Second, most clinics only accept a limited number of publicly funded patients per day. This unmet need for critical medical care is even more prominent in the case of specialist services, like bariatric surgery. Medicaid beneficiaries are one of the few insurance groups who have received bariatric surgery less often during the last 10 years; in some states few, or no, bariatric centers will perform surgeries on Medicaid beneficiaries (61, 106). Without timely and equitable access to bariatric surgery, the compounding health effects of severe obesity will continue to disproportionately affect Medicaid beneficiaries. These baseline differences have several important implications for the studies summarized here and are described in the subsequent sections.

Short-term outcomes

The studies reporting on healthcare utilizations and mortality measures consistently reported worse outcomes among Medicaid beneficiaries. However, because pre-operative BMI and number of comorbidities were not available in most of the studies examining mortality and healthcare utilization, the baseline health differences were unaccounted for in their analyses. Thus, the results of these studies should be interpreted with caution. Patients with an elevated surgical risk are subsequently at a greater risk of developing post-operative complications, a prolonged length of stay, admission to the ICU, increased total charges, and mortality (107, 108). Also, as previously discussed, poor overall health is an independent risk factor associated both with Medicaid status and mortality. It is possible that the observed increase in Medicaid healthcare utilization and mortality arises because of the initial delay in care for Medicaid beneficiaries. Consequently, delayed access to care adversely propagates obesity severity, baseline health status, and in turn distorts the estimates of surgery effectiveness between the insurance groups. Without adequately controlling for confounding factors or recognizing the potential for biased selection of surgical patients, the findings that increased risk of healthcare utilization and mortality were associated with Medicaid status are likely overestimations of the true associations. In order to parse out these effects, it is necessary to adequately control for baseline characteristics such as severity and number of comorbid conditions, degree of obesity, and duration of obesity.

Moreover, Medicaid patients may have had limited options for immediate access to treatment except through emergency services. The observed increase in number of emergency room visits and hospital readmissions may be related to a patient's inability to obtain timely care elsewhere or related barriers, like distance to, cost, and means of transportation to a non-emergency clinic. Not only does this raise concern that the quality of insurance (e.g., reimbursement levels) influences equitable access to post-surgical treatment, these modifiable barriers may pose a threat to the long-term success of the surgery. Several studies highlight the inequitable access to bariatric surgery and pre-operative appointments among Medicaid patients, yet few studies to date have focused on access and receipt of appropriate care post-operatively (58, 59, 106).

Medium- and Long-term outcomes

Several studies focused on weight loss and resolution of comorbidities through one to two years post-operatively. In general, the reported studies concluded Medicaid patients achieved similar proportions of weight loss and disease remission, but remained sicker at follow-up. Though, most studies did not conduct formal statistical comparisons or modeling; these methods aim to control for important confounding factors, especially the baseline health differences. Additionally, studies often reported one disease metric at baseline and another at follow-up, limiting the ability to compare change over time. Without reporting baseline information, formal statistical comparisons, and consistent disease measures, it remains difficult to make accurate inferences about the comparative success of surgery between these patient populations.

In general, the goal of bariatric surgery is to mitigate the chronic effects of obesity that would occur over the long term, including increasing QOL. Consequently, one of the most important considerations in evaluating the effectiveness of bariatric surgery is the long-term (>3-years) durability of the surgery. The issue of net benefit of surgery over many years is uncertain among Medicaid beneficiaries given the need to implement lifestyle and diet changes for long-term success. With limited financial resources to implement lifestyle changes, Medicaid patients may be at risk for earlier onset of and higher level of weight regain. Additionally, it is possible that patients with more advanced disease at baseline have larger barriers to overcome in achieving long-term weight loss and disease remission. However, the absence of studies examining long-term outcomes leaves these critical questions unanswered. Of the 21 studies reviewed, 10 studies followed patients for 60-days or less and only four followed for 2-years or more. Of these four, only one assessed the durability of weight loss and remission of comorbidities through two-years, while the other three examined hospital admissions and mortality. Furthermore, the studies utilizing EMR data were either selected based on available follow-up or had substantial loss to follow-up, with attrition ranging from 24% to 87% of the initial study sample. Attrition not only introduces the potential for bias but it also suggests the studies were likely underpowered and the estimated associations are not precise.

Future research directions for understanding bariatric surgery outcomes among Medicaid patients

In order to further improve and mitigate risk among Medicaid patients undergoing bariatric surgery, we need greater understanding of the complex pre-operative and post-operative processes which contribute to successful operative outcomes. Here, we consider several strategies and key pieces of missing information that will significantly contribute to this evidence base.

Address baseline differences.

In order to clarify the association among patient subgroups, bariatric surgery, and outcomes, future studies should employ methods such as matching, propensity scores, and risk adjustment, which aim to balance the treatment groups on confounding factors. Perhaps more importantly, the chosen study designs must allow for the data collection process to include these confounding factors. While existing data sources (e.g., billing databases) provide easily accessible information on large study populations, they often lack information on key confounding factors like pre-operative body weight or BMI. Prospectively collected data or utilization of existing bariatric surgery studies to address baseline differences will strengthen the evidence base.

Pre- and post-operative procedures.

Universally, there are strict patient requirements for initial qualification for surgery in addition to specific post-operative guidelines that are designed to increase the longevity of surgical intervention. Financial restraints, transportation barriers, language barriers, and limited social support may hamper the ability of patients to comply with these requirements; this may be more common amongst Medicaid patients, limiting their capacity to achieve comparable post-operative outcomes. It is possible that certain patient sub-groups could benefit from additional educational resources, more intensive counseling, or other support systems to ensure adequate pre-operative preparation and post-operative care compliance; or more intensive screening and management of comorbidities pre-operatively. Identifying these kinds of actionable steps rely on epidemiologic studies designed to understand how various clinical pathways contribute to long term success and where differences might emerge. Moreover, analyses designed to identify critical post-operative periods when patients are at the greatest risk of weight regain would allow for more targeted post-operative interventions.

Longitudinal studies

Understanding of the patterns of change over time in subpopulations requires examination of consistent metrics from baseline through follow-up. Additionally, because weight regain is associated with drop-out from weight loss clinical trials (109), longitudinal studies with high levels of follow-up are crucial to comparing the effectiveness of surgery between patient groups.

Exploration of additional outcomes

Social and behavioral (e.g., QOL, psychosocial health), and economic (e.g., return to work, levels of work impairment) post-operative outcomes are understudied but potentially critical benefits of bariatric surgery in Medicaid populations. Yet secondary data sources, such as EMR and claims data, used in the reviewed studies lack information on these types of outcomes. Also, while two studies discussed the direct cost of surgery, the cost effectiveness of the surgical treatment of severe obesity compared to medical management among Medicaid patients remains largely unexplored.

Generalizability

The Medicaid patient population is sociodemographically diverse, yet nearly half of the reviewed studies focused on a single center or a single surgeon, while several others drew samples from claims databases (e.g., HCUP-NIS) covering similar time periods, in turn limiting the generalizability of findings to broader patient populations. More research in representative and low-income U.S. study populations is needed to understand bariatric surgery outcomes in underserved populations.

Conclusion

In the U.S., patients whose lives are most affected by extreme obesity have the greatest barriers to effective obesity treatment (61). The costs associated with failing to address this obesity disparity potentially includes increased excess mortality, rising health care costs, uncontrolled morbidity, and lower QOL (59). Although reasons why Medicaid patients may not experience the same benefits as the commercially insured have been highlighted in recent research, research testing these hypotheses in respect to bariatric surgery is scant (62, 63). Advancing knowledge of improving obesity treatment guidelines to support Medicaid patients is needed to reduce obesity-related health disparities.

Table 2.1 Study characteristics and post-operative outcomes examined in the reviewed studies

						Outcomes							
Reference	**Population**	**Study Design**	**N baseline (N analysis)**	**Procedures**	**F/U**	**Weight/BMI**	**Comorbidities**	**Mortality**	**Admissions**	**ER Visit**	**LOS**	**Total Charges**	**Complications**
Alexander 2008	Single surgeon; single center	Retrospective EMR review	830 (280)[1]	RYGB; Banded SG	1-yr	X	X	X					
Banka 2012	2005-2007 HCUP-NIS	Retrospective database review	156,271[2]	RYGB	Dis								X
Carbonell 2005	2000 HCUP-NIS	Retrospective database review	5786[2]	RYGB	Dis		X	X			X	X	
Chen 2016	Three surgeons; single center	Retrospective EMR review	132 (91)	RYGB	1-yr	X	X	X	X	X	X	X	X
Dallal(a) 2008	Single surgeon; two centers	Retrospective EMR review	122 (122[3])	RYGB	60-d				X	X			
Dallal(b) 2007	2002-2004 NHDS	Retrospective database review	34312[2]	Any	Dis						X		
Funk 2014	Consecutive patients; single center	Retrospective EMR review	120 (120[3])	RYGB	2-yr	X	X	X	X	X	X		
Gomez 2016	Surgical Review Corporations BOLD database	Retrospective database review	1681 (222)	BP; DS	18-m	X	X						
Hayes 2015	Consecutive patients; single center	Retrospective database review	2553 (1364)	RYGB	1-yr	X	X				X		
Jensen-Otsu 2015	Consecutive patients; single center	Retrospective EMR review	450 (224)	RYGB	1-yr	X			X		X		
Masoomi(a) 2011	2006-2008 HCUP-NIS	Retrospective database review	226,452	RYGB	Dis								X
Masoomi(b) 2013	2006-2008 HCUP-NIS	Retrospective database review	304,515	RYGB, LAGB, VBG	Dis								X

Table 2.1 (continued)

Reference	Population	Study Design	N baseline (N analysis)	Procedures	F/U	Outcomes: Weight/BMI	Comorbidities	Mortality	Admissions	ER Visit	LOS	Total Charges	Complications
Melton 2008	Consecutive patients; single surgeon; single center	Retrospective EMR review	555 (495)	RYGB	1-yr	X							
Nguyen(a) 2011	2006-2008 HCUP-NIS	Retrospective database review	304,515[2]	RYGB; LAGB; VBG	Dis			X					
Nguyen(b) 2013	1999-2007 HCUP NIS	Retrospective database review	115,507[2]	RYGB; DS; SG; VBG; LAGB; BPD	Dis			X					
Poulose(a) 2005	2001 HCUP-NIS	Retrospective database review	11,077[2]	RYGB; VBG	Dis			X					
Poulose(b) 2005	2002 HCUP-NIS	Retrospective database review	69,490[2]	RYGB; VBG	Dis								X
Telem(a) 2015	2006-2008 NYS SPARCS	Retrospective database review	22,139[2]	LGB; RYGB; SG	2-yr				X				
Telem(b) 2015	1999-2005 NYS SPARCS	Retrospective database review	7,682[2]	AGB; RYGB; VBG; SG	8-yr			X					
Weiss 2016	1995-2009 California OSHPD hospital discharge database	Retrospective database review	129,432	RYGB	15-yr			X					
Zingmond 2005	1995-2004 California OSHPD hospital discharge database	Retrospective database review	60,092	RYGB	1-yr				X				

Abbreviations: LOS: Length of stay; Y: Year; D: Day; M: Month; Dis: Discharge; RYGB: Roux-en-Y gastric bypass; SG: Sleeve gastrectomy; BP: biliopancreatic bypass; DS: Duodenal switch; BPD: biliary pancreatic diversion; AGB: adjustable gastric banding; LGB: laparoscopic gastric banding; VBG: vertical banded gastroplasty; LAGB: laparoscopic adjustable gastric banding; HCUP-NIS: Healthcare Cost and Utilization Project Nationwide Inpatient Sample; NHDS: National Hospital Discharge Survey; NYS SPARCS: New York State Statewide Planning and Research Cooperative. ; OSHPD: Office of Statewide Health Planning and Development[1]conducted matched analysis on subset with available 1-year follow-up; [2]Baseline and analysis sample size equivalent; [3]Selected based on follow-up available

Table 2.2 Studies reporting body weight (kg) or BMI (kg/m^2) differences from baseline to post-operative follow-up

	Baseline		Follow-up	
Reference	**Commercial**	**Medicaid**	**Commercial**	**Medicaid**
Alexander	*Mean BMI*		*Mean BMI*	
	57.0	58.3	37.0	38.0
Chen	*Mean BMI*		*% excess body weight loss*	
	47.1	*49.6*	**65.6%**	***50.7%***
Funk	*Mean BMI*		*Total % Excess body weight loss*	
	49.5	**58.4**	**64.6**	**53.8**
Gomez	*Mean (SD) BMI*		*Mean (SD) BMI*	
	51 (9)	**56 (10)**	29 (5)	30 (6)
Hayes	*Mean (SD) BMI*		*% of excess weight loss nadir (SD)*[1]	
	48.9 (8.1)	52.1 (10.4)	77.6 (24.0)	78.0 (25.0)
Jensen-Otsu	*Mean* (SD) *Weight*		*Adjusted mean % weight loss*	
	136.9 (28.4)	**136.4 (30.1)**	37	39
Melton	*Mean (range) BMI*		*Adjusted OR (95% CI) sub-optimal weight loss*	
	54 (37-91)	**62 (38-96)**	1.0 (Ref)	2.0 (0.7, 3.2)

Boldface indicates statistically significant difference (p<0.05)
Abbreviations: BMI: body mass index; kg: kilogram; SD: standard deviation; AOR: adjusted odds ratio; CI: confidence interval
[1]Nadir: defined as the maximum weight loss achieved from at least three available measurements between 6 and 36 months after surgery

Table 2.3 Studies reporting comorbidity differences from baseline to post-operative follow-up

		Baseline		**Follow-up**	
Reference	**Comorbidity**	**Commercial**	**Medicaid**	**Commercial**	**Medicaid**
Alexander		*Total N (%)*		*Total N (%)*	
	Diabetes Mellitus	**27 (19.3)**	**55 (39.3)**	7 (5.0)	15 (10.0)
	Hypertension	57 (40.7)	67 (47.9)	22 (15.7)	24 (24.3)
	Hyperlipidemia	23 (16.4)	24 (17.1)	4 (2.9)	7 (5.0)
	Obstructive Sleep Apnea	44 (31.4)	56 (40.0)	**10 (7.1)**	**25 (15.9)**
	DJD	95 (67.9)	108 (77.1)	57 (40.7)	88 (62.9)
Carbonell				*Score*[1]	
	Comorbidity Index	--		**0.36**	**0.54**
Chen		*Total %*		*Total % Resolved*	
	Hypertension	68.7	66.7	47.8	60.0
	Obstructive Sleep Apnea	67.7	48.5	--	--
	Gastroesophageal reflux	50.5	54.6	62.2	36.4
	Hyperlipidemia	**50.5**	**24.2**	30.6	40.0
	Diabetes Mellitus	40.4	54.6	63.3	76.9
	Coronary artery disease	11.1	0	--	--
Funk		*Total %*		*Total % Resolved*	
	Diabetes Mellitus	**44.4**	**73.3**	48.7	66.7
	Hyperlipidemia	56.7	63.3	34.0	50.0
	Hypertension	74.4	86.7	44.8	40.0
	Gastroesophageal reflux	**57.8**	**80.0**	21.6	29.2
	Obstructive Sleep Apnea	**51.1**	**83.3**	22.2	16.7
				Absolute Decrease	
	Hemoglobin A1c	--	--	-2.0	-2.9
Gomez				*Total %*	
	Hypertension	--	--	**25.6**	**45.8**
	Obstructive Sleep Apnea	--	--	**33.1**	**62.5**
	Asthma	--	--	**12.5**	**29.2**
	Angina	--	--	**0.63**	**8.3**
	Dyslipidemia	--	--	15.6	12.5
	Congestive Heart Failure	--	--	**1.9**	**4.2**
	Diabetes Mellitus	--	--	**10.0**	**37.5**
	Impaired Function	--	--	2.5	25.0
	Alcohol Use	--	--	26.9	25.0
Hayes		*Total N (%)*		*Total N (%) Remission*[2]	
	Diabetes Mellitus	**592 (36.9)**	**160 (38.8)**	--	--
	Diabetes-Insulin Use	--	--	143 (13.3)	41 (14.6)
	Diabetes-No insulin	--	--	**243 (72.8)**	**59 (69.5)**

Boldface type indicates statistically significant difference (p<0.05)
Abbreviations: DJD: Degenerative joint disease; N: number
-- Data not reported
[1]Comorbidity score: sum of the combined weights assigned to several ICD-9 codes for common comorbid conditions
[2]Insulin Use: Out of 386 with 1-year follow-up; No Insulin Use: Out of 100 with 1-year follow-up

Table 2.4 Studies reporting mortality differences

Reference	Measure of association	Commercial	Medicaid
Alexander	*Total N (%) 1-yr Deaths*	**4 (0.8)**	**7 (4.8)**
Carbonell	*Total % In-hospital Mortality*	**0.38**	**1.70**
Chen	*Total % 90-day Mortality*	0	0
Funk	*Total N (%) 2-yr Deaths*	1 (1.1)	1 (3.3)
Nguyen(a)	*Adjusted OR In-hospital Mortality (95% CI)*	1.0 (Ref)	1.3 (0.8, 1.9)
Nguyen(b)	*Adjusted OR In-hospital Mortality (95% CI)*	**1.0 (Ref)**	**3.35 (2.29, 4.91)**
Poulouse(a)	*Adjusted OR In-hospital Mortality (95% CI)*	**1.0 (Ref)**	**3.9 (1.2, 13)**
Telem(b)	*Adjusted HR (95% CI) 8-Yr All-Cause Mortality*	**1.0 (Ref)**	**2.8 (1.7, 4.8)**
Weiss	*Adjusted HR (95% CI) 15-Yr All-Cause Mortality*	**1.0 (Ref)**	**2.53 (2.08, 3.08)**

Boldface type indicates statistically significant difference (p<0.05)
Abbreviations: N: number; OR: odds ratio; CI: confidence interval; Ref: referent; HR: hazard ratio; Yr: Year

Table 2.5 Studies reporting healthcare utilization differences at post-operative follow-up

Reference	Healthcare Utilization Measure	Commercial	Medicaid
	Hospital Admissions / Discharges		
Alexander	*Total N (%) Hospital admissions**	10 (7.1)	20 (14.3)
Chen	*90-day Readmission %*	**14.7**	**37.0**
Dallal(a)	*OR (95% CI) 60-d Readmission*	1.0 (Ref)	3.7 (1.0, 13.0)
Funk	*Total N (%) 90-d Readmission*	6 (6.7)	6 (20)
	Total N (%) 90-d ICU admission	6 (6.7)	4 (13.3)
Jensen-Otsu	*OR (95% CI) 30-d Hospital Readmission*	**1.0 (Ref)**	**2.8 (1.2, 7.0)**
Telem(a)	*OR (95% CI) 2-yr Hospital Readmission*	**1.0 (Ref)**	**1.4 (1.2, 1.6)**
Zingmond	*OR (95% CI) 1-yr hospital Readmission*	**1.0 (Ref)**	**1.37 (1.24,1.50)**
	Emergency Room Visit		
Chen	*90-day ER visit %*	27.4	48.2
Dallal(a)	*OR (95% CI) 60-d* ER Visit	**1.0 (Ref)**	**3.2 (1.1, 9.1)**
Funk	*Total N (%)* 90-d ER Visit	**9 (10)**	**10 (33.3)**
	Length of Hospital Stay (LOS), Days		
Carbonell	*Total LOS*	**3.91**	**5.07**
Chen	*Length of stay (mean)*	2.3	2.2
Dallal(b)	*OR (95% CI) Prolonged LOS≥7*	**1.0 (Ref)**	**3.2 (1.2, 8.9)**
Funk	*Median LOS*	3.0	3.0
Hayes	*Mean (SD) LOS*	2.4 (3.1)	2.7 (3.1)
Jensen-Otsu	*OR (95% CI) LOS≥3*	**1.0 (Ref)**	**2.0 (1.1, 3.8)**
	Total Charges		
Carbonell	*Total Charges*	**$24,234**	**$30,165**
Chen	*Total Charges (median)*	$59,795	$51,190

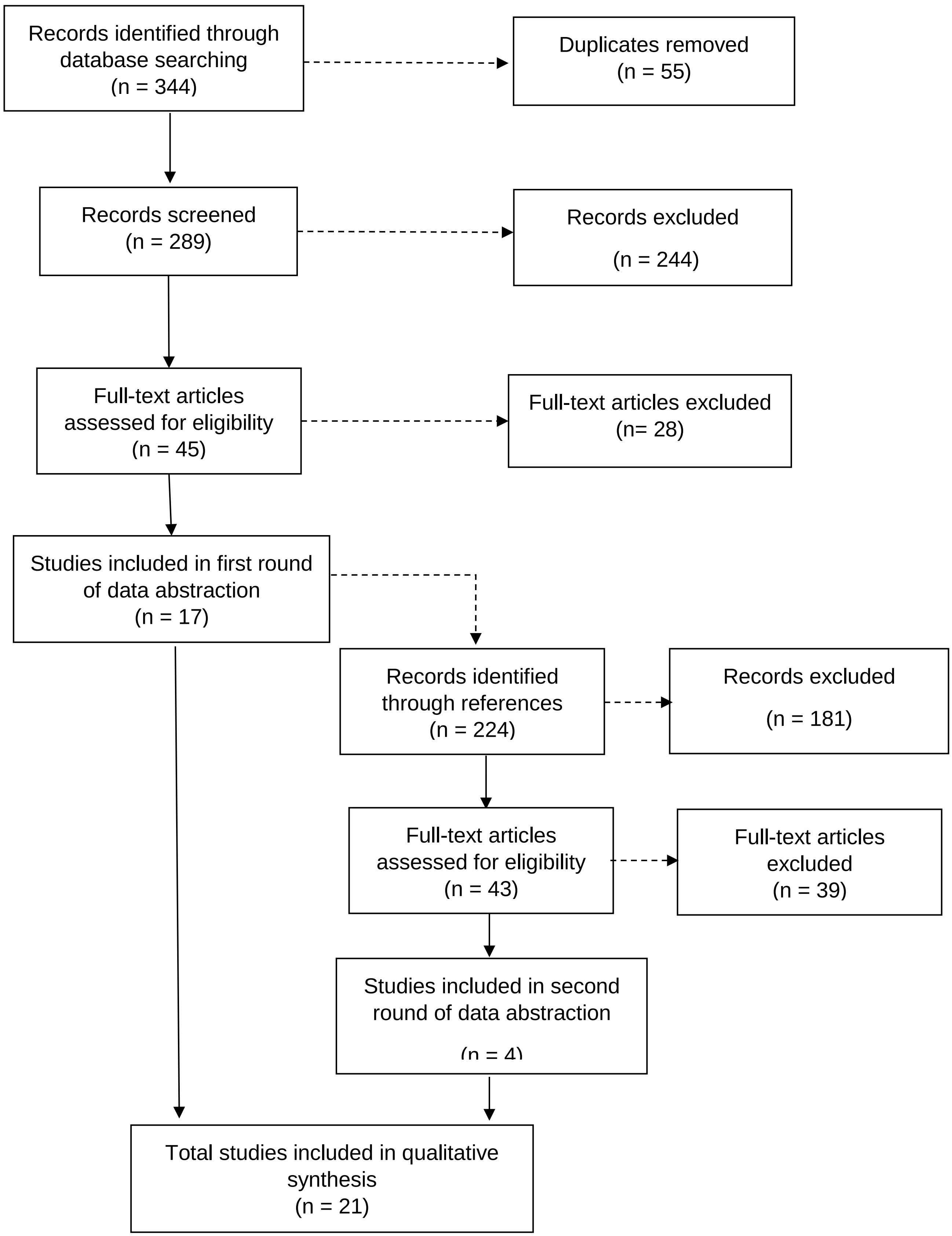
*Boldface type indicates statistically significant difference (p<0.05), *differences not tested.*
Abbreviations: d: day; yr: year; N: number; OR: odds ratio; CI: confidence interval; Ref: referent; ICU: intensive care unit; ER: emergency room; LOS: length of stay*;* d: days

Table 2.6 Studies reporting complication differences

Reference	Measure of Association	Commercial	Medicaid
Banka	*AOR (95% CI) 1+ in-hospital complications*	1.0 (Ref)	1.2 (0.98, 1.4)
Chen	*Total % with any 90-day complication*	30.3%	33.3%
	AOR In-hospital accidental puncture or laceration	1.0 (Ref)	1.8
Poulose(b)	*AOR In-hospital PE/DVT*	1.0 (Ref)	0.5
	AOR In-hospital respiratory failure	1.0 (Ref)	1.6
Masoomi(a)	*AOR (95% CI) In-hospital gastrointestinal track leak*	1.0 (Ref)	0.83 (0.6, 1.1)
Masoomi(b)	*AOR (95% CI) In-hospital acute respiratory distress*	1.0 (Ref)	1.1 (1.0, 1.3)

Boldface type indicates statistically significant difference (p<0.05)
*Abbreviations: A*OR: adjusted odds ratio; CI: confidence interval; Ref: Referent; PE: pulmonary embolus; DVT: deep vein thrombosis

Figure 2.1 Selection of studies for inclusion in review



Chapter 3: Insurance status differences in weight loss and regain over five years following bariatric surgery

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3.1 Abstract

The effectiveness of bariatric surgery among Medicaid beneficiaries, a population with a disproportionately high burden of obesity, remains unclear. We sought to determine if weight loss and regain following bariatric surgery differed in Medicaid patients compared to commercial insurance. Data from the Longitudinal Assessment of Bariatric Surgery, a ten-site observational cohort of adults undergoing bariatric surgery (2006-2009) were examined for patients who underwent Roux-en-Y Gastric Bypass (RYGB), Laparoscopic Adjustable Band (LAGB), or Sleeve Gastrectomy (SG). Using piecewise spline linear mixed-effects models, weight change over five years was modeled as a function of insurance type (Medicaid, N=190; commercially insured, N=1448), time, procedure type, and sociodemographic characteristics; additionally, interactions between all time, insurance, and procedure type indicators allowed time- and procedure-specific associations with insurance type. For each time-spline, mean (kg) difference in weight change in commercially insured versus Medicaid patients was calculated. Medicaid patients had higher mean weight at baseline (138.3 kg vs 131.2 kg). From 0-1 year post-operatively, Medicaid patients lost similar amounts of weight to commercial patients following all procedure types (mean weight Δ difference [95% CI]: RYGB: -0.9 [-3.2, 1.4]; LAGB: -1.5 [-6.7, 3.8]; SG: 5.1 [-4.0, 14.2]). From 1-3 years post-operatively Medicaid and commercial patients continued to experience minimal weight loss or began to slowly regain weight (mean weight Δ difference [95% CI]: RYGB: 0.9 [0.0, 2.0]; LAGB: -2.1 [-4.2, 0.1]; SG: 0.7 [-3.0, 4.3]). From 3-5 years post-operatively, the

rate of regain tended to be faster among commercial patients compared to Medicaid patients (mean weight Δ difference [95% CI]: RYGB: 1.1 [0.1, 2.0]; LAGB: 1.5 [-0.5, 3.5]; SG: 1.0 [-2.5, 4.5]). Although Medicaid patients had a higher baseline weight, they achieved similar amounts of weight loss and tended to regain weight at a slower rate than commercial patients.

3.2 Introduction

In the U.S., obesity and its cardiometabolic sequelae are among the leading causes of preventable disease and death (3). In the general population, bariatric surgery is well documented as the most effective treatment for severe obesity (class II and III) that facilitates important sustained weight loss (35, 110-112). However, the need to characterize patient subgroups who are most likely to benefit from bariatric surgery has been highlighted in the recent obesity treatment guidelines developed by The American College of Cardiology, the American Heart Association, and The Obesity Society (1).

The evidence regarding the effectiveness of bariatric surgery among Medicaid beneficiaries—a low-income population with a disproportionately high burden of obesity—is scant. In recent years, Medicaid eligibility and surgery eligibility have expanded, yet the long-term durability of surgically-induced weight loss among Medicaid recipients remains unknown. Seven observational studies have examined weight loss following bariatric surgery among Medicaid beneficiaries. In all but one study, Medicaid patients had a higher baseline weight. Despite these differences, four studies reported similar weight loss outcomes between the groups at follow-up (82, 85-87), while three reported inferior weight loss outcomes among Medicaid patients (83, 84, 88). However, results from these studies are limited by small sample sizes (n<500), (82, 84, 87, 88) short follow-up (<2yrs), (82, 85-88) substantial attrition, (82, 85-87) and focus on a single surgeon or center (82, 84, 86-88). Importantly, these studies did not examine the variable weight loss and regain that may occur beyond 2 years post-operatively and, as a result, may overestimate the procedure's effectiveness among the subgroups. Investigation of long-term weight loss and regain patterns among Medicaid patients remains a critical step in informing appropriate obesity treatment guidelines for low-income patient populations with severe obesity. Notably, the amount of weight loss and regain following bariatric surgery is central to a patient's ability to achieve and maintain remission of associated comorbidities, like diabetes (37).

To investigate long-term weight loss and regain patterns following bariatric surgery, we compared 5-year weight change between Medicaid beneficiaries and commercially insured patients. We utilize data from the Longitudinal Assessment of Bariatric Surgery (LABS) (113), a large, multi-site, observational cohort with levels of follow-up greater than 85%. We hypothesized that Medicaid patient's experience a similar magnitude of weight loss but earlier onset of and greater weight regain.

3.3 Methods

Study Population

Between March 2006 and April 2009, 2458 individuals 18 years and older undergoing bariatric procedures were enrolled in the LABS study, a prospective observational cohort study designed to assess the risks and benefits of bariatric surgery. Upon enrollment, LABS participants underwent first-time bariatric procedures with a surgeon participating in the LABS consortium at one of 10 hospitals at six clinical centers in the U.S, as previously described (113). The institutional review boards at each center approved the protocol and consent forms; IRB exemption was obtained from Oregon Health & Science University for this analysis of existing data. LABS is registered at ClinicalTrials.gov (NCT00465829).

Analytic Sample

Of the 2458 LABS participants, we first excluded participants who were missing baseline health insurance information or reported self-paying for surgery (N=389). Next, participants reporting Medicare only (N=210), Tricare only (N=67) or Other insurance (N=86) were excluded. Participants undergoing Biliary Pancreatic Diversion with Duodenal Switch (N=16) and Banded Bypass (N=26) were uncommon in this cohort and thus excluded. Finally, participants with only a single weight measurement over the five post-operative time points were excluded from analyses (N=26), leaving 1638 participants in the final analytic cohort (**Figure 3.1**).

Data collection

LABS-certified trained personnel collected study data using standard protocols (44, 114). Data collection consisted of blood and urine samples, physical measurements, self-assessment forms, surgeon and medical staff forms, and chart review procedures. Baseline weights and other clinical data were collected within 30 days before surgery. Annual follow-up assessments were conducted within 6 months of surgery anniversary date for five consecutive years. Data were entered twice using a web-based data entry system developed, distributed, and maintained by the University of Pittsburgh LABS Data Coordinating Center (DCC).

Study Variables

Weight

During in-person visits, weight was measured using a standard protocol ("protocol" weight) on a study-purchased standard scale (TanitaR Body Composition Analyzer, model TBF-310) (44). If a protocol weight was not obtained, weight was measured by research or medical personnel on a non-study scale and is referred to as a "clinical weight". If neither a protocol nor clinical weight was available, a validated patient self-reported weight was used (ranging from 3-14% of weights across visits) (**Figure 3.2**) (115). Weight measurements of women who reported being currently pregnant and those up to 6-months postpartum at the time of weight measurement were excluded from analyses (47 person-time observations). Weight was analyzed as continuous weight in kilograms at each study time point; weight, as opposed to weight change, provides more precise statistical estimates and enables comparison of weight at baseline. We additionally examined weight change as a percent of weight at baseline to provide results comparable to most other bariatric surgery literature; and continuous BMI (kg/m^2) to incorporate height and weight, and provide results in a measure commonly used by clinicians in patient discussions.

Insurance Type

Self-reported insurance type was collected using a self-assessment form at the baseline study visit. Participants with available baseline insurance information were classified into two categories: 1) Medicaid with or without Medicare; and 2) Commercial insurance with or without Medicare. Participants reporting other insurance types were excluded from this analysis as they were heterogeneous in regards to their sociodemographic and clinical profile. Insurance classification at baseline was analyzed as a time constant variable; potential changes to insurance status over time were not incorporated given the desire to understand how the differences in baseline health status between groups influenced long-term outcomes.

Surgery type

Three primary weight-loss procedures were ascertained from surgeon reports at baseline: 1) Roux-en-Y Gastric Bypass (RYGB); 2) Laparoscopic Adjustable Gastric Banding (LAGB); and 3) Sleeve Gastrectomy (SG). Participants whose initial bariatric surgery was subsequently revised or reversed (n=132) remain classified with the baseline surgery type to represent the natural history of each participant's post-surgical course.

Covariates

Covariates included self-reported age at surgery, sex (male, female), and baseline smoking status (never, current/former). Comorbidities (diabetes, hypertension, ischemic heart disease, congestive heart failure, history of stroke, sleep apnea, pulmonary hypertension, asthma, history of deep vein thrombosis or pulmonary embolism, and venous edema with ulcerations) were determined using a combination of self-report, clinical assessment, and medical chart review and are all defined elsewhere (113). An index of comorbidities was created as the number of comorbidities at baseline (range: 0-10) to provide a rough estimate of disease burden.

Statistical Analysis

Descriptive statistics summarize baseline characteristics for each insurance category. Pearson's chi-square test for categorical variables and t-tests for continuous variables were used to assess statistical significance of differences in baseline characteristics between the payer groups. Data management was conducted using SAS version 9.4, descriptive analyses and mixed models were conducted using Stata version 13.

To compare the timing and magnitude of weight loss and regain over the 5-year post-operative period, we fit piecewise linear mixed-effects models via maximum likelihood estimation. Piecewise models allowed us to examine non-linear weight change over time (**Figure 3.3**) by fitting linear slopes within each of three-time periods. Among the insurance and surgery subgroups, mixed-effects models enable direct comparison of 1) baseline weight and 2) the timing and magnitude of weight loss and regain during distinct post-operative time periods. Further, mixed-effects models account for correlations among repeated measurements taken on the same individual over time, and missing weight measurements at varying post-operative time points (missingness ranged from 4-13% across time points; **Figure 3.2**) (116); with maximum likelihood estimation, all available follow-up data are optimally used, and, missing outcome data are ignorable under the assumption of missing at random (MAR) (117).

To determine the number of knots that best fit the pattern of post-operative weight change, we compared models with one, two, and three knots placed at different time points including at one-, two-, and three-years post-operatively. Using Akaike information criteria (AIC), Bayesian information criteria (BIC), and Likelihood Ratio Tests (LRT), we selected the model with two knots, placed at 1-year and 3-years post-operatively as the best fit to the data. These time points are also consistent with known periods of weight regain, which typically begins 1-2 years postoperatively (35, 118).

The following equation represents the general form of the final fitted model, with the two insurance types (Commercial [referent] vs. Medicaid) and simplified to demonstrate just two surgery types (RYGB [referent] vs. LAGB). Surgery interactions were included because weight loss/regain patterns are known to distinctly vary by surgical type (35, 119).

$$(1)\ WGT_{ij} = \beta_{0j} + \beta_{1j} * TIME_{yrs0-1_{ij}} + \beta_{2j} * TIME_{yrs1-3_{ij}} + \beta_{3j} * TIME_{yrs3-5_{ij}} + \beta_{4j} * INSUR_i + \beta_{5j} * SURG_i + \beta_{6j} * INSUR_i * SURG_i + \beta_{7j} * TIME_{yrs0-1_{ij}} * INSUR_i + \beta_{8j} * TIME_{yrs0-1_{ij}} * SURG_i + \beta_{9j} * TIME_{yrs0-1_{ij}} * INSUR_i * SURG_i + \beta_{10j} * TIME_{yrs1-3_{ij}} * INSUR_i + \beta_{11j} * TIME_{yrs1-3_{ij}} * SURG_i + \beta_{12j} * TIME_{yrs1-3_{ij}} * INSUR_i * SURG_i + \beta_{13j} * TIME_{yrs3-5_{ij}} * INSUR_i + \beta_{14j} * TIME_{yrs3-5_{ij}} * SURG_i + \beta_{15j} * TIME_{yrs3-5_{ij}} * INSUR_i * SURG_i + \beta_{16j} * COVS + e_{ij}$$

In equation (1), WGT_{ij} denotes the estimated weight in kilograms for individual i at time point j; $INSUR_i$ and $SURG_i$ denote the type of insurance and procedure the individual had at baseline. Equation (1) further includes two- and three-way interactions terms with the time splines, insurance type, and surgery type, generated to allow differential slope estimates for the insurance groups and surgery types; the referent group is commercially insured patients undergoing RYGB. In the presence of these interactions, B_{0j} represents the baseline weight (intercept) for the referent group while B_{4j} represents the difference in baseline weight for Medicaid patients, compared to commercially insured patients. Similarly, B_{5j} represents the difference in the baseline weight for commercially insured patients in the LAGB group, compared to RYGB; and B_{6j} represents the difference in baseline weight for Medicaid patients in the LAGB group. B_{0j}, B_{4j}, B_{5j}, and B_{6j} were used in linear contrast statements to calculate baseline weight for the insurance and surgery-related groups. B_{1j}, B_{2j}, and B_{3j} represent the estimated weight change over time (slope) for the referent group (Commercial RYGB patients) in the 0-1 year, 1-3 year, and 3-5 year post-operative periods, respectively. B_{7j} - B_{15j} represent the insurance and surgery-related differences in weight change over time for the non-referent groups during the 0-1 year, 1-3 year, and 3-5 year post-operative periods. B_{1j}-B_{3j} and B_{7j}-B_{15j} were used in linear contrast statements to calculate the time-period specific slopes for the insurance and surgery-related groups. B_{16j} represents a vector of coefficients for covariates included in the model: sex, age at surgery, index of baseline comorbidities, and baseline smoking status. To obtain the group differences in weight loss/regain for each time-period, the linear contrast statement for Medicaid was subtracted from the Commercial statement.

We included the spline functions as fixed and random effects, to estimate overall mean trajectories at the population level, and individual trajectories at the subject-specific level. Baseline covariates (age, sex, smoking status, and comorbidity index) were included as fixed effects.

Sensitivity Analyses

First, a similar model was fit that examined percent weight loss from baseline as the primary dependent variable. Continuous weight in kilograms was the primary measure because it yields the most accurate and precise statistical model (120) and allows for comparison of baseline weight; we conducted this sensitivity analysis to provide results that are comparable with most bariatric surgery research. Second, we also fit a similar model with BMI (kg/m^2) as the primary dependent variable. In addition to statistical precision, continuous weight was also chosen as the primary measure as it provides the most logical interpretation over time (weight loss in kilograms per year); we conducted this sensitivity analysis to take into account weight and height and to provide a second clinically relevant outcome. Third, we repeated the primary analyses after restriction of the analytic cohort to patients with no revision or reversal surgery reported during the 5-year post-operative period. The revision or reversal of the primary bariatric surgery may alter the magnitude and timing of post-operative weight loss and regain, thus potentially impacting the group results over time. Fourth, we restricted the Medicaid group excluding Medicaid-Medicare dual eligible patients and repeated the primary analyses. Medicaid bariatric surgery patients who also qualify for Medicare likely do so on the basis of permanent disability given the relatively young age distribution of the study population, thus representing a unique population.

3.4 Results

Description of the sample

At baseline, Medicaid patients were slightly younger than commercial patients (mean age: 43.6 vs 45.2 years) and were more likely to be female (85.7% vs. 79.8%). The baseline comorbidity index was higher among Medicaid patients (mean score: 2.2 vs 1.9). In summarizing the most common four comorbidities included in this score, the baseline prevalence of diabetes (39.3% vs 31.4%) and asthma (36.8% vs 24.1%) was higher among Medicaid patients compared to commercial patients; in contrast, the baseline prevalence of hypertension (68.3% vs 67.2%) and sleep apnea (53.4% vs 50.7%) was similar in both groups). RYGB was the predominant surgery type in Medicaid (79.4%) and commercial (72.4%) patients. Less commonly Medicaid and commercial patients underwent LAGB (14.4% vs. 25.6%, respectively) and SG (6.4% vs. 2.1%, respectively). Selected characteristics of the analytic sample are reported in **Table 3.1**. Follow-up through 5-years was high: 90.5% for Medicaid patients and 87.0% for commercial patients (**Figure 3.2**).

Five-year estimated weight change in patients undergoing RYGB, LAGB, and SG

At baseline, baseline weight was higher in Medicaid compared to commercially insured patients for RYBG and SG, but not LAGB (**Table 3.2;**

Figure 3.4). Baseline weight was the highest among the 12 Medicaid and 30 commercial patients undergoing SG (165.7 and 154.0 kg, respectively), and lower among the 150 Medicaid and 1,037 commercial patients undergoing RYGB (137.6 and 132.3 kg), and the 28 Medicaid and 381 commercial patients undergoing LAGB (125.5 and 125.6 kg).

During the 0-1 year post-operative period, both insurance groups lost substantial but similar amounts of weight (kg). Medicaid and commercial patients undergoing SG lost the most weight (53.3 and 48.2 kg per year, respectively; weight Δ difference [95% CI]: 5.1 [-4.0, 14.2]), those undergoing RYGB lost similar amounts (45.1 and 46.0; weight Δ difference [95% CI]: -0.9 [-3.2, 1.4]), while those undergoing LAGB lost the considerably less (18.1 and 19.5; weight Δ difference [95% CI]: -1.5 [-6.7, 3.8]).

In the 1-3 year post-operative period, both insurance groups either continued to lose minimal amounts of weight or slowly regain weight, depending on the procedure type. For RYGB, Medicaid patients began to regain weight, but at a marginally slower rate than commercial patients (0.9 and 1.8 kg per year, respectively; weight Δ difference [95% CI]: 0.9 [0.0, 1.9]). For LAGB, Medicaid patients were regaining weight while commercial patients continued to lose weight (1.4 and -0.6 kg, respectively; weight Δ difference [95% CI]: -2.1 [-4.2, 0.1]). And for SG, Medicaid patients continued to lose weight at a slightly faster rate compared to commercial patients (-1.5 and -0.9 kg, respectively; weight Δ difference [95% CI]: 0.7 [-3.0, 4.3]).

Finally, in the 3-5 year post-operative period, the rate of regain was approximately 1-kg slower among Medicaid patients, compared to commercial patients for both RYGB (1.2 and 2.3, kg per year respectively; weight Δ difference [95% CI]: 1.1 [0.1, 2.0]) and SG (0.9 and 1.9; weight Δ difference [95% CI]: 1.0 [-2.5, 4.5]). For LAGB, Medicaid patients were relatively stable in loss/regain while commercial patients slowly regained weight (-0.3 and 1.2; weight Δ difference [95% CI]: (1.5 [-0.5, 3.5]).

Sensitivity Analyses

We performed four sensitivity analyses. First, we reran the foregoing analyses specifying percent weight loss from baseline as the primary dependent variable. The patterns of post-operative regain for the groups and surgery types were analogous to the primary analyses. In the 0-1 year time period, RYGB resulted in 32.5% loss (LAGB: 15.0%; SG: 31.5%) from baseline among Medicaid patients and 34.6% (LAGB: 15.7%; SG: 30.8%) among commercial patients (**Table 3.3; Figure 3.5**). In the 3-5 year post-operative period, Medicaid patients maintained a similar percent weight loss than commercial patients following RYGB (28.9% vs. 28.5%, respectively) and SG (30.4% vs. 29.4%, respectively). While examining percent weight loss yields similar overall results, analysis of weight in kg enabled comparison of baseline differences between groups.

Second, we repeated the primary analyses after specifying BMI (kg/m^2) as the primary dependent variable; results were homologous to the results of the primary analyses (**Table 3.4; Figure 3.6**). Medicaid patients had higher BMIs at baseline across all three surgery types and experienced similar response to surgery in the 0-1 and 1-3 year time period. In the 3-5 year post-operative period, Medicaid patients experienced slightly slower increases in BMI levels across surgery types.

Third, we removed any patients who reported undergoing a revision or reversal of their primary procedure and repeated the analyses. Few patients who underwent RYGB (N=6) or SG (N=8) underwent revisions or reversals of their primary surgery. The majority of revisions/reversals occurred in patients undergoing LAGB (Medicaid=14; Commercial=87). Upon removing these patients, the pattern of weight loss and regain among patients undergoing RYGB remain unchanged. For both insurance groups undergoing SG and LAGB, the magnitude of weight regain was slightly increased in the 3-5 year post-operative period. (**Table 3.5**).

Fourth, we restricted the analytic cohort to include Medicaid patients only (N=124), excluding any dual eligible Medicaid-Medicare patients (N=66). The magnitude of the differences in baseline weight between Medicaid and commercial patients decreased (**Table 3.6**). The post-operative weight loss and regain patterns were otherwise similar to the results of the primary analysis.

3.5 Discussion

In this study of weight loss and regain patterns following bariatric surgery, we provide new information on the long-term durability of surgery among

Medicaid and commercially insured patients. For all three surgery types examined, Medicaid and commercially insured patients lost a substantial and similar amount of weight in the first post-operative year. During the 1-3 year post-operative period, both insurance groups began to experience minimal amounts of weight regain, with a slight increase in the rate of regain in the 3-5 year period. Contrary to our initial hypothesis, Medicaid patients, on average, exhibited a marginally slower rate of post-operative weight regain compared to commercially insured patients; this difference was more pronounced during the 3-5 year post-operative period.

Seven studies have examined weight loss following bariatric surgery between Medicaid and commercially insured patients, all within 2 years postoperatively (82-88). Our findings are consistent with prior research in that Medicaid patients were heavier at baseline and lost a similar amount of weight in the first year. However, no other studies have compared Medicaid and commercially insured patients with respect to weight loss beyond two-years post-operatively or, correspondingly, rate of weight regain over time. Notably, our results demonstrate that modest levels of regain tend to occur after the first post-operative year and then may escalate at 3-years post-operatively; studies with short-term follow-up may consequently overestimate long-term treatment effects.

Baseline differences

Our study findings corroborate the existing body of evidence in that, at baseline, Medicaid patients present with more severe obesity and comorbid disease, which despite similar surgical response, persists post-operatively.

Although we observed that initial weight loss was similar and long-term patterns of regain were slightly superior among Medicaid beneficiaries, Medicaid patients remained heavier at all follow-up time points. A few studies have reported similar differences between the insurance groups at follow-up time points (82-84, 88). The methods utilized in this study illustrate that those differences are likely attributable to the differences present at baseline, and not the response to surgical intervention.

Several factors likely contribute to these differences, including the strong association between poverty, poor health, and disability, cost prohibitive primary-care health maintenance, delayed diagnosis, and limited access to specialty providers. Hayes et al reported Medicaid patients had a 1.5-month longer interval between initial consultation and surgery compared to the commercially insured; (86) similarly, among insurer groups, Medicaid patients comprise the largest proportion of bariatric surgery eligible patients, who undergo surgery the least often (58, 59). The contribution of poverty to poor baseline health may be partially modifiable by reducing cost- and provider-related barriers among Medicaid patients, in turn lessening the persistent disparities in post-operative health.

Period specific differences

Our analysis differed from previously published research examining insurer sub-group differences by examining period-specific weight loss and regain through 5-years post-operatively. Although Medicaid patients presented with a greater burden of baseline disease, they experienced similar amounts of weight loss in the first post-operative year and very minimal weight regain through 5-years post-operatively. Medicaid patients, on average, only regained 1-kilogram per year over both the 1-3 and 3-5 year period. On the other hand, Commercial patients regained nearly 2-kilograms per year in the 1-3 and 3-5 year post-operative periods. Although this is not a large clinical difference, it suggests that for patients with severe baseline disease and limited resources, bariatric surgery is a successful and potentially life-saving treatment.

These findings were relatively consistent when we removed patients who either underwent a revision/reversal of their primary bariatric procedure or were dual eligible Medicaid-Medicare. Revisions/reversals were most common in the LAGB group and a slight increase in the magnitude of weight regain in the 3-5 year period was observed. These results suggest that the exclusion of revisions and reversals, when they occur in a large proportion of the study population, may lead to the overestimation of weight regain in the long-term. When dual eligible patients were removed, the magnitude in difference in baseline weight lessened between the insurer groups, suggesting the inclusion of dual eligible patients may be important to inform pre-operative care and surgery selection but are less important in informing loss and regain over time.

Despite potential post-operative financial limitations and barriers, Medicaid patients are as successful as commercially insured patients following bariatric surgery. The mechanisms underlying these findings can only be hypothesized, but could occur, at the individual, provider, or community level. Individual level factors could include the general younger age distribution of Medicaid patients or an increased level of motivation due to the longer pre-operative wait times. At the provider level, it is possible that simply gaining and maintaining access to a specialty provider may be associated with improved outcomes. Finally, at the community level, factors like level or quality of social support may contribute to the successful outcomes.

Future directions

To date, no bariatric surgery-specific clinical guidelines exist that help guide surgeons to the best procedure type for a given patient; commonly, the selected procedure is largely a result of surgeon or patient preference. Future research comparing distinct patient sub-groups and their outcomes following varied bariatric surgery procedure types and outcomes will help inform an evidence base to guide clinical decision making and further improve long-term patient outcomes.

Also, while SG is a relatively new procedure, it is now the most commonly performed procedure in the U.S. (53.8% of all procedures) (50). The small number of patients in this cohort undergoing SG, likely a function of the time interval of patient recruitment, limits the ability to draw strong conclusions. Studies with larger samples of patients undergoing SG are essential to further elucidate our findings and better understand the long-term durability of this procedure type among patient sub-groups.

More evidence is also needed on the post-operative period extending beyond 5-years post-operatively. No current studies have examined weight loss between insurance or other important patient sub-groups in this post-operative period. The apparent upward trend of our 5-year results suggest the rate of weight regain may continue to increase for both insurance groups and surgery types. It is possible that the increased magnitude in regain could be mitigated by the development of time- and group-specific post-operative interventions.

Finally, the further exploration of post-operative predictors of successful long-term outcomes (e.g., physical activity, patient-provider relationship) remains an important area of ongoing research. Although we hypothesize several reasons why the Medicaid sub-group experienced slightly superior weight regain over time, the post-operative mechanisms through which these outcomes function remain unclear. Attributes beyond individual-level, like provider and contextual characteristics, should be explored as potentially important predictors.

Clinical and Public Health Implications

These findings suggest that baseline levels of disease are critical to long-term surgical success. For most patient groups, the clinical and administrative pathway to receiving authorization for bariatric surgery is extensive, including identifying and scheduling with specialty providers, myriad of paperwork, and clinical milestones with numerous providers (e.g., dieticians, psychiatrists/psychologists, surgeons). Medicaid beneficiaries face additional barriers to authorization, including the limited number of clinics and clinicians accepting publicly funded patients, the additional pre-operative qualifications required by the state (e.g., requiring type II diabetes), or exclusion of bariatric surgery by the state Medicaid plan. Increasing access to bariatric surgery among

Medicaid beneficiaries by universally aligning pre-operative qualifications with the national guidelines and providing consistent state-level coverage may mitigate the disease severity differences that persist post-operatively and help to alleviate the disproportionate burden of obesity carried by this population. Finally, given the increased disease severity prevalent at younger ages among Medicaid beneficiaries, targeted upstream obesity prevention efforts among this sub-population remain a critical area of public health importance.

Strengths and limitations

There were several limitations to this study. First, a relatively small number of bariatric surgery patients in this cohort were covered by Medicaid, although the proportion was similar to national estimates. Further, the small number of patients undergoing SG and LAGB limit the precision of the generated estimates. However, this study is one of the largest samples with five years of follow-up to examine weight loss outcomes among Medicaid patients. Second, it is possible that results may under estimate the amount of weight regain due to loss to follow-up, as drop-out from weight loss trials is associated with weight regain (109). LABS placed a strong emphasis on maximizing retention over time, high levels of weight ascertainment minimized the possibility of this bias.

The primary strength of this study is the availability of long-term follow-up data with high levels of retention, enabling investigation of differences in weight regain between insurance groups. Outcome measures were prospectively collected via a standardized research protocol with objective measurement procedures conducted by trained evaluators. Additionally, our study results provide a high level of generalizability as LABS is a multicenter geographically diverse cohort with long-term follow-up. Finally, our study provides one of the largest sample sizes to date, filling a gap from prior studies.

Conclusions

Both Medicaid and commercial patients enrolled in a nationally representative longitudinal cohort undergoing bariatric surgery, lost and maintained a substantial amount of weight through 5-years post-operatively. We observed that Medicaid patients undergoing RYGB, LAGB, and SG regained weight at a similar or slightly slower rate over the 5-year post-operative period compared to commercially insured patients. We also observed that Medicaid patients had more severe levels of obesity at baseline and this persisted through post-operative time points even with the slower rate of regain. These results provide important evidence for the beneficial association between surgery and long-term weight loss among Medicaid patients.

Table 3.1 Baseline characteristics of 1638 patients undergoing bariatric surgery

Characteristic	Overall (n=1638)	Commercial (n=1448)	Medicaid (n=190)
Age [Mean (SD)]	45.1 (10.7)	**45.2 (10.7)**	**43.6 (11.0)**
Sex [n (%)]			
Male	316 (19.5)	**289 (20.2)**	**27 (14.3)**
Female	1305 (80.5)	**1143 (79.8)**	**162 (85.7)**
Smoking Status [n (%)]			
Never Smoker	948 (58.5)	**850 (59.4)**	**98 (51.9)**
Current/Former Smoker	673 (41.5)	**582 (40.6)**	**91 (48.2)**
Weight (kg) [Mean (SD)]	132.0 (25.6)	**131.2 (25.0)**	**138.3 (29.8)**
Comorbidity index [Mean (SD)]	1.9 (1.3)	**1.9 (1.3)**	**2.2 (1.4)**
Comorbidity prevalence [n (%)]			
Diabetes	524 (32.3)	**451 (31.4)**	**73 (39.3)**
Hypertension	1090 (67.3)	961 (67.2)	129 (68.3)
Sleep Apnea	835 (51.0)	734 (50.7)	102 (53.4)
Asthma	410 (25.5)	**343 (24.1)**	**67 (36.8)**
Procedure Type [n (%)]			
RYGB	1186 (73.2)	**1036 (72.4)**	**150 (79.4)**
LAGB	393 (24.2)	**366 (25.6)**	**27 (14.3)**
SG	42 (2.6)	**30 (2.1)**	**12 (6.4)**

Abbreviations: RYGB: Roux-en-Y Gastric Bypass; LAGB: Laparoscopic Adjustable Gastric Band; SG: Sleeve gastrectomy; SD: standard deviation; kg: kilogram
Note: boldface indicates statistical significance ($p<0.05$) for Commercial versus Medicaid, per t-test or chi-square test for continuous or categorical variables, respectively.

Table 3.2 Estimated mean weight loss/regain between insurance groups by surgery type

Estimated mean	Commercial	Medicaid	Difference (Comm - Med)
Roux-en-Y Gastric Bypass			
Baseline weight (kg)	132.3 (131.0, 133.6)	137.6 (134.1, 141.1)	**5.3 (1.6, 9.0)**
Weight Δ 0y → 1y	-46.0 (-46.8, -45.1)	-45.1 (-47.2, -42.9)	-0.9 (-3.2, 1.4)
Weight Δ 1y → 3y	1.8 (1.5, 2.1)	0.9 (0.0, 1.8)	0.9 (0.0, 1.9)
Weight Δ 3y → 5y	2.3 (2.0, 2.6)	1.2 (0.4, 2.1)	**1.1 (0.1, 2.0)**
Laparoscopic Adjustable Gastric Band			
Baseline weight (kg)	125.6 (123.5, 127.8)	125.5 (117.5, 133.5)	-0.1 (-8.4, 8.1)
Weight Δ 0y → 1y	-19.5 (-20.9, -18.2)	-18.1 (-23.1, -13.0)	-1.5 (-6.7, 3.8)
Weight Δ 1y → 3y	-0.6 (-1.2, -0.1)	1.4 (-0.6, 3.5)	-2.1 (-4.2, 0.1)
Weight Δ 3y → 5y	1.2 (0.6, 1.7)	-0.3 (-2.2, 1.6)	1.5 (-0.5, 3.5)
Sleeve Gastrectomy			
Baseline weight (kg)	154.0 (146.3, 161.6)	165.7 (153.6, 177.9)	11.8 (-2.6, 26.2)
Weight Δ 0y → 1y	-48.2 (-53.1, -43.4)	-53.3 (-61.0, -45.7)	5.1 (-4.0, 14.2)
Weight Δ 1y → 3y	-0.8 (-2.8, 1.1)	-1.5 (-4.6, 1.6)	0.7 (-3.0, 4.3)
Weight Δ 3y → 5y	1.9 (0.0, 3.8)	0.9 (-2.1, 3.8)	1.0 (-2.5, 4.5)

Abbreviations: Δ: change; kg: kilograms; y: year
Note: boldface indicates a statistically significant difference ($p<0.05$)

Table 3.3 Estimated mean percent weight loss between insurance groups by surgery type

Estimated mean	Commercial	Medicaid	Difference (Comm - Med)
Roux-en-Y Gastric Bypass			
% Weight Loss Δ 0y→ 1y	-34.6 (-35.1, -34.1)	-32.5 (-33.8, -31.3)	**2.1 (0.7, 3.4)**
% Weight Loss Δ 1y → 3y	1.4 (1.1, 1.6)	0.8 (0.2, 1.5)	0.6 (-0.1, 1.2)
% Weight Loss Δ 3y → 5y	1.7 (1.4, 1.9)	1.0 (0.4, 1.6)	**0.7 (0.0, 1.4)**
Laparoscopic Adjustable Gastric Band			
% Weight Loss Δ 0y → 1y	-15.7 (-16.5, -14.9)	-15.0 (-18.0, -12.1)	0.6 (-2.4, 3.7)
% Weight Loss Δ 1y → 3y	-0.5 (-0.9, -0.1)	1.0 (-0.5, 2.5)	-1.5 (-3.0, 0.1)
% Weight Loss Δ 3y → 5y	1.0 (0.6, 1.4)	-0.1 (-1.5, 1.3)	1.1 (-0.4, 2.5)
Sleeve Gastrectomy			
% Weight Loss Δ 0y → 1y	-30.8 (-33.6, -28.0)	-31.5 (-35.9, -27.0)	-0.6 (-5.9, 4.6)
% Weight Loss Δ 1y → 3y	-0.5 (-1.9, 1.0)	0.5 (-1.8, 2.7)	-0.9 (-3.6, 1.7)
% Weight Loss Δ 3y → 5y	1.2 (-0.2, 2.6)	0.1 (-2.1, 2.2)	1.1 (-1.5, 3.7)

Abbreviations: Δ: change; y: years; Comm: Commercial; Med: Medicaid
Note: boldface indicates a statistically significant difference ($p<0.05$)

Table 3.4 Estimated mean BMI change between insurance groups by surgery type

Estimated mean	Commercial	Medicaid	Difference (Comm - Med)
Roux-en-Y Gastric Bypass			
Baseline BMI (kg/m^2)	48.5 (48.1, 48.9)	50.9 (49.7, 52.0)	**-2.4 (-3.6, -1.2)**
BMI Δ 0y → 1y	-16.9 (-17.2, -16.6)	-16.8 (-17.5, -16.0)	-0.1 (-0.9, 0.7)
BMI Δ 1y → 3y	0.6 (0.5, 0.8)	0.3 (0.0, 0.7)	0.3 (-0.1, 0.6)
BMI Δ 3y → 5y	0.8 (0.7, 1.0)	0.5 (0.2, 0.8)	**0.4 (0.0, 0.7)**
Laparoscopic Adjustable Gastric Band			
Baseline BMI (kg/m^2)	45.9 (45.2, 46.6)	47.2 (44.6, 49.8)	-1.3 (-4.0, 1.4)
BMI Δ 0y → 1y	-7.1 (-7.6, -6.7)	-6.8 (-8.6, -5.1)	-0.3 (-2.2, 1.5)
BMI Δ 1y → 3y	-0.2 (-0.4, -0.0)	0.5 (-0.2, 1.3)	-0.7 (-1.5, 0.0)
BMI Δ 3y → 5y	0.4 (0.2, 0.6)	-0.0 (-0.8, 0.6)	0.5 (-0.2, 1.2)
Sleeve Gastrectomy			
Baseline BMI (kg/m^2)	57.6 (55.0, 60.1)	62.5 (58.6, 66.5)	**-5.0 (-9.7, -0.3)**
BMI Δ 0y → 1y	-17.6 (-19.3, -16.0)	-19.9 (-22.6, -17.2)	2.2 (-0.9, 5.4)
BMI Δ 1y → 3y	-0.3 (-1.1, 0.4)	-0.3 (-1.4, 0.8)	-0.0 (-1.4, 1.3)
BMI Δ 3y → 5y	0.7 (-0.0, 1.4)	0.2 (-0.9, 1.3)	0.5 (-0.8, 1.8)

Abbreviations: Δ: change; kg: kilograms; m:meter; y: year
Note: boldface indicates a statistically significant difference ($p<0.05$)

Table 3.5 Estimated mean weight loss/regain between insurance groups by surgery type with individuals who reported revision or reversal to primary surgery removed

Estimated mean	Commercial	Medicaid	Difference (Comm - Med)
Roux-en-Y Gastric Bypass			
Baseline weight (kg)	132.5 (131.2, 133.9)	137.7 (134.2, 141.2)	**5.2 (1.5, 8.9)**
Weight Δ 0y → 1y	-46.0 (-46.8, -45.1)	-45.1 (-47.3, -42.8)	-0.9 (-3.3, 1.4)
Weight Δ 1y → 3y	1.8 (1.5, 2.1)	0.9 (0.0, 1.7)	**0.9 (0.0, 1.9)**
Weight Δ 3y → 5y	2.3 (2.0, 2.6)	1.2 (0.4, 2.0)	**1.1 (0.2, 1.9)**
Laparoscopic Adjustable Gastric Band			
Baseline weight (kg)	126.5 (124.0, 129.1)	131.7 (119.9, 143.5)	5.2 (-6.9, 17.3)
Weight Δ 0y → 1y	-19.9 (-21.5, -18.3)	-21.7 (-29.3, -14.1)	1.8 (-5.9, 9.6)
Weight Δ 1y → 3y	-0.6 (-1.2, 0.0)	0.8 (-2.2, 3.9)	-1.4 (-4.5, 1.6)
Weight Δ 3y → 5y	1.3 (0.7, 1.9)	1.7 (-1.0, 4.4)	-0.4 (-3.2, 2.3)
Sleeve Gastrectomy			
Baseline weight (kg)	149.6 (140.7, 158.4)	162.7 (149.9, 175.5)	13.1 (-2.4, 28.7)
Weight Δ 0y → 1y	-46.7 (-52.3, -41.1)	-52.5 (-60.6, -44.4)	5.8 (-4.1, 15.7)
Weight Δ 1y → 3y	2.9 (0.7, 5.1)	0.5 (-2.6, 3.6)	2.4 (-1.4, 6.2)
Weight Δ 3y → 5y	1.9 (-0.2, 4.0)	0.1 (-2.9, 3.0)	1.9 (-1.7, 5.5)

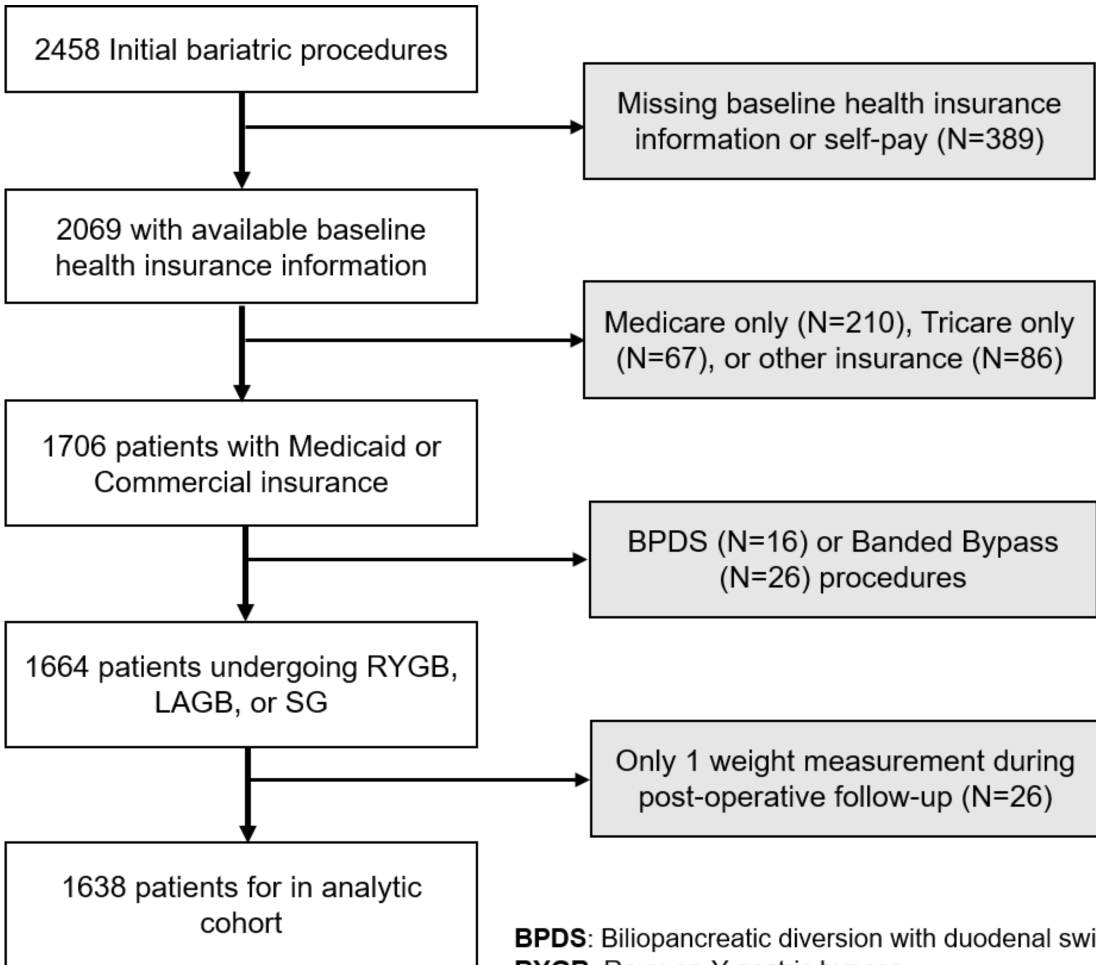
Abbreviations: Δ: change; kg: kilograms; y: years; Comm: Commercial; Med: Medicaid
Note: boldface indicates a statistically significant difference ($p<0.05$)

Table 3.6 Estimated mean weight loss/regain between insurance groups by surgery type with dual eligible Medicaid-Medicare patients removed

Estimated mean	Commercial	Medicaid	Difference (Comm - Med)
Roux-en-Y Gastric Bypass			
Baseline weight (kg)	132.3 (131.0, 133.6)	135.8 (131.6, 140.0)	3.5 (-0.9, 7.9)
Weight Δ 0y → 1y	-46.0 (-46.8, -45.2)	-43.8 (-46.5, -41.1)	-2.2 (-5.0, 0.6)
Weight Δ 1y → 3y	1.8 (1.5, 2.1)	0.8 (-0.3, 1.9)	1.0 (-0.1, 2.1)
Weight Δ 3y → 5y	2.3 (2.0, 2.6)	1.3 (0.3, 2.4)	1.0 (-0.1, 2.1)
Laparoscopic Adjustable Gastric Band			
Baseline weight (kg)	125.6 (123.5, 127.7)	120.8 (110.2, 131.5)	-4.7 (-15.6, 6.1)
Weight Δ 0y → 1y	-19.5 (-20.9, -18.2)	-16.8 (-23.6, -10.0)	-2.7 (-9.7, 4.2)
Weight Δ 1y → 3y	-0.6 (-1.2, -0.1)	0.6 (-2.2, 3.3)	-1.2 (-4.0, 1.6)
Weight Δ 3y → 5y	1.2 (0.6, 1.7)	-2.0 (-4.6, 0.6)	**3.1 (0.5, 5.8)**
Sleeve Gastrectomy			
Baseline weight (kg)	153.9 (146.4, 161.5)	156.6 (144.1, 169.0)	2.6 (-11.9, 17.2)
Weight Δ 0y → 1y	-48.2 (-53.0, -43.4)	-48.2 (-56.1, -40.2)	0.0 (-9.3, 9.3)
Weight Δ 1y → 3y	-0.8 (-2.8, 1.1)	0.3 (-2.9, 3.5)	-1.1 (-4.8, 2.6)
Weight Δ 3y → 5y	1.9 (0.0, 3.8)	0.2 (-2.9, 3.3)	1.7 (-1.9, 5.4)

Abbreviations: kg: kilograms; y: years; Δ: change; Comm: Commercial; Med: Medicaid
Note: boldface indicates a statistically significant difference ($p<0.05$)

Figure 3.1 Flow diagram, creation of analytic cohort



BPDS: Biliopancreatic diversion with duodenal switch
RYGB: Roux-en-Y gastric bypass
LAGB: Laparoscopic adjustable gastric band
SG: Sleeve gastrectomy

Figure 3.2 Flow diagram, weight measurements and missing data over study visits

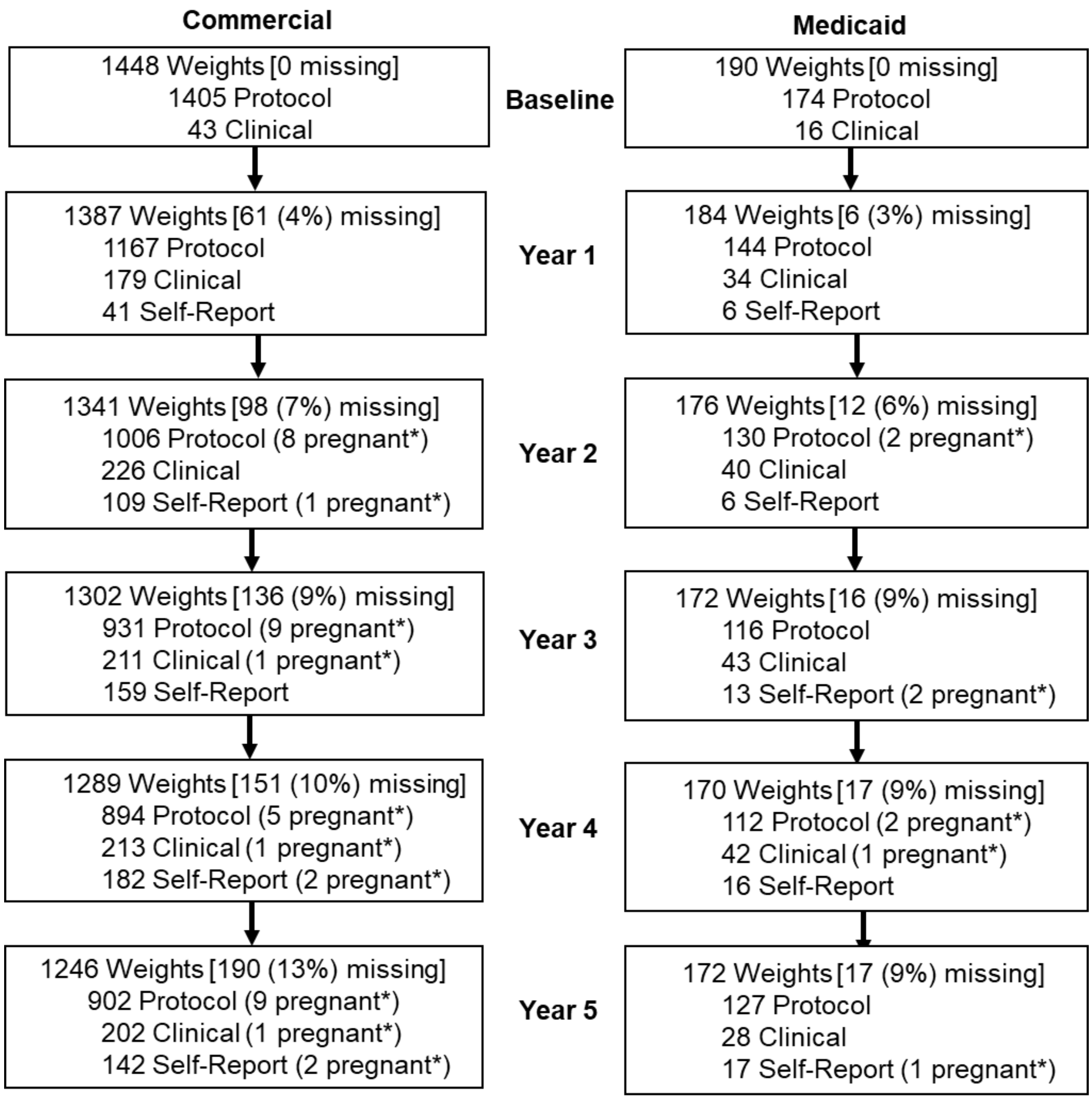


Figure 3.3 Individual weight (kg) change trajectories of a random sample of patients

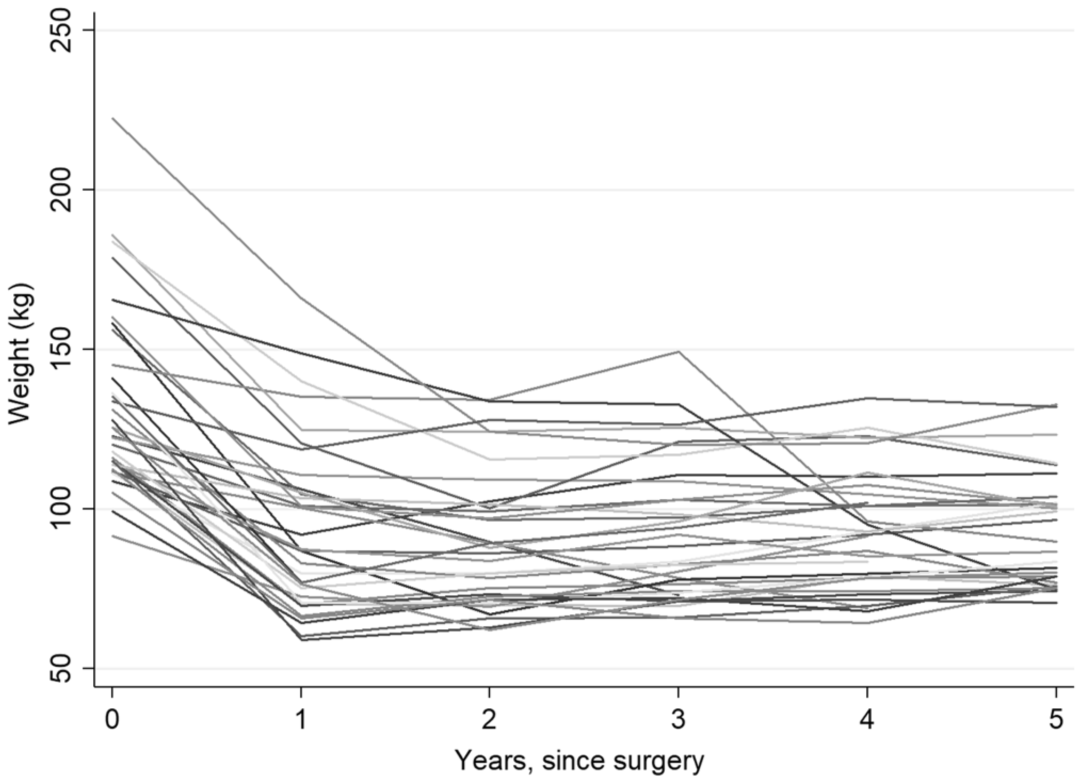


Figure 3.4 Estimated weight (kg) over time by insurance type and surgical procedure type

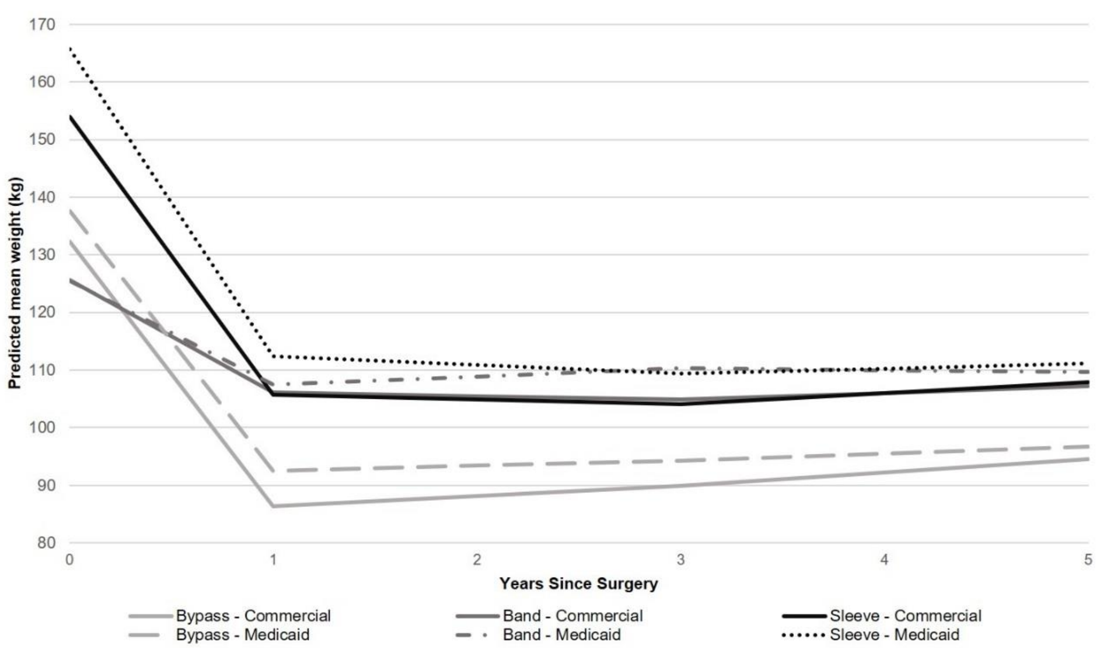


Figure 3.5 Estimated percent weight loss over time by insurance type and surgical procedure type

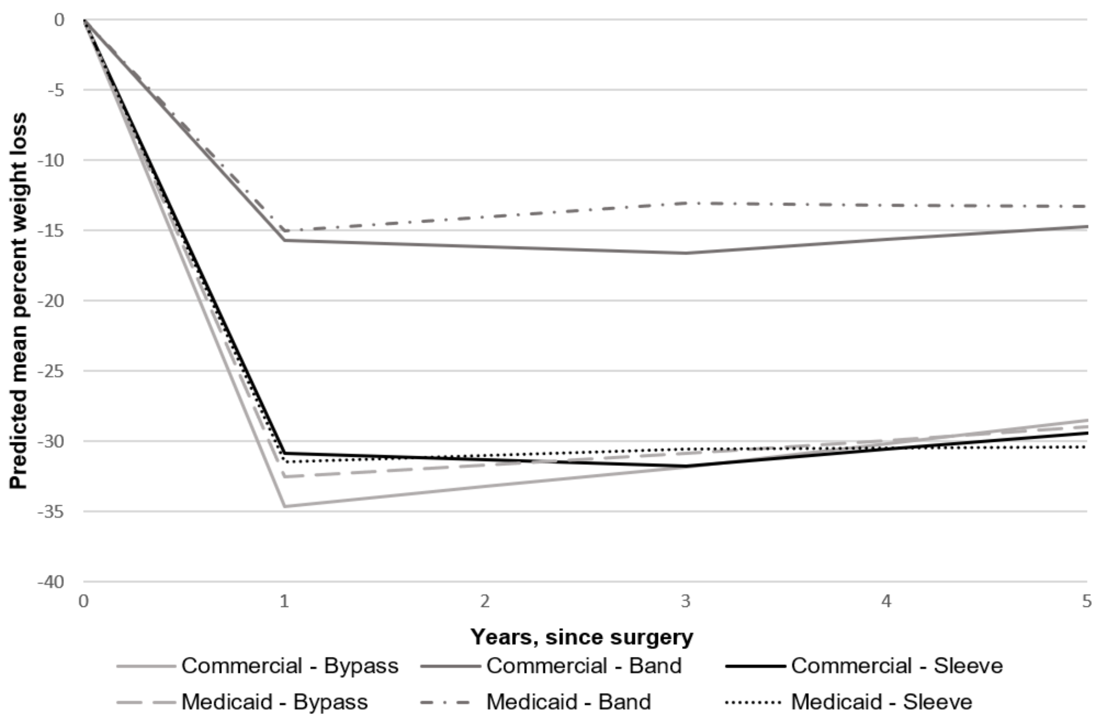
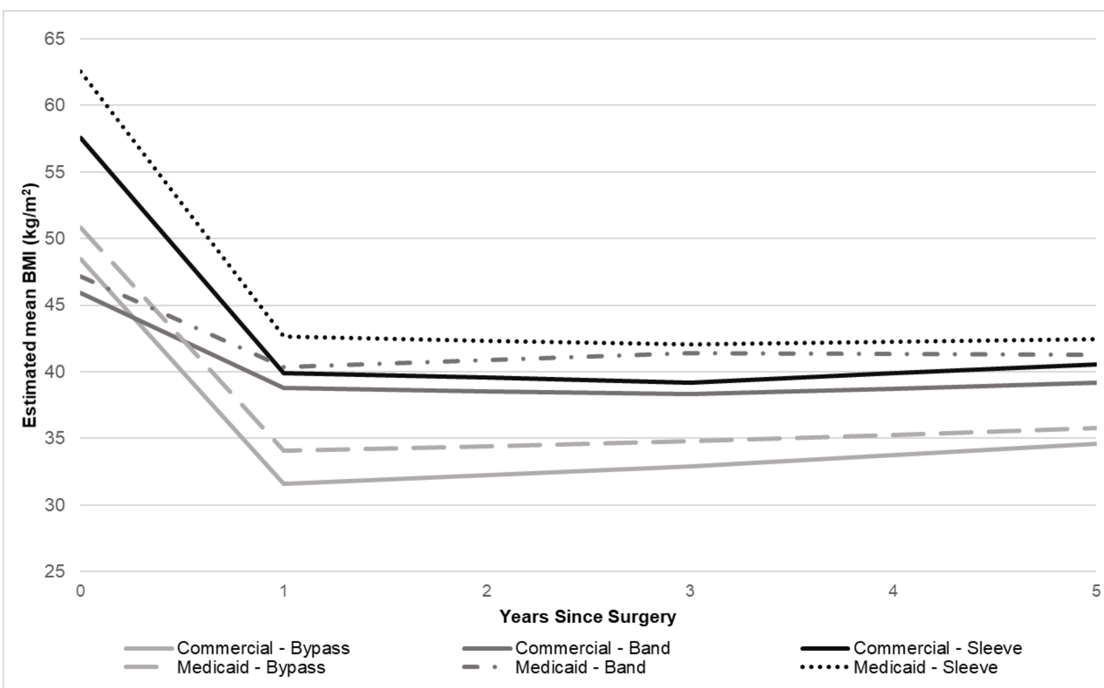


Figure 3.6 Estimated mean BMI over time by insurance type and surgical procedure type



Chapter 4: Long-term reduction in comorbid conditions following bariatric surgery in Medicaid and commercially insured patients

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Author Contributions: ET, JBH, JL and CLN contributed to the study design, data analysis, data interpretation, and manuscript preparation. BMW contributed to the study design, data interpretation, and manuscript preparation. ET is the guarantor of this work, and as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the analysis. JBH supervised all aspects of the study. An abstract of this study will be presented at the Society for Epidemiologic Research annual meeting in Baltimore, MD on June, 21st 2018.

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4.1 Abstract

Bariatric surgery is the most durable obesity treatment with demonstrated potential to alleviate the heavy burden of comorbid disease among patients with severe obesity. Bariatric surgery effectiveness among Medicaid patients, a population with the highest burden of comorbid disease, remains unclear. We sought to determine if changes in the prevalence of comorbid disease following bariatric surgery differs in Medicaid compared to commercially insured patients. Data were obtained from the Longitudinal Assessment of Bariatric Surgery, an observational cohort study of adults undergoing bariatric surgery (2006-2009) at one of 6 geographically diverse centers in the US. We identified 1201 patients who underwent Roux-en-Y Gastric Bypass and were followed for 5 years. In step 1, Poisson mixed models with robust error variance were used to estimate relative risks (RR) and compare changes in common comorbidities (Type 2 diabetes mellitus [DM]; hypertension [HTN]; dyslipidemia [DYS]; sleep apnea [OSA]; asthma [ASTH]; depression [DEP]) between insurance groups over time. Continuous time was coded into 2 linear spline functions with a knot at 1-year post-surgery to allow for non-linear changes. Interactions between time terms and insurance group allowed differential estimates for Medicaid (N=152) and commercially insured (N=1049) patients. In Step 2, Poisson mixed models were re-run employing propensity score weighting in order to achieve balance in the baseline comorbidity burden between Medicaid and Commercial patients. In the 0-1 year time period, risk of all six comorbidities decreased substantially over time in both insurer groups, ranging from 32 to 69% decrease from baseline (Medicaid RR and Commercial RR: DM: 0.40 and 0.32; DYS: 0.61 and 0.41; HTN: 0.66 and 0.57; OSA: 0.53 and 0.34; ASTH: 0.68

and 0.42; DEP: 0.57 and 0.31). In years 1-5 post-surgery, the risk of disease was stable in both groups (RRs ranged from 1.0 to 1.1). After propensity score weighting, the RRs in the 0-1 year period were more similar in magnitude while the RRs in the 1-5 year period were unchanged. These results provide important evidence for the beneficial association between surgery and long-term reduction in comorbid disease among Medicaid patients.

4.2 Introduction

Currently 5-10% of American adults have severe obesity (body mass index; BMI ≥ 40kg/m^2) (5, 121). Severe obesity is strongly associated with a multitude of conditions or comorbidities, including, but not limited to, Type II diabetes mellitus (diabetes), hypertension, cardiovascular disease, asthma, and mental illnesses such as depression (2, 64). Adults with Medicaid—a low income and racial/ethnically diverse population—carry a disproportionate burden of severe obesity and related comorbidities but are least likely to receive treatment (19, 80, 122).

Currently, bariatric surgery is the only weight loss treatment demonstrated to alter or slow the progression of comorbid disease among patients with severe obesity (35, 110-112). We recently demonstrated that both initial weight loss and the long-term durability of weight loss following bariatric surgery was substantial and comparable in Medicaid and commercially insured patients (123). Less is known about changes to comorbidities following surgery among Medicaid patients. Among the five studies that have examined changes to comorbid disease prevalence among Medicaid beneficiaries, findings are mixed (82-86), with a few reporting less disease improvement in Medicaid patients. However, these studies all were short term (<2 years) in duration, and most focused on a single center or surgeon (82-84, 86). Given the chronic nature of obesity and related comorbidities, further investigation of long-term changes to comorbid disease prevalence among Medicaid patients is needed.

Moreover, Medicaid patients have higher prevalence of comorbidities that persist post-operatively (82, 85, 86). Given that Medicaid patients experience delays in the receipt of specialty medical care such as bariatric surgery (80), persistent differences by insurance type may result from more advanced disease progression in Medicaid patients at the time of treatment. In patients with diabetes, those receiving bariatric surgery earlier have the greatest likelihood of post-operative remittance of diabetes (124). However, the extent to which baseline burden of disease contributes to less pronounced post-operative comorbidity improvement in Medicaid patients is unknown.

The goal of this investigation was twofold. First, investigate changes in the prevalence of six common comorbid diseases (diabetes, hypertension, hyperlipidemia, sleep apnea, asthma, and depression) over five years following bariatric surgery among Medicaid and commercially insured patients. Second, determine if differences in comorbidity change by insurance group remains after accounting for baseline comorbid disease profile. We utilize data from the Longitudinal Assessment of Bariatric Surgery (LABS), a large, multi-site, observational cohort with objectively measured comorbidities and levels of follow-up greater than 80% (113). We hypothesized that, compared to commercially insured patients, Medicaid patients have a greater burden of baseline comorbid disease and experience similar response to surgery after control for baseline disease profile.

4.3 Methods

Study Population

Between March 2006 and April 2009, 2458 individuals 18 years and older undergoing bariatric procedures were enrolled in the LABS study, a prospective observational cohort study designed to assess the risks and benefits of bariatric surgery. Upon enrollment, LABS participants underwent first-time bariatric procedures with a surgeon participating in the LABS consortium at one of 10 hospitals at six clinical centers in the U.S, as previously described (113). The institutional review boards at each center approved the protocol and consent forms. IRB exemption was obtained from Oregon Health & Science University for this analysis. LABS is registered at ClinicalTrials.gov (NCT00465829).

Data collection

LABS-certified trained personnel collected study data using standard protocols (44, 114). Data collection consisted of blood and urine samples, physical measurements, self-assessment forms, surgeon and medical staff forms, and chart review procedures. Baseline weights and other clinical data were collected within 30 days before surgery. Annual follow-up assessments were conducted within 6 months of surgery anniversary date for five consecutive years. Data were entered twice using a web-based data entry system developed, distributed and maintained by the University of Pittsburgh LABS DCC.

Study Variables

Outcomes

For each patient, six comorbidities were classified as present or not present at each time point, based on a combination of patient self-report, clinical assessment, and medical chart review by trained researchers. We chose these comorbidities because they are important contributors to morbidity and mortality, validly measured, prevalent in this cohort, and are plausibly modifiable by substantial weight loss. Each comorbidity was defined based on prior studies in the LABS population (113) as follows:

Diabetes was defined as currently taking diabetes medication or having glycated hemoglobin (HbA1c) of at least 6.5%, or if HbA1c was not available, an 8-hour fasting glucose of at least 126 mg/dL. Participants reporting having Polycystic Ovarian Syndrome who did not meet laboratory criteria for diabetes and were not taking a diabetes medication other than Metformin were not considered to have diabetes.

Hypertension was defined as having systolic blood pressure (SBP) of at least 140 mm Hg, diastolic blood pressure (DBP) of at least 90 mm Hg, or taking any antihypertensive medication. At each in-person visit, a single blood pressure measurement was performed by clinically trained staff following a standardized protocol.

Dyslipidemia was defined as meeting one of the following: low density lipoprotein (LDL) of at least 160 mg/dL, high density lipoprotein (HDL) of less than 40 mg/dL, fasting triglycerides of at least 200 mg/dL, or taking a lipid lowering medication.

Sleep apnea at baseline was defined by either an Apnea-Hypopnea Index (AHI) of at least 5 from a diagnostic polysomnogram in the 12 months before the LABS baseline visit, self-reported use of continuous positive airway pressure (CPAP), or self-reported AHI result. At all follow-up time points, sleep apnea was assessed by self-reported use of a CPAP or self-reported diagnostic AHI result.

Asthma at baseline and at all follow-up time points was assessed by self-report ("In the past 12 months have you been told by a doctor or other healthcare professional that you have asthma?").

Depressive symptoms at baseline and at all follow-up time points was assessed using the Beck Depression Index (BDI) version 1. The BDI is a 21-question multiple-choice self-report rating inventory that measures characteristic attitudes and symptoms of depression with high levels of internal consistency (125, 126). Because many patients are advised to lose weight in preparation for bariatric surgery, no points were assigned to the BDI item that assesses weight loss for participants who indicated that they were purposefully trying to lose weight by eating less (113). Patients with a BDI score greater than or equal to 10 were classified as having depressive symptoms.

Insurance Type

Self-reported insurance type was collected using a self-assessment form at the baseline study visit. Participants with available baseline insurance information were classified into two primary categories: 1) Medicaid with or without Medicare, to represent low socioeconomic participants who could not afford private insurance; and 2) Commercial insurance with or without Medicare, to represent a non-disadvantaged group. Participants reporting other insurance types were excluded from this analysis because they were heterogeneous in regards to their socioeconomic profile. Insurance classification at baseline was analyzed as a time constant variable; potential changes to insurance status over time were not incorporated given the desire to understand how the differences present at baseline between groups influenced long-term outcomes.

Surgery type

Roux-en-Y gastric bypass (RYGB) was the most common procedure at the time of patient recruitment; it remains a commonly used procedure and thus was the focus of this analysis. Laparoscopic adjustable gastric banding (25% of LABS procedures) is a less effective procedure and only conducted in 5% of current bariatric cases and thus was excluded from this analysis. Biliopancreatic diversion with or without duodenal switch, sleeve gastrectomy, and banded bypass procedures were uncommon in this cohort (<3% of LABS procedures) and were excluded from this analysis. The choice of surgery type was a result of patient and surgeon preference. Participants whose initial bariatric surgery was subsequently revised or reversed remain classified as RYGB to represent the natural history of each participant's post-surgical course.

Covariates

Covariates included self-reported age at surgery, sex (male, female), and smoking status (never, current/former) at baseline; and baseline BMI (kg/m^2) calculated using measured height and weight.

Analytic Sample

Of the 2458 LABS participants, we first excluded participants who were missing baseline health insurance information or reported self-paying for surgery (N=389). Next, participants reporting Medicare only (N=210), Tricare only (N=67) or Other insurance (N=86) were excluded. Participants undergoing Laparoscopic Adjustable Gastric Band (N=420), Sleeve Gastrectomy (N=43), Banded Bypass (N=26), and Biliary Pancreatic Diversion with Duodenal Switch (N=16) were excluded. Among the 1,201 remaining patients, for each of the outcomes included in multivariable models, participants who contributed fewer than two outcome responses over the six-time points were excluded from analyses because they contribute no information about change in the response, leaving a variable number of participants for analysis of each outcome (N=963-1151; **Figure 4.1**).

Statistical Analysis

Descriptive statistics summarize baseline characteristics and comorbidity prevalence for each insurance category; we summarized a set of both common and less common chronic diseases. Pearson's chi-square test for categorical variables and t-tests for continuous variables were used to assess statistical significance of differences in baseline characteristics and comorbidities between the payer groups. Data management was conducted using SAS version 9.4, descriptive analyses and mixed models were conducted using Stata version 15.

Step 1: Compare changes in prevalence of comorbidities in Medicaid and commercially insured patients. We analyzed repeated measures data using generalized linear mixed-effects models (GLMM) with a random intercept for participant. GLMM are an extension of linear mixed models which allow response variables from distributions other than a normal distribution; GLMM allows the linear model to be related to the response variable via a link function. Specifically, Poisson mixed models (link: $\log \mu_i = X_i\beta$) with robust error variance were used to estimate relative risks (RR), separately for each binary response (127, 128). This approach accounts for the correlated structure of the data, uses all available follow-up data, and employs maximum likelihood estimation that is robust to missing data under the missing at random (MAR) assumption, and therefore is ignorable.

To allow for non-linear changes in the response, continuous time was coded into 2 linear spline functions with a knot placed at 1-year post-surgery. We determined the number and placement of knots that best fit the pattern of post-operative change in comorbidity prevalence, for each outcome by comparing models with one, two, and three knots placed at different time points including at one-, two-, and three-years post-operatively. Using Akaike information criteria (AIC) and Bayesian information criteria (BIC), for each of the six responses, the model with one knot placed at 1-year post-operatively best fit the data. This time point aligns with the period in which weight loss and, consequently, changes to comorbidity prevalence, typically level off (32, 129).

Interactions between insurance group and the two time terms allowed differential estimates for Medicaid and commercially insured patients during the both time periods. All baseline covariates were included in each model. Model coefficients were exponentiated to generate relative risks (RR) with 95% confidence intervals (e.g., decrease/increase in risk of disease per change in time) for each insurance group; additionally, model estimates were used to calculate the adjusted prevalence of disease at each time point by insurance group. The RRs compare change in disease with increasing time and are interpreted as “A patient with commercial insurance has XX times the risk of comorbidity A for each year increase in time”. Ratios of the RRs (RR for Medicaid / RR for commercially insured) were also generated to determine if the change in disease risk over time was different between groups. Ratios greater than 1.0 indicate the improvement in disease over time is better in Commercial; ratios less than 1.0 indicate the improvement in disease over time is superior in Medicaid patients. Change over time is similar between groups if the 95% confidence interval includes the null value of 1.0.

Step 2: Compare changes in prevalence of comorbidities in Medicaid and commercially insured patients, after balancing comorbidity burden at baseline. Our Step 1 analysis estimated heterogeneity of treatment effects, allowing for differences in baseline disease levels, findings which are generalizable to current patient populations. Given the difference in disease burden at baseline, it was also of interest to construct Medicaid and commercial groups that were similar in regard to baseline disease and re-evaluate any observed heterogeneity in treatment effectiveness. We achieved these comparable groups with propensity score analysis.

The propensity score is the probability of “treatment” for each patient; “treatment” in this case is insurance type (130). In essence, the propensity score is a balancing score: conditional on the propensity score, the distribution of observed baseline covariates will be similar between treated and untreated subjects. We estimated the propensity score using a logistic regression model, in which insurance status was regressed on baseline chronic conditions (all conditions in **Table 4.2**); based on the estimated model parameters, we then calculated the predicted probability of treatment. Next, we restricted the analysis to observations within a propensity score range that was common to both treated and untreated patients, that is, we excluded patients in non-overlapping regions of the propensity score distribution (131, 132). We applied asymmetric trimming which excludes those patients who were treated most contrary to prediction—that is, Commercial patients who had a high probability of receiving Medicaid but whose ‘treatment’ assignment was Commercial; and Medicaid patients who had a low probability of receiving Medicaid but whose ‘treatment’ assignment was Medicaid (132). The distribution of the propensity score was trimmed using an upper cut-point value equal to the 95^{th} percentile of the propensity score distribution for Commercially insured patients and a lower cut-point value equal to the 5^{th} percentile of the propensity score distribution for Medicaid patients (**Figure 4.2**) (132).

Within this trimmed population (N=742), we employed inverse probability of treatment weighting (IPTW), which based on the propensity score assigns each individual a weight, the weight is equal to the inverse probability of receiving the actual treatment. As a result, a synthetic sample is created in which individuals account for themselves and contribute copies of subjects with similar characteristics; individuals with a low-propensity, or who are 'unusual', are up-weighted so that balance is achieved between groups on baseline covariates. Within this pseudo-population, the distribution of measured baseline covariates is independent of treatment assignment. We used stabilized weights to the reduce variance of the estimated treatment effect—that is, we multiplied the IPTW weights by the marginal prevalence of the treatment actually received (132). Within the trimmed population, we used the IPTW as a sampling weight and re-ran the Step 1 analyses (130).

Sensitivity Analyses

Medicaid bariatric surgery patients who also qualify for Medicare likely do so on the basis of permanent disability given the relatively young age distribution of the study population, thus representing a potentially unique population. To examine this possibility, we restricted the Medicaid group by excluding Medicaid-Medicare dual eligible patients and repeated the Step 1 analyses.

4.4 Results

Description of the sample

At baseline, Medicaid patients were slightly younger than commercial patients (mean age: 43.4 vs 44.8 years) and were more likely to be female (88.2% vs. 80.6%). Selected characteristics of the analytic sample are reported in **Table 4.1**. Follow-up through 5-years was adequate, ranging from 64 to 80% of the initial sample depending on the outcome.

Baseline prevalence of chronic conditions

At baseline, the most common chronic conditions were dyslipidemia (DYS), hypertension (HTN), obstructive sleep apnea (OSA), depression (DEP), diabetes (DM), and asthma (ASTH); the prevalence at baseline ranged from 24-69%. More severe conditions, such as history of stroke and pulmonary hypertension, were less common, the prevalence ranged from less than 1% up to 21% of the patient cohort (**Table 4.2**). With the exception of HTN and venous edema, all chronic conditions were more prevalent in Medicaid as compared to Commercial patients (**Table 4.2**). On average, Medicaid patients had 3.6 chronic conditions compared to 3.1 among commercial patients, a statistically significant difference.

Five-year estimated risk of comorbidity in patients undergoing RYGB

At 1-year, both insurer groups had substantially lower relative risk (RR) of all six comorbidities, ranging from a 32 to 69% decrease from baseline (Medicaid RR and Commercial RR: DM: 0.40 and 0.32; DYS: 0.61 and 0.41; HTN: 0.66 and 0.57; OSA: 0.53 and 0.34; ASTH: 0.68 and 0.42; DEP: 0.57 and 0.31) (**Figure 4.3; Table 4.3**). The ratios comparing the change in risk over time between the groups were generally greater than 1.0, indicating Medicaid patients experienced less improvement in disease prevalence from baseline than did commercially insured patients; significant differences were observed for DYS, OSA, ASTH, and DEP.

In the post-operative years 1-5, the risk of disease began to increase, ranging from a 2-10% increase per year; in one exception, the risk of sleep apnea continued to decline with each additional year. Ratios for group comparisons were close to 1 for all disease measures, suggesting both insurance groups experience similar changes to disease risk in the 1-5 year post-operative period.

Five-year estimated risk of comorbidity in patients undergoing RYGB after propensity score weighting

Upon accounting for the differences in baseline disease prevalence, RRs in the 0-1 year time period for DM, DYS, HTN, and OSA were more similar in magnitude for Medicaid versus commercial, and none of the ratios remained statistically significant (**Table 4.4**). However, for ASTH and DEP the RRs in the 0-1 year time period were unchanged from the initial analyses. In the 1-5 year time period, the RRs were similar to the initial analyses.

Sensitivity Analyses

We performed one sensitivity analysis where we restricted the analytic cohort to include Medicaid patients only, excluding any dual eligible Medicaid-Medicare patients. Among Medicaid patients in the 0-1 year post-operative period, the RR estimates were more similar in magnitude for DM, DYS, and DEP, while the RRs for HTN, OSA, and ASTH were analogous to the primary analysis (**Table 4.5**). In the 1-5 year period among Medicaid patients, all RRs were slightly attenuated towards the null value of 1.0.

4.5 Discussion

In this study of comorbid disease prevalence following bariatric surgery, we provide new information on the short and long-term changes in disease prevalence among Medicaid and commercially insured patients. Both insurance groups experienced substantial reductions in the prevalence of all six comorbid diseases in the first post-operative year, albeit slightly less improvement among Medicaid patients. Both patient groups experienced minimal increases in disease prevalence during the 1-5 year post-operative period. Importantly, our propensity score analysis suggests that the diminished response observed among Medicaid patients is partially due to greater burden of comorbid disease at baseline.

Five previous studies have examined changes to comorbid disease among Medicaid patients. Three studies examined one-year outcomes (82, 83, 86), one study examined 18-month outcomes (85), and one examined 2-year outcomes (84), limiting their inference to short-term outcomes. Our findings were consistent in that Medicaid patients tended to have more comorbid disease at baseline, a trend that remained at post-operative time points despite comparable surgical response. Additionally, most prior studies reported unadjusted disease prevalence at baseline and at follow-up, which does not take into account any baseline differences or examine the change in disease risk over time.

Period specific differences

Our analysis differed from previously published research examining insurer sub-group differences by examining period-specific changes to comorbid disease through 5-years post-operatively.

Baseline. Our study further substantiates the existing body of evidence (82-86) that suggests that Medicaid patients present for surgery with a greater burden of comorbid disease, despite representing a slightly younger population. All but two chronic conditions investigated in our descriptive analyses were more common amongst Medicaid patients. It is important to note that some of these differences may be partially attributable to stricter state qualification criteria for Medicaid patients. For example, until recently, in Oregon state, bariatric surgery was only covered by the state Medicaid program as a treatment for individuals with Type II diabetes. However, its well-documented Medicaid patients have a higher burden of chronic diseases and our estimates aligned with previously published research.

The greater prevalence and therefore burden of baseline disease may have important implications for success of surgical intervention. For example, recent evidence suggests that bariatric surgery is more effective in changing the clinical course of diabetes when implemented in earlier stages (e.g., pre-diabetes) then it is amongst patients experiencing macro- and micro-vascular major events (124).

Short-term changes [0-1 years]. In the first post-operative year among both groups, the prevalence of baseline disease was reduced by one- to two-thirds of the level observed at baseline, a degree of improvement which support the effectiveness of surgery in Medicaid patients. Across all six disease outcomes measured, Medicaid patients did experience a slightly smaller magnitude of improvement, but after propensity score weighting the magnitude of these differences decreased. This finding suggests that the higher level of baseline disease observed among Medicaid patient does partially contribute to a slightly lesser surgical response. Notably, the group differences observed for asthma and depression remained unchanged by propensity score weighting. It is possible, if not likely, that the mechanisms in which baseline disease burden influences post-operative disease improvement may operate through different pathways for these diseases. For example, asthma and depression may be more closely related to environmental or socioeconomic drivers that are experienced differentially between the insurer groups, which were not accounted for in the propensity score analysis.

When we removed dual eligible Medicaid-Medicare patients, patients who likely qualify for Medicare based on permanent disability, many of the RRs were also more similar in magnitude between the insurer groups. These results provide further evidence that when Medicaid patients are more similar in regards to baseline disease burden, the improvements following surgery are similar.

Long-term changes [1-5 years]. After the first post-operative year, four of the six outcomes RRs were at or near the null value of 1.0 for both insurer groups, suggesting little change to disease prevalence after that time point. Hypertension among Commercial patients increased significantly with time and may or may not be related to the weight regain that was observed to be slightly higher among this group (123) as compared to Medicaid patients. Similarly, Commercial patients experienced a considerably greater risk of depression in the long-term as compared to Medicaid patients. These findings may be explained by the differences in the magnitude of weight regain observed between the insurer groups, given that weight gain is closely linked with the onset of depression. Conversely, the insurer groups may experience varying levels of social or economic changes following bariatric surgery, which could have important differential implications for mental health outcomes. Finally, moderate increases in diabetes risk over time were observed in both groups is not surprising given that a small proportion of patients who achieve remission after bariatric surgery are known to relapse in the post-operative period (37).

Contrary to the short-term results, the RR estimates for 1-5 years were largely unchanged when accounting for baseline disease burden via propensity score weighting. The results imply baseline disease complexity contributes primarily to changes in the short-term following surgical intervention, while it has little impact on long-term changes.

Future directions

More evidence is needed on how the comorbid conditions interact with one another, the severity of comorbidities, and how different groups of disease occurring at different levels of severity may influence the weight loss response and remission of comorbid disease. For example, a patient with diabetes and sleep apnea may experience a different comorbidity response than a patient with diabetes, dyslipidemia, and hypertension. Or a patient with diabetes requiring insulin and hypertension under poor control may experience a difference response than a similar patient with diabetes treated with Metformin and well-controlled hypertension. Given that Medicaid patients have more baseline chronic conditions at younger ages, these findings could have important implications for the further optimization of surgical care and pre-operative preparations.

Additionally, we aimed to characterize patterns of disease prevalence in highly diseased sub-groups to provide a holistic picture of disease patterns over time. We did not separately analyze remission of disease present pre-operatively or incidence of new onset disease occurring after surgery. For those aiming to create a more individualized approach to bariatric surgery care, future studies may be able to identify specific at-risk patients by modeling these two pathways distinctly.

Clinical and Public Health Implications

Our findings suggest bariatric surgery is effective even in patient populations with high levels of chronic disease. The finding that post-operative improvement was greater in those with lesser disease burden suggests that initiating bariatric surgical treatment early in the clinical progression of disease may result in greater chances of overcoming comorbidity-associated clinical deterioration. There is recent discussion of revising the arbitrary BMI cutoff of 35 kg/m^2 established in 1991, by offering surgical intervention to those with class I obesity (30-35kg/m^2) given the opportunity to intervene earlier in the clinical course of disease (133). Improving access to specialty providers and identifying bariatric surgery as a treatment earlier in the clinical course of disease among Medicaid patients may allow for an even more substantial improvement in comorbid disease outcomes. Also, given the clear disparity in disease burden at younger ages, upstream obesity prevention among this sub-group remain vital areas for public health improvement.

Strengths and Limitations

There are several limitations to this study. First, a relatively small number of bariatric surgery patients in this cohort were covered by Medicaid, although the proportion was similar to national estimates. However, this study contributes the largest sample of Medicaid patients to date with five years of follow-up. Second, two of the reported outcomes were constructed using self-reported disease status, introducing the potential for bias. Finally, follow-up through five years was adequate, missingness ranging from 20-36%. However, the levels of follow-up observed in this study are considerably higher than previously published studies and our methods are robust to missingness.

The primary strength of this study is the availability of long-term follow-up data with robust outcome measures, enabling investigation of differences in comorbid disease between insurance groups. Outcome measures were prospectively collected via a standardized research protocol collected by trained evaluators, many of which incorporated objectively-measured or clinically derived values. We employed the use of statistical methods which are robust in balancing baseline differences. Additionally, our study results provide a high level of generalizability as LABS is a multicenter geographically diverse cohort with long-term follow-up. Finally, our study provides one of the largest sample sizes to date, filling a gap from prior studies.

Conclusions

Medicaid patients experience important improvements in disease prevalence following bariatric surgery. Despite a similar magnitude of initial weight loss, the observed improvement in disease prevalence is to a slightly lesser extent than that observed among commercially insured patients. These differences were partially explained by the greater disease burden at baseline and could be improved by increasing obesity prevention strategies and identifying surgery as a viable treatment option earlier in the clinical course of disease.

Table 4.1 Baseline characteristics of 1,201 patients undergoing Roux-en-Y Gastric Bypass

Characteristic	Overall (N=1,201)	Commercial (N=1,049)	Medicaid (N=152)
Age [Mean (SD)]	44.6 (10.4)	44.8 (10.4)	43.4 (10.3)
Sex –n (%)			
Male	222 (18.5)	**204 (19.5)**	**18 (11.8)**
Female	979 (81.5)	**845 (80.6)**	**134 (88.2)**
Smoking Status –n (%)			
Never Smoker	686 (57.1)	**611 (58.3)**	**75 (49.3)**
Current/Former Smoker	515 (42.9)	**438 (41.8)**	**77 (50.7)**
BMI (kg/m^2) [Mean (SD)]	48.9 (7.4)	**48.6 (7.2)**	**51.3 (8.5)**

Abbreviations: SD: standard deviation; BMI: body mass index; kg: kilogram; m: meter; n: number

Note: boldface indicates statistical significance ($p<0.05$) for Commercial versus Medicaid, per t-test or chi-square test for continuous or categorical variables, respectively.

Table 4.2 Prevalence of baseline comorbid conditions 1,201 patients undergoing Roux-en-Y Gastric Bypass, ranked according to prevalence

Comorbid Condition	**Commercial** (N=1,049)	**Medicaid** (N=152)	*P-value*
Number of comorbid conditions [Mean(SD)]	3.06 (1.8)	3.58 (2.0)	<0.01
	N (%)		
Dyslipidemia	630 (66.0)	101 (74.3)	0.05
Hypertension	714 (68.6)	101 (66.5)	0.60
Obstructive Sleep Apnea	531 (50.7)	80 (52.6)	0.65
Depression	326 (31.4)	67 (45.9)	<0.01
Type II Diabetes Mellitus	353 (33.8)	58 (38.9)	0.22
Asthma	249 (24.1)	50 (34.5)	<0.01
Chronic Kidney Disease	164 (16.8)	28 (20.9)	0.24
Cardiovascular Disease	68 (6.5)	17 (11.5)	0.03
Ischemic Heart Disease	55 (5.3)	12 (8.1)	0.16
Venous Edema	62 (5.9)	7 (4.6)	0.52
History of PE/DVT	27 (2.6)	7 (4.9)	0.13
Congestive Heart Failure	14 (1.3)	5 (3.3)	0.07
Chronic Obstructive Pulmonary Disease	7 (0.7)	5 (3.3)	<0.01
Pulmonary Hypertension	7 (0.7)	4 (2.6)	0.02
History of Stroke	4 (0.4)	2 (1.3)	0.13

Table 4.3 Estimated Relative Risk (RR) of Outcome with 95% Confidence Intervals by Insurance Groups

	Diabetes (N=1,073)		Dyslipidemia (N=963)		Hypertension (N=1,143)		Sleep Apnea (N=1,151)		Asthma (N=1,145)		Depression (N=1,112)	
Time [0-1 year]	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**
Bypass												
Medicaid	0.40	(0.29, 0.56)	0.61	(0.50, 0.73)	0.66	(0.56, 0.76)	0.53	(0.42, 0.67)	0.68	(0.53, 0.87)	0.57	(0.44, 0.75)
Commercial	0.32	(0.27, 0.38)	0.41	(0.37, 0.45)	0.57	(0.54, 0.61)	0.34	(0.30, 0.38)	0.42	(0.37, 0.49)	0.31	(0.26, 0.37)
RR Ratio	*1.26*	*(0.87, 1.83)*	*1.48*	*(1.19, 1.84)*	*1.14*	*(0.97, 1.35)*	*1.56*	*(1.20, 2.04)*	*1.63*	*(1.22, 2.19)*	*1.84*	*(1.34, 2.53)*
Time [1-5 year]												
Bypass												
Medicaid	1.10	(1.01, 1.19)	1.00	(0.95, 1.06)	1.02	(0.97, 1.07)	0.94	(0.85, 1.03)	1.03	(0.96, 1.11)	1.10	(1.03, 1.17)
Commercial	1.08	(1.04, 1.12)	1.02	(0.99, 1.05)	1.07	(1.05, 1.09)	0.91	(0.87, 0.96)	1.00	(0.96, 1.05)	1.23	(1.17, 1.28)
RR Ratio	*1.01*	*(0.93, 1.11)*	*0.99*	*(0.93, 1.05)*	*0.95*	*(0.91, 1.00)*	*1.03*	*(0.92, 1.14)*	*1.03*	*(0.94, 1.12)*	*0.90*	*(0.83, 0.97)*

Table 4.4 Estimated Relative Risk (RR) of Outcome with 95% Confidence Intervals by Insurance Groups after Propensity Score Weighting

	Diabetes (N=657)		Dyslipidemia (N=597)		Hypertension (N=710)		Sleep Apnea (N=712)		Asthma (N=706)		Depression (N=686)	
Time [0-1 year]	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**
Bypass												
Medicaid	0.37	(0.22, 0.63)	0.50	(0.35, 0.70)	0.67	(0.54, 0.83)	0.46	(0.31, 0.68)	0.72	(0.52, 1.00)	0.57	(0.36, 0.91)
Commercial	0.32	(0.25, 0.40)	0.39	(0.34, 0.45)	0.58	(0.53, 0.63)	0.35	(0.30, 0.41)	0.41	(0.35, 0.49)	0.30	(0.25, 0.37)
RR Ratio	*1.17*	*(0.66, 2.08)*	*1.27*	*(0.88, 1.83)*	*1.15*	*(0.91, 1.46)*	*1.32*	*(0.88, 2.00)*	*1.78*	*(1.22, 2.60)*	*1.89*	*(1.14, 3.15)*
Time [1-5 year]												
Bypass												
Medicaid	1.10	(0.99, 1.22)	1.03	(0.92, 1.14)	1.00	(0.94, 1.07)	0.94	(0.81, 1.09)	1.00	(0.93, 1.09)	1.09	(0.92, 1.22)
Commercial	1.10	(1.04, 1.15)	1.02	(0.98, 1.06)	1.08	(1.05, 1.10)	0.89	(0.83, 0.95)	1.01	(0.95, 1.06)	1.21	(1.14, 1.28)
RR Ratio	*1.00*	*(0.89, 1.13)*	*1.01*	*(0.90, 1.12)*	*0.93*	*(0.87, 1.00)*	*1.06*	*(0.90, 1.25)*	*1.00*	*(0.90, 1.10)*	*0.90*	*(0.79, 1.02)*

Table 4.5 Estimated Relative Risk (RR) of Outcome with 95% Confidence Intervals by Insurance Groups after Removing Dual Eligible Medicare-Medicaid Patients

	Diabetes (N=1,026)		Dyslipidemia (N=895)		Hypertension (N=1,093)		Sleep Apnea (N=1,101)		Asthma (N=1,094)		Depression (N=1,064)	
Time [0-1 year]	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**	**RR**	**(95% CI)**
Bypass												
Medicaid	0.39	(0.25, 0.62)	0.57	(0.43, 0.75)	0.68	(0.56, 0.82)	0.56	(0.43, 0.74)	0.74	(0.53, 1.04)	0.54	(0.37, 0.79)
Commercial	0.32	(0.27, 0.38)	0.41	(0.37, 0.45)	0.57	(0.54, 0.61)	0.34	(0.30, 0.38)	0.42	(0.36, 0.49)	0.31	(0.26, 0.37)
RR Ratio	*1.22*	*(0.75, 1.99)*	*1.40*	*(1.04, 1.88)*	*1.18*	*(0.97, 1.44)*	*1.66*	*(1.22, 2.25)*	*1.78*	*(1.23, 2.60)*	*1.75*	*(1.15, 2.65)*
Time [1-5 year]												
Bypass												
Medicaid	1.08	(0.98, 1.19)	0.97	(0.89, 1.05)	0.98	(0.93, 1.04)	0.90	(0.80, 1.01)	0.99	(0.90, 1.10)	1.14	(1.05, 1.24)
Commercial	1.08	(1.04, 1.12)	1.02	(0.99, 1.05)	1.07	(1.05, 1.09)	0.91	(0.87, 0.96)	1.00	(0.96, 1.05)	1.23	(1.17, 1.28)
RR Ratio	*1.00*	*(0.90, 1.11)*	*0.95*	*(0.87, 1.04)*	*0.92*	*(0.86, 0.97)*	*0.98*	*(0.87, 1.12)*	0.99	(0.89, 1.10)	0.93	(0.85, 1.02)

Figure 4.1 Flow diagram, creation of analytic cohort

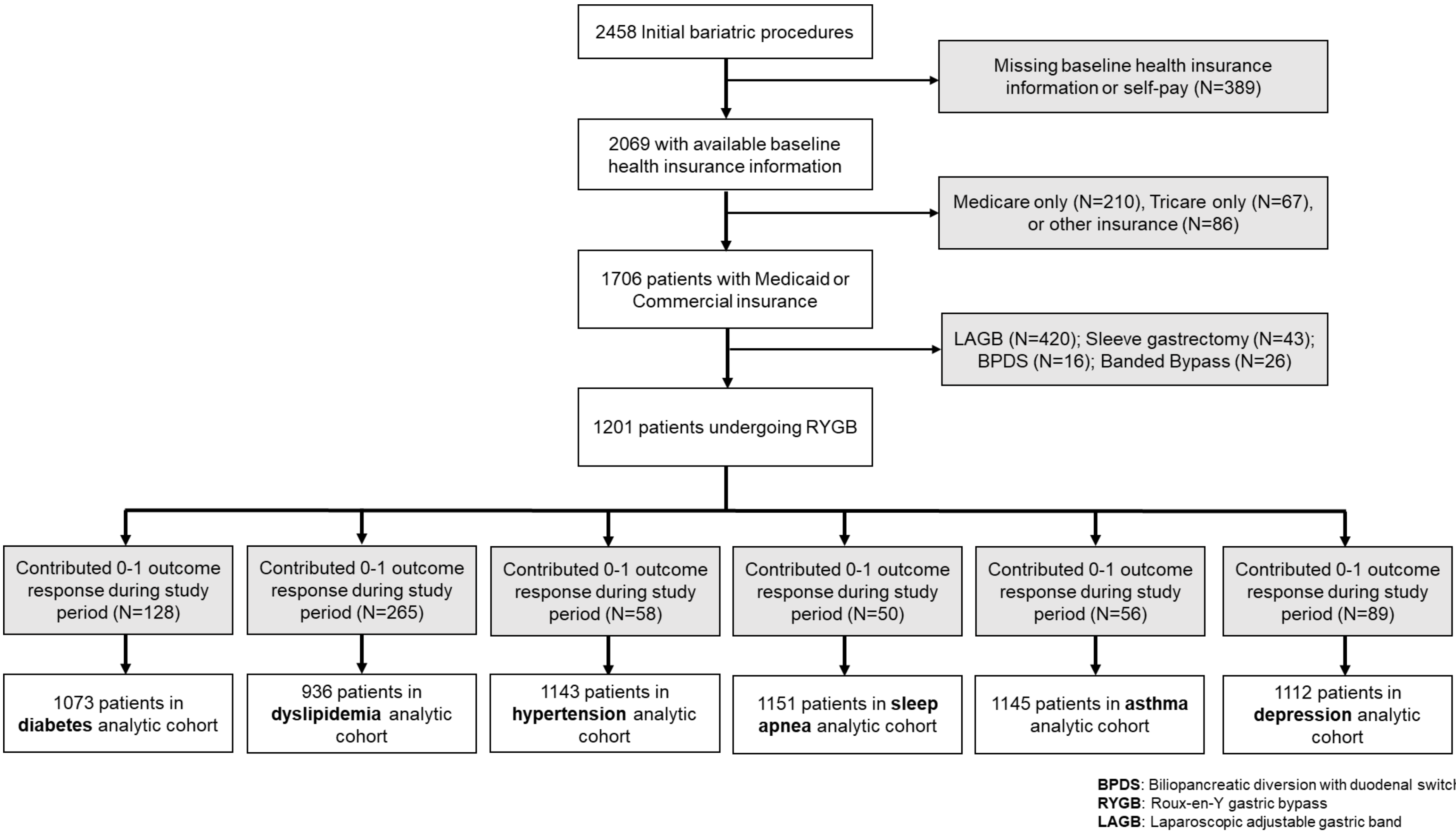


Figure 4.2 Propensity score range, before and after asymmetric trimming

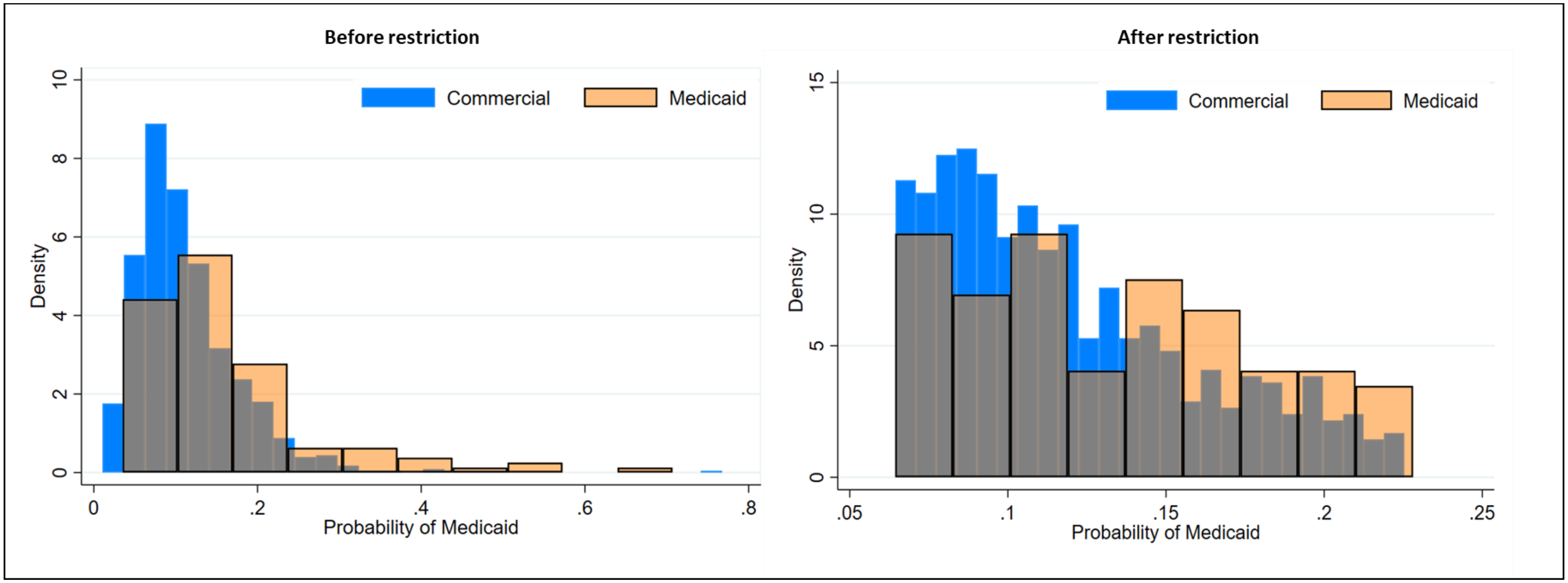
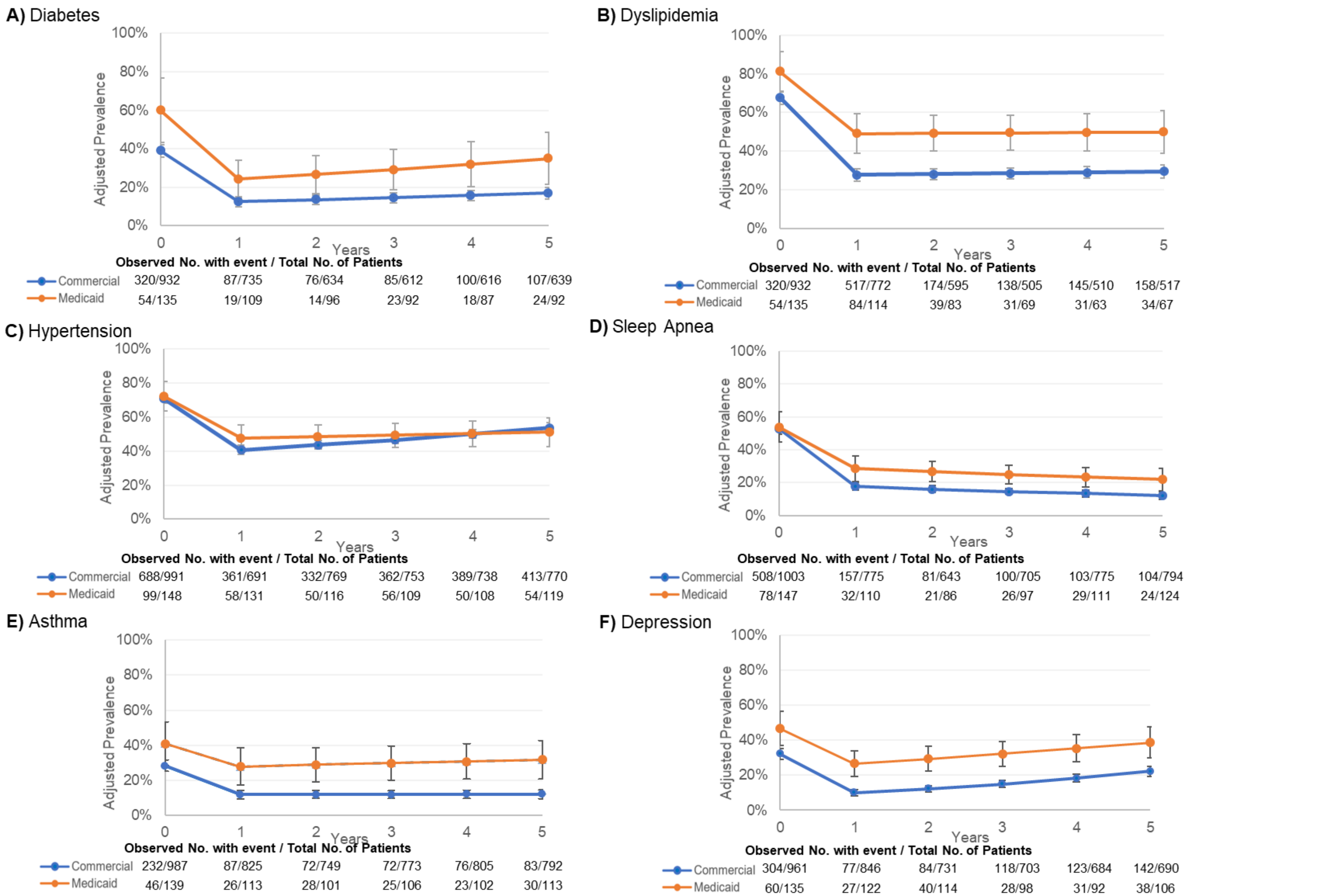


Figure 4.3 Observed and modeled (95% CI) prevalence of common comorbid diseases over time for Medicaid and Commercial patients



Chapter 5. Discussion

5.1 Summary

The current obesity epidemic poses an unprecedented challenge on public health programs, policy-makers, clinicians, and individuals. In 2015-2016, more than 72 million adults (39.8%) have obesity, including 5-10% with severe obesity (3-5). Moreover, obesity is a complex disease in which behavior is affected by numerous heterogeneous and interdependent individual-level and socioenvironmental factors (24). In addition to public health prevention interventions, effective treatment options are fundamental to curtailing the substantial health and financial impacts of obesity.

This study investigated the long-term effectiveness of bariatric surgery, the treatment widely accepted as the most effective for severe obesity, in an undertreated population. Our systematic review suggested outcomes related to healthcare utilization and mortality were potentially worse among Medicaid patients but weight loss, comorbidities, and complications were similar between the groups. However, this body of literature was limited by inadequate control for confounding, the lack of longitudinal and diverse data sources, and focusing on a limited number of outcomes, consequently leaving large gaps in the evidence base to be filled.

In filling these gaps, our analyses indicate that long-term weight loss following bariatric surgery among Medicaid beneficiaries was substantial and regain in the subsequent five years was minimal. Importantly, the higher baseline weight observed among Medicaid patients persisted in the post-operative period.

These findings were important in informing our comorbidity analyses, which illustrated the stark differences in the burden and complexity of baseline comorbid disease among Medicaid patients. Across most disease measures explored, Medicaid patients had a greater prevalence of disease, despite being on average a younger patient population. This increased burden of disease among Medicaid patients prior to surgical intervention contributed to a slightly diminished post-surgical improvement in the prevalence of comorbid disease. However, when comparing insurance groups with similar clinical profiles at baseline, short-term outcomes were more similar, suggesting levels of baseline disease are important in informing treatment effects. Overall, even among a patient population with a high burden of pre-operative disease, bariatric surgery continued to demonstrate excellent long-term effectiveness.

The new long-term evidence provided in this study confirms the effectiveness and long-term durability of bariatric surgery among Medicaid patients, despite presenting for surgery with a greater severity of obesity and more concomitant chronic conditions.

5.2 Future research needs

The current study leaves many questions unanswered. First, the use of sleeve gastrectomy is becoming more common and now the most widely used bariatric procedure, surpassing the Roux-en-Y Gastric Bypass. At the time of recruitment of the LABS cohort, the sleeve had only begun to gain popularity, which limited our sample size. The weight loss following sleeve gastrectomy was excellent among both insurer groups but the small sample size precluded our ability to examine changes in comorbidity prevalence over time. Additional studies should focus on long-term sleeve gastrectomy outcomes in patient sub-groups.

Second, the scope of this investigation was limited to clinical outcomes related to bariatric surgery. Social and behavioral (e.g., QOL, psychosocial health), and economic (e.g., return to work, levels of work impairment) post-operative outcomes remain understudied outcomes for future study. Additionally, it remains unknown if patients supported by Medicaid at baseline are able to transition off Medicaid support after undergoing bariatric surgery, a potentially critical but currently unexamined benefit of surgery.

Finally, an important area of future exploration are the post-operative mechanisms through which changes to disease occur and how these differ between groups. The goal of this study was to characterize the health trajectories over time and we did not explore specific post-operative mechanisms. Future studies should characterize the specific changes occurring in the post-operative period that drive the decreases in disease prevalence, especially for diseases in which the prevalence decreased over time at varying levels between the groups. For example, changes to eating and exercise habits, the use or availability of social support groups, on-going appointments with dieticians, and long-term contact with the surgical team. Identifying these kinds of actionable steps relies on additional studies designed to understand how the various post-operative clinical pathways contribute to long-term success and how these might differ in patient sub-groups.

5.3 Implications

This study contributes to a better understanding of the long-term effectiveness of bariatric surgery among Medicaid beneficiaries. One of the most consistent trends across all aims was the higher burden of disease among Medicaid patients at baseline, which persisted through post-operative periods despite good surgical response. Medicaid provides coverage for some of the poorest and sickest individuals in the U.S., thus the observed disparity in baseline disease is not surprising. However, these persistent post-operative disparities may be modifiable through improvements to clinical care and changes to healthcare policy.

Additionally, the hypothesis that limited access to bariatric surgery among Medicaid patients is grounded in poor surgical outcomes lacks justification from our study findings. Potential modifiable reasons for this observed disparity, where the patient populations with the highest burden of obesity and related diseases undergo surgery the least often, deserve further consideration and are explored in the following sections.

Clinical Care

There are several components to clinical care which may contribute to the observed disparities and the lack of utilization in this sub-group. First, despite its well-established effectiveness, bariatric surgery remains an underutilized treatment. This is not only driven by third party payers but also by negative views of surgery among both patients and providers (134). Some evidence suggests that primary care physicians are reluctant to refer their patients to bariatric surgeons (134-136); many patients are also reluctant to undergo surgery themselves and believe it is not an effective treatment (136, 137). Additionally, an accumulation of research has found that healthcare settings in general are a consistent source of weight stigma, findings which point to the potential for substandard healthcare experiences for individuals with obesity (138, 139). These sources of stigma may be further exacerbated among low-income patients, who already face stigma in healthcare settings due to their insurance status (140). Efforts to raise awareness of the effectiveness and safety of surgery, change the narrative that bariatric surgery is “the easy way out”, and reduce weight-related stigma in healthcare are all steps to ensure stigma-related barriers to surgery are not perpetuated among those patients most in need.

The second barrier with important implications to clinical care is related to the extensive clinical and administrative pathways to receiving authorization for bariatric surgery. Although the majority of these are required by insurance companies, there are simplifications of the process that can be implemented at the clinic level. The extensive nature of the required clinical milestones requires coordination with multiple subspecialists, often whom do not have availability on the same day or even in the same locations (141). Consequently, patients have multiple appointments on different days and locations with important effects on a patient’s time (141). While these barriers are difficult for most patients, they are likely more pronounced among Medicaid patients who may have greater transportation barriers, live further distances from care locations, and have less flexibility in work scheduling (142). Working to consolidate appointments, eliminate unnecessary tests, and providing electronically delivered services are all potential avenues for reducing time-related barriers in pursuing bariatric surgery.

Finally, two major changes to clinical care that will require greater discussion, research, and systems-level change are worth noting. First, there is recent discussion of revising the BMI cutoff of 35 kg/m^2 established in 1991, by offering surgical intervention to those with class I obesity (30-35kg/m^2). The discussion revolves around the potential for additional increases in long-term benefits by providing the intervention earlier in the clinical course of disease (133). Our findings also suggest that outcomes could be further optimized by earlier intervention. While additional evidence is needed, allowing surgery in early stage disease progression might therefore increase the potential benefits of bariatric surgery on long-term morbidity and mortality and reduce the persistent differences observed in this study.

Second, identifying effective obesity treatments and increasing access among those most in need is just one component necessary in the clinical effort to reduce the associated costs and health impacts of obesity among all patient populations. Efforts to better integrate all clinical domains—prevention, screening, and treatment—remain important avenues for improvement to clinical care.

Healthcare Policy

At the healthcare system level, there are many hypothesized factors that contribute to the persistent disease disparity and underutilization of surgery in Medicaid patients which are outlined here. Although recent expansions to Medicaid have demonstrated improvements in healthcare access and health outcomes, gaps in access to certain providers, particularly specialty providers like bariatric surgeons, are ongoing challenges (80, 122). One of the fundamental barriers to access is the shortage of specialty providers participating in Medicaid. Low rates of physician participation stem from low reimbursement rates, high administrative burdens, and the increased complexity in caring for Medicaid patients (80, 143, 144). Additionally, the general shortage of providers in low-income communities presents an ongoing challenge for state programs. While the community health center model has extended the reach of primary health care to these locations, there is no obvious or comparable mitigation strategy for access to specialty providers (122). Public hospitals play an important role in filling gaps in access to specialty care, but their numbers and geographic reach are limited (122). Furthermore, amongst those specialty clinics and providers who do participate in Medicaid, the number of appointments available for publicly funded patients are often restricted to a certain proportion of overall appointments. Because of such practices, the wait time for a publicly funded patient in California prior to receiving bariatric surgery was expected to exceed ten years (61). Policies that aim to increase the supply of specialty providers, increase reimbursement rates, and encourage physicians to provide care to underserved patients are needed to increase access to specialty providers among low-income patients. Additionally, explorations into non-traditional applications of care, like telehealth and specialized midlevel professionals, remain potential avenues for extending specialized care to harder to reach patients (122).

For patients able to successfully navigate the challenges of scheduling with a specialty provider, further barriers ensue. Insurers have systematically placed additional pre-operative qualification requirements, beyond the standard NIH requirements. Generally little or no clinical evidence base exists to support their use (145-147). For example, there is no evidence that insurance-mandated pre-operative weight loss requirements impact postoperative outcomes (145-147). These requirements function largely as hurdles in which to delay or potentially dissuade patients from further pursuing surgery. This is generally universal across all insurance programs including commercial programs, Medicare, and Medicaid. However, these hurdles result in a disproportionate negative impact on patients with lower SES who already face an increasingly high burden of disease, resulting in avoidable morbidity and additional long-term costs to the healthcare system.

Finally, state Medicaid programs are heterogeneous in the coverage of obesity treatments, levels at which consistently remain lower than commercial insurance programs. For example, in 2014, nearly half of the state programs had no coverage for obesity-related preventive care treatments, nutritional care treatments, or behavioral counseling; and well over half exclude all coverage for any pharmacotherapy treatments (148). All but three states cover bariatric surgery, 37 of which require criteria other than BMI alone to determine eligibility (148). Comprehensive coverage of bariatric surgery and related obesity treatments remains an opportunity for improvement at the state level.

5.4 Conclusions

In the U.S., patients whose lives are most affected by severe obesity receive the most effective treatment for severe obesity the least often (61). The evidence provided in this study confirms the effectiveness of surgery in this low income, ethnic/racially diverse population with a high burden of obesity. Patients with limited resources who rely on our safety net system deserve high-quality health care and access to the most effective treatments. Bariatric surgery has the potential to provide a pathway for those suffering with severe obesity to improve health, longevity, and quality of life, and should be available to individuals regardless of their sociodemographic profile.

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Appendices

Appendix A

OREGON HEALTH & SCIENCE UNIVERSITY

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

August 31, 2016

Dear Investigator:

On 8-31-2016, the IRB reviewed the following submission:

Title of Study:	Longitudinal Assessment of Bariatric Surgery: Medicaid outcomes
Investigator:	Erin Takemoto
IRB ID:	STUDY00016382
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office

PROTECTION OF HUMAN SUBJECTS

The proposed research will not involve any further contact with human subjects to collect data. We propose an analysis of existing data that will eventually be available to the public by request according to NIH policy.

Human Subjects Involvement and Characteristics

Proposed involvement of human subjects. The proposed research entails analysis of existing data held by an NIDDK-NIH funded national research consortium, LABS. This data is currently held by the DCC and will be stripped of any remaining identifiers (e.g., dates of service) and distributed to the six site principal investigators. Additionally, the dataset will eventually be managed by the NIH and publicly available by request. **No recruitment of subjects if proposed; the investigators will have no contact with study subjects.**

Characteristics of study population. LABS is an existing dataset from an observational cohort study of 2,458 adults who underwent first-time bariatric surgery procedures at one of 10 clinical centers. The purpose of this dataset is to understand the safety and effectiveness of bariatric surgery as a treatment for obesity. The proposed study will include 2,458 patients who underwent initial RYGB or LAGB surgery during the 2003-2015 study period.

Sources of materials. This study relies on secondary data analysis and entails no contact with study subjects. Identifiers are not accessible to the researchers on this project except through deductive disclosure.

Potential Risks. Study procedure is observational and involves no further contact with participants. Study procedures pose no more than minimal risk.

Adequacy of Protection Against Risks

Recruitment and Informed Consent. This study is a secondary data analysis, thus informed consent is not applicable.

Protection Against Risk. The primary risk to study patients relates to confidentiality through deductive disclosure. We will use existing, de-identified LABS data available from the DCC. LABS reduces risk of deductive disclosure by omitting patient identifiers, including the individual hospital site. We will further reduce this risk by reporting study findings only in aggregate form, and omitting cell counts smaller than 10. Also, in accordance with HIPPA regulations and our local IRB requirements, all appropriate compliance requirements for data transfer and use will be met. All reasonable measures will be taken to ensure the privacy and confidentiality of the participant’s data. Data will be stored on the OHSU encrypted network. Response to adverse effects to subjects is not applicable, as this is an observational study.

Potential Benefits of the Proposed Research to the Subjects and Others

There is minimal direct benefit to study participants. The proposed benefit of this study involves findings applicable to health policy, and potentially to clinic practice.

Importance of the Knowledge to be Gained

This study will provide an understanding of the effectiveness of bariatric surgery in subgroups of patients, specifically Medicaid beneficiaries. This information will provide critical guidance for policymakers and clinical practice. This knowledge is needed to appropriately allocate scarce healthcare resources.

INCLUSION OF WOMEN AND MINORITIES

This study requires no new subject ascertainment. The proposed study will include all women initially enrolled in the LABS study.

INCLUSION OF CHILDREN

Subjects less than 18 years of age were excluded by default, as they were not eligible for enrollment in LABS.

Appendix B

Search terms		
Concept	**Terms for PubMed**	**Terms for Scopus**
Bariatric Surgery	Search **("bariatric surgery" OR "obesity surgery" OR "weight loss surgery" OR "Bariatric Surgery"[Mesh] OR "Bariatrics"[Mesh])**	Search **("bariatric surgery" OR "weight loss surgery" OR "obesity surgery")**
Medicaid	Search **("Medicaid" OR "low income" OR "Medicaid"[Mesh] OR "Centers for Medicare and Medicaid Services (U.S.)"[Mesh] OR "Healthcare Disparities"[Mesh] OR "Poverty"[Mesh]) OR "Insurance, Health" [Mesh] OR "Insurance Coverage" [Mesh] OR "Socioeconomic Factors"[Mesh])**	Search (**"medicaid" OR "low income" OR "insurance")**
Outcomes	Search **("outcomes" OR "clinical outcomes" OR "social outcomes" OR "Treatment Outcome"[Mesh] OR "Treatment Failure" [Mesh] OR "Postoperative period"[Mesh] OR "Outcome Assessment(Health Care)"[Mesh] OR "Comorbidity"[Mesh] OR "Weight Loss"[Mesh] OR "Diabetes Mellitus, Type 2" [Mesh] OR "Hypertension" [Mesh] OR "Dyslipidemias" [Mesh] OR "Sleep apnea, obstructive"[Mesh] OR "Delivery of Health Care" [Mesh] OR "Health Care Costs" OR "Mortality"[Mesh] OR "Quality of Life"[Mesh] OR "Return to Work" [Mesh] OR "Presenteeism"[Mesh] OR "Absenteeism"[Mesh] OR "Substance related disorders"[Mesh])**	Search **("outcome*" OR "treatment outcome*" OR "social outcome*" OR "weight loss" OR "diabetes" OR "hypertension" OR "comorbidity" OR "dyslipidemia" OR "sleep apnea" OR "health care utilization" OR "mortality" OR "morbidity" OR "absenteeism" OR "presenteeism" OR "return to work" OR "substance abuse disorders")**
Population	Search **("adult" [Mesh] AND Obesity"[Mesh])**	Search **("adult" and "obesity")**
Restrictions	Filters: **Publication date from 2000/01/01** and **English** and **United States**	

Appendix C

Study characteristic eligibility criteria		
	Include	Exclude
Population	United States patients ages 18 and older with some classification of obesity (moderate, severe, morbid) with or without comorbidities.	Populations not eligible for bariatric surgery based on national criteria.
Interventions	Any bariatric procedure type including Roux-en-Y gastric bypass; adjustable gastric banding; vertical sleeve gastrectomy; biliopancreatic diversion (with or without duodenal switch); vertical banded gastroplasty; jejunoileal bypass. Both open and adjustable approaches.	All bariatric surgery types were included.
Comparator	Medicaid patients undergoing one of the procedure types above compared to commercial or privately insured patients undergoing the same procedure	No quantitative comparison between insurance groups; comparison between Medicaid and other insurance group (e.g., Medicare)
Outcomes	At least one clinical or social outcome related to surgical intervention: weight loss; remission or reduction of comorbidities; healthcare utilization (e.g., length of stay); mortality; quality of life; return to work; absenteeism; presenteeism; substance use disorders.	All outcomes were included.
Sources	Clinical trials; retrospective and prospective cohort studies; case control studies	Case series; case reports; letters; reviews

Appendix D. Study extraction and quality assessment tool

Reviewer	Click here to enter text.
First Author	Click here to enter text.
Year	Click here to enter text.
Journal	Click here to enter text.
Title	Click here to enter text.

Extraction Component	Details
Study characteristics	
Aim/objectives of study	Click here to enter text.
Setting/Data source (e.g. clinic, claims/billing data, single surgeon)	Click here to enter text.
Study Design (e.g., retrospective cohort, case-control)	Click here to enter text.
Study inclusion criteria (e.g. age)	Click here to enter text.
Total length of follow-up	Click here to enter text.
Bariatric procedure type(s)	Click here to enter text.
Participant characteristics	
Overall Baseline Size (N=?)	Click here to enter text.
Baseline N by Insurance group (e.g. N or % Medicaid, % private)	Click here to enter text.
Overall Analytic Size (N=?)	Click here to enter text.
Analytic sample by insurance group (e.g. N or % Medicaid, % private)	Click here to enter text.
Exposure and covariates	
Exposure defined (e.g., insurance type, surgery type)	Click here to enter text.
Exposure ascertainment (e.g. self-report, billing)	Click here to enter text.
Outcome(s)	

Baseline measure of outcome (e.g., mean BMI at baseline, percent weight loss at follow-up)	Click here to enter text.
Defined (e.g. remission of diabetes, percent weight loss, return to work)	Click here to enter text.
Time(s) at outcome (e.g., in-hospital, 90-days, 24-months)	Click here to enter text.
Analytic method	Click here to enter text.
Missing Data (E.g. how did they deal with missing data, what proportion missing, etc.)	Click here to enter text.
Results- Medicaid vs. Commercial (e.g. ORs, RRs, beta coefficients) If available, include baseline levels of outcomes. If available, present crude and adjusted.	Click here to enter text.
Control of Confounding (if applicable to method, variables controlled for)	Click here to enter text.
Notes	Click here to enter text.

Criteria	Yes	No	Other*	Notes
1. Research question or objective clearly stated	☐	☐	Choose an item.	Click here to enter text.
2. Study Population clearly defined	☐	☐	Choose an item.	Click here to enter text.
3. Participation rate of eligible persons at least 50%	☐	☐	Choose an item.	Click here to enter text.
4. All subjects selected from the same or similar populations (including the same time period)	☐	☐	Choose an item.	Click here to enter text.
5. Inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants	☐	☐	Choose an item.	Click here to enter text.

6. Exposures of interest were measured prior to the outcome being measured	☐	☐	Choose an item.	Click here to enter text.
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	☐	☐	Choose an item.	Click here to enter text.
8. Exposure measures (independent variables) were clearly defined, valid, reliable, and implemented consistently across all study participants	☐	☐	Choose an item.	Click here to enter text.
9. Outcome measures (dependent variables) were clearly defined, valid, reliable, and implemented consistently across all study participants	☐	☐	Choose an item.	Click here to enter text.
10. Loss to follow-up after baseline was 20% or less	☐	☐	Choose an item.	Click here to enter text.
11. Key potential confounding variables were measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)	☐	☐	Choose an item.	Click here to enter text.
***CD, cannot determine; NA, not applicable; NR, not reported**				

Overall Quality Rating	**Notes**
Choose an item.	Click here to enter text.