BARIATRIC SURGERY, A COST-SAVING TREATMENT FOR OBESITY—RESULTS FROM A STUDY ON MEDICATION UTILIZATION AND EXPENDITURE AFTER BARIATRIC SURGERY AND EFFECTIVENESS OF ERAS PROGRAM IMPLEMENTATION AT A HOSPITAL CENTER

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ABSTRACT

I. Background

The bariatric surgery utilization rates have barely budged despite a rise in severe obesity and an avalanche of data demonstrating it to be the most effective treatment with very low complication rates.[2] Bariatric surgery performed in more than 135,000 patients was found to affect type 2 diabetes in nearly 90% of patients by lowering blood sugar, reducing the dosage and type of medication required and improving diabetes-related health problems.[1]

Per the American Society for Bariatric Surgery, untreated obesity costs the nation $1.72 trillion (9.3 % of GDP) in health care expenses alone. The thesis attempts to add to existing literature on effectiveness of bariatric surgery to influence patients and primary care physicians to advocate for this treatment and help decelerate the obesity epidemic. Additionally, the study on effectiveness of Enhanced Recovery after surgery (ERAS) protocol is important for this particular population to handle growing volume of potential surgical candidates.[3]

II. Methods

Published literature on ERAS implementation compared with traditional perioperative care in patients undergoing bariatric surgery was reviewed to synthesize findings and report on the results. The second manuscript is a retrospective study on the association between implementation of ERAS program in bariatric surgery and specific outcomes at a large academic medical center. Lastly, aim of the third manuscript is to evaluate the efficacy of bariatric surgery in reducing Type 2 Diabetes Mellitus medication use and costs at different time points.

III. Results

Our findings reinforce existing literature on impact of bariatric surgery on major comorbidities. The observed decrease in pharmacy claims associated with Type 2 diabetes suggests that the presurgery condition resulted from patients' excess weight is alleviated by bariatric surgery for at least 3 years. After controlling for other factors, implementation of ERAS protocol was associated with decreased cost, length of stay (LOS) and 30-day readmissions.

IV. Conclusion

We conclude that bariatric surgery is effective for decreasing use of medications for obesity-related diabetes. The implementation of standardized enhanced recovery program resulted in improved LOS, cost and 30 day readmissions.

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CHAPTER 1: INTRODUCTION

I. Background

For the first time since the Great Depression, crippling financial losses threaten the viability of substantial numbers of hospitals and office practices, especially those that were already financially vulnerable. It has been over two years since the start of the pandemic whereby hospitals have endured historic financial challenges due to revenue losses from forced shutdowns and a slow resurgence of non-emergent care as well as increased costs associated with the pandemic and treating COVID-19 patients.[19] In 2020, hospitals lost an estimated $323 billion in revenue, leaving nearly half of America's hospitals and health systems with negative operating margins by the end of 2020.[19] The American Hospital Association projects that hospitals and health systems could lose an additional $53 to $122 billion in revenue in 2021.[19] Hospitals had an extremely difficult month under the apex of Omicron and saw more severe patients requiring longer hospital stays.[20] Nationwide labor shortages continue to drive up labor expenses while supply chain challenges are contributing to inflation of non-labor costs, exacerbating hospital operating pressures amid unstable pandemic volumes and revenues.

The financial pressures faced by our nation's hospitals and health systems has only accelerated the transition to value-based care as employers and consumers look for ways to manage spending, driving the demand for value. Federal health officials have not kept secret their desire to link healthcare payments to value-based care, with the Centers of Medicare & Medicaid Services (CMS) saying that they want to have 100 percent of providers taking on some downside

financial risk by 2025. Currently, however, less than 20 percent of Medicare spending is value-based, meaning $1 trillion of healthcare risk will be shifting from the government to hospitals, health systems, and physician practices across the U.S., should CMS' benchmarks be met, according to a new report released by Coverys, a Boston-based provider of medical professional liability insurance. The pandemic has painfully exposed the vulnerability and unsustainability of fee-for-service, creating the potential for more widespread adoption of value-based care by providers, insurers and government agencies. It has been a powerful engine of transformation that has accelerated the trend to adopt remote technology and move care out of big acute-care complexes to ambulatory settings closer to patients.[31]

Value based care and reimbursement structures provide incentives for healthcare providers to offer the best care at the lowest cost. Organizations can create a high-value stack of analytics, with meaningful high-touch consumer experience and end-to-end technology experience that drives great outcomes at a reasonable cost. Many hospitals are responding to these changes by exploring initiatives that can achieve what Don Berwick, MD coined in 2008 as the "Triple Aim". Goal is improving the experience of care, health, and reducing the per capita cost of care.[12]

Because of these pressures, hospitals and physicians have been working to identify services and evidence based guidelines that have potential for cost related efficiencies. One such service is Bariatric Surgery, which has shown to provide long term weight loss, however, it is highly underutilized. Several barriers to bariatric surgery have been identified including limited patient and referring physician knowledge as well attitudes regarding the effectiveness and safety of

bariatric surgery.[21] Lack of knowledge about insurance coverage for bariatric surgery, coupled with out-of-pocket costs have posed limitations to referrals and the treatment. In a national survey of primary care providers, 53% believed that most of their patients could not afford the surgery.[25] Patient cost sharing has been identified as one of the barriers to utilization of bariatric surgery.[26] However, the role of insurance coverage and benefit design as a barrier to access to care has received less attention to date.[21] Per the experts at the University of Michigan, the underuse of weight-loss surgery has been largely attributed to "the reluctance of the medical community and patients to accept surgery as a safe, effective and durable treatment of obesity.[16] Per a 2018 study by Eric Maria in the Journal Surgery for Obesity and related diseases, most bariatric surgeries are performed in the northeast, and fewest in the south where obesity rates are highest, and economies are weakest[15]. The economic status and insurance coverage play a greater role in determining utilization of bariatric surgery than the prevalence of obesity.[15] Some states cover weight-loss surgery as an essential health benefit (EHB) under the Affordable Care Act of 2010 (ACA). None of the states with the five highest obesity rates crack the top 20 in terms of bariatric surgery, and all but one are in the bottom 10 in terms of its economic rank.[15] See Table 1 below. This suggests that those with the greatest need for bariatric surgery, the standard of care for severe obesity, may have the least access and opportunity to receive treatment.[15]

Table 1: Top 5 states for Obesity

	ObesityRank	SurgeryRank	EconomicRank	EHB
West Virginia	1	25	49	Yes
Mississippi	2	45	48	No
Alabama	3	22	38	No
Arkansas	4	35	40	No
Louisiana	5	36	44	No

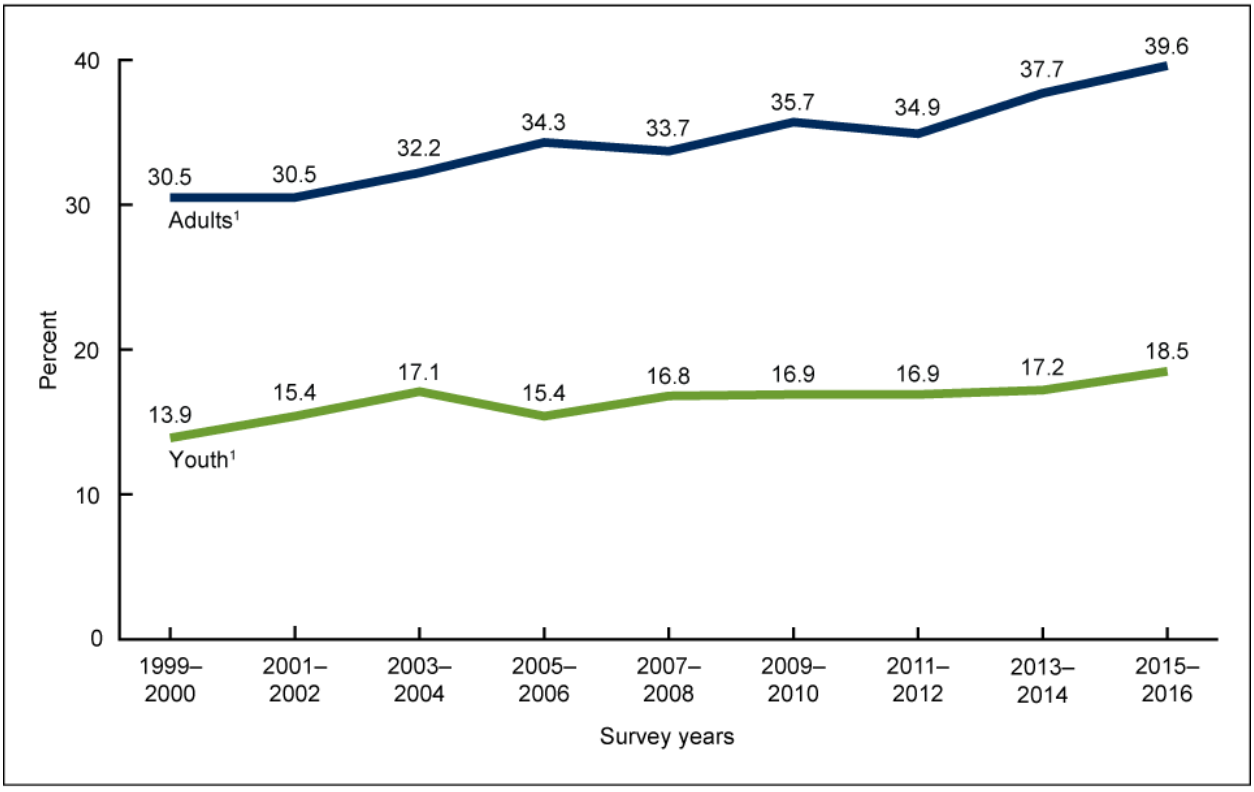
Note: "Articles: New Releases." American Society for Metabolic and Bariatric Surgery, Last accessed February 22, 2022

While variety of socioeconomic factors may contribute to disparities in receipt of bariatric surgery[22], lack of health insurance is likely a reason for blacks undergoing bariatric surgery at lower levels than whites[23]. Additionally, a study on bariatric surgery among eligible black and white mean and women in USA, shows another potential explanation for this health-care disparity may be lack of trust by blacks of physicians and that being obese is more culturally accepted in the African-American population.[31] Approximately 60–65 % of bariatric surgery patients in 2009–2012 were white; the majority of patients were mid-aged (median age 44 to 45 years) women who typically suffer from one or more obesity-related comorbidities.[24] In contrast, among those eligible for surgery in 2005–2006, the majority were non-white, with significantly lower family incomes and education levels, as well as less access to healthcare, compared to the adult non-eligible population.[22]

As we know, obesity is a growing epidemic in the United States – and has been for decades. CDC estimates 42.4% of U.S. adults had obesity and 9.2% had severe obesity in 2017, the highest incidence ever recorded in America (latest report). Currently, about one in three Americans of all

ages – or more than 100 million people – have obesity with a significantly increasing linear trend from 1999 to 2016 in adults and youths.[30] See Figure 1 below.[30] Obesity is a risk factor with serious health consequences including increased risk for type 2 diabetes, high blood pressure, stroke and many types of cancers.[5] Obesity is estimated to increase national healthcare spending by $149 billion annually (about half of which is paid for by Medicare and Medicaid).[5] Growing rates of obesity among Americans are clear evidence that even the best intentions and strongest motivations are often not enough to help seriously overweight people lose a significant amount of weight and, more important, keep it off.

Figure 1: Obesity trends among adults and youths



[1]Significant increasing linear trend from 1999–2000 through 2015–2016.
NOTES: All estimates for adults are age adjusted by the direct method to the 2000 U.S. census population using the age groups 20–39, 40–59, and 60 and over.
Access data table for Figure 5 at: https://www.cdc.gov/nchs/data/databriefs/db288_table.pdf#5.
SOURCE: NCHS, National Health and Nutrition Examination Survey, 1999–2016.

Some are reluctant to pursue surgical treatment because they may be judged by others for taking the easy way out and not having the willpower to diet and exercise. Yet this stigma, real or imagined, may be keeping many people from a treatment that not only can result in long-term weight loss but can also significantly improve physical and emotional health and even longevity. Bariatric surgery is now simpler, safer and more effective than in its early days in the 1990s.The number of bariatric procedures performed per year has been increasing worldwide. Increased practice, improved surgeon expertise, standardized preoperative care, and meticulous selection of surgical candidates, has improved bariatric surgery outcomes. With the introduction of minimally invasive techniques, bariatric surgery has undergone a major overhaul.

II. Significance

Bariatric surgery results in significant weight loss and helps prevent, improve or resolve more than 40 obesity-related diseases or conditions including type 2 diabetes, heart disease, obstructive sleep apnea and certain cancers.[4] Studies have shown that weight loss obtained after bariatric surgery is associated with a highly significant reduction in cardiovascular risk factors.[6] In most patients, this results in a reduction or discontinuation of corresponding prescription medications. Bariatric surgery offers great potential to improve the value of care for obese patients.

Medical management of obesity has proven disappointing on both the amount of weight loss and its maintenance over time for patients. Therefore, the number of patients undergoing bariatric surgery indicated for the most severe form of obesity (BMI >40), has increased dramatically. Most importantly, it is currently the only efficient mean to achieve major and sustainable weight

reduction.[7] Despite many efforts to improve the control of glucose levels in medical management of diabetes, including clinical guidelines and patient and provider education, less than half of all patients with type 2 diabetes mellitus achieve the American Diabetes Association recommendation of a hemoglobin A1c level of less than 7%.[11]

A recent meta-analysis found that the percentage of excess weight loss was 61.6–70.1 percent with gastric bypass, the most common bariatric surgery. As a result, diabetes was completely resolved in 76.8 percent of patients.[8] Another recent study found that gastric bypass patients had an 89 percent reduced relative risk of death.[9] Meta-analysis of 796 participants in 11 studies comparing metabolic and bariatric surgery to nonsurgical treatment for obesity found surgery results in greater weight loss and higher type 2 diabetes remission rates.[10]

In 2021, per the American Society for Metabolic and Bariatric Surgery (ASMBS), nearly all individuals who have bariatric surgery show improvement in their diabetic state. Bariatric surgeries performed in more than 135,000 patients were found to affect type 2 diabetes in nearly 90% of patients by lowering blood sugar, reducing the dosage and type of medication required and improving diabetes-related health problems. From literature review, we know the efficacy of bariatric surgery for weight reduction is well established. [13, 14]

Additionally, designing optimal insurance coverage is important to incentivize the use of bariatric surgery among patient subgroups that are likely to benefit the most. The results from a recent study that evaluated the potential impact of selectively lowering patient cost-sharing for bariatric procedures showed that payers (both private payers and government payers) would reap a higher return on investment if they provide full coverage (i.e., 0% patient cost-sharing) for bariatric procedures among patients with BMI≥40 and Type 2 Diabetes Mellitus.[27] Providing full

coverage could incentivize its utilization among these patient subgroups for whom the anticipated benefits and value proposition of bariatric procedures are much higher.[27]

The number of procedures performed in the USA increased from 158,000 to 256,000 between 2011 and 2019, with Roux-en-Y gastric bypass and sleeve gastrectomy accounting for more than 75 % of all procedures per the American Society of Metabolic and Bariatric Surgery, as reflected in Table 2 below.[5] The next logical step as patient and referring physician's awareness is enhanced and optimal insurance coverage is designed, is to seek strategies to optimize bariatric perioperative care to handle the growing volume of potential surgical candidates.

Table 2: Estimate of bariatric surgery numbers 2011-2019

Published March 2021

	2011	2012	2013	2014	2015	2016	2017	2018	2019*
Total	**158,000**	**173,000**	**179,000**	**193,000**	**196,000**	**216,000**	**228,000**	**252,000**	**256,000**
Sleeve	17.8%	33.0%	42.1%	51.7%	53.6%	58.1%	59.4%	61.4%	59.4%
RYGB	36.7%	37.5%	34.2%	26.8%	23.0%	18.7%	17.8%	17.0%	17.8%
Band	35.4%	20.2%	14.0%	9.5%	5.7%	3.4%	2.7%	1.1%	0.9%
BPD-DS	0.9%	1.0%	1.0%	0.4%	0.6%	0.6%	0.7%	0.8%	0.9%
Revision	6.0%	6.0%	6.0%	11.5%	13.6%	14.0%	14.1%	15.4%	16.7%
Other	3.2%	2.3%	2.7%	0.1%	3.2%	2.6%	2.5%	2.3%	2.4%
Balloons	—	—	—	—	0.3%	2.6%	2.8%	2.0%	1.8%

The ASMBS total bariatric procedure numbers are based on the best estimation from available data (BOLD,ACS/MBSAQIP, National Inpatient Sample Data and outpatient estimations).

**New methodology for estimating outpatient procedures done at non-accredited centers.*

Note: Reprinted from "Archives: Resources." *American Society for Metabolic and Bariatric Surgery*, Last accessed February 15, 2022

Since introduction of ERAS, successful implementation of protocols have been seen in various surgical subspecialties, including colorectal, urology, and thoracic surgery. However, the uptake of ERAS protocols for bariatric surgery has been slow. This is undoubtedly due in part due to the fact that bariatric patients represent a complex and high-risk cohort, but also due to the lack of robust evidence supporting a change in practice. Much of the evidence for ERAS has been derived from patients undergoing lower gastrointestinal surgery. The only published study from the United Kingdom was an observational case series of 406 laparoscopic Roux en-Y gastric bypass (LRYGB) patients that described a 'fast-track' anesthetic pathway.[1] However, the latter investigators did not utilize traditionally described ERAS interventions.[2] A recently reported randomized clinical trial examined an enhanced recovery pathway versus standard care following 78 patients undergoing laparoscopic sleeve gastrectomy.[3]

In the latter study, patients in the ERAS group demonstrated significantly shorter LOS and reduced hospital costs with no increase in occurrence of complications, although there was a 20 % re-admission rate in both ERAS and control groups.[3]

More research is needed at facility and specialty level to support and predict the success of ERAS implementation at a site and to detail strategies for successful implementation allowing scalability, and sustainability of Enhanced Recovery strategies across organizations. Although guidelines for ERAS related to colorectal surgery exist, variation in the number and definition of protocol components contributes to difficulties in determining effectiveness. There is increasing focus on procedure-specific specialty items as an attempt to improve outcomes.

The combination of the increasing demand of bariatric procedures worldwide and the specific perioperative difficulties and risks for this particular population makes this type of surgery highly eligible for ERAS protocols.[17] Implementation of evidenced-based interventions and standardization of bariatric care can increase efficiency and cost-effectiveness in these procedures, without the loss of safety.[18] A practical limitation to providing bariatric surgery to those who would benefit is the imbalance between workforce supply, health system capacity and patient demand. The problem of demand far outstripping supply and constrained capacity and budgets is reflected internationally.[28] A meta-analysis in 2019 by Qing Xia and his colleagues found that delayed provision of bariatric surgery could lead to reduced health outcomes, e.g., life years and/or quality-adjusted life years (QALYs).[28] Qing Xia and his colleagues have shown that bariatric surgery is largely cost saving, yet the climate of excess demand bariatric surgery remains a substantial problem for health care payer decision makers.[28]

In a 2021 cost utility analysis by Lester and colleagues from Canada demonstrated that from the societal perspective, surgery becomes the lowest cost option over time, dominating medical therapy and standard care.[29] Surgery also exhibits the highest level of utility gains, and therefore increases quality of life more than medical or standard therapy.[29]

Findings from this dissertation will have both policy and practical implications. The research will help influence policy makers to consider covering bariatric surgery as an essential health benefit with minimal out of pocket costs and preoperative requirements in an effort to reverse the obesity epidemic. In terms of practical implications, the research will add to the existing literature on ERAS. The cost of bariatric surgery in institutions that have implemented ERAS is substantially

lower than organizations that have not. The goal is to improve value of care for obese patients, and reduce the costs of providing care. The policy implications have potential to expand coverage and optimize perioperative care strategies to handle growing volume of potential surgical candidates.

Simplified pathways, better outcomes and shorter hospital stays have significantly lowered the overall cost of surgery and that is not counting all the health care cost savings that come with eliminating obesity.

III. Research Aims

My dissertation follows the three manuscript-oriented format with three research aims.

Research Aim #1:

The first aim is to conduct a literature review on ERAS in obesity surgery and report on the results. Despite several studies documenting the feasibility of ERAS generally in surgery and specifically in bariatric surgery, there is minimal evidence with empirical analysis thus far due to limited related analysis. Therefore, the study aims to systematically evaluate and summarize available evidence on ERAS pathway in bariatric surgery.

Research Aim #2

The second aim is to study the effectiveness of implementation of ERAS in bariatric surgery using evidence-based measures.

Sub aim #1: study association between ERAS and Length of stay (LOS) and median cost of patient stay

Sub aim #2: study the association between ERAS and 30 day unplanned readmissions

Research Aim #3

The third aim of this proposal is to measure the use and associated cost of diabetes medications at specified time intervals before and after bariatric surgery. The hypothesis is that the use of diabetes medication would decrease after surgery.

The study goal is to measure the short- and long-term impact of bariatric surgery on the use of diabetes medication among obese patients. The use of diabetes medication will be measured at 3 and 6 months before surgery, at the time of surgery, and at 3, 6, 9, and 12 months after surgery. Results will be stratified by type of bariatric procedure.

IV. **Organization of Dissertation**

This dissertation is composed of three manuscripts, each of which addresses one study aim and is intended for individual submission to a peer-reviewed journal for publication. Each manuscript has been written to stand alone. Thus, background material may be repetitive throughout the dissertation.

Chapter 1 of this dissertation introduces data concerning the obesity epidemic, underutilization of bariatric surgery and its associated stigma, effectiveness of the procedure in managing comorbidities and perioperative solutions to improve health system capacity to handle growing

demand for bariatric surgery. The first manuscript (Chapter 2) is a literature review that aims to systematically evaluate and summarize available evidence on ERAS pathway in bariatric surgery.

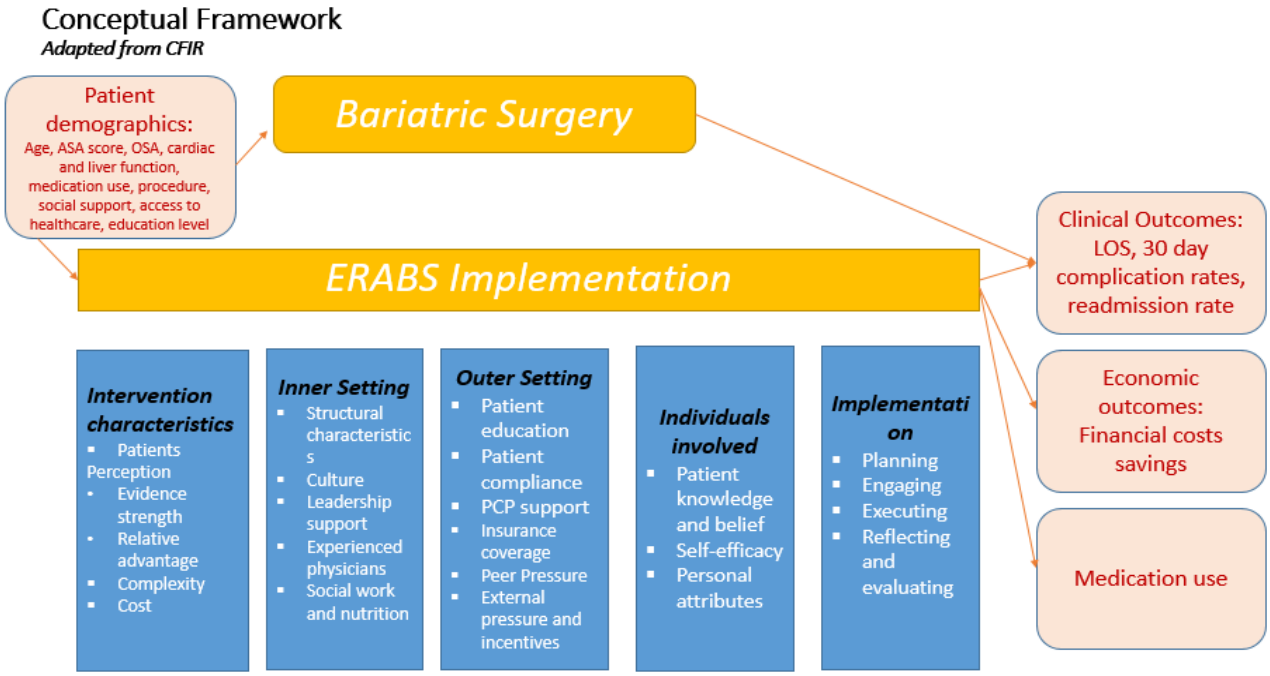
The second manuscript (Chapter 3) studies the effectiveness of implementation of ERAS in bariatric surgery using evidence-based measures. The third manuscript (Chapter 4) measures the use and cost of diabetes medications at specified time intervals before and after bariatric surgery.

Chapter 5 summarizes the findings and discusses the strengths and limitations of the complete study. In addition, this chapter presents implications for policy formulation and recommendations for future research.

Conceptual Framework

The Consolidated Framework for Implementation Research (CFIR) was used to explore the topic and develop a list of questions, considering each CFIR domain and respective (sub-) constructs that was thought to be necessary and helpful for the assessment of ERAS in bariatric surgery, could reveal influential factors during the course of the study and, finally, be used to evaluate the implementation of the process itself and systematically assess potential barriers and facilitators in preparation for implementing of the program. The CFIR includes five major domains (intervention characteristics, outer setting, inner setting, characteristics of individuals and process) with underlying constructs and sub-constructs that can potentially influence efforts to change the practice. The framework also helps consider characteristics important to medication utilization before and after bariatric surgery.

Figure 2: Conceptual Framework



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CHAPTER 2: THE ENHANCED RECOVERY AFTER SURGERY PROGRAM FOR BARIATRIC SURGERY: A LITERATURE REVIEW

I. Abstract

Objective: The aim of this study was to conduct a review of current literature on Enhanced Recovery after Surgery (ERAS) in obesity surgery compared with traditional perioperative care patients undergoing bariatric surgery and report on the results. The study systematically evaluated and synthesized the findings.

Design: The study was a systematic literature review and analysis.

Methods: Articles published between 2000 and 2020 were searched electronically to identify studies reporting ERAS in bariatric surgery. Specifically, searched for evidence-based guidelines for ERAS in bariatric surgery and outcomes after implementation. Data on study design, size, patient demographics, operative details, clinical outcomes, and follow-up were extracted, analyzed, and synthesized.

Main outcome measures: Evidence of the effectiveness of ERAS in bariatric surgery compared with traditional perioperative care.

Results: 16 studies were selected that met the inclusion criteria. All of them showed significant improvement in length of stay and operative time. There were three[2,11,16] studies measuring median cost of patient stay and all of them showed significant improvement in hospital median cost. Few studies showed improvement in 30-day complications and readmissions.

Conclusions: Implementation of ERAS protocols is superior to traditional perioperative care in terms of operative time, LOS, cost and in some instances intraoperative medication use without

any significant increase in overall complications or readmissions. Our study showed no significant improvement in readmissions or complications after ERAS implementation. ERAS protocols appear safe and effective for use in bariatric surgery and are associated with improved perioperative outcomes without any compromise in patient's long-term safety.

II. Background

Change is the new normal for the global health care sector. As providers, payers, governments, and other stakeholders strive to deliver effective, efficient, and equitable care, they do so in an ecosystem that is undergoing a dramatic and fundamental shift in business, clinical, and operating models. This shift is being fueled by aging and growing populations; the proliferation of chronic diseases; heightened focus on care quality and value; evolving financial and quality regulations; informed and empowered consumers; and innovative treatments and technologies — some of which are leading to rising costs and an increase in spending levels for care provision, infrastructure improvements, and technology innovations. Healthcare in general and perhaps surgery in particular, is facing major challenges as it relates to staffing shortages, site of service shifts, value based care and price transparency. The population in many countries worldwide is growing older, there is a demand for increasingly better care and many developments in surgical technology are costly and may not show immediate benefits.[1]

Obesity is a worldwide issue and its prevalence is growing every year. Bariatric surgery as a method of treatment has become an established and renowned therapy for the management of patients with morbid obesity. The expanding popularity of surgical therapy for morbid obesity has led to an increase in the awareness of the peculiar challenges that bariatric patients pose to

both anesthesiologists and surgeons.[4] Although bariatric surgery was introduced in the late 1950s, the use of minimally invasive surgery had the most significant impact on improving outcomes.

Enhanced recovery after surgery (ERAS) protocol is well established in many surgical disciplines and leads to a decrease in the length of hospital stay and morbidity. Although multimodal protocols have been introduced to bariatric surgery, there is still a paucity of ERAS data originating from patients undergoing bariatric and metabolic surgery.[2] Delayed adoption of ERAS pathways within bariatric centers could be due to lack of robust evidence within this group of patients and concerns regarding the presence of complex high-risk medical co-morbidities that require specialist perioperative care.

The inertia is probably generated from the thinking that obese patients are not medically healthy as compared to those presenting for other surgeries. This casts a doubt regarding safety of the efforts to expedite the throughput time by utilizing principles of ERAS in bariatric surgery cases. On the other hand, the question that whether ERAS can even improve the perioperative care in bariatric surgery needs to be addressed through a detailed review of the available literature. Therefore, the study aims to systematically review and summarize available evidence on ERAS pathway in bariatric surgery.

ERAS, in contrast to fast tracking, utilizes evidence-based protocols that need to be initiated well in advance in the preoperative phase. Classically, ERAS in preoperative phase includes patient and family counseling, metabolic preparation (motivated weight loss regimens especially in bariatric patients), and enrollment into the pre-habilitation programs which help guide patients

toward better functional postoperative recovery. Immediate preoperative phase in ERAS focuses on short fasting periods, encouraging the use of carbohydrate-rich infusions and avoiding sedation, etc.[3] The spectrum of ERAS appropriately covers intraoperative phase to favor minimally invasive procedures, avoiding use of drains, catheters, and initiating thromboprophylaxis during surgery. On the other hand, fast tracking focuses primarily on the postoperative recovery phase, more so in near isolation. Our analysis focuses on the newer concept of ERAS in perioperative period rather than the conventional fast-tracking protocol. The aim of this study is to include studies that made evidence-based alterations in all three phases, i.e., preoperative, intraoperative, and postoperative^ for defining ERAS protocols during bariatric surgery.[3]

The aim of this study was to conduct a review of current literature on ERAS in obesity surgery compared with traditional perioperative care patients undergoing bariatric surgery and report on the results. The study systematically reviewed and summarized available evidence on ERAS pathway in bariatric surgery.

III. Methods

Literature search was conducted to identify studies reporting ERAS in bariatric surgery. Specifically, studies were searched for evidence-based guidelines for ERAS in bariatric surgery and outcomes after implementation- LOS, complications, readmissions, and costs. Abstract and manuscript reviews were completed to identify, grade, and categorize relevant studies.

Steps:

a) PubMed, Google Scholar and the Cochrane library were searched, covering period from January 2000 to June 2020 with language restricted to English. A narrative review was conducted using search terms which included 'bariatric surgery', 'weight loss surgery', 'gastric bypass', 'ERAS', 'sleeve gastrectomy', 'sleeve resection', 'gastric bypass', 'enhanced recovery', 'enhanced recovery after surgery', 'fast-track surgery', 'perioperative care', 'postoperative care', 'intraoperative care' and 'preoperative care' multimodal perioperative^ and perioperative protocol^, using the Boolean operators AND^ and OR. Reference lists of relevant publications were assessed for additional references. Furthermore, bibliographies from other systematic reviews or meta-analyses on the subject were searched.

b) A paper was included when the study concerned adult patients who underwent bariatric surgery, the study described an enhanced recovery program or fast track program with at least four different perioperative elements according to the guidelines by Thorell et al.[13] Or if the study reported at least the LOS and the overall complication rate. The papers included had to be either a randomized controlled trial (RCT) or a comparative study with a control group. All criteria mentioned above were required to enroll a study for further evaluation. The exclusion criteria were: the study described a single intervention in perioperative care, the study was a review, guidelines, or single group or the study was not in English or not on human subjects.

c) Articles were selected for review by reading titles and abstracts and full texts.

The following scheme was used to select and reject articles for literature review- accept if study is relevant to study question, has relevant population and sample size and relevant interventions, discusses outcome of interest, published within determined date range, published in English and published in required format. This scheme was used to go through each and every article retrieved initially on the basis of reading their titles and abstracts. Usually only one clause is good enough to reject a study and note that the study got rejected on that criterion, and the first clause that rejects the study is noted down as the main cause.

d) The following information was abstracted from these articles:
    - Name of first author and year article was published
    - The population on whom the study was conducted
    - Type of study (RCT, observational)
    - ERAS protocol elements included in study
    - Intervention used (Sleeve gastrectomy, bypass)
    - Comparison group
    - Outcome and how was it measured
    - Number of individuals in intervention and control arm
    - Measurement of relevant outcomes-number of patients, mean and standard deviation

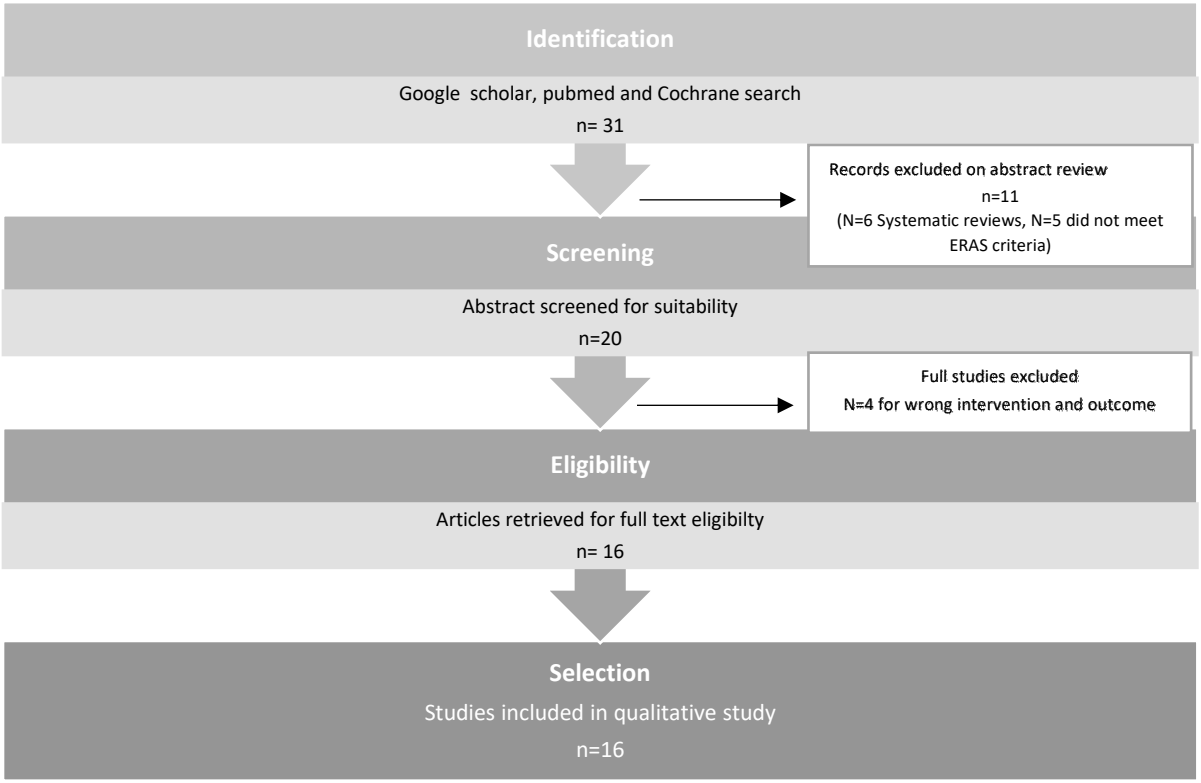
e) The information was systematically summarized and evaluated for commonalities, difference, and nuances. We reported on the outcome measures -length of hospital stay, overall morbidity, readmission, and cost.

IV. Results

Study Selection

Initial searches using search terms described above produced thirty one records. Eleven records were excluded on abstract review as they failed to meet the eligibility criteria. Twenty studies were reviewed for full text eligibility, of which four were excluded for wrong intervention and outcomes. Finally, sixteen records were included in the literature review. Figure 1 below summarizes literature search and study selection.

Figure 1: Literature search and study selection strategy



Study Characteristics

Of the studies selected for literature review, one was a randomized controlled trial, 13 were retrospective studies and 2 were prospective studies. Majority of the studies reported on consecutive patients with historical control and prospective ERAS group.

Five studies were conducted in the USA and 11 outside of USA, primarily from Europe. All studies were published in 2013 or later, with the most recent study in 2020. The studies included a total of 13,556 patients of which majority underwent primary laparoscopic sleeve gastrectomy (LSG) (>65%), followed by laparoscopic Roux-en-Y Gastric Bypass (LRYGB) procedure.

Table 1 below summarizes the study characteristics.

Table 1: Study Characteristics

Year	Author	Country	Sample size	Study Type	ERAS Protocol	Intervention
2013	Daniel P. Lemanu	New Zealand	116	Randomized controlled trial	ERAS Protocol	LSG
2013	Noelle Geubbels	Netherlands	464	Retrospective Study	Fast Track	LGB
2014	Kemal Dogan	Netherlands	150	Prospective Study	Fast Track	LRYGB
2015	Anthony Petrick	USA	2061	Retrospective Study	Clinical pathway	RYGB-lap or open
2016	Vincenzo Simonelli	Luxembourg	206	Retrospective Study	ERAS Protocol	LSG and LRYGB
2016	Marco Barreca	UK	288	Prospective Study	ERAS Protocol	LSG and LRYGB
2016	Monika Proczko	UK	374	Retrospective Study	ERAS Protocol	all procedures
2016	Guido H. H. Mannaerts	Netherlands	2126	Retrospective Study	ERAS Protocol	LSG and LRYGB
2018	Anissa Deneuvy	France	1667	Retrospective Study	ERAS Protocol	LSG and LGB
2018	Jaime Ruiz-Tovar	Spain	519	Retrospective Study	ERAS Protocol	SG and RYGB
2018	Amlish B. Gondal	USA	435	Retrospective Study	ERAS Protocol	SG and Gastric bypass
2019	James Taylor	USA	625	Retrospective Study	ERAS Protocol	LSG and LGB
2019	Hugo Meunier	France	464	Retrospective Study	ERAS Protocol	LSG and LRYGB
2019	Manuela Trotta	Italy	1365	Retrospective Study	ERAS Protocol	LSG and RYGB
2019	Jenny Lam	USA	214	Retrospective Study	ERAS Protocol	LSG only
2020	Tamara Dı´az-Vico,	USA	366	Retrospective Study	ERAS Protocol	SG and RYGB

Table 1 Key: Laparoscopic Sleeve Gastrectomy (LSG); Sleeve Gastrectomy (SG); Laparoscopic Gastric Bypass (LGB); Laparoscopic Roux-en-Y gastric bypass (LRYGB)

Results of individual studies

Data elements from these studies were analyzed under the headings: patient demographics, ERAS components, clinical outcomes, and follow-up.

Patient demographics

Patients in this group ranged from 32 to 58 years of age, and mean age ranged from 40.0 to 49.5 years of age. The majority of the patients were female, about an average of 75%. BMI ranged from 35 to 60 kg/m2 and mean BMI varied from 41.8 to 49.3 kg/m2 across the studies.

The most commonly reported comorbidities were hypertension, Type 2 diabetes mellitus, dyslipidemia and sleep apnea. There was a high rate of co-morbidities in patients, most commonly hypertension with a mean at 43% of patients, followed by high lipid levels and type 2 diabetes mellitus at an average of 31% and 31% of patients respectively.

ERAS components

A number of multidisciplinary interventions employed in the pre, intra and postoperative settings were aimed in majority of the studies to facilitate recovery by reducing the stress response to major surgery and attendant functional decline as reflected in Figure 2.

Patients were prepared for surgery through pre-operative consultation with the surgeon, endocrinologist and clinical nutritionist, together with a psychological evaluation, counselling and health education in 80% of the studies. Preoperative weight loss was encouraged, with the aim of decreasing fatty infiltration of the liver, and hence, decreasing the difficulty of Laparoscopic Gastric Bypass (LGB). Mannaerts et al performed mandatory weighing 1 week prior to surgery.

Weight gain prior to surgery is prohibited and surgery was postponed for patients that did not lose any weight.[6] The mean operative time for LAGB ranged from 41 to 116 min across all studies. In the study by Gondal et al. the compliance with ERAS elements increased significantly with the implementation of a checklist.[8]

Figure 2: Multimodal interventions utilized within (ERAS) pathway

Abbreviations: intraop. intraoperative, LPP low pressure pneumoperitoneum, NG nasogastric, PONV postoperative nausea and vomiting, preop. preoperative

Outcomes

Table 2 below summarizes the outcomes of the selected studies.

Table 2: Qualitative Synthesis of Selected Studies

Author	Intervention	Design	Conclusion
Lemanu (2013)	LSG	Randomized controlled trial	Shorter LOS, Reduction in mean cost but no difference in complications or readmissions
Geubbels (2013)	LGB	Retrospective Study	Shorter LOS, but no difference in complications or readmissions
Dogan (2014)	LRYGB	Prospective Study	Shorter LOS, improvement in complications, operative time and intraoperative medications
Petrick (2015)	RYGB-lap or open	Retrospective Study	Shorter LOS, improvement in complications and readmissions
Simonelli (2016)	LSG and LRYBG	Retrospective Study	Shorter LOS, Reduction in cost and operating time, but no difference in complications or readmissions
Barreca (2016)	LSG and LRYBG	Prospective Study	Shorter LOS, but no difference in complications or readmissions, ERAS strongest predictor of discharge on the first postop day after lap BS
Proczko (2016)	all proc	Retrospective Study	Shorter LOS, Reduction in cost and operating time, but no difference in complications or readmissions
Mannaerts (2016)	LSG and LRYBG	Retrospective Study	Shorter LOS, Reduction in cost and operating time, but no difference in complications or readmissions
Deneuvy (2018)	LSG and LGB	Retrospective Study	Shorter LOS, No difference in readmissions
Ruiz-Tovar (2018)	SG and RYBG	Retrospective Study	Shorter LOS, but no difference in complications or readmissions, post op pain significantly less in ERAS group
Gondal (2018)	SG and GB	Retrospective Study	Shorter LOS, improvement in complications, but no difference in readmissions
Taylor (2019)	LSG and LGB	Retrospective Study	Shorter LOS, improvement in readmissions and cost
Meunier (2019)	LSG and LRYBG	Retrospective Study	Shorter LOS, but no difference in complications
Trotta (2019)	LSG and RYBG	Retrospective Study	Shorter LOS, but no difference in complications
Lam (2019)	LSG only	Retrospective Study	Shorter LOS, no difference in complications or readmission, decreased median intraop opioid consumption
Dı´az-Vico (2020)	SG and RYBG	Retrospective Study	Shorter LOS, no difference in complications or readmission, fewer ERAS patients required postoperative opioids and antiemetic's

Three studies [8,9,10] reported on compliance with ERAS elements where compliance was between 70% and 85% and increased significantly with the implementation of a checklist.[8] In the study by Anissa Deneuvy[10], over all compliance was almost 80%. There is a previous Grace audit

databank study[15] that suggests that a minimum of 15 elements must be implemented to obtain a significant reduction in length of hospital stay.

Mean length of stay was reported in all studies and showed a significant improvement in the post ERAS group. The ERAS length of stay ranged from 1 day to 2 days.

Rates of same-day discharge was infrequently reported in the literature. The study by Marco Barreca[14] and his team in the UK analyzed the effect of ERAS implementation on discharge on the first postoperative date using multivariate analysis and determined that ERAS protocol remained the strongest predictor of discharge on the first postop day after laparoscopic bariatric surgery.

There were no intraoperative or postoperative deaths in any study. 12 studies of the 16 reported on readmissions and there was no significant change in 75% of the studies in readmissions between the conventional group compared to ERAS group. Three studies showed an improvement in 30-day readmission rates with the ERAS protocol by 50%.

Thirty-day complication rates were reported in four studies[8,11,12,13]. Of the four, two did not show any significant difference in complication rate with ERAS implementation. The James Taylor study showed no association between ERAS protocol implementation and complications.[11] Only procedure type was identified as significant factor for complications. Logistic regression highlighted Laparoscopic Sleeve Gastrectomy (LSG) as the safest procedure with lowest LOS, cost, complications and readmissions.[11] In the Amlish Gondal study, the post-ERAs group had lower rates of 30-day postoperative morbidity.[8] There was no significant difference between the two groups with respect to readmission rates.[8]

Four studies reported on procedural times.[6,13,16,17] All four demonstrated procedural times, such as surgical times, significantly decreased after ERAS implementation.

Two studies[17,18] reported on intraoperative medication use. All three showed a significant improvement in intraoperative medication use, including opioid consumption. One study[19] reported on postoperative medication use and demonstrated that fewer ERAS patients required postoperative opioids and antiemetic's with a significant difference in postoperative nausea control in favor of ERAS patients.

Cost

Three studies[2,11,16] analyzed the mean cost per patient in conventional group compared to ERAS group. In the three studies, the mean cost per patient was significantly higher in the control group than in the ERAS group. In the study by Taylor, et al, the median cost of patient stay was cut from $11,739 to $9,482.[11]

V. Discussion

Historically, attempts to improve surgical performance have focused on technological innovations, checklists, centralizing complex cases, and outcome measurements. Nevertheless, surgery in obese patients is met with several anesthetic and technical concerns in the perioperative period, warranting greater attention as obesity rates soar.[31] The implementation of multimodal and multidisciplinary perioperative care in the form of enhanced recovery and fast-track programs has achieved multiple noteworthy improvements in the outcomes of a variety of surgical procedures.[21,22]

My literature review results suggest that the implementation of ERAS protocol reduces the length of stay without any significant increase in the overall major complications or readmissions. Pooled results for re-admissions, complication and mortality, were equivalent. However, patients managed with specifically designed enhanced perioperative protocols saw benefits in length of stay, operative duration, and ultimately cost. The technical and clinical success rates associated with obesity surgery have led to an increase in the number of procedures performed globally, providing a promising alternative to refractory efforts in weight loss management.[23] Bariatric patients appear to benefit from specifically designed perioperative pathways in dedicated bariatric units, and the current study emphasizes the encouraging results. Enhanced protocols demonstrate superiority in LOS significantly shortening overall hospital stay. This reduction in LOS outcome was consistently demonstrated in all 16 studies and also parallels with other studies in the literature,[24,25] providing a measure of both efficacy and overall quality. However, by including ERAS, fast track and other clinical pathways in the study, we hoped to display the global effects of such protocols without excluding other evidence-based perioperative efforts which may not strictly adhere to ERAS. The originality of ERAS protocols relies on the avoidance of nasogastric tubes and early mobilization, among other factors, which may not be prioritized in other clinical pathways. The significance of reduced stays, associated with no effects on readmission rates, will likely positively affect cost efficiency, because bariatric surgery is still an expensive operation.[26] Reducing LOS will contribute to improved patient access to bariatric care and adds potential for obesity surgery to be widely introduced.

The significantly reduced operation times in the present review have not been reported elsewhere in the literature.[24,25] This could also be related to several factors. The standardization

of protocols often coincides with higher volume centers and surgeons and may be subject to the Hawthorne effect.[27] Improved reproducibility of protocols also contributes to institutional productivity and efficiency. These efforts combined with the use of dedicated bariatric teams may ultimately increase efficiency and result in reduced operating times when comparisons to no standardized approaches are made.

VI. Strengths and Limitations

The current review is limited by the quality of the included studies, mainly in the form of nonrandomized studies. Only one randomized study is included in the review. The increased heterogeneity in the data reflects the variations within the described clinical pathways. While majority of studies included describe multimodal elements applied in enhanced recovery, only few report on compliance with the protocol and no paper reports on patient satisfaction. There is also no data to describe the encountered difficulties and challenges within each protocol, which is well described in the literature, likely contributing to the considerable heterogeneity seen in the current selected studies.[28] The variable methodology in ERAS programs combined with low compliance among hospital personnel is a major challenge.[29] Such programs are also known to be highly labor intensive further contributing to the inertia towards their application. Little is known from literature about the economic effects of implementing multiple ERAS guidelines in both the short and long term. A return on investment (ROI) study of multiple ERAS guidelines by Dr. Thanh and his colleagues from Canada in 2020, demonstrated that every dollar invested in ERAS brought $1.05 to $7.31 in return.[31] The effects of ERAS were found to be larger in the longer time horizons, indicating that if only the 30-day time horizon had been used, the benefits of ERAS would have been underestimated.[31] A US study in 2016 by Dr. Stone and his colleagues, also

demonstrated an annual net cost savings of implementing ERAS at a quaternary hospital.[32] The other limitation is that the studies showed significant heterogeneity in the length of hospital stay. Some of this heterogeneity may be explained by the fact that different studies have included different bariatric procedures. In addition, one of the major reasons for increased heterogeneity in the results is due to variations within the ERAS protocols used by different studies. As already stated, ERAS for bariatric surgery is at the starting stage and needs standardization. The current review sums up the evidence from studies on ERAS protocols within the bariatric surgery field and paves way for future enhancement and standardization of evidence-based guidelines. Since documentation on complications across the studies was not uniform, strong conclusions about these outcomes cannot be made. This however warrants further collection and analysis of evidence on these aspects of ERAS for bariatric surgery.

However, inclusion of consecutive patients without any exclusion in these studies strengthens their quality and reduces the risk of selection bias. Inclusion of consecutive patients decreases the risk of selection bias and increases the generalizability of the results. Most other studies that have evaluated ERAS protocols in other surgeries have only included well selected patients, thereby restricting the applicability of the results to only low-risk patients.

The results on the STAMPEDE (Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently) trial are encouraging and further support the efficacy of bariatric surgery compared to medical management contributing to its growing popularity.[30] As obesity rates continue to soar, more institutions are likely to perform bariatric procedures warranting further evidence based guidelines on perioperative care.

VII. Conclusion

The current literature review demonstrates superiority of ERAS protocols in terms of operative time, LOS, cost and in some instances, intraoperative medication use, morbidity rates and readmission rates. ERAS protocols appear safe and effective for use in bariatric surgery and are associated with improved perioperative outcomes without any compromise in patient's long-term safety. The real question to ask would be: what does a hospital lose by not applying ERAS? As we know, the positive clinical and economic impact of expansive new surgical technologies, like robotic surgery, has not been demonstrated, yet we invest in robotic surgery at a cost 20 times higher than investment in ERAS. Lastly, during this time of global crisis, clinicians who provide perioperative care must unite and make the changes that will bring further enhancements for patients and health systems. This is an opportunity to reinvent the entire patient experience while optimizing care standards and procedures to help increase cost savings. ERAS makes it easy to keep track of patients and streamline their treatment to not only give them the best, most positive outcome possible, but also to improve the efficiency of those treating them. COVID-19 has presented the opportunity for transformative change as the healthcare industry braces for the future. ERAS makes that evolution simple for patients and care providers alike.

However, it must be noted that these results have often been attained following preoperative selection of patients with fewer predictors of adverse postoperative outcomes. Therefore, it is not possible to draw conclusions about the global applicability of this practice. While several studies have supported implementation of ERAS protocol with outcomes, which compare positively with those for conventional management, we believe more research needs to be done

on its effectiveness on cost, medication utilization, and postoperative outcomes to promote routine adoption of ERAS protocols for bariatric surgery.

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CHAPTER 3: A STUDY OF THE EFFECTIVENESS OF IMPLEMENTATION OF AN ENHANCED RECOVERY PROGRAM IN BARIATRIC SURGERY

I. Abstract

Objective: We aimed to study the association between implementation of Enhanced Recovery after Surgery (ERAS) program in bariatric surgery and specific outcomes at a large academic medical center. This institution implemented the program with specific pre-, intra-, and post-operative protocols aimed at patients, nursing staff, and physicians.

Methods: Using the 2015–2019 Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database, patients 18 years and older, who underwent primary bariatric surgery at a single academic institution were included. Patients were divided into pre- and post-ERAS groups. Data including basic demographic information, length of hospital stay, readmission, and costs was collected. Poisson and quantile regressions were used to examine the association between ERAS protocol and length of stay (LOS) and cost, respectively. Logistic regression was used to assess the impact of ERAS on 30-day readmissions.

Results: 680 bariatric surgical procedures were performed in the pre-ERAS group, compared to 1,124 procedures post-ERAS. While there was a 65% increase in volume, there was no statistical difference in the average age among patients in the Pre-ERAS period (44.2+/10.9) and patients in the post-ERAS period (43.7 +/-11.1) (p=0.353). There were no statistically significant differences in proportion of patients between Pre-ERAS and Post-ERAS by sex, average BMI, Diabetes status, hypertension, hyperlipidemia, American Society of Anesthesiologists (ASA) physical status class, primary bariatric procedure, and emergency procedure. The median length

of hospital stay in the post-ERAS patients was shorter compared to that in the pre-ERAS patients by 1 day (p=0.001). There were disproportionately higher proportion of patients in the pre-ERAS periods with 1 or more unplanned readmissions compared to the post-ERAS period (p<0.001). The median cost of surgery among the post-ERAS patients was $2000 lower than the median cost among pre-ERAS patients. After controlling for other factors, ERAS protocol was associated with decreased LOS (IRR 0.72, p < 0.001), decreased median cost (− $2230, p < 0.001), and lower risk of 30-day unplanned readmission (OR 0.48, p < 0.001).

Conclusion: The implementation of a standardized enhanced recovery program resulted in reduced length of stay, cost, and 30-day readmissions. Total costs saved were greater than $600,000 in one calendar year. This study highlights the value of an enhanced recovery program in bariatric surgery, benefiting both patients and health systems.

II. Background

Bariatric surgery remains the most effective treatment for obesity as studies demonstrate long-term weight loss and decreased incidence of obesity-related complications.[1] Per the American Society of Metabolic and Bariatric Surgery (ASMBS), patients may lose as much as 60% of excess weight six months after surgery and 77% of excess weight as early as 12 months after surgery.[5] It is an ever-evolving field, and the increase in popularity of surgery as a treatment for obesity has led to a recognition of specific challenges healthcare providers face in the care of bariatric surgery candidates.

Despite the results, metabolic and bariatric surgery is significantly underutilized. An estimated 256,000 bariatric surgeries were performed in 2019, about 62% increase from 2011[4] in United States, which represents less than 1% of the currently eligible surgical population based on body mass index (BMI). The increase in procedure volumes is not commensurate with the increasing obesity rates per the CDC.[5] The number of bariatric procedures performed per year has also been increasing worldwide.[2] With increased practice, improved surgeon expertise, standardized preoperative care, and meticulous selection of surgical candidates, outcomes have improved in bariatric surgery; reported complication rates are low with earnest perioperative care and follow-up.[3]

With the introduction of minimally invasive techniques, bariatric surgery has undergone a major overhaul. With nearly 40% of American adults aged 20 being obese, the next logical step is to seek strategies to optimize bariatric perioperative care to handle the growing volume of potential surgical candidates.[24] The Enhanced Recovery after Surgery (ERAS) program is a multifaceted

approach to the perioperative care of the surgical patient. After the introduction of the protocol for colorectal surgery patients in 2001, these guidelines have been widely studied among various surgical specialties including thoracic, orthopedic, and urological surgery and their implementation has demonstrated reduced length of stay, faster recovery, and favorable surgical outcomes.[7,8] The ERAS society published the recommendations for bariatric surgery in 2016. ERAS for bariatric surgery consists of multimodal recommendations that introduced preoperative, intraoperative, and postoperative measures of care for surgical candidates. The aim of these guidelines is to optimize operative stress, reduce postoperative pain, and enhance early mobilization.[6]

The combination of the increasing number of bariatric procedures worldwide and the specific perioperative difficulties and risks for this particular population[12] makes this type of surgery highly eligible for ERAS protocols. Implementation of evidenced-based interventions and standardization of bariatric care can increase efficiency and cost-effectiveness in these procedures,[13] without the loss or compromise of safety aspects.

Recent meta-analyses have concluded that ERAS implementation in bariatrics leads to a reduction in hospital stay while maintaining no negative influence on overall morbidity.[9,10,11] We conducted a literature review on implementation of ERAS protocols and found that ERAS is superior to traditional perioperative care in terms of operative time, complications, LOS, cost and in some instances, intraoperative medication use, morbidity rates and readmission rates. In this study, we aimed to compare the perioperative outcomes in bariatric surgery before and after implementation of a homogenous ERAS protocol in the bariatric program studied.

III. Methods

Study population

Data was extracted from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP®) Data Registry for our individual institution. The MBSAQIP is a large US based, bariatric-specific, clinical dataset and serves as an invaluable resource to investigators looking to answer important clinical questions in this field. The Johns Hopkins University School of Medicine Institutional Review Board approved this study. MBSAQIP is a nationwide joint initiative of the American College of Surgeons (ACS) and the American Society of Metabolic and Bariatric Surgery (ASMBS) that tracks outcomes at bariatric surgery centers with the goal of identifying best practices and improving low-performing centers.

All patients within the MBSAQIP data registry who underwent either a Sleeve Gastrectomy (SG) or Roux-en-Y Gastric Bypass (RYGB) between January 1, 2015 and December 31, 2019 at Johns Hopkins Bayview Medical Center were included in this study. Johns Hopkins Bayview is a 463-bed academic medical center in East Baltimore, Maryland with an accredited comprehensive bariatric center with adolescent qualification. Patients undergoing primary robotic-assisted and conventional laparoscopic approach or open for RYGB and SG were identified within the MBSAQIP registry using the Current Procedural Terminology (CPT) codes 43644 and 43755. To reflect a similar patient population, inclusion criteria were restricted to patients 18 years and older. Exclusion criteria included trauma patients and patients with cancer and patients who underwent other approaches besides conventional laparoscopic/robotic-assisted or open such

as single incision, and natural orifice transluminal endoscopic surgery. After a preoperative assessment, all patients who lived within a 2-hour commute from the hospital (approximately 30 miles distance), and had appropriate home social support (an adult to care for them postoperatively) were included into the ERAS pathway. Less than 1% of cases had missing data specifically related to patient demographic data, which were eliminated.

The official MBSAQIP quality improvement project called Employing New Enhanced Recovery Goals for Bariatric Surgery (ENERGY) (Table 1) was implemented in 2017 at Johns Hopkins Bayview Medical Center. For patients identified using the criteria defined above, the pre ERAS cohort was identified as patients who underwent bariatric surgery in calendar year 2015 and 2016. They were compared to a post ERAS cohort of patients who underwent bariatric surgery in calendar year 2017, 2018, and 2019.

The following patient demographic factors were reviewed: age, sex, BMI, comorbidities like hypertension, hyperlipidemia, Diabetes mellitus, and sleep apnea. Patient clinical factors included the procedure performed, laparoscopic sleeve gastrectomy (LSG), laparoscopic gastric bypass (LGB), open and other (includes revisions, conversions and band removal), ASA classification, and pre- and post-ERAS time. Information on length of hospital (LOS) stay, attending surgeon, unplanned readmissions and total costs was reviewed as well.

Data Source

Data for one academic institution, Johns Hopkins Bayview Medical center was obtained from the 2015 through 2019 MBSAQIP data registry. There were 1,805 bariatric cases performed between January 1, 2015 and December 31, 2019. The MBSAQIP registry is a bariatric surgery-specific clinical data set, which contains nearly 200 variables including preoperative patient

characteristics, procedure details, as well as details on complications, reoperations, readmissions, or interventions within 30 days in both the inpatient and outpatient setting.

We collected retrospective data on consecutive patients 18 years of age and older that had a primary bariatric procedure (LRYGB or sleeve gastrectomy or gastric banding) with an ENERGY pathway for procedures performed over three calendar years 2017, 2018 and 2019 at the Johns Hopkins Center for Bariatric Surgery that employs four bariatric surgeons and a bariatric fellow. These patients were compared to 18 years of age or older patients, who underwent primary bariatric procedures during the calendar years 2015 and 2016. The data were matched with the hospital cost database to obtain total cost of hospital stay.

Table 1 MBSAQIP enhanced recovery after surgery protocol for bariatric patients

Preoperative intervention	
Patient optimization/pre-habilitation	OSA, T2DM control Increase activity Preoperative Weight Loss
Baseline patient experience survey patient education	Set expectations for LOS, pain management Clearly define pathway and patient responsibility
Intraoperative overview	Avoid opioids Region block and/or Lidocaine drip Goal-directed fluid management Glucose Control PONV prophylaxis Other anesthetic options to decrease PONV, stress, pain
Post-operative overview	Early initiation of PO liquids (night of surgery) Early ambulation Scheduled non-narcotic analgesics Scheduled anti-emetics Opioids for breakthrough pain, avoid routine PCA Patient experience survey (× 2)
Discharge overview	
Discharge checklist	Prescriptions filled for pain medications Prescriptions filled for nausea medications Home medications reconciled Glucose management plan as needed Extended VTE prophylaxis meds filled if needed Important discharge numbers (help card) given Initial post-op visit scheduled

Key: OSA obstructive sleep apnea, *T2DM* type 2 diabetes mellitus, *LOS* length of stay, *PONV* post-operative nausea and vomiting, *PCA* patient-controlled analgesia, *PO* per oral, *VTE* venous thromboembolism

Bariatric procedures

Bariatric surgical status was identified using the CPT codes for procedures performed through 2019. Included procedures were open and laparoscopic vertical sleeve gastrectomy (VSG) and open and laparoscopic Roux-en-Y gastric bypass surgery (RYGB), laparoscopic gastric banding (LADB) and revisions, conversions and band removals.

The National Institutes of Health (NIH) has standardized guidelines and criteria for determining whether or not the patient is a qualified candidate for bariatric surgery. The Johns Hopkins Center for Bariatric Surgery adheres to these guidelines. The candidate should:

-have a Body Mass Index of 40 kg/m2 or higher. This is approximately 100 pounds overweight.

-Patients may qualify if their BMI is between 35 and 40 and they have a significant obesity related disease.

-be healthy enough to have surgery, have tried and failed dietary management regimes.

Outcomes

Primary outcomes of interest were length of hospital stay (LOS), and total hospital costs (referred to as 'cost'). LOS was defined as the number of nights spent in the hospital after surgery. Secondary outcome of interest included 30-day post-operative readmission to the same institution. Chi-squared test was utilized to compare categorical data, while two-sample t-test was employed for continuous variables. Poisson regression was used for modelling count data in this study. It was used to evaluate factors associated with the dependent variables, LOS and readmissions. Quantile regression methodology was used for median cost data that is non-normally distributed to understand its nonlinear relationships with predictor variables in this study. Statistical significance was considered as $p < 0.05$.

Statistical Analysis

All statistical analyses were conducted with STATA 16 (StataCorp, LLP, College Station, TX).[25] Patient characteristics were reported using frequency and descriptive analyses. Univariate

analysis using the chi-squared test, two-sample t-test and Kruskal-Wallis test was performed on patient demographic and baseline characteristics to understand the differences between the two groups. For multivariate analysis, stepwise backward regression model and Akaike criteria was used to arrive at the best model. The co-variates from the best model were used to fit a multivariate Poisson regression model for effect on length of stay and number of unplanned readmissions. A multivariate quantile regression model was run to determine the effect of patient factors and ERAS status on median cost of hospital stay. A p value of <0.05 was considered statistically significant.

IV. Results

Patient demographics and baseline clinical characteristics

From Table 2, the total number of participants in this ERAS cohort was 1804 with 680 patients (37.7%) having surgery Pre-ERAS period and 1124 patient (62.3%) having surgery post-ERAS period. There was no significant difference in the average age among patients in the Pre-ERAS period (44.2+/10.9) and patients in the post-ERAS period (43.7 +/-11.1) (p=0.353). In both the pre-ERAS and post-ERAS periods majority of cases were primary bariatric procedures (p=0.023). There were no statistically significant differences in proportion of patients between Pre-ERAS and Post-ERAS by sex, average BMI, Diabetes status, hypertension, hyperlipidemia, ASA class, primary bariatric procedure and emergency procedure. We did see a difference in proportion of patients with surgeon 2 between pre ERAS and post ERAS groups.

Table 2: Baseline variables of participants in the cohort

Variable	Pre-ERAS (N=680,37.7%)	Post-ERAS (N=1124,62.3%)	P value
Age			
Mean +/- SD	44.2 +/- 10.9	43.7 +/- 11.1	0.353
Sex			
Male	138(20.3%)	211(18.8%)	0.423
Female	542(79.7%)	914(81.2%)	
BMI			
Mean +/- SD	46.2 +/- 9.8	46.0 +/- 9.2	0.67
Diabetes Mellitus (DM))			
Non-Insulin Dependent	50(7.4%)	106(9.4%)	
Insulin-Dependent	104(15.3%)	172(15.3%)	0.308
No DM	526(77.3%)	846(75.3%)	
Hypertension			
Yes	325(47.8%)	545(48.5%	0.775
No	355(52.2%)	579(51.5%)	
Hyperlipidemia			
Yes	143(21.0%)	216(19.2%)	0.35
No	537(79.0%)	908(80.8%)	
ASA class			
Class I	3(0.4%)	6(0.5%)	
Class II	343(50.5%)	536(47.7%)	0.666
Class III	330(48.5%)	577(51.3%)	
Class IV	4(0.6%)	5(0.5%)	
Primary Bariatric proc.			
Yes	558(82.1%)	968(86.0%)	0.023
No	122(17.9%)	157(14.0%)	
Primary Procedure			
open	46(7.0%)	73(6.6%)	
LRYGB	136(20.9%)	180(16.3%)	0.097
LVSG	393(60.3%)	718(65.1%)	
others	77(11.8%)	153(13.0%)	
Emergency Procedure			
Yes	3(0.4%)	6(0.5%)	0.787
No	677(99.6%)	1,118(99.5%)	
Surgeon			
surgeon 0	51(7.5%)	28(2.5%)	
surgeon1	0(0.0%)	100(8.9%)	
surgeon 2	18(2.6%)	125(11.1%)	<0.001
surgeon 3	67(9.9%)	108(9.6%)	
surgeon 4	147(21.6%)	254(22.6%)	
surgeon 5	336(49.4%)	478(42.5%)	
others	61(9.0%)	31(2.8%)	

Outcomes: Univariate Analysis

As shown in Table 3, the median length of hospital stay in the post-ERAS patients was shorter compared to that in the pre-ERAS patients (p=0.001). There were disproportionately higher proportion of patients in the pre-ERAS periods with 1 or more unplanned readmissions compared to the post-ERAS period (p<0.001). The median hospital costs among the post-ERAS patients was significantly lower than the median cost among pre-ERAS patients. There was only 1 perioperative death among the cohort that occurred among the pre-ERAS patients and none among the post-ERAS patients.

Table 3: Univariate analysis of Outcomes between Pre-ERAS and Post-ERAS periods

Outcomes	Pre-ERAS	Post-ERAS	P value
Length of Stay			
Median	2	1	0.001
Perioperative death			
Yes	1(0.2%)	0(0.0%)	0.198
No	679(99.8%)	1,124(100%)	
Number of unplanned readmissions			
0	615(90.5%)	1,072(95.4%)	
1	60(8.8%)	46(4.1%)	<0.001
2	5(0.7%)	6(0.5%)	
Cost			
Median	5,853.50	3,848	<0.001

Length of Stay and risk factor analysis

As shown in Table 4, the multivariate Poisson regression analysis results show that patients who had their bariatric surgery done in the post-ERAS period have a 28% decreased likelihood of a longer length of stay compared to patients who had surgery during the pre-ERAS period ($p<0.001$). For each additional increase in age of patient, there is a 1% increase in the likelihood of a longer length of stay ($p=0.001$). Presence of hyperlipidemia is associated with a 12% reduction in the likelihood of a longer hospital stay ($p=0.008$). A patient's surgeon can influence the length of hospital stay after bariatric surgery. Patients with insulin dependent diabetes mellitus had a 15% increased likelihood of a longer hospital stay compared to non-diabetic patients($p=0.023$). There was, however, no difference in the length of hospital stay between patients who had non-insulin dependent diabetes and patients who were non-diabetics ($p=0.174$). Patients with a primary bariatric procedure had 66% increased risk of longer hospital stay ($p<0.001$). Patient's sex, BMI, type of bariatric procedure and ASA class did not show an association with the likelihood of a longer hospital stay.

Table 4: Multivariate Poisson regression: effect of patient factors, procedure type, surgeon, ASA classification and ERAS status on LOS

Risk factor	Univariate			Multivariate		
	OR	95% CI	P value	OR	95% CI	P value
ERAS status						
Pre-ERAS		Reference			Reference	
Post-ERAS	0.72	0.67 - 0.76	<0.001	0.72	0.67 - 0.77	<0.001
Age	1.01	1.01 - 1.02	<0.001	1.01	1.01 - 1.02	0.001
Sex						
Female		Reference			Reference	
Male	1.08	1.00 - 1.17	0.051	1.08	0.99 - 1.17	0.075
BMI	1.01	1.01 - 1.02	0.001	1.00	1.00 - 1.01	0.170
Procedure						
Open		Reference			Reference	
LRYGB	0.51	0.45 - 0.57	<0.001	1.20	0.98 - 1.46	0.074
LVSG	0.43	0.39 - 0.48	<0.001	1.09	0.90 - 1.31	0.393
Other	0.66	0.59 - 0.75	<0.001	2.02	1.54 - 2.66	<0.001
Hyperlipidemia						
No		Reference			Reference	
Yes	1.00	0.92 - 1.08	0.237	0.88	0.80 - 0.97	0.008
Surgeon						
surgeon 0		Reference			Reference	
surgeon 1	0.46	0.37 - 0.57	<0.001	0.61	0.49 - 0.76	<0.001
surgeon 2	0.52	0.43 - 0.63	<0.001	0.63	0.52 - 0.77	<0.001
surgeon 3	1.53	1.32 - 1.77	<0.001	1.72	1.40 - 2.11	<0.001
surgeon 4	0.65	0.56 - 0.76	<0.001	0.71	0.61 - 0.83	<0.001
surgeon 5	0.61	0.53 - 0.71	<0.001	0.67	0.58 - 0.77	<0.001
other	0.63	0.52 - 0.77	<0.001	0.73	0.60 - 0.90	0.003
DM						
No DM		Reference			Reference	
Non-insulin	1.03	0.94 - 1.13	0.504	1.07	0.97 - 1.18	0.174
Insulin	1.20	1.08 - 1.34	0.001	1.15	1.02 - 1.29	0.023
Primary Procedure						
No		Reference			Reference	
Yes	0.87	0.80 - 0.95	0.002	1.66	1.32 - 2.09	<0.001
ASA						
class I		Reference			Reference	
class II	1.00	0.63 - 1.59	0.940	1.27	0.72 - 2.24	0.415
class III	1.07	0.67 - 1.70	0.814	1.21	0.68 - 2.14	0.517
class IV	1.87	1.07 - 3.34	0.029	1.75	0.90 - 3.41	0.100

Readmissions and risk factor analysis

As shown in Table 5, the multivariate analysis results show that patients who had their bariatric surgery during the post-ERAS period has a 52% reduction in the number of unplanned readmissions compared to patients who had bariatric surgery in the pre-ERAS period ($p<0.001$). Patients who had LSG has a 66% reduction in the number of unplanned readmissions compared to patients who had open bariatric surgery ($p=0.023$). However, there was no difference in the likelihood of unplanned readmissions between patients who had Laparoscopic Roux-en gastric bypass and patients who had open bariatric surgery ($p=0.286$). Patient's age, sex, BMI, hyperlipidemia, patient's surgeon, diabetes, primary bariatric procedure, and ASA class had no association with the number of unplanned readmissions.

Table 5: Multivariate Poisson regression: effect of patient factors, procedure type, surgeon, ASA classification and ERAS status on Readmissions

Risk factor	Univariate			Multivariate		
	OR value	95% CI	P	OR	95% CI	P value
ERAS status						
Pre-ERAS		Reference			Reference	
Post-ERAS	0.50	0.35 - 0.71	<0.001	0.48	0.33 - 0.70	<0.001
Age	0.99	0.98 - 1.01	0.854	0.98	0.97 - 1.01	0.255
Sex						
Female		Reference			Reference	
Male	0.77	0.48 - 1.24	0.288	0.70	0.42 - 1.16	0.170
BMI	1.01	0.99 - 1.03	0.444	1.00	0.98 - 1.02	0.995
Procedure						
Open		Reference			Reference	
LRYGB	0.48	0.27 - 0.84	0.010	0.59	0.22 - 1.56	0.286
LVSG	0.25	0.15 - 0.41	<0.001	0.34	0.13 - 0.86	0.023
Other	0.67	0.38 - 1.19	0.171	0.81	0.23 - 2.80	0.737
Hyperlipidemia						
No		Reference			Reference	
Yes	1.29	0.86 - 1.93	0.222	1.39	0.85 - 2.27	0.182
Surgeon						
surgeon 0		Reference			Reference	
surgeon 1	1.31	0.31 - 5.51	0.706	2.73	0.63 - 11.97	0.181
surgeon 2	0.74	0.16 - 3.29	0.689	1.08	0.24 - 4.88	0.924
surgeon 3	4.66	1.43 - 15.26	0.011	2.63	0.66 - 10.50	0.170
surgeon 4	2.16	0.66 - 7.06	0.200	2.75	0.84 - 9.03	0.095
surgeon 5	1.49	0.46 - 4.78	0.505	1.59	0.48 - 5.22	0.444
other	1.72	0.43 - 6.87	0.444	1.87	0.46 - 7.52	0.377
DM						
No DM		Reference			Reference	
Non-insulin dependent	1.13	0.71 - 1.82	0.601	1.06	0.63 - 1.79	0.812
Insulin dependent	1.43	0.83 - 2.47	0.196	1.30	0.71 - 2.40	0.392
Primary Procedure						
No		Reference			Reference	
Yes	0.62	0.41 - 0.94	0.024	0.82	0.28 - 2.39	0.717
ASA						
	1.00	0.72 - 1.40	0.999	0.89	0.61 - 1.28	0.528

Effect of patient factors, procedure and ERAS status on median cost of hospital stay

As shown in Table 6, the multivariate quantile regression analysis results show that ERAS protocol impacted the median cost of patient stay. The adjusted median cost was $2230.34(95% CI: -3173.82 to -1286.86, p<0.001) lower after ERAS adaptation. When compared to open bariatric procedure, LSG was the only bariatric procedure that costs $2546.33(95% CI: -4535.66 to – 556.99, p=0.012) less. A patient's surgeon influenced the median cost of hospital stay with patient managed by surgeon #5 having a $2333.56(95% CI: -4506.42 to – 160.69, p=0.035) less cost compared to patient who were managed by surgeon #0. Patient's age, sex, BMI, DM, primary bariatric procedure, hyperlipidemia and ASA class had no effect on the median cost associated with patient stay at the hospital.

Table 6: Multivariate quantile regression: effect of patient factors, procedure type and ERAS status on median cost of hospital stay

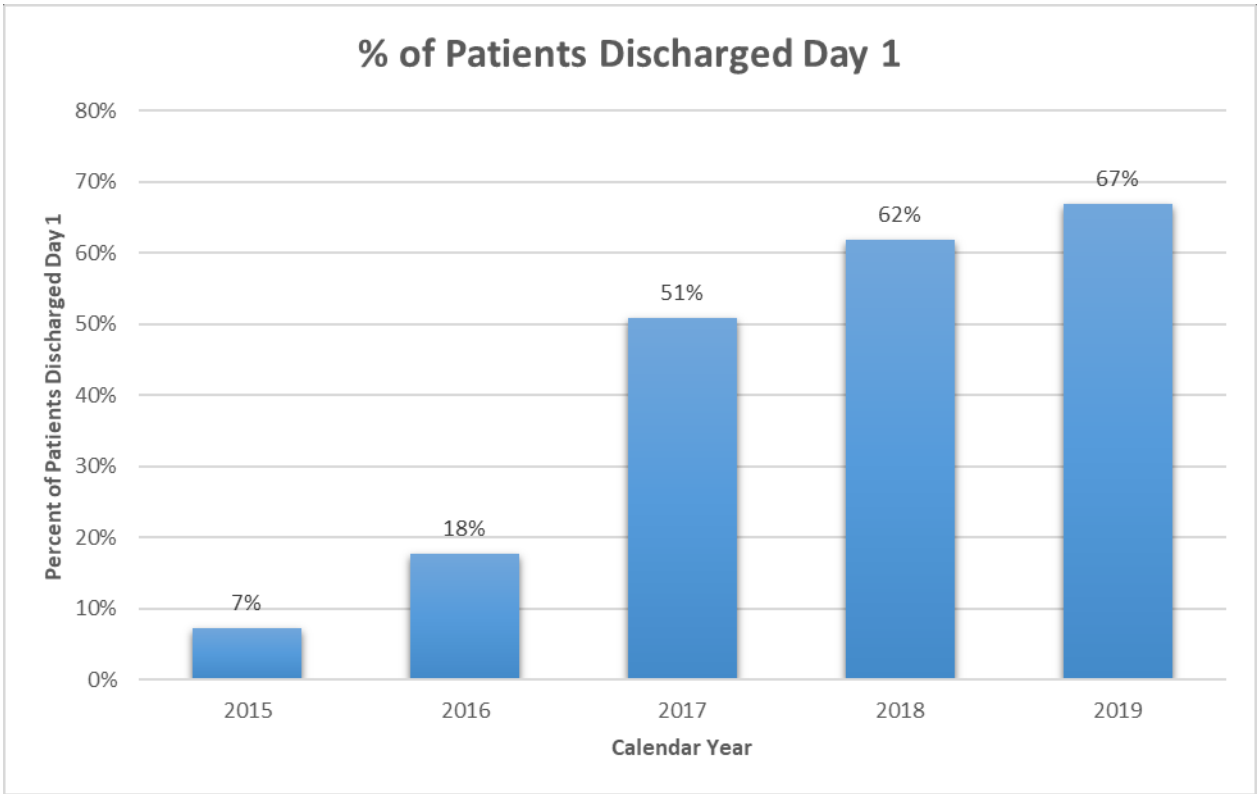
Risk factor	Coefficient(B) 95% CI	p value
ERAS		
Pre-ERAS	Reference	
Post-ERAS	-2230.34(-3173.82- -1286.86)	<0.001
Age	5.05(-40.25 - 50.34)	0.827
Sex		
Female	Reference	
Male	68.23(-1106.62 - 1243.08)	0.909
BMI	7.85(-47.89 - 63.59)	0.782
Procedure		
Open surgery	Reference	
LRYGB	-1682.50(-3857.58 - 492.58)	0.129
LVSG	-2546.33(-4535.66 - -556.99)	0.012
Other	2249.30(-6267.26- 1768.67)	0.272
Hyperlipidemia		
No	Reference	
Yes	100.79(-1212.10 - 1413.67)	0.88
Surgeon		
surgeon 0	Reference	
surgeon 1	-1724.35(-4532.77 - 1084.07)	0.229
surgeon 2	-2061.25(-4645.55 - 523.04)	0.118
surgeon 3	1193.16(-2218.41 - 4604.73)	0.493
surgeon 4	-2226.30(-4476.94 - 24.34)	0.053
surgeon 5	-2333.56(-4506.42- -160.69)	0.035
other	861.57(-3745.24 - 2022.09)	0.558
DM		
No	Reference	
Non-insulin dependent	151.92(-1142.74 - 1446.58)	0.818
Insulin dependent	388.26(-1316.21 - 2092.74)	0.655
Primary Procedure	Reference	
Yes	-853.55(-4259.36 - 2552.25)	0.623
ASA	-3.93(-931.09 - 923.22)	0.993

V. Discussion

Our study utilized a standardized ERAS protocol created by the MBSAQIP, and reports on patient outcomes and cost associated with pre- and post-implementation of the protocol in bariatric surgery. Following its introduction at our academic medical center, a statistically significant decrease in the LOS was observed ($p < 0.001$). This finding correlates with prior evidence of the effectiveness of ERAS pathways at reducing the LOS.[10,14]

While the reduction in length of stay is consistent with the current evidence in favor of *effectiveness* of ERAS in bariatric surgery, reduction in diabetes medication utilization as demonstrated by one of our studies and readmissions justifies the case for *safety* of ERAS protocols. ERAS protocol in our setting emphasized on early ambulation, early feeding, and an anticipation of early recovery, which contributed to a faster return to function. This demonstrates the feasibility of shift in expedited perioperative care of the bariatric surgery patients. The increase in postoperative day 1 discharge rates after 2017 in Figure 1 indicates that experience with enhanced recovery guidelines facilitates their effective implementation without compromising on safety. In their study, Sheaffer et al. showed that a simple pre-operative education system involving patients and healthcare providers regarding the ERAS guidelines reduces the length of stay significantly without adversely affecting readmission and complication rates.[15]

Figure 1: Percent of patients discharged post-operative day 1



The reduction in the LOS was paralleled by a decrease in the median cost per case of over $2000, and an overall net savings by the department of $600,000 for a period of one calendar year (CY). It assumes 300 cases per calendar year at this academic institution. This is analogous with data presented by Stone et al., who showed that a reduction in LOS by 0.7 days translated to a net savings of nearly $400,000 at their institution[16] and Taylor et al. who showed that a reduction in LOS by 0.9 days translated to a net savings of nearly $800,000 at their institution.[17]

Though we did not study complications, it was interesting to see the rate of readmission decrease significantly following the implementation of the ERAS protocol, with 8.8% of patients readmitted pre-ERAS, compared to just 4.1% of patients post-ERAS. Evidence from a few prior studies that utilized clinical pathways or earlier versions of ERAS protocol has suggested that readmission

odds are usually unaffected, or marginally increased, with the introduction of ERAS,[18,19] which may suggest that the MBSAQIP ERAS protocol may be more effective than prior ERAS studies.

Our results showed some variability in the influence of type of procedure performed on LOS, cost, and readmissions. Logistic regression highlighted LSG as the safest procedure with only readmissions with a 66% reduction in the number of unplanned readmissions compared to patients who had open bariatric surgery (p=0.023). The "Other' category of procedures that includes revisions, conversion and band removal, showed a significantly higher length of stay, almost twice, as compared to open bariatric procedures. When compared to open bariatric procedure, LSG was the only bariatric procedure that costs $2546.33 (95% CI: -4535.66 to –556.99, p=0.012) less.

Out study did show an association between patient's surgeon and median cost of surgery and likelihood of a longer hospital stay. This could be related to multiple factors, like technical skill, experience, volume, and age of surgeon that would require further study. Stulberg et al. found that better surgeon technical skills, measured by video-based peer review of laparoscopic colectomy, appeared to be significantly associated with better patient outcomes following colectomy.[20] Additionally, results from a systematic review by Morche et al. support a positive volume-outcome relationship for most procedures/conditions especially in colorectal cancer, bariatric surgery, and breast cancer.[21] Patient's BMI and ASA class has no association with the likelihood of a higher cost of surgery, length of stay or unplanned readmission.

VI. Limitations

There are several limitations to this study. First, is bias related to time. Since the groups in our study were stratified sequentially there may have been an inherent difference in the operations performed, i.e. related to technology, support staff, surgeon performance that improves with experience. Our study is further limited by the fact that it is an observational retrospective design with lack of patient randomization which leaves open the possibility that other factors beyond those measured (e.g. lurking variables or Hawthorne effect) could have an influence on the observed results. The absence of randomization does prevent us from inferring causality in any of the findings. The study was conducted at one large academic medical center with considerable resources focused on quality improvement which may not be generalizable to all settings or be a representative sample. There could be bias related to manual data entry by trained registry staff, however since MBSAQIP conducts data integrity audits of selected participating centers, we expect minimal quality issues. Moreover, our data comes from a bariatric center of excellence, which allowed for structured implementation of guidelines.

Reductions in LOS, cost, and readmission rate may be influenced by bias as a result of increased surgeon experience between the pre- and post-ERAS periods. The increasing body of literature on the safety of early discharges, and the changing expectations of both surgeons and patients also may contribute to the decreased LOS.[22,23] Despite these potential sources of bias, we believe that the data strongly supports the benefits of a standardized ERAS pathway in bariatric surgery centers.

VII. Opportunities for future study

The study also does not include costs related to implementation of the program or net revenue from increased surgical capacity and bed availability at our center. It would be nice to study the annual net savings and return on investment of the ERAS program. Perhaps most importantly, studying the potential cost savings associated with improvement in patient outcomes and experience that have been reported in evaluations of numerous ERAS programs, both of which are important elements of most value-based purchasing contracts in the United States. With increase in adult obesity trends, in the future, bariatric surgery will consume an increasing part of limited health economic and surgical resources of our already burdened health care system. Many studies demonstrate reduction in LOS, but it would be appropriate to study procedural times, which may lead to more efficient and cost-effective bariatric care. Additionally, based on the multivariate analysis results by surgeon, it would be appropriate to conduct a subset analysis by surgeon for the different outcomes to assess associations.

VIII. Conclusion

The results of this study strongly support the existence of a relationship between implementation of bariatric surgery ERAS protocol and desired outcomes benefiting both patients and hospital systems. From a practice perspective, as the prevalence of obesity continues to increase, the requirement for a higher volume of bariatric procedures becomes imperative, and as such, implementation of standardized ERAS pathways also becomes essential. The use of ERAS guidelines should be encouraged as a standard of care in bariatric surgery programs.

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CHAPTER 4: MEDICATION UTILIZATION AND COSTS IN PATIENTS WITH TYPE 2 DIABETES BEFORE AND AFTER BARIATRIC SURGERY

I. Abstract

Objective: Bariatric surgery is an obesity intervention, which leads to weight loss and improvement in many obesity-related conditions, including diabetes.[6] While there is a reduction in medical costs and prescription drug use after bariatric surgery, there is little information about drug utilization and cost outcomes in patients with type 2 diabetes after bariatric surgery.[7,8] Understanding sustained costs and utilization in this population is important given that one-third of all patients undergoing bariatric surgery have type 2 diabetes. The aim of the present retrospective study is to evaluate the efficacy of bariatric surgery in reducing the medication use and costs after bariatric surgery. We explored this by assessing the change in use and cost of medications to treat diabetes mellitus in the three years following surgery.

Methods: We studied a retrospective cohort study of 14,832 patients in the IBM MarketScan research database with a diagnosis of type 2 diabetes, on antidiabetic medication and have undergone bariatric surgery using pharmacy claims data from 2010 to 2017. We compared the mean number of medications and associated cost to the payer at different time points before and after bariatric surgery. To determine the effect of baseline patient characteristics and comorbidities such as age categories, sex, BMI, hypertension status, sleep apnea status, hyperlipidemia status, length of hospital stay, etc. on the odds of discontinuation of medication, univariate and multivariate logistic regression models were performed.

Results: Our cohort included 14,832 patients with bariatric surgery with a diagnosis of type 2 diabetes and on antidiabetic medications. 49% patients underwent VSG, 46.5% patients

underwent RYGB, the rest underwent LADB or BPD/DS. The average age of patients in our study was 49.9(+/-9.0) years with 65% females in the cohort. Majority of patients had a clinical diagnosis of hypertension (66.5%) and Hyperlipidemia was present in 39.1% of the patient's whiles sleep apnea was present in 40.9% of the patients in the cohort. On an average, patients were taking 1.7 (+/-0.9) antidiabetic medications at the time of surgery. Compared to the immediate year prior to surgery, there was a reduction in average annual medication cost per person by 57% totaling to an annual savings of $1,453,135 at $154 per patient to the insurer. There was no statistically significant difference in the average medication cost by the presence or absence of comorbidities such as hypertension, sleep apnea, and hyperlipidemia within the first, second and third year post surgery. Older age group >54 years, female sex, presence of hyperlipidemia, higher Charlson Comorbidity Index score were associated with lower odds of medication discontinuation. There was a decreasing trend in the odds of discontinuation with increasing number of diabetes medications at the time of surgery.

Conclusion: Medication use for obesity related diabetes decreased promptly following surgery. The clinical and economic benefits of reduced medication requirements should be considered when making decisions about the effects of bariatric surgery.

II. Background

As we know, the prevalence of obesity has increased worldwide over the last few decades, thereby also increasing the prevalence of obesity-related diseases (such as type 2 diabetes mellitus (T2DM), dyslipidemia, hypertension, cardiovascular diseases (CVD), but also obstructive sleep apnea (OSA), asthma, joint arthritis, and depression).[1] Obesity is a major independent risk factor for developing Type 2 diabetes, and more than 90% of type 2 diabetics are overweight or obese.[11] Per the American Society for Metabolic and Bariatric Surgery (ASMBS), modest weight loss, as little as 5% of total body weight, can help to improve type 2 diabetes in patients who are overweight or obese. Metabolic and bariatric surgery may result in resolution or improvement of type 2 diabetes independent of weight loss. Therefore, obese individuals are prone to increased consumption of drugs compared to lean individuals.[1]

Bariatric surgery for morbid obesity can help correct several comorbid conditions, including diabetes and hypertension. In most patients, this results in a reduction or discontinuation of corresponding prescription medications. Data from a very large UK primary health care database shows that bariatric surgery increases the chance of remission of type 2 diabetes.[11] Gastric bypass and sleeve gastrectomy show higher remission rates compared with gastric banding.[11] As so, patients who undergo bariatric surgery should see a significant reduction in medication spending after the operation. A recent meta-analysis found that the percentage of excess weight loss was 61.6–70.1 percent with gastric bypass, the most common bariatric surgery. As a result, diabetes was completely resolved in 76.8 percent of patients.[2] Another recent study found that gastric bypass patients had an 89 percent reduced relative risk of death.[3] Meta-analysis of 796

participants in 11 studies comparing metabolic and bariatric surgery to nonsurgical treatment for obesity found surgery results in greater weight loss and higher type 2 diabetes remission rates.[5] Dietary, pharmaceutical, and behavioral treatments for obesity are associated with high failure rates, and medical management of diabetes obesity has also proven disappointing on both the amount of weight loss and its maintenance over time for patients.[4] Despite many efforts to improve the control of glucose levels in diabetes, including clinical guidelines and patient and provider education, less than half of all patients with type 2 diabetes mellitus achieve the American Diabetes Association recommendation of a hemoglobin A1c level of less than 7%.[4] Therefore, the number of patients undergoing bariatric surgery indicated for the most severe form of obesity (BMI >40) has increased dramatically and is currently the only efficient mean to achieve major and sustainable weight reduction.[1]

There are a few studies published on bariatric surgery failure based on weight regain. A study by Dr. Morell a very high percentage (93%) of patients achieve ≥50% excess weight loss (EWL) after surgery.[13] In another 2019 study by Dr. Chang and colleagues, while presence of hypertension and diabetes initially appeared to be associated with weight recidivism, their impacts were negligible on multivariable analysis. Age and sleeve gastrectomy were associated with poor percent total weight loss and BMI change at 3 and 5 years.[14]

III. Methods

This is a retrospective cohort study of patients in the IBM MarketScan research database who have a diagnosis of Type 2 Diabetes Mellitus, are on antidiabetic medication and have

undergone bariatric surgery. Diabetes medication usage and associated cost of medication to the payer was determined at different time points before and after bariatric surgery.

Data Source

The MarketScan databases are a family of administrative claims databases that contain data on inpatient and outpatient claims, outpatient prescription claims, clinical utilization records, and healthcare expenditures. This database used for this study is comprised of individuals under age 65 who obtain health insurance through their employers, their spouses, and dependents covered by employer-sponsored private health insurance in the US. The database includes enrollee identification number, age, sex, diagnoses, medical and surgical procedures, date of surgery, medications, prescription fill dates and number of days of insurance coverage. Detailed pharmacy data including brand/generic drug names, strength, dosing, route of administration, day of service charge, and quantity charged are available in MarketScan.

Study Population

We selected patients who had bariatric surgery as primary procedure, age 18 to 65 years, had a clinical diagnosis of Type 2 Diabetes Mellitus at least 6 months prior to surgery, and had antidiabetic medication use for at least 6 months prior to surgery with continuous insurance coverage for at least 1 year after surgery. Our exclusion criteria included endocrinopathies, polycystic ovarian syndrome, discontinuation of antidiabetic medication prior to surgery, paraneoplastic syndromes, and performance of revision bariatric procedures. For the purpose of the study, patients who had undergone a previous bariatric surgery, as well as those who did not

attend postoperative follow-up, were excluded. For patients identified using the criteria defined above, the pre surgery period was specified as starting with claims made up to 365 days before the date of the first observed surgery claim. The post-surgery period was defined by claims made 30 to 365 days after the first surgery claim. The post-surgery period was initiated 30 days after the surgery to eliminate biases resulting from immediate post-surgery medication use or early surgery-related complications.

Bariatric procedures and comorbidities

Bariatric surgical status was identified using International Classification of Disease 9th edition (ICD 9), 10th edition (ICD 10) and Current Procedural Terminology (CPT) codes for procedures performed through 2017 (see supplementary table S1). Included procedures were open and laparoscopic vertical sleeve gastrectomy (VSG) and open and laparoscopic Roux-en-Y gastric bypass surgery (RYGB), laparoscopic gastric banding (LADB) and biliopancreatic diversion with duodenal switch (BPD/DS). Patient level comorbidities were standardized using the Charlson Comorbidity Index (CCI), a weighted index that predicts risk of death within 1 year of hospitalization in patients with specific comorbidities. Specific pre-operative comorbidities (hypertension, sleep apnea and hyperlipidemia) were identified using ICD 9/10 codes.

Diabetes Medications

Using pharmacy claims data from 2010 to 2017, the database was queried using therapeutic class codes, national drug coding numbers, and generic names to identify diabetes mellitus and antidiabetic medication usage before and after surgery to identify and to investigate remission

and relapse. Diabetes medications were classified as insulin, sulfonylureas, metformin, alpha glucosidase inhibitors, thiazolidinediones, or meglitinides. To determine the duration of drug usage, the number of days' supply of each prescription was added to the date of prescription fill. The number of medications that patients were taking before surgery, at the time of surgery and after surgery were categorized for ease of comparison.

Outcomes

The main outcomes of the study were antidiabetic annual total medication cost and average cost between time periods before surgery (i.e., 3 years to 2 years, 2 years to 1 year and 1 year to date of surgery) and after surgery (i.e., first year postoperative, 1 year to 2 years postoperative and 2 years to 3 years postoperative). The annual total medication cost was defined as the total cost of antidiabetic medication to the insurer which included the ingredient cost, sales tax and dispensing fee. The annual average cost was defined as the average cost of medication per patient to the insurer which included the ingredient cost, sales tax and dispensing fee.

IV. Statistical Analysis

Descriptive statistics of our cohort was reported using STATA 15. The number of patients taking any antidiabetic medication and the summary statistics of the number of medications were determined at different preoperative and postoperative time points. Average annual cost of antidiabetic medication per person in this population was compared between time periods before surgery and after surgery. Postoperative costs were compared to preoperative cost and the difference and percentage change were calculated. To determine the effect of baseline

patient characteristics and comorbidities such as age categories, sex, BMI, hypertension status, sleep apnea status, hyperlipidemia status, length of hospital stay, CCI and number of medications patients were taking at the time of surgery on the odds of discontinuation of medication, univariate and multivariate logistic regression models were performed. Using a two-sample t test, differences in mean annual medication cost by comorbidities was determined at different time periods. Differences in mean annual medication cost by bariatric procedures were determined using a one-way ANOVA with the Scheffé option which contrast all procedures at the same time.

V. Results

Patient Characteristics

As shown in Table 1, 14,832 patients met the study eligibility criteria at the time of surgery. Of these, 7,265 (49%) patients underwent VSG, 6,905(46.5%) patients underwent RYGB, 488(3.3%) patients underwent LADB and 174(1.2%) underwent BPD/DS. The average age of patients in our study was 49.9(+/-9.0) years. There were more females (65.1%) than males (34.9%) in the cohort. Majority of patients had a clinical diagnosis of hypertension (66.5%). Hyperlipidemia was present in 39.1% of the patient's while sleep apnea was present in 40.9% of the patients in the cohort. On an average, patients were taking 1.7 (+/-0.9) antidiabetic medications at the time of surgery. Majority of patients (85.5%) had a CCI score of 0 or 1 with 14.5% of patients having a CCI score of 2 or more. The median length of hospital stay was 2 days. The median observation days per person in the cohort was 1637 days.

Table 1: Baseline Characteristics of 14,832 Diabetic Bariatric Patients

Baseline Characteristics	Data
Mean Age, years(+/- SD)	49.9(+/-9.0)
Sex, n (%)	
Females	9,655 (65.1%)
Males	5,177 (34.9%)
Type of Operation, n (%)	
Vertical sleeve gastrectomy	7,265 (49.0%)
Roux-en Y gastric bypass	6,905 (46.5%)
Laparoscopic Banding	488 (3.3%)
BPD with Duodenal switch	174 (1.2%)
Obesity, n(%)	
Yes	14,756 (99.5%)
No	76 (0.5%)
Hypertension, n(%)	
Yes	9,863 (66.5%)
No	4,969 (33.5%)
Sleep Apnea, n(%)	
Yes	6,071 (40.9%)
No	8,761 (59.1%)
Hyperlipidemia, n(%)	
Yes	5,796 (39.1%)
No	9,036 (60.9%)
Mean No. antidiabetic Meds at Surgery, n(+/-SD)	1.7 (+/- 0.9)
Number of Medications at Surgery, n (%)	
1	7,845 (52.9%)
2	4,422(29.8%)
3	1,987 (13.4%)
4	491 (3.3%)
5	87 (0.6)
Charlson Comorbidity Index Score, n (%)	
0	3,520 (25.3%)
1	8,382(60.2%)
>/=2	2,014(14.5%)
Median observation days per person, n	1,637
Median length of hospital stay days, n	2.0

Acronyms: BPD: Biliopancreatic diversion, SD: standard deviation, n: number, >: greater than, =: equal to, %:percentage

Diabetes Medication Usage Before Surgery

As shown in Table 2, 3 years prior to surgery, 3,651(61.2%) of patients in the cohort (5,966) had a clinical diagnosis of Type 2 diabetes and were taking at least 1 diabetic medication with an average of 1.9 (+/-1.0) medications per patient. There was a progressive increase in the percentage of patients taking at least 1 diabetic medication and the average number of medications patients were taking at 2 years (69.2%, 2.0), 1 year (77.5%,2.0), 6 months (84.4%,1.6) and 3 months (91.9%,1.9) prior to surgery. At the time of surgery, all patients in our cohort (14,832) were taking at least 1 diabetic medication with an average of 1.7 medications per patients.

Table 2: Diabetes Medication Usage before Surgery

Time Points	-3 years	-2 years	-1 year	- 6 months	-3 months	At time of Surgery
No. of Patients in cohort	5,966	8,650	12,193	14,832	14,832	14,832
No. of Patients on any Medication	3,651(61.2%)	5,989(69.2%)	9,452(77.5%)	12,517(84.4%)	13,636(91.9%)	14,832(100%)
Mean No. of Medications	1.9 +/- 1.0	2.0 +/-1.0	2.0 +/-1.0	2.0 +/-1.0	2.0 +/- 1.0	1.7 +/- 0.9

Diabetes Medication Usage After Surgery

As shown in Table 3, at 3 months post-surgery, 7,756 (59.5%) of patients in our cohort had discontinuation of diabetes medications with 5,280 patients (40.5%) of patients in the cohort taking at least 1 diabetes medication at an average of 1.4 medications per patient. The percentage of patients with taking at least one medication post-surgery decreased to 32.1% ,29.1% and 30.2% at 6 months, 1 year and 2 years respectively. At 3 years post-surgery, follow-up data was available in 3,614 patients with complete discontinuation of diabetes medication in 2,383 (65.9%) of patients. However, 1231 (34.1%) of patients were still taking at least 1 diabetes medication at 1.6 medications per patient.

Table 3: Diabetes Medication Usage after Surgery

Time Points	At time of surgery	+3 months	+6 months	+1 year	+2 years	+3 years
No. of Patients in cohort	14,832	13,036	11,533	9,384	5,955	3,614
No. Discontinued Medication		7,756(59.5%)	7,829(67.9%)	6,656(70.9%)	4,155(69.8%)	2,383(65.9%)
No. on Any Medication	14,832(100%)	5,280(40.5%)	3,704(32.1%)	2,728(29.1%)	1,800(30.2%)	1,231(34.1%)
Mean No. of Medications	1.7 +/- 0.9	1.4 +/- 0.6	1.4 +/-0.6	1.4 +/- 0.6	1.5 +/- 0.7	1.6 +/- 0.8

Annual Medication Cost

As shown in Table 4 below, the total annual cost of medication among 5,966 patients present in our cohort between 3 years and 2 years prior to surgery was $557,362 at an average cost of $97.8 per patient. The total annual cost increased to $1,144,395 among 8,650 patients between 2 years and 1 year prior to surgery at an average of $132.30. Within the year prior to surgery, total medication cost to the insurer was $2,196,134 among 12,193 patients at an average of $177.90. Within the first-year post-surgery, the total annual medication cost was $715,999 among 9,384 patients at an average of $76.30. Compared to the immediate year prior to surgery, this was a reduction in average annual medication cost per person (57%) totaling an annual savings of $1,453,135 at $154 per patient to the insurer. Within the second post-surgery year, the total annual medication cost was $349,558 among 5,955 patients at an average of $58.70. The annual savings among these patients was $1,819,576 (84.0%) at $305.5 per patient when compared to the immediate year prior surgery. As reflected in Table 5 below, there is a statistically significant difference in the average annual medication cost per patient before and after surgery at the different time periods studied.

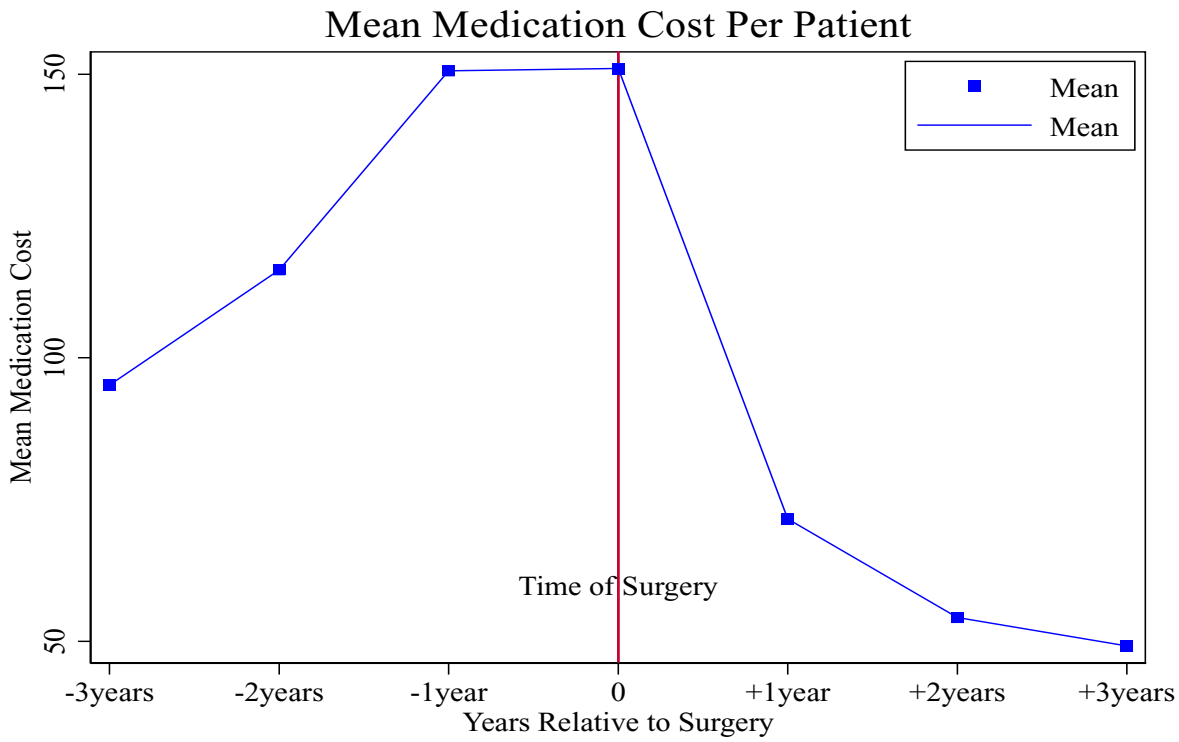
Table 4: Average Annual Medication Cost Per Patient Before and After Surgery

Time Periods	No. of Patients in Cohort	Total Annual Medication Cost	Mean Medication Cost
Before Surgery			
-3years to -2 years	5,966	$557,362.2	$97.8
-2years to -1 year	8,650	$1,144,395	$132.3
-1 year to Surgery	12,193	$2,169,134.7	$177.9
After Surgery			
First year post-surgery	9,384	$715,999	$76.3
+1 year to +2 years	5,955	$349,558.5	$58.7
+2 years to +3 years	3,614	$214,310.2	$59.3

Table 5: Average Annual Medication Cost Per Patient Before and After Surgery

After Surgery	2 years to 3 years	1 year to 2 years	Surgery to 1 year
Number of Patients	3,614	5,955	9,384
Average, ($)	59.3	58.7	76.3
Total,($)	214,310.20	349,558.50	715,999.20
Before Surgery	3 years to 2 years	2 years to 1 year	1 year to Surgery
Number of Patients, n	5,966	8,650	12,193
Average, ($)	97.8	132.3	177.9
Total, ($)	557,362.20	1,144,395	2,169,134.70
Difference			
Average, ($)	-38.5	-73.6	-101.6
Total,($)	-343,052	-794836.5	-1,453,135.5
p vlaue	0.03	<0.001	<0.001

Figure 1: Mean Medication Cost Per Patient



Medication Cost by Comorbidity and Bariatric Procedure

There was no statistically significant difference in the average medication cost by the presence or absence of comorbidities such as hypertension, sleep apnea and hyperlipidemia within the first, second and third year post-surgery as reflected in Table 6. Within the first post-surgery year, the average cost of diabetes medication was similar among the various bariatric procedures. However, the average cost in patients who underwent RYGB was lower than those who underwent VSG within the second post-surgery year (p=0.021) and third post-surgery year (p=0.042).

Predictors of medication discontinuation

After adjusting for risk factors, older age group >54 years, female sex, presence of hyperlipidemia, higher Charlson Comorbidity Index score were associated with lower odds of medication discontinuation as reflected in Table 6. There was a decreasing trend in the odds of discontinuation with increasing number of diabetes medications at the time of surgery. BPD/DS and RYGB was associated with a higher odds of medication discontinuation compared with VSG. AGB was associated with a lower odds of discontinuation compared to VSG.

Table 6: Risk factors for discontinuation of diabetes medication after surgery

Risk factors	Univariate			Multivariate		
	OR	95% CI	P value	OR	95% CI	P value
Bariatric Procedure						
VSG		Reference			Reference	
RYGB	1.44	1.25 - 1.66	<0.001	1.60	1.38 - 1.86	<0.001
AGB	0.54	0.38 - 0.75	<0.001	0.61	0.43 - 0.86	0.005
BPD/DS	2.75	1.03 - 7.27	0.042	3.31	1.19 - 9.15	0.021
Sex						
Male		Reference			Reference	
Female	0.95	0.82 - 1.10	0.478	0.80	0.68 - 0.93	0.003
Age groups						
<35 years		Reference			Reference	
35-44 years	0.95	0.66 - 1.38	0.807	1.03	0.71 - 1.52	0.845
45-54 years	0.76	0.53 - 1.07	0.120	0.90	0.63 - 1.30	0.579
55-65 years	0.48	0.34 - 0.68	<0.001	0.59	0.41 - 0.85	0.005
Hyperlipidemia						
No		Reference			Reference	
Yes	0.75	0.65 - 0.87	<0.001	0.83	0.71 - 0.98	0.030
Hypertension						
No		Reference			Reference	
Yes	0.78	0.67 - 0.89	<0.001	0.86	0.74 - 1.01	0.052
Sleep Apnea						
No		Reference			Reference	
Yes	0.91	0.78 - 1.05	0.196			
GERD						
No		Reference			Reference	
Yes	0.82	0.69 – 0.97	0.019			
Meds. At Surgery						
1		Reference			Reference	
2	0.47	0.40 - 0.56	<0.001	0.46	0.39 - 0.54	<0.001
3	0.30	0.25 - 0.37	<0.001	0.29	0.24 - 0.36	<0.001
4	0.23	0.16 - 0.34	<0.001	0.23	0.16 - 0.34	<0.001
5	0.12	0.05 - 0.30	<0.001	0.19	0.05 - 0.29	<0.001
Charlson Comorbidity Index						
1		Reference			Reference	
>/=2	0.73	0.61 - 0.88	0.001	0.77	0.63 - 0.94	0.013

OR: odds ratio, CI: confidence intervals, p value<0.005: statistically significant difference, n: number of patients, <:less than, >: greater than, = : equal to; meds =medications, RYGB: roux-en y gastric bypass, VSG: vertical sleeve gastrectomy, AGB: adjustable gastric banding, BPD/DS: biliopancreatic diversion with duodenal switch. GERD: gastroesophageal reflux disease

VI. Discussion

Our findings reinforce existing literature on the impact of bariatric surgery on major comorbidities. The observed decrease in pharmacy claims associated with Type 2 diabetes suggests that the pre-surgery condition resulted from patients' excess weight and is alleviated by bariatric surgery for at least 3 years. The parallel and persistent decreases in disease prevalence and related medication use and costs as early as 3 months after surgery have important medical implications and demonstrate the immediate benefits of bariatric surgery on health status. Interestingly, there was no statistically significant difference in the average medication cost by the presence or absence of comorbidities such as hypertension, sleep apnea and hyperlipidemia within the first, second and third year post surgery. The metabolic changes that occur early after bariatric surgery may be playing an important role in reducing needs for medication. Reduction in diabetes medications is likely not due to weight loss alone but may be mediated by gastric hormones;[9] t three most implicated being peptide YY, glucagon-like peptide (GLP-1), and pancreatic polypeptide. GLP-1, a known mediator of insulin regulation, increases immediately following bariatric surgery, which may explain the very rapid resolution of diabetes.[10] The resolution of diabetes may also be a consequence of the forced, substantial reduction in caloric intake due to the restrictions of the surgical procedures. A recent study of bariatric surgery that used Blue Cross Blue Shield data found reductions in comorbid conditions after surgery comparable to what we observed.[7] Our observations complement this study and advance their observations with respect to time period in that we examined with diabetes medications at different time intervals up until 3 years after surgery. We cannot conclude definitively that bariatric surgery eliminates diabetes; however, we hope that the decreased use of these

medications is due to resolution of these conditions, rather than physician and patient non-adherence to treatment recommendations.

VII. Strengths and Limitations

The study has its strengths. Pharmacy and medical claims data offer the unique power of very large samples with detailed longitudinal histories that allows us to follow patients to study use patterns, outcomes, and costs of care and how they change over time, but demand a careful and sophisticated approach to measurement and interpretation. With the use of pharmacy claims, we were less likely to miss comorbid conditions that were under coded at the time of visits. The study also provides expenditure information from a payer's perspective, which constitutes about 82% of total retail prescription drug costs. Using claims data brings a different perspective to existing literature on this topic by studying health plan's coverage decisions and drug utilization management while medical record data reflects clinicians' decisions and practice patterns.

This study has several limitations. The patients studied are covered by commercial health care plans, therefore the conclusions may not be generalizable to other payor categories like Medicare and Medicaid patients, uninsured patients, patients with limited coverage, or patients in other health care plans. However, we believe that the patients studied are a reasonable sample of patients undergoing bariatric surgery in the United States at present. A major limitation is lack of use of a comparison group. One study by Segal et al, used a comparison group (matched enrollees without surgery but with a propensity score suggesting obesity) to strengthens the evidence that the changes observed were causally related to the surgery rather than to secular changes or due

to how pharmacy claims were recorded or our method for counting medications.[7] Although we had good longitudinal data that are comprehensive during enrollment, limited variables without missing information were available. For example, we do not know the impact of bariatric surgery stratified by body mass index. In addition, owing to the high turnover that is characteristic of health insurance coverage in the United States, 3-year follow-up data were available for a limited number of patients. Nonetheless, the results for these patients were consistent with the trend observed 1, 2 and 3 years after surgery for the larger cohort.

The use of pharmacy claims data has its inherent challenges, like fulfillment of a prescription at the pharmacy does not ensure that the patient used the drug, and samples given by the physician do not appear in the claims data. Some patients may have had more than one health insurance provider and filled one or more prescriptions using other or no insurance. For patients who fill prescriptions but do not use the medications as prescribed, pharmacy claims metrics will overstate the true adherence to treatment. If patients fill prescriptions outside of the plan or use samples, adherence estimates will be lower than actual use. Possession of prescription drugs are generally a necessary, but not a sufficient, condition for use/adherence; the duration of a prescription supply is also a source of potential inaccuracy when estimating adherence. For this analysis, however, filling the medication should be an adequate proxy for use of the medication because our primary interest is not a physiological measure but is the change in medication use over time. There are studies that have utilized fasting plasma glucose concentration and HbA1c as a measure of presence of Type 2 Diabetes. These enrollees were all privately insured patients, and we cannot conclude that the same changes in medication utilization would be observed in patients with coverage from Medicaid or Medicare. Furthermore, we have no reason to believe

that switching insurance (i.e., being unavailable for follow-up in this analysis) would be associated with an enrollee being more likely to have a better or worse outcome than someone who maintained continuous insurance coverage. As in other studies, the patient population who underwent bariatric surgery is over 65% women, limiting the applicability of our findings to men. Furthermore, our data did not include race to study effect of bariatric surgery on medication use across racial groups. However, given the small fraction of patients taking only metformin, this group, if underappreciated, would not influence our results significantly. Finally, we used the assumption that most patients undergoing bariatric surgery lose weight because this effect has been clinically validated. However, it is possible that patients who did not have resolution of obesity did have an improvement in their diabetes owing to caloric restriction.

VIII. Public Health Implications

Current trends in rates of obesity and diabetes threaten to overwhelm the already strained health care resources in many countries. Diabetes is but one of several health consequences of the escalating global obesity epidemic, with heart disease, hypertension, hyperlipidemia, degenerative joint disease, and decreased activity further compounding the complications and disability associated with diabetes. Thus, the obesity epidemic has created a deferred influx of demand for diabetes-related health care services not yet realized. Until a successful nonsurgical means for preventing and reversing obesity is developed, bariatric surgery appears to be the only intervention that can result in a sustained reversal of both obesity and type 2 diabetes mellitus in most patients receiving it. Increased health care costs in the United States have been partly attributed to the growing prevalence of diabetes and obesity.[12] This cost is seen in

direct medical costs, in the indirect costs of decreased productivity and disability, and in the costs of obesity and diabetes related complications such as renal failure, gestational diabetes, and cardiac disease. Thus, the current study has implications not only for disease management but also for public health and health care policy.

Bariatric surgery is effective for decreasing the use of medications for obesity-related diabetes and has great potential to improve the value of care for obese patients. Results from this study can inform decisions about bariatric surgery and should be included in discussions with patients making decisions about bariatric surgery. Our results should be motivating to physicians caring for patients with these lethal, obesity-associated illnesses. Additionally, the possibility of eliminating medications and the resulting cost reductions and reduction in risks associated with medications maybe highly valued by patients.

We have identified several important implications for health care delivery and public policy. Foremost, eligible obese patients should be properly informed of the risks and benefits of bariatric surgery compared with nonsurgical health management. Health care providers should consider discussing bariatric surgery in the treatment of obese patients with type 2 diabetes. Currently, there is lack on consistency in insurance coverage of bariatric surgery. Health insurers, private and public, should enhance access to bariatric surgery for appropriate candidates, recognizing a potential annualized cost savings in addition to the benefit to health. Bariatric surgery centers should be supported in providing excellence in outcomes through regular means of standardization and quality improvement.

Coverage of bariatric surgery should be available to all obese patients who meet criteria, regardless of their degree of coverage, provided the patient possesses the appropriate degree of personal health responsibility and access to a physician in the event of a surgical complication. Medicaid patients currently do not have equal and uniform access to bariatric surgery. In most states, enrollees are not given the certainty of coverage they need to proceed with such a potentially expensive endeavor. This disparity results in some obese patients with diabetes having limited access to the procedure and, as a result, suboptimal management of diabetes in some cases.

Although Medicaid expansion was associated with an increase in the volume and rate of bariatric surgery, it accounts for removal of only one barrier faced by patients in accessing bariatric surgery. Additional policy changes and clinical programs may be necessary to address barriers disproportionately faced by racial and ethnic minority populations to ensure more equitable access to evidence-based treatment of obesity. Future research may help elucidate the role of bariatric surgery in general medical care by studying its effect on common operations, maternal and neonatal outcomes, and long-term health outcomes. Ultimately, bariatric surgery—or a future less-invasive variant—could play a key role in the management of common medical conditions such as heart disease and diabetes-related organ failure.

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SUPPLEMENTARY TABLE S3: ICD; INTERNATIONAL CLASSIFICATION OF DISEASES, CPT; CURRENT PROCEDURAL TERMINOLOGY USED FOR DATA ANALYSIS

CHARACTERISTICS/RISK FACTOR	ICD-9	ICD-10	CPT
SLEEVE GASTRECTOMY	4389 4382	0DB64Z3 0DB60ZZ 0DB63ZZ 0DB67ZZ	43775
ROUX-EN Y GASTRIC BYPASS	4431 4439	0D16079 0D1607A 0D160J9 0D160JA 0D168Z9 0D168ZA	43846 43847
	4438	0D1607A 0D160JA 0D160KA 0D160ZA 0D1687A 0D168JA 0D160Z9 0D160ZA 0D16879 0D1687A 0D168ZA 0D168J9 0D160K9 0D160KA 0D168K9 0D168KA 0D168JA 0D168KA 0D164ZA 0D16479 0D1647A 0D164J9 0D164JA 0D164K9 0D164KA 0D164Z9 0D164ZA	43645
OBESITY	27802 2780 27801 27800 2788 2781	E66	
BMI		V8530 V8534 V8535 V8539 V8541 V8542 V8543 V8544 V8545	
HYPERTENSION	401	I10	
DIABETES MELLITUS	25000 25002	E11	
SLEEP APNEA	327 780	G47	
HYPERLIPIDEMIA	2720 2721 2722 2723 2724	E78	
ENDOCRINOPATHIES	2599 2598 7964	E34	
HEART FAILURE	4282 4283 4284 4289 4280 4281	I50	
RENAL FAILURE	5851 5859	I12	
PEPTIC ULCER	531 533	Z871	
CANCERS	150 151 152 157 199	C15 C16 C49A	

CHAPTER 5: DISCUSSION

I. Synthesis of Key Findings

For the first manuscript of this dissertation, a literature review was conducted to synthesize the findings to date on ERAS in obesity surgery compared with traditional perioperative care patients undergoing bariatric surgery. A total of 16 studies were selected that met the inclusion criteria. All of them showed significant improvement in length of stay and operative time. There were three studies measuring median cost of patient stay and all of them showed significant improvement in hospital median cost. Only a few studies showed improvement in 30-day complications and readmissions. In conclusion, implementation of ERAS protocols is superior in terms of operative time, complications, LOS, cost and in some instances, intraoperative medication use, morbidity rates and readmission rates. ERAS protocols appear safe and effective for use in bariatric surgery and are associated with improved perioperative outcomes without any compromise in patient's long-term safety.

The purpose of the second manuscript was to compare the perioperative outcomes in bariatric surgery before and after implementation of a homogenous ERAS protocol at a single institution bariatric program. The combination of the increasing demand of bariatric procedures worldwide and the specific perioperative difficulties and risks for this particular population makes this type of surgery highly eligible for ERAS protocols.[11] Implementation of evidenced-based interventions and standardization of bariatric care can increase efficiency and cost-effectiveness in these procedures, without the loss of safety. The results of this study strongly support the existence of an association between implementation of bariatric surgery ERAS protocol and desired outcomes

benefiting both patients and hospital systems. From a practice perspective, as the prevalence of obesity continues to increase, the requirement for a higher volume of bariatric procedures becomes imperative, and as such, implementation of standardized ERAS pathways also becomes essential. The use of ERAS guidelines should be encouraged as a standard of care in bariatric surgery programs.

In the third manuscript, my goal was to understand drug utilization and cost outcomes in patients with type 2 diabetes after bariatric surgery given that one-third of all patients undergoing bariatric surgery have type 2 diabetes. We explored this by assessing the change in use and cost of medications to treat diabetes mellitus in the three years following surgery. The observed decrease in pharmacy claims associated with Type 2 diabetes suggests that the pre-surgery condition resulted from patients' excess weight and is alleviated by bariatric surgery for up to at least 3 years. There was no statistically significant difference in the average medication cost by the presence or absence of comorbidities such as hypertension, sleep apnea and hyperlipidemia within the first, second and third year post surgery. Considering the relatively narrow scope of my study, further research is needed on effectiveness of bariatric surgery in patients with different insurance types and different socioeconomic backgrounds. This study's results can be used to encourage physicians to include such information in discussions with patients and their families making decisions about bariatric surgery. Physicians caring for patients with these lethal, obesity associated illnesses may feel encouraged by our study results. An additional value proposition for the patients is the possibility of eliminating medications and the resulting cost reductions, and reduction in risks associated with medications.

II. Policy and Practice Implications

The reasons for underutilization of bariatric surgery are multifactorial:

1. Financial: health insurance coverage, out of pocket costs
2. Social: social status and support, misunderstanding, social stigma, and bias about obesity
3. Provider driven: Limited knowledge, lack of communication

As context, in 2006, less than 0.4% of the over 22 million Americans eligible for bariatric surgery received an operation.[7] A rough analytic estimation shows that, with roughly 22 million obese Americans, it would take 5500 bariatric surgeons doing 400 cases a year each for 10 years to attempt to surgically treat every obese American. These numbers are not achievable with the country's current surgical capacity, health care resources, current access, and insurance coverage and with the limited patient and referring physician knowledge on effectiveness.

The obesity epidemic can potentially be reversed by two approaches- supporting *long-term* concerted policy efforts at the local, state, and national levels including gradual infrastructure change and incentives designed to encourage healthy commuting, reformation and regulation of our nation's food supply, education, and continued research into novel, nonsurgical treatments for obesity. In addition, supporting efforts with more *immediate* impact like improving awareness, overcoming the social stigma, access and insurance coverage of bariatric surgery and health system capacity to manage the increased demand. Bariatric surgery offers great potential to improve the value of care for obese patients.

Policy implications of this study

- *Access and insurance coverage:* Potentially reconsider insurance-mandated precertification requirements to enhance access. The study is expected to influence policy makers, payers, health systems and employers to expand coverage for bariatric surgery as an essential health benefit with minimal out of pocket costs and preoperative requirements in an effort to decelerate the obesity epidemic.

- *Redesign insurance coverage for bariatric surgery:* Influence payers to redesign health coverage for bariatric surgery where they would achieve higher return on investment if the utilization of bariatric surgery increases among patients with BMI≥ 40 kg/m2 and T2D. Encourage employers to incorporate bariatric surgery into their self-administered benefit plans via utilizing value-based insurance design (VBID)

Practical implications of this study

- *Workforce supply and health system capacity:* Encourage policy makers to research and address the shortage in bariatric surgeons to help ensure that the sickest patients in our health care system — adults with class II or III obesity — are treated like any other patient with a chronic disease, with full access to the most effective, evidence-based treatments available.

- *Public and Referring Physician Education and Awareness*: Improve efforts to educate both the public and health professionals about obesity and bariatric surgery. The best weapons

we have against the misconceptions and bias are existing data and literature. Familiarize referring physicians, primary care providers, and other specialists with national obesity guidelines and the key clinical evidence demonstrating the safety and effectiveness of bariatric surgery.

Policy Implications

From a patient perspective, influence policy makers, payers and employers to redesign coverage for bariatric surgery as an essential health benefit with minimal out of pocket costs and preoperative requirements via optimal health insurance benefit design in an effort to decelerate the obesity epidemic. We are now at a crossroads of two intersecting public health crises, with catastrophic potential: the widening obesity epidemic and the system-wide inequalities in access to affordable, high-quality healthcare.

In 2009, the Centers for Medicare & Medicaid Services officially announced it would cover bariatric surgery for beneficiaries with morbid obesity and type 2 diabetes. The 2014 Affordable Care Act (ACA) state-level Medicaid expansions have been associated with substantial reductions in the uninsured population. To date, evidence of changes in bariatric surgery following Medicaid expansion is limited to 1 study that showed that, during 2014-2015, surgical volume increased in 2 expansion states (Kentucky and Maryland) 10.7% more than in 2 comparison states (Florida and North Carolina).[12]

While bariatric surgery can be beneficial, it is an expensive intervention costing anywhere between $15,000 to $25,000 in the first year.[1] Individual payers who have been reluctant to adopt widespread coverage of the procedure,[2] undoubtedly share the cost concerns of this

expensive procedure. The payer perspective is important because the majority of the costs occur in the first year after surgery, whereas the benefits occur over the patient's lifetime. For those with bariatric surgery insurance benefits, a multidisciplinary medical assessment may be initiated to determine medical candidacy according to evidence-based guidelines. However, even when medical providers determine bariatric surgery is indicated, sometimes the complexities of the insurance approval process delays or restricts access.[21] Since insurance companies are able to determine and use their own definitions of "medical necessity" to either deny or approve bariatric claims, approval criteria are often more stringent than those applied by a multidisciplinary bariatric team.[21] For instance, many insurance companies require documentation of a period of intensive "assisted" weight loss by either a nutritionist, health care professional, or a dietician. Many of these "hurdles" continue despite studies showing they do not positively alter postoperative outcomes or compliance, and are associated with a 50 per cent increase in drop out.[22]

Although uninsured patients form 16% of the people who are eligible for bariatric surgery, they account for only 0.3% of surgery recipients.[7] Besides a lack of health insurance and stringent insurance policy requirements as described above, underuse of bariatric surgery has been associated with referral hesitation among primary care clinicians, patient preference for nonsurgical options and rigid treatment protocols.[8-11]

As mentioned above, there could be social, economic or weight bias that contributes to underutilization as well. The limited scope of my study is expected to enhance access to bariatric surgery but it is only one aspect of the challenge. Further research is needed on the barriers

disproportionately faced by racial and ethnic minority populations to ensure more equitable access to evidence-based treatment of obesity.

As we know, private insurance coverage of bariatric surgery varies widely. Bariatric surgery coverage is determined as an "essential health benefit" in 23 of 50 states,[13] and the essential health benefit (EHB) policy applies only to insurance plans in the Affordable Care Act's (ACA) individual and small group marketplaces—not to employer-sponsored insurance, which represents the majority of bariatric surgery patients. However, study by Dimick et al, showed utilization of bariatric surgery increased in all states after ACA implementation, and the increase was no greater in states with a bariatric surgery EHB.[10] Chhabra and Dimick's 2019 study introduced the concept of value-based insurance design (VBID) to the bariatric surgery community. VBID decreases patients' out-of-pocket burden for high-value care and increases their out-of-pocket payments for low-value services (e.g., unnecessary imaging or procedures). VBID approach to bariatric surgery would not only cover weight loss operations, but encourage their utilization by those targeted patient groups.[14]

Much of the progress toward VBID has actually been through innovative insurance benefit design on the part of employers seeking to improve employee health and well-being.[14] The authors, Drs. Chhabra and Dimick, tell the story of MGM Resorts International, which in 2010 began reimbursing patients' out-of-pocket payments if they met weight loss targets 2 years after bariatric surgery.[22] Gasoyan et al.[16] proposed a clinically nuanced insurance benefit design for bariatric surgery, tailoring it toward those most likely to see dramatic benefit—for instance, employees with BMI ≥40 and type 2 diabetes. They also suggest using VBID to steer patients toward high-quality, low-cost providers at bariatric surgery centers of excellence by reducing

cost-sharing for high-performing surgeons and centers.[16] Further research could help evaluate the health and economic implications of applying value-based insurance design to bariatric surgery coverage.

A business case for providing bariatric surgery coverage for employees could be argued because an association has been shown between bariatric surgery and a decrease in lost workdays.[23] Payors would achieve higher return on investment if the utilization of bariatric surgery increases among these subgroups of bariatric surgery eligible patients (BMI ≥40 and T2D); such a result could be achieved via optimal health insurance benefit design.[16]

We should ensure that our own hospitals' and health systems' employee health benefits include value-based coverage of bariatric surgery and campaign for value-based designs that limit out-of-pocket cost barriers. For instance, the Cleveland Clinic's employee health plan recently lowered its BMI threshold for bariatric surgery for diabetic patients from 35 to 30.[17] This reflected their confidence in the efficacy of bariatric surgery for diabetes remission, as well as the safety of bariatric operations.[17] In fact, the American Society for Metabolic and Bariatric Surgery's most recent position statement on bariatric surgery in class I obesity (BMI 30–35) strongly recommends considering bariatric surgery in these patients in light of emerging high-quality evidence—though insurance coverage has not kept pace with the data.[18]

We can start with our own healthcare system and collaborate with them to show the positive returns of bariatric surgery and advocate for a value based insurance that expands access to bariatric surgery to our employees. On the public insurance front, it is time to implement universal guidelines for bariatric benefits. Increasing coverage for bariatric surgery without any

preoperative requirements or mandates, which will require convincing payers that bariatric surgery for obesity is at least cost effective, if not cost-saving, in the short term.

Studies have shown success with bundled payments for surgical procedures with copay waivers that create cost savings.[26] Bundled payments are gaining popularity in the Medicare system, but have not been adopted as widely by private insurance plans. As a strategy to reduce costs for complicated procedures, health care payers have been turning to bundled payments where doctors, hospitals and other health providers share one fee for treating all aspects of a procedure.[26] The approach is intended to encourage health providers to work together to eliminate unnecessary care and improve quality. In a recent study on bundled payment program by Whaley et al, episode prices for three selected surgical procedures declined by $4,229, a 10.7 percent relative reduction.[26]

Additionally, findings a recent study shows an association between weight loss achieved with surgery, and improved outcomes of COVID-19 infection, suggesting that obesity can be a modifiable risk factor for the severity of COVID-19 infection.[25]

Practical Implications

Limited patient and referring physician knowledge regarding the effectiveness and safety of bariatric surgery are key barriers to bariatric surgery utilization.[16] Most primary care and subspecialist physicians do not discuss bariatric surgery as a treatment option, although the majority indicates a positive attitude toward bariatric surgery.[16]

This dissertation delivers strong evidence on the effectiveness of bariatric surgery in utilization and cost of diabetes medications that will assist to strengthen the case for bariatric surgery, for patients, referring physicians and policy makers. We know misconceptions and bias persists. Clinicians can identify and address their own implicit biases toward underrepresented sociodemographic patient populations. Individual practices can work to equalize access to bariatric care for sociodemographic minorities by reconsidering insurance options they accept. The best weapons we have against that are existing data and literature, like Manuscript 3. Familiarize local surgeons, gynecologists, primary care providers, and other specialists with national obesity guidelines and the key clinical evidence demonstrating the safety and effectiveness of bariatric surgery. Share data on specific bariatric programs, experience of multidisciplinary team, and specific patient outcomes. Surgeons must improve educational efforts with other health care providers. The third manuscript of the dissertation delivers strong evidence that bariatric surgery is effective in reducing diabetes medication use and costs after bariatric surgery. Patients and referring physicians should consider the clinical and economic benefits of reduced medication requirements and costs when making decisions about bariatric surgery. The long-term success of bariatric surgery should also be communicated. Bariatric surgery patients surveyed 10 years out from operation have enhanced health perceptions, social interactions, psychosocial functioning, and less depression.[20]

Another practical limitation to providing bariatric surgery to those who would benefit is the imbalance between workforce supply, health system capacity, and patient demand. No doubt strategies to prevent obesity or achieve weight maintenance should become a priority to avert the future burden to the health system. Nonetheless, health services have an important role to

play in prevention efforts in so far as many individuals with overweight or obesity come into contact with health services regularly. To support the future growth of bariatric surgery as obesity trends continue, we need to consider the growth of the workforce and health system capacity. Quantification of the bariatric surgeon shortage is challenging since bariatric surgery is not an accredited surgical subspecialty. However, it is known that most bariatric surgeons are general surgeons,[3] and it is clear that there is a general surgery crisis with anticipated deficits of at least 1,875 surgeons by 2020.[4] Shortages in the number of general surgeons will undoubtedly translate into shortages of bariatric surgeons. In addition to the limited surgeon supply, there is already a high demand for bariatric surgeries,[5] which will likely grow as more populations are exposed to benefits of bariatric surgery. Presently, the bariatric surgeon workforce increases by roughly 2% annually, which is appropriate for current utilization rates.[6]

The next decade of research will need to identify interventions that improve obesity treatment education for both patients and providers and create health system solutions that support referral and provision of bariatric surgery.[19]

The global pandemic interrupted daily healthcare around the world. Surgeries, like bariatric procedures, were some of the first appointments to halt as operating rooms began to double as intensive care units for the patients needing ventilator support for COVID-19 pulmonary failure. This change in everyday practice has led to a fast-growing surgical backlog where ERAS can help healthcare professionals implement the best standard of care across hospitals to improve outcomes for surgical patients, minimize the use of hospital resources and save cost.

The literature review from Manuscript 1 suggests that ERAS protocols appear safe and effective for use in bariatric surgery and are associated with improved perioperative outcomes without any compromise in patient's long-term safety. Additionally, Manuscript 2 adds to the literature on the positive impact of the ERAS protocols in improving capacity at reduced costs. This will help inform payers and policy makers to incentivize health systems to adopt ERAS that fulfills the recently described Quadruple Aim: achieving better patient outcomes, at lower cost, with improved patient, medical, nursing, and provider satisfaction.[23] The real question to ask would be: what does a hospital lose by not applying ERAS? Investments in robotic surgery are made at a cost 20 times higher than investment in ERAS. Lastly, during this time of global crisis, clinicians who provide perioperative care must unite and make the changes that will bring further enhancements for patients and health systems. This is an opportunity to reinvent the entire patient experience while optimizing care standards and procedures to help increase cost savings. ERAS makes it easy to keep track of patients and streamline their treatment to not only give them the best, most positive outcome possible, but also to improve the efficiency of those treating them. COVID-19 has presented the opportunity for transformative change as the healthcare industry braces for the future. ERAS makes that evolution simple for patients and care providers alike.

I will note that additional research is warranted on barriers to ERAS implementation for bariatric surgery at health systems across the country and the potential effect of national bed capacity if ERAS was applied to all bariatric surgery patients.

III. Future direction

Advocacy and Public Policy

It is important for all of us to challenge people and organizations around the barriers to care and help them understand whether their views or policies are based on bias or misinformation or on scientific evidence. The American Society for Metabolic and Bariatric Surgery (ASMBS), medical societies, advocacy organizations, referring physician groups, surgeons and industry leaders should lead the efforts to shape federal, state, and local government policies; promote the approval of safe and effective treatment options; improve funding for obesity research; expand patient access; and fight stigma .[24] This may help change payers' perceptions about obesity care. We also must stop the spread of stigma and counter inaccurate and hurtful portrayals of obesity and its treatment with greater humanity, sensitivity, and evidence-based communication. A study in 2016 by Raves and colleagues on weight related stigma and post-surgical dietary adherence shows that internalized stigma and general experiences of weight-related stigma predicts worse dietary adherence, even after weight is lost.[27] They concluded that reducing perceptions of weight-related stigma in healthcare settings and weight bias internalization could enhance dietary adherence, regardless of time since patient's weight-loss surgery.[27]

A Call for a National Obesity Strategy and a Patient Bill of Rights

Being a risk factor for many non-communicable diseases, a national obesity strategy will help provide structure and momentum for the much needed evolution in its perception and treatment. We as a nation must change our thinking about obesity and begin to remove the

policy, social, medical, discriminatory, economic, and perceptual barriers that deny people appropriate treatment and support. Doing the same things to fight a losing war against the obesity epidemic will not yield a different result.[24]

We need a national obesity strategy that encompasses both prevention and treatment. In addition, there is need to create a patient bill of rights that would ensure access to care is not limited by a person's size, weight, or economic status.[24] This national initiative could be headed by a newly created obesity task force by the federal government to bring the public and private sectors together on prevention and treatment strategies and policies that destigmatize the disease and do not unnecessarily deny, delay, or defer proven evidence-based treatments across the continuum of care.[24] These effort can be combined with the current U.S. Preventive Services Task Force on behavioral weight loss interventions. In this new and improved environment, the most effective treatment for severe obesity will no longer be reserved for less than 1% of the patients who could benefit.

IV. References

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Lisa Doshi, MHA

PROFESSIONAL PROFILE

Experienced leader with 10+ years of business management in an academic medical center setting. Possess significant knowledge in operational and financial management, physician /midlevel provider relations, business development, business process redesign, strategic planning, grants management and community practice management. Highly developed interpersonal and communication skills. Strong analytical skills, with ability to facilitate diverse groups of people to identify, evaluate and solve problems.

AREAS OF EXPERTISE

- Clinical Operations & Practice Management
- Strategic planning and project management
- Financial/Budget Management
- Business Development
- Patient Satisfaction and Customer Service
- Revenue Cycle Management
- Quality Improvement
- Process improvement

PROFESSIONAL EXPERIENCE

Johns Hopkins University, Department of Surgery, Baltimore 2012- present

Department Administrator (7/2018-present)
Responsible for operational, financial and administrative activities of Department of Surgery for over 110 faculty, 75+ residents and fellows, and 280 employees across 7 sites. This includes management of a $110 million annual operating budget and supervision of +14 direct and +250 indirect staff.

- Responsible for the strategic development and operations, and continuous performance improvement of a clinical, academic and research department. The role has a matrix reporting relationship to the CFO, JHM, and COO, JHH.
- Expanded academic and geographic clinical presence with associated faculty recruitment and negotiation of respective clinical services agreements.
- Function as a liaison with all levels of administration within the School of Medicine, the affiliated hospitals and ambulatory sites utilized by the Department's providers.
- Responsible for the non-faculty administrative staff in executing the Department's clinical, academic and research activities.
- Perform analysis, consultation and planning for Department Director and executive leadership team. Perform and manage financial management/analysis, budget development and execution, grants management, contract administration, compensation planning, personnel and management recruiting, utilization and productivity management, marketing and space management.
- Responsible for the Department's Professional Fee Billing Office, the Access Call Center and the staff in the clinical areas managed by the Department.
- Developed and evaluated business plans and pro formas associated with new and existing programs or service lines and determining whether to invest in or close existing business units
- Responsible for the Department's and staff's satisfactory compliance with the rules and regulations of The Johns Hopkins University School of Medicine and Clinical Practice Association.
- Developed clinical and research faculty compensation plan to align with department and SOM mission.

Assistant Administrator, Department of Surgery (2015-2018)
Sr. Administrative Manager (2012-2015)

Responsibilities and Accomplishments
Financial and Budgetary

- Operational and financial management of 5 clinical divisions including financial projections, budgeting, variance analysis and reporting. Responsible for development, preparation and review of divisional budgets, including discretionary, operating and clinical budgets in excess of $28 million dollars
- Manage affiliation efforts with community hospitals to ensure operations, systems and services are organized and delivered effectively and efficiently for surgical programs in the National Capitol region
- Responsible for assisting in the development and implementation of the division's operational plans. Provide management for division's immediate and long term strategic plans
- Develop strategies with chiefs for establishing and utilizing discretionary funds for preservation of division's teaching, research, and patient care missions. Through monthly review, improved compliance to budget by 40%
- Successfully developed business plan and implemented nurse navigator program in HPB (Hepatobiliary and pancreatic surgery) to enhance care coordination, serve as point of contact for patients/families and grow volumes.
- Led a revenue cycle and provider documentation improvement project team in acute care surgery leading to increase in collections by 15%

Clinical Operations

- Supported Outpatient EPIC EMR implementation and development of centralized surgery intake center by conducting a staffing analysis and new patient scheduling protocols for first call resolution that led to an increase in scheduling of appointments on initial call by 50%.
- Manage clinical practice for 47+ clinical faculty at multiple sites with a combined responsibility for approximately 12,000 clinic visits and 4,800 surgical cases annually
- Collaborate with program leaders and CAO to evaluate and project shift of outpatient surgical volumes to new ASC
- Led roll out of EMMI, an interactive multimedia program designed to empower patient's to take more active role in their care, by training and educating staff and faculty on the program and monitoring feedback via surveys from patients. Led to increase in patient satisfaction by 20% by managing expectations upfront.
- Develop and implement physician practice growth strategies to ensure financial success of the Ambulatory enterprise

Human Resources

- Made decisions concerning employment, performance appraisals, promotions, transfers and terminations for 14 employees including administrative coordinators, laboratory and research staff and supervisory staff
- Remodeled recruiting practices by developing a work plan on hiring, evaluating and retaining staff. Includes a new hiring process, 360 degree evaluation, monthly feedback, and recognition program.
- Led recruiting initiative for several surgeons, designed business plans, compensation model and employment contracts with the SOM administrator and University business office to expand busy clinical programs

Surgical Services Program Development

- Developed business plan to expand complex GI oncology program by 20% by addition of new oncologist
- Successfully operationalized Multidisciplinary Rectal Cancer and Breast Cancer clinics
- Provided business planning and clinical operational support for expansion of endocrine surgery clinical program to the national capital region

Quality and Safety

- Reviewed and shared NSQIP and NHSN SSI data with faculty monthly to discuss and identify areas of improvement
- Supported the development of service specific dashboards to include quality, safety and outcome metrics, including LOS, readmissions, MHACs, mortality, etc. to share with faculty

Lisa Doshi, MHA

Johns Hopkins Hospital, Department of Surgery, Baltimore **2009- 2012**

Administrative Resident, Department of Surgery (2009-2010)
Sr. Project Manager (2010-2012)
Manage the operational and administrative functions of multiple small and large scale projects including the formulation of department operating budgets, capital budgets, program development, and marketing initiatives.

Accomplishments

- Developed, managed and analyzed monthly operational reports pertaining to case volumes, occupancy, length of stay and operating room efficiency metrics
- Led a quality improvement project to improve patient satisfaction in ambulatory surgery center from 40th percentile to 65th percentile
- Provided project management support to a perioperative transformation project anticipated to improve throughput by 10%, decrease OR overtime by 50% and decrease urgent case waiting time by 75% resulting in $500,000 savings annually
- Coordinated team to decrease same day surgery missing type and screen samples from 45% to 15%. This effort resulted in development of recommended type and screen guidelines for each service, reducing over ordering by 50%
- Led process improvement project by conducting current state analysis and assisted in creating strategies for improving physician practice operations, including amending clinic block schedule to maximize efficiency and implementing initiatives to improve patient satisfaction from 10th percentile to above 50th percentile
- Operating Room Utilization and Efficiency: Assisted in the development of new clinical building operating room utilization model to project targeted occupancy rates consistent with staffed operating rooms that facilitated executive decision making on operating room efficiency to 86% occupancy for the next 5years
- Service Line Projections and Opportunities: Facilitated the 10 year 'Volume Work Group' with organization-wide service line projections to advance business and strategic planning at JHH for expansion of services in the New Clinical Building
- Six Sigma and Lean: Led a team to optimize surgical pathology specimen identification and accessioning process through improved work flow, standardization of specimen labeling and by eliminating clinical inaccuracies resulting in reduction in process variability by 70%, decrease in specimen defect rate by 50%

Dental Care Center, Mumbai, India **2004- 2008**

Co-founder and Practice Manager
Private dental office with 3 dental operatories, 10 employees and annual revenue of $180,000

- Directed and managed setup, budgets, vendor relations, state and federal regulations
- Managed staff and decisions concerning employment, performance appraisals and promotions
- Developed and implemented a robust marketing plan to generate demand and enhance presence in the community
- Improved operational efficiency and clinical quality by streamlining throughput and use of innovative technology
- Lowered operational costs 20% by effectively managing vendor negotiations to improve buying power

Associate Dentist, Private Dental Practice, Mumbai, India **2001- 2004**

Lisa Doshi, MHA

EDUCATION

Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD
Doctor of Public Health (DrPH), Healthcare Management and Leadership — *Anticipated May 2022*

Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD
Master of Health Science, MHS, Health Finance and Management — May 2010

Nair Hospital Dental College, Mumbai, India
Bachelor of Dental Surgery, BDS — August 2000

Lean Sigma Green Belt, Baltimore MD
Johns Hopkins Medicine Center for Innovation in Quality Patient Care — September 2009

PROFESSIONAL AFFILIATIONS

- Member, American College of Healthcare Executives (ACHE), 2010- present
- Affiliate member, Healthcare Financial Management Association (HFMA), 2010-2011
- Association of Academic Surgical Administrators (AASA), Member, 2012 – present
- Medical Group Management Association (MGMA) – Member
- Association of American Medical Colleges, GBA Group on Business Affairs member, 2019-present

CERTIFICATION/ AWARDS

- Award recipient of 'Impression Materials in Dentistry' presentation at the Indian Dental Association Convention
- Health Finance and Management Case competition Winner 2009, Johns Hopkins School of Public Health
- Second Place Honors at the 2010 UAB National Health Administration Case Competition

COMMUNITY PARTICPATION

- Served as Mentor to group of mentees for Vivien Thomas Mentorship Program
- United Way participant in United Way fundraising and activities

PRESENTATIONS

- Perioperative Workshop, Johns Hopkins Hospital, November 2010 and 2011
  "Specimen Labeling Defects"
- AORN and Lean Sigma gallery walk poster presentation, March 2011
  "Reducing specimen Identification Defects"

SKILLS

- Working knowledge of Press Ganey Infoedge , UHC, Epic 2012, SAP, ORMIS, Tableau, etc.
- Proficient in MS Office Suite (Word, Access, Excel, Outlook and PowerPoint), DATAMART

**References Available upon request*