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HEALTH SERVICES AND PROGRAMS (R WELBOURN, SECTION EDITOR)

Evidence Base for Optimal Preoperative Preparation for Bariatric Surgery: Does Mandatory Weight Loss Make a Difference?

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Abstract
Purpose of Review Preoperative weight loss regimens prior to bariatric surgery have been a routine and common practice for many centers, in the US and around the world. The mandated participation in such programs has largely been influenced by loco-regional payer requirements. The relationship between adherence to a mandatory weight loss regimen and achieved preoperative weight loss as well as the clinical impact of preoperative weight loss on bariatric outcomes remains uncertain.
Recent Findings This review examines the available current literature, in the context of previous findings, regarding the impact of mandated preoperative weight loss regimens and mandatory weight loss on bariatric outcomes.
Summary The reviewed studies do not provide sufficient evidence that mandatory participation in a preoperative weight loss regimen prior to bariatric surgery is associated with achieved weight loss or durable bariatric outcome benefit. Preoperative weight loss, when achieved, may confer a positive benefit on postoperative complications; however, this is not a consistent finding in the literature and requires further validation. The practice of mandating participation in a preoperative weight loss regimen or requiring mandatory weight loss prior to bariatric surgery is not supported by current literature and may serve as an obstacle to medically necessary and potentially life-saving treatment.

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Introduction

Obesity is a serious public health challenge that remains a leading cause of morbidity and mortality throughout the developing world. Overweight and obesity represent about 13% of the world's adult population and are linked to more deaths worldwide than from underweight causes. The prevalence of obesity in certain global populations (Middle East, Asia and Africa) previously defended against obesity by traditional dietary and activity patterns has also risen steeply over the past two decades [1]. The adverse effects of obesity on health and longevity were formally recognized in the United States (US) by the National Institutes of Health (NIH) in 1985 [2]. Class II and III obesity (clinically severe obesity) are well-established risk factors for cardiovascular disease (the leading cause of death worldwide), hypertension, diabetes, sleep apnea, musculoskeletal disorders and certain cancers. The presence of obesity alone (body mass index [BMI] ≥ 30 kg/m^2) is associated with more than 50% increase in all-cause mortality [3]. Currently, roughly one-third of the US adult population is obese, resulting in more than 300,000 deaths annually. In addition to health consequences, obesity is also associated with reduced health-related quality of life [4] and psychological well-being [5]. The yearly economic impact of adult obesity in the US has been estimated at over $315 billion in direct medical costs alone [6].

Obesity results from an energy imbalance between the calories consumed and expended, leading to the accumulation of excess body fat over time. The pathophysiology of this

chronic disease, however, is far more complex and involves the multifactorial interplay between genetic, social, environmental, perinatal, hormonal and metabolic factors. The treatment of clinically severe obesity with non-surgical methods has generally been shown to be unsuccessful and ineffective, particularly over the long term. A recently published population-based cohort study from the United Kingdom's Clinical Practice Research, Datalink, prospectively followed a sample of more than 278,000 obese men and women for 9 years and evaluated the probability of attaining normal weight or a 5% reduction in body weight through non-surgical means. The authors found that the higher a person's BMI, the lower the likelihood that they would ever achieve normal body weight. Among those with clinically severe obesity, only 1 in 1290 men and 1 in 677 women were able to achieve this through non-surgical means. They found that the probability of achieving a 5% reduction of body weight was considerably higher among patients with morbid obesity, at 1 in 8 for men and 1 in 7 for women; however, among those who lost 5% body weight, 52.7% had regained this weight within 2 years and 78% by 5 years [7]. An earlier reported study revealed similar findings that 80% of individuals who are able to intentionally achieve weight loss of 10% or more of their body weight will regain that weight within 1 year [8].

Metabolic and bariatric surgery in contrast has been shown to be safe and remains the most effective and durable treatment for clinically severe obesity with a documented reduction in all-cause mortality and long-term survival benefit [9]. The wide adoption of minimally invasive techniques, technical standardization and quality reporting efforts combined with accreditation programs such as the Metabolic and Bariatric Surgery Accreditation Improvement Program (MBSAQIP) have continued to help improve safety outcomes of bariatric procedures over the past two decades [10]. The most commonly performed bariatric procedures in the US today are laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB). The 30-day mortality rate for these procedures in the US has been published in the literature at 0.12% [11] or less with similar safety outcomes reported in other countries at 0.08% which is significantly lower than mortality rates for many commonly performed operations such as appendectomy, elective cholecystectomy and knee arthroplasty [12]. Metabolic and bariatric surgery is cost-effective, particularly when type 2 diabetes (T2D) is present, providing a return on investment in as little as 25 months to 5 years [13–17].

Historical Background

In 1991, the NIH held a consensus panel to develop selection criteria and a standardized approach for patients seeking surgical treatment for clinically severe obesity that included BMI, previous weight loss attempts by nonoperative means and completion of a multidisciplinary evaluation in a clinical setting with resources to provide such management and life-long support [18]. Patients were also expected to be "motivated" and determined to be an acceptable operative risk. The NIH consensus statement, however, did not mandate or require any specific preoperative weight loss program be completed (by type, duration or degree of weight loss), given the understanding that the majority of individuals with clinically severe obesity have suffered a life-long battle with obesity and have almost uniformly failed multiple prior efforts without long-term efficacy before seeking surgical treatment. The provider was felt to be best able to determine what constituted failed efforts for each patient [18–20]. In 2005, a panel of broad-based and experienced experts modeled the format used by the NIH and published an updated consensus statement in which it was specified that "… Candidates should have attempted to lose weight by selfdirected dieting, nutrition counseling, and commercial and hospital-based weight loss programs, but should not be required to complete formal nonoperative obesity therapy as a precondition for the operation" [21]. Medicare similarly requires that patients have been unsuccessful with medical treatment for obesity, before pursuing surgical treatment, but does not require successful weight loss or mandate any specified type of diet or duration of diet, relying on providers to detail such efforts [22].

There are 18 million adults in the US alone that could qualify for bariatric surgery based on current BMI inclusion metrics (BMI $\geq$ 40 kg/m^2 with or without associated co-morbidity or BMI of $\geq$35 kg/m^2 with at least one obesity-related disease) as defined by the NIH consensus guidelines; however, only 1% of these potential candidates will undergo bariatric surgery [23]. Although the reasons for this finding are not completely understood, weight bias and discrimination, which continues to surround obesity, are likely contributing factors. Although the numerous serious health implications of obesity have been understood for many decades, the official listing of obesity as a disease by the American Medical Association (AMA) did not occur in the US until June 2013. Despite the AMA resolution, the perception by lay public as well as physicians has not been significantly impacted as many medical providers continue to hold divergent opinions on whether obesity is a disease or merely a risk factor [24, 25]. Another factor contributing to the gap in treatment is the lack of patient access to care. Unlike other life-threatening diseases such as cancer, heart disease, and diabetes, universal insurance coverage for treatment of clinically severe obesity has not been established in the US, in spite of the overwhelming high-quality data demonstrating the safety and health benefits of metabolic and bariatric surgery as well as data supporting financial returns on investment. In a national survey of US employer-sponsored health plans by Mercer in 2015, only 58% of large employers cover bariatric surgery, unchanged

from 2013, (https://www.mercer.com/newsroom/national-survey-of-employer-sponsored-health-plans-2015.html) and fewer than half the states in the US require state-run insurance exchanges to cover bariatric surgery, some of which have very high deductibles and out-of-pocket costs for patients that make surgery prohibitive despite coverage. Obesity is a chronic disease, and like other chronic diseases, such as cancer, coronary artery disease and peripheral vascular disease, may remit and recur. Although insurance companies will allow for revisional vascular and cardiac procedures, some insurance plans limit bariatric coverage to one lifetime procedure making treatment even for complications related to bariatric surgery difficult to obtain.

Preoperative Weight Loss

Prior to 2005, there were only two publications regarding the impact of preoperative weight loss on bariatric surgery. One study published in 1995 evaluated the practicality and safety of preoperative weight loss in patients with morbid obesity undergoing open gastric bypass. Although the dieter cohort lost an average of 17 kg, there was no difference in postoperative morbidity or outcomes between dieters and non-dieters [26]. A second case series in 1999 evaluated patients undergoing open vertical banded gastroplasty and open gastric bypass who had lost more than 50% excess weight loss (EWL) by self-diet and also reported on the safety of preoperative weight loss and in addition found an association with larger postoperative weight loss although it was not associated with any decreased perioperative morbidity and mortality [27]. Although a seemingly safe and benign practice, preoperative weight loss should not be considered mandatory standard practice or policy unless there is an abundance of high-quality evidence related to improved postoperative outcome benefits, such as reduced complications, improvement in co-morbid disease status and better long-term weight loss, that clearly outweigh the risk of delaying or deterring medically necessary treatment.

Insurance-Mandated Preoperative Weight Loss

Insurance companies, however, have long imposed arbitrary requirements in the form of mandated preoperative weight loss programs as a prerequisite to surgical coverage despite the lack of any national and global guidelines or high-level evidence to warrant such practices. Coverage requirements became more restrictive in the 2000s when the US saw an exponential growth in the number of bariatric procedures being performed annually. Many bariatric programs have historically initiated preoperative weight loss participation or modeled their preoperative patient preparation based on the requirements of local insurers as a way of minimizing subsequent insurance denials.

Although there is great variability among insurance-mandated preoperative weight loss requirements in the US, the far majority of insurance companies do not require any actual weight loss prior to surgery, but that patients are compliant with the type and duration of a specified program. Insurance-mandated preoperative weight loss requirements are most commonly based on meeting a specified number and duration of visits (e.g., monthly over a period of 3–24 months) that may also need to be consecutive (without any gaps) and generally must be completed within the immediate 1–2 years prior to initiating evaluation for bariatric surgery. In certain plans, patients must also meet a specified percentage of preoperative weight loss of (e.g., 5–15%), whereas in other plans, patients must document failure to achieve a certain percentage of weight loss or gain weight as proof of inability to respond to nonoperative means [28]. Finally, some insurance companies will also require a 5-year or more history of clinically severe obesity, the requirement of which has not been supported by any published clinical study and the practice of which is unheard of for other potentially life-threatening diseases. It is not surprising that the majority of patients denied insurance coverage for bariatric surgery will have progression of their obesity and obesity-related diseases, particularly diabetes, as well as a higher incidence of new-onset diabetes, hypertension and sleep apnea while awaiting insurance approval [29–31], even though it is well understood that the likelihood of achieving healthy weight without surgery is exceedingly low. The outcome of insurance-mandated preoperative weight loss requirements is patient attrition, delay in obesity treatment, progression of obesity and obesity-related diseases, and increased direct and indirect healthcare costs [28–34]. The widespread practice of insurance companies to require unsubstantiated and arbitrary requirements as a condition to bariatric coverage has been challenged by evidence-based statements from the American Society for Metabolic and Bariatric Surgery (ASMBS), initially published in 2011 and updated in 2016, with little impact [28, 35•].

The role of the insurance companies in developing policies dictating the practice of mandated preoperative weight loss requirements has also made it difficult to evaluate the true clinical value of preoperative weight loss, mandated or not, as most studies looking at the impact of preoperative weight loss on postoperative outcomes are based on duration of participation v. degree of preoperative weight loss achieved. Although modest weight loss (5–10% of initial weight) is associated with an improvement in established risk factors for cardiovascular disease related to obesity, these positive effects will not endure unless weight loss is achieved and maintained [36, 37]. As mentioned earlier, not all morbidly obese patients are able to achieve even a 5% weight loss [7, 38]. The majority of dietary weight loss clinical trials show that maximal weight loss will have

generally occurred and begun to plateau by 6 months with roughly one-third of patients regaining lost weight within a year and gaining more thereafter [37, 39]. Participation in preoperative weight loss programs that are mandated and structured solely based on length of time/duration alone is unlikely to achieve any consistent degree of weight loss [32], with data suggesting that programs that require a duration of longer than 6 months risking weight regain above and beyond starting weights [33]. Although numerous preoperative weight loss strategies have been proposed, the majority of studies reviewed did not define or detail the specific diet utilized to achieve preoperative weight loss. As such, there is no clear evidence to support any one preoperative weight loss strategy as standard or superior. Based on medical weight loss data, very low calorie diets (VLCD) defined as 800 kcal/day and low calorie diets (LCD) defined as 800–1200 kcal/day are generally associated with the greatest absolute losses in the shortest periods of time but are also associated with lower rates of long-term compliance and weight loss maintenance. Of those studies reporting detail on the type of diet utilized, VLCD and LCD were most common. To date, no published study (including one randomized controlled trial, and three retrospective reviews) specifically looking at insurance-mandated participation in preoperative weight loss has shown any clinical postoperative benefit [32, 33, 40, 41].

What Are the Intraoperative Benefits of Weight Loss Prior to Bariatric Surgery?

Modest weight loss (5–10% of initial weight) has been shown to be safe and feasible, even within a very short period of time (2–6 weeks) and has been associated with reduced liver volume and visceral adiposity [42, 43]. Although in theory this should lead to improved operative feasibility and perioperative outcomes, reports have been inconsistent, and the overall quality of reporting measures in most studies is poor. In a systematic review and meta-analysis from 2009 [44], a meta-analysis of three studies (including one RCT) [45–47] reported reduced operating times resulted in a reduction in mean operating time of 23 min (95% confidence interval (CI) 13.8–32.8). Significant heterogeneity ($P = 0.07$) between the three studies and widely varying mean operative times, ranging from 105 to 220 min, were also noted. In a more recent systematic review from 2011, the reduction in operative time from six pooled studies was reported to be only 12.5 min, also with significant heterogeneity in reporting measures noted [48]. A RCT from 2011 that was not included reported no difference in operative time [49]. Data regarding other intraoperative complications such as reduced operative blood loss have also varied among studies, but generally, there is more evidence to support a lack of benefit. One retrospective case series reported reduced blood loss [50], whereas other studies including two RCTs have reported no difference [45, 49]. The majority of studies that have measured length of stay (LOS) including one RCT have reported no difference [45, 47, 50, 51].

What Are the Postoperative Benefits of Weight Loss Prior to Bariatric Surgery?

As far as reduction of postoperative complications, there are some uncontrolled studies that have reported a reduction in postoperative complications [52–54]; however, the far majority including one RCT have reported no benefit [45, 47, 51, 55]. In addition, studies looking at the impact of weight gain prior to bariatric surgery have not demonstrated any difference in postoperative complications or long-term weight loss [46, 56].

One notable exception, although not a RCT, is a recent large prospective population-based cohort study from the Scandinavian Obese Subjects Registry (SOReg) that analyzed data on 22,327 patients of whom 96.5% underwent LRYGB. Two-year follow-up data and preoperative weight loss data were available for 9570 patients. The cohort ($n = 9570$) was divided into percentiles based on the amount of preoperative weight loss, as there was no standardized protocol or mandatory requirement for weight loss. Preoperative weight change in the 25th, 50th and 75th percentiles was 0.5, −4.7 and −9.5%, respectively. In multivariate analysis, comparing patients in the 75th percentile to the 25th percentile preoperative weight loss groups, the risk of any complication was reduced by 13% (odds ratio (OR) 0.87, 95% CI 0.33–0.64). More specifically, the risk of leak was reduced by 24% (OR 0.76, 95% CI 0.64–0.91) and deep infection/abscess by 37% (OR 0.63, 95% CI 0.43–0.93) and minor wound complications by 54% (OR 0.46, 95% CI 0.33–0.64). For patients in the highest range of BMI (>45.8 kg/m^2), the risk reduction associated with preoperative weight loss was statistically significant for all analyzed complications and was also associated with a 15.2 and 13.6% higher weight loss at 1 and 2 years, respectively, compared to those in the 25th percentile. In conclusion, the authors found that the degree of risk reduction seems related to the amount of weight lost, and patients in the higher range of BMI are likely to benefit most from preoperative weight reduction as well as achieve greater postoperative weight loss. Although a large-scale study, the limitations include the lack of preoperative dietary strategy, the lack of follow-up beyond 2 years to assess long-term durability, the lack of randomization as well as the inability to include data on more than half of the original cohort [57•].

What About Long-Term Postoperative Outcomes, Such as Weight Loss?

There are to date four randomized controlled trials that have evaluated the benefit of preoperative weight loss prior to

bariatric surgery [40, 45, 49, 58, 59]. There are no studies, controlled or uncontrolled, that have evaluated postoperative outcomes beyond 2 years; therefore, the true durable long-term impact (5 or more years) on postoperative weight loss is unknown.

The first RCT published its initial findings in 2007, and 1-year findings in 2009 involved 100 consecutive patients preparing to undergo laparoscopic gastric bypass who were randomly assigned to lose 10% or more of their excess body weight or no weight loss. Sixty-one patients underwent surgery with data on 26 patients in the weight loss group (which averaged 8.2% EWL (range 1.3–15.9%) and 39 patients in the no weight loss group which gained 1.1% ($P = 0.007$) which found reduced average operative time in the weight loss group at 220.2 and 257.6 min for the no weight loss group ($P = 0.0084$). There were no differences in length of stay, major morbidity or mortality between the two groups. Although short-term weight loss was greater in the weight loss group, by 1 year, there was no overall difference between the two groups with data available on 26/26 in the weight loss group and 18/39 in the no weight loss group. When subsequent subgroup analysis was performed, however, on those patients who lost more than 5% EWL ($n = 19$) v. less than 5% EWL ($n = 25$), the patients that had lost more than 5% EWL preoperatively had significantly lower BMI and %EWL at 1 year [45, 58]. The relatively low number of patients available for evaluation is a limitation of this study.

In a second multicenter, single-blinded RCT, 294 patients were randomly allocated to a 2-week preoperative VLCD regimen ($n = 137$) or no specific diet ($n = 136$) to assess impact on perioperative outcomes after laparoscopic Roux-en-Y gastric bypass (LRYGB). There was a significant weight loss seen in the VLCD group vs. control (4.9 ± 3.6 compared to 0.4 ± 3.2 kg; $P < 0.001$) with good reported compliance, but there was no significant difference in mean operative time, estimated blood loss (EBL), visual scale of difficulty or intraoperative complications. There were a significantly reduced number of total complications, eight in the VLCD group and 18 in the control group, mostly related to reduced infectious complications. No difference in postoperative weight loss was reported at 3 months, and long-term weight loss outcomes were not reported [49].

Behavioral lifestyle interventions (BLI) for individuals with clinically severe obesity have been extensively studied in medical weight loss trials and found to be more effective than standard diet alone with 5–10% weight loss achieved in 6–12 months [60, 61]. A third RCT compared BLI defined as dietary education, physical activity and behavioral strategies with 24 weekly contacts of which 12 were face-to-face and 12 via telephone for 6 months with three monthly telephone contacts postoperatively compared to usual care (UC) which consisted of any 6-month physician-supervised weight loss in patients undergoing laparoscopic adjustable gastric band (LAGB) and LRYGB. One hundred and twenty-one patients were randomized to the BI group, and 119 patients were randomized to the UC group. Of the 240 patients, 71 patients in the BI group and 72 patients in the UC group underwent surgery. Although the patients in the BI group had greater preoperative weight loss (5.7 vs. 2.6% mean EWL%; $P < 0.001$), there was no difference in postoperative complications or excess weight lost at 6 and 12 months, with slightly less weight loss seen in the BI group compared to the UC group at 24 months (26.5 vs. 29.5% mean EWL%; $P = 0.02$). Aggressive behavioral lifestyle intervention, with over 80% group completion of weekly contacts, failed to show any overall postoperative outcome benefit despite greater preoperative weight loss [40].

A fourth RCT identified 55 patients who met the NIH consensus guidelines for bariatric surgery and randomized them into a mandatory 6-month medically supervised weight management (MSWM) program or 6 months of usual care and then followed them postoperatively after undergoing LAGB (initial and at 6 months) looking at patient behaviors and weight loss outcomes. Mandatory participation in MSWM was not found to have any difference in postoperative weight loss or behavior outcomes [59].

Three recently published systematic reviews did not determine that there was sufficient evidence to support mandated preoperative weight loss as effective in achieving preoperative weight loss or that preoperative weight loss was associated with improved postoperative weight loss outcomes, with the notable exception of the inclusion of the SOReg population study mentioned previously [48, 62•, 63•].

Several recently published uncontrolled case series have also shown no difference in postoperative weight loss outcomes. One study looked at 141 consecutive patients who underwent LSG without any specified or mandated preoperative diet. Of the 141 patients, 72 patients lost weight prior to surgery, 64 patients gained weight and six patients were unchanged. There was no difference found in operative time or postoperative weight lost at 1 year between the weight loss and the weight gain group [64]. In another series, 548 consecutive patients underwent LRYGB with no specified preoperative diet and were analyzed based on the percentage of preoperative weight loss achieved, <5, 5–10 and >10% with 166, 239 and 143 patients, respectively. Mean operative time and length of stay were greater for the <5% weight loss group compared with the two other groups ($P = 0.001$), but there was no difference in weight loss between the three groups at 6 months and at 2 years. A recent retrospective study looked specifically at the effect of insurance-mandated medical weight management programs on weight loss outcomes and included patients who underwent LSG, LRYGB and LAGB. A total of 1432 patients were reviewed and stratified by payer mix based on whether their insurance mandated preoperative weight loss and resulted in 500 patients for analysis after

bucket matching algorithm. The regression model found no significant difference in weight loss outcomes between the mandated weight management group and the comparison group at 1 and 2 years [41].

Conclusions

Although preoperative weight loss participation prior to bariatric surgery has been a routine and common practice in most centers, a preponderance of high-quality evidence to support this practice as standard has generally been lacking and controversial at best. That mandated participation in such preoperative programs have generally been structured on the number, type and duration of visits without any specific targeted goal of weight loss or irrespective of achieved weight loss underscores the pervasive influence that health care payers have had under the guise of "improved patient outcomes," in dictating health care policy and patient access to treatment for clinically severe obesity.

Modest weight loss in patients with clinically severe obesity, regardless of whether they are seeking bariatric surgery, has been shown to be safe and able to confer health benefits and improve cardiovascular risk factors. The majority of patients with clinically severe obesity may not easily or timely achieve a targeted weight loss of 10%, or even 5%, however, whether for general health efforts or as part of mandated preoperative weight loss prior to bariatric surgery. Moreover, the vast heterogeneity of reviewed studies, most often with small sample size, inconsistencies and violations in study design and methodologies as well as omissions of dietary strategy, inability to determine how weight loss was achieved and lack of true long-term weight loss outcomes (5+ years), clearly limits the validity and overall clinical applicability to conclude that preoperative weight loss, mandatory or not, improves bariatric outcomes. Many of the uncontrolled studies supporting a positive impact of preoperative weight loss on perioperative or postoperative bariatric outcomes were written over a decade ago, whereas most recent studies including several meta-analyses and RCTs have failed to show any clear benefit. Other considerations that may impact future research in this area include the recent shift in case type seen in the US and in some parts of the world as the majority of studies reviewed involved patients undergoing LRYGB, whereas, today LSG is performed more frequently comprising 58% of annual procedures performed in MBSAQIP facilities with mortality rates for bariatric procedures lower than many commonly performed procedures [65].

Given the global obesity epidemic and the overwhelming data that supports the safety, efficacy and durability of bariatric surgery for treatment of clinically severe obesity, it is imperative that we do not impose policies that may worsen the already staggering gap in treatment or further limit patient access to care, that have not been carefully validated or do not provide strong clinical justification for implementation. It is also important to carefully dissect the implications of any mandated weight loss program and make a distinction between mandatory weight loss and mandatory participation in a preoperative weight loss program, which may or may not achieve any actual weight loss or improved health benefit. There continues to be insufficient validated high-quality data to require either mandatory weight loss or mandated participation in preoperative weight loss program as a precondition to obtain bariatric surgery. Patient selection and preparation prior to bariatric surgery should remain at the discretion of an experienced multidisciplinary team of providers with active inclusion and participation from the patient and his or her primary physician.

Compliance with Ethical Standards

Conflict of Interest Julie J. Kim declares that she has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by the author.

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