#### REVIEW





# Systematic Review and Meta-Analysis of the Effectiveness of Insurance Requirements for Supervised Weight Loss Prior to Bariatric Surgery

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#### Abstract

Many insurance plans impose strict criteria mandating preoperative weight loss attempts to limit patient's access to surgery. Preoperative acute weight loss has been hypothesized to reduce perioperative risk and to identify compliant patients who may have improved long-term weight loss. In this review, the evidence from studies examining clinical and weight loss outcomes both with and without preoperative weight loss are summarized. Although preoperative weight loss may have modest impact on some factors related to perioperative conduct, the evidence does not support these programs' effectiveness at promoting long-term weight loss. Provision of weight loss surgery should not be contingent on completion of insurance-mandated weight loss goals preoperatively, and these programs may, through patient attrition, actually do more harm than good.

**Keywords** Bariatric surgery  $\cdot$  Morbid obesity  $\cdot$  Patient non-compliance  $\cdot$  Insurance-mandated weight loss  $\cdot$  Postoperative weight loss  $\cdot$  Preoperative bariatric surgery screening

# Introduction

Bariatric surgery is the most effective treatment for patients with morbid obesity and its associated complicating comorbidities. It provides superior weight loss maintenance with better long-term outcomes than diet, exercise, and weight loss medications alone and is associated with reduced

#### **Key Points**

• Many insurance plans impose strict criteria mandating preoperative weight loss attempts to limit the indications for surgery which reduce access to treatments while potentially improving outcomes among those who undergo surgery

• The reviewed evidence does not support these programs effectiveness at reducing perioperative complications or promoting long-term weight loss

• Provision of weight loss surgery should not be contingent on completion of insurance-mandated weight loss goals preoperatively as these programs may, through patient attrition, actually do more harm than good.

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mortality over time [1–4]. Furthermore, bariatric surgery has shown long-term direct health care savings, and initial surgery costs may be recovered within 3.5 years [5]. Despite clear evidence about the clinical effectiveness and cost-effectiveness of bariatric surgery, the low but non-zero risks of serious postoperative complications, observation of variability in weight loss outcomes based on postoperative patient dietary compliance, and the huge size of the eligible population based on BMI criteria alone have led some to question whether additional criteria should be used to limit provision of surgery to those who have lower postoperative risks or better long-term weight loss.

Preoperative acute weight loss has been hypothesized to reduce perioperative risk and be a marker to identify compliant patients who may have improved long-term weight loss. Many insurance plans impose strict criteria mandating preoperative weight loss attempts to limit the indications for surgery which has the effect of reducing the population with access to these treatments while potentially improving outcomes among those who undergo surgery [6]. Some insurance providers require documentation of supervised diet attempts over various lengths of time (3–18 months), require provider visits over a specific time period, and even necessitate a specific amount of weight loss (5–15%) needed before coverage is granted [7]. These insurance-mandated preoperative weight loss requirements do not consider the patient's underlying obesity-related comorbidities or severity of obesity nor the patient's ability to afford the additional costs of the adjunct dietary and exercise programs, medications, and additional visits to providers [7]. The purpose of this review is to systematically evaluate the evidence that mandated acute preoperative weight loss attempts reduce postoperative complications and improve long-term weight loss related to improved dietary compliance.

# **Materials and Methods**

A literature search of English language publications from 1999–2019 was used to identify published data on the effectiveness of pre-operative weight loss programs prior to bariatric surgery. Databases searched were PubMed, Google Scholar, and Cochrane Evidence Based Medicine. Terms used in the search were "preoperative weight loss programs," "insurance mandated weight loss," "physician mandated weight loss" AND ("postoperative weight loss" OR "perioperative weight loss" OR "perioperative weight loss" OR "perioperative weight loss" OR "perioperative search is included for reference (Table 1).

Studies examining both open and minimally invasive bariatric surgery were included. Patients undergoing Roux en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), laparoscopic adjustable gastric band (LAGB), and vertical banded gastroplasty (VBG) were included. There were no exclusion criteria. Manual review of identified studies was also used to identify appropriate studies not identified in the aforementioned search strategy. A number of randomized controlled trials as well as prospective and retrospective cohort studies were identified and the outcomes measured and quality of the data were assessed. Interventions in these trials included insurance-mandated preoperative weight loss plans, physician-directed plans, and classification of preoperative weight change without specification of the origin of that weight change. Although insurance-mandated plans are of most concern due to the potential to limit access to bariatric surgery, we included data from all studies examining preoperative weight loss to more fully address the question of whether acute preoperative weight loss and/or a program to attempt preoperative weight loss are effective at improving patient outcomes.

In total, four [4] meta-analyses were performed. Two separate meta-analyses assessed the effect of preoperative weight loss on postoperative percent excess weight loss (%EWL). First, randomized trials evaluating the use of a structured preoperative weight loss program were evaluated for their effect on %EWL. Second, prospective and retrospective cohort studies were evaluated for the combined effect of preoperative weight loss on 12-month postoperative %EWL. Studies that reported EWL for separate groups were

Table 1         PICO table			
P (Patients)	I (Intervention)	C (Comparator)	O (Outcomes)
Patients with morbid obesity undergoing weight loss surgery	Insurance-mandated preoperative weight loss programs	Standard preoperative bariatric surgery/physi- Postoperative weight loss, perioperative cian-driven work-up complications/outcomes, rate of comor correction	Postoperative weight loss, perioperative complications/outcomes, rate of comorbidity correction

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included separately (i.e., Carlin et al. had 3 groups according to BMI, Giordano had 3 groups based on % preoperative weight loss, and Mrad et al. had 2 groups based on gender) [8]. A random effects model was used to calculate the standardized mean difference (SMD) with 95% confidence intervals (CI). When the standard deviation was not provided by the source manuscript, it was estimated using the mean standard deviation from the other studies [8]. Cohen's rule of thumb for interpretation of SMD statistics was applied: a value of 0.2 indicates a small effect, a value of 0.5 indicates a medium effect, and a value of 0.8 or larger indicates a large effect [9].

The third meta-analysis was performed to assess the effect of preoperative weight loss on the risk of perioperative complications. All randomized control trials and cohort studies evaluating perioperative complications postoperatively up to 90 days were included in the analysis. Studies that reported complications for separate groups were included separately (i.e., Anderin et al. had grouping according to percentile preoperative weight lost, Benotti et al. had groupings based % weight lost preoperatively, and Giordano had 3 groups based on % preoperative weight loss) [8]. The last metaanalysis reviewed whether enrollment of patients in a medically supervised weight loss (MSWL) program or a lifestyle program was associated with an increased rate of patient attrition as compared to the standard of care. For the final two meta-analyses, an odds ratio of < 0.05 was considered statistically significant.

Heterogeneity for all meta-analyses was measured with Cochran's Q statistic (low *p* values representing the presence of statistical heterogeneity; p-value of 0.10 set at significant) and the  $I^2$  statistic (larger values indicating more heterogeneity) [9, 10]. Calculations were carried out via MedCalc Version 20.010 (Belgium).

## Results

The literature search yielded a varied collection of papers including several systematic review articles, as well as randomized and non-randomized cohort studies. Manual review of these studies was used to exclude studies where there were no appropriate comparison groups, exclude duplicates, as well as to identify appropriate related studies that were not captured by the search strategy. We identified two systematic review articles addressing whether preoperative weight loss prior to bariatric surgery affected postoperative patient outcomes [8, 11]. Published in 2009, Livhits et al. identified 15 articles (3404 patients) matching their search criteria: 5 articles reported a positive correlation between preoperative weight loss and postoperative weight loss, 2 had a positive short-term effect that was not sustained long term, 5 showed no effect, and 1 had a negative effect [8]. Meta-analysis indicated a significant increase in 1-year postoperative weight loss for patients who had lost weight preoperatively as well as decreased operative times for these same patients. However, there is great heterogeneity in the studies included in their analysis. There is no standardization in the preoperative weight value that was reported: some studies defined weight loss from the time of surgery and others from the patient's initial consultation. Additionally, studies employing physician or insurance-driven preoperative programs were lumped with studies that divided their patient cohorts into preoperative weight loss achievers or non-achievers irrespective of whether a mandatory program was completed.

Cassie et al. in 2011 reviewed 27 studies measuring perioperative complications, operative time, conversion rate, length of stay, and/or weight loss outcomes. Nine articles specifically reported a positive correlation between preoperative and postoperative weight loss whereas 15 conveyed no benefit, and the meta-analysis did not show any relationship. Among the eight studies reporting periop complications, there was a reduction in complication rate from 21% down to 19% among groups with preop weight loss [11]. Cassie et al. were hampered by many of the same limitations as Livhits, including the lack of uniformity of reporting pre- and postoperative weight loss values and the difficulty of pooling a large number of retrospective studies. Based on these systematic reviews, there is no high-quality evidence to support or refute whether preoperative weight loss improves patient's postoperative outcomes.

Among the remaining 21 original articles, we identified 4 randomized controlled trials involving a total of 693 patients, 4 non-randomized prospective cohort studies of nearly 24,000 patients, and 13 non-randomized retrospective cohort studies comprising over 5000 patients. The pertinent study characteristics and summary of outcome measures and results are summarized in Tables 2, 3, and 4.

## **Perioperative Outcomes**

Preoperative acute weight loss has metabolic benefits for the patient, but does acute preop weight loss or an attempt at weight loss result in improved perioperative outcomes? Several groups have concluded that patients have less overall perioperative complications with increased preoperative weight loss [16, 21, 23]. A multicenter trial based in Sweden randomized 298 patients undergoing LRYGB to either a preoperative 14-day very low-calorie diet (VLCD) or no dietary restriction [15]. The median visual analog scale of difficulty as determined by the operating surgeon was significantly higher in the control group, but no differences were observed in median blood loss, number of intraoperative complications, or the number and/or degree of liver lacerations [15]. No conversion to an open procedure was

Table 2         Randomized control trials included in the review	d control trials inc	luded in the review							
Author	Year published	Year published Randomization groups	Number of patients rand- omized	Procedure(s)	Procedure(s) Primary outcomes	Attrition data	ITT?	Quality of evidence Result of primary outcome	Result of primary outcome
Alami et al. [12]	2007	10% weight loss requirement vs. no weight loss requirement	100	LRYGB	% excess weight loss at 3 and 6 months postop- eratively	61% (61/100) underwent surgery	Violated	Violated Low quality	% excess weight loss greater at 3 months in weight loss requirement group; equal at 6 months
Kalarchian et al. [13]	2016	6-month behavior lifestyle interven- tion vs. 6-month usual care	240	LRYGB LAGB	% weight loss from study enrollment	60% (143/240) underwent surgery	Violated	Violated Low quality	Equivocal % weight loss at 6 and 12 months; less weight loss in the treatment group at 24 months
Parikh et al. [14]	2012	6-month MSWM program or usual care for 6-months	55	LAGB	Weight loss, patient adherence, and patient activation	42% (23/55) com- pleted surgery and follow-up	Honored	Honored Low quality	No difference in weight loss and most patient behaviors; MSWM associated with positive effect on physical activity
Van Nieuwenhove et al. [15]	2011	2-wk preoperative VLCD regimen vs. no preopera- tive diet regimen	298	LRYGB	OT, operation diffi- culty, liver lacera- tions, blood loss, 30-day weight loss	92% (273/298) included in intention to treat analysis	Honored	Honored Moderate quality	No difference in OT, blood loss, intraoperative com- plications; VLCD with fewer 30-day complications and less reported opera- tive difficulty

ITT intention to treat, LRYGB laparoscopic Roux en-Y gastric bypass, VLCD very low-calorie diet, MSWM medically supervised weight management, LAGB laparoscopic adjusted gastric band, OT operative time

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Author	Year published Cohorts	Cohorts	Number of patients ana- lyzed	Procedure(s)	Primary outcome	Quality of evidence	Quality of evidence Result of primary outcome
Anderin et al. [16] 2015	2015	Four groups based on percen- 22,327 tile of preoperative weight loss	22,327	RYGB (open and lap)	RYGB (open and lap) Postoperative complications Low quality within 6 weeks	Low quality	Reduced complication rate in patients achieving weight loss prior to surgery (anas- tomotic leak, deep abscess, minor wound complications)
Jamal et al. [17]	2006	Insurance-mandated PDC or no insurance-mandated PDC	324	RYGB (open and lap)	RYGB (open and lap) One year % excess weight loss	Low quality	Non-PDC group with greater % excess weight loss, lower BMI, and lower body weight at 1 yr
Kuwada et al. [18] 2011	2011	Insurance-mandated MMP vs. no MMP	440	LRYGB LAGB	% excess weight loss	Low quality	No difference in % excess weight loss at 6 and 12 months
Still et al. [19]	2007	Patients achieving > 10% excess body weight loss vs. non achievers following standardized multidiscipli- nary preoperative program	884	RYGB (open and lap)	RYGB (open and lap) Postoperative weight loss; length of stay	Low quality	Patients achieving 10% excess weight loss preoperatively more likely to achieve 70% excess weight loss at 12-month follow-up
PDC preoperative	dietary counseling	PDC preoperative dietary counseling, MMP mandated medical program, LRYGB laparoscopic Roux en-Y gastric bypass, LAGB laparoscopic adjusted gastric band, Lap laparoscopic, yr year	ram, <i>LRYGB</i> lap	aroscopic Roux en-Y ga	stric bypass, LAGB laparoscopi	c adjusted gastric ban	d, Lap laparoscopic, yr year

 Table 3
 Prospective cohort studies included in review

Author	Year published Cohorts	Cohorts	Number of patients ana- lyzed	Procedure(s)	Primary outcome	Quality of evidence	Quality of evidence Result of primary outcome
Alvarado et al. [20]	2005	No cohort-All patients under- going LRYGB at single institution	06	LRYGB	% excess weight loss and comorbidity correction	Very low quality	Preoperative weight loss cor- related with an increase in postoperative weight loss; preoperative weight loss did not correlate with comorbid- ity correction
Benotti et al. [21]	2009	Cohort groupings based on preoperative weight loss following 6-month obesity treatment program	881	RYGB (open and lap)	RYGB (open and lap) Total/major complication rate	Very low quality	Increased preoperative weight loss associated with reduced postoperative complication rate
Carlin et al. [22]	2008	Patients meeting preopera- tive weight loss goals (5 pounds for BMI < 50; 5% for BMI 50–59; and 10% for BMI > 60)	295	LRYGB	Postoperative excess weight loss	Very low quality	Preoperative weight loss not predictive of postoperative excess weight loss
Giordano et al. [23]	2014	Groups based on preopera- tive weight loss percentage	629	LRYGB	Intra/postoperative complica- Low quality tions	Low quality	Preoperative weight loss associated with decreased OT, hospital stay, and overall morbidity
Harnish et al. [24]	2008	Preoperative weight gain vs. preoperative weight loss of≥10 pounds	1629	LRYGB	% excess weight loss at 1 and Low quality 2 years	Low quality	Preoperative weight loss not predictive of postoperative excess weight loss at 1 or 2 yrs
Horwitz et al. [25]	2016	Insurance required MWM vs. no requirement	540	LAGB; LRYGB; SG	% weight loss	Very Low quality	No difference in % weight loss
Huerta et al. [26]	2008	Patients achieving preop- erative weight loss vs. no preoperative weight loss	40	RYGB (open)	Perioperative complications and weight loss at 2 years	Very low quality	Similar rates of postoperative complications and weight loss at 2 yrs
Kieth Jr. et al. [1]	2018	Insurance requirement for physician-supervised pre- operative diet	284	LRYGB; SG	Weight loss at 6, 12, and 24 months	Low quality	No insurance requirement associated with improved excess weight loss at 6, 12, and 24 months
Liu et al. [27]	2005	Patients achieving preopera- tive weight loss vs. patients with no preoperative weight loss (self-directed)	95	LRYGB	Perioperative clinical outcomes (blood loss, organomegaly, deviation from standard procedure, operative time)	Very low quality	Preoperative weight loss associated with less opera- tive blood loss, fewer reports of organomegaly, and less deviation from standard procedure; No difference in OT, length of stay, wound infections or major compli- cations

Table 4 Retrospective cohort studies included in review

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Author	Year published Cohorts	Cohorts	Number of patients ana- lyzed	Procedure(s)	Primary outcome	Quality of evidence	Quality of evidence Result of primary outcome
Mrad et al. [28]	2008	Groups based on patients who preoperatively lost weight, gained weight, and had no weight change. Weight change defined as $\pm 2\%$ baseline body weight	146	RYGB (open and lap); LAGB; VBG	Postoperative weight loss at 1 and 2 years	Very low quality	Preoperative weight loss predictive of postoperative weight loss in men, but not in women
Ochner et al. [29]	2010	Insurance-mandated preop- erative weight loss regimen vs. no insurance require- ment	153	LAGB; LRYGB	Weight loss at 3 months	Very low quality	No difference in weight loss at 3 months
Riess et al. [30]	2008	Physician mandated weight loss of >4.54 kg preopera- tively vs. no weight loss requirement	353	LRYGB	OT and length of stay; per- centage of excess weight loss at 1-year	Very low quality	No difference in OT, length of stay, or postoperative weight loss
Sherman et al. [31] 2015	2015	Preoperative weight loss vs. preoperative weight gain	141	SG	% of excess BMI lost at 1 year	Low quality	No difference in % excess BMI lost at 1 yr
LRYGB laparoscopic Roux en-Y gastric lanaroscopic. OT onerative time. vr vear	c Roux en-Y gas	LRYGB laparoscopic Roux en-Y gastric bypass, LAGB laparoscopic adjusted gastric band, SG sleeve gastrectomy, VBG vertical banded gastroplasty, MWM medical weight management, Lap laparoscopic. OT operative time. vr vear	adjusted gastric	c band, SG sleeve gastre	ectomy, VBG vertical banded g	astroplasty, MWM me	dical weight management, Lap

laparoscopic, OT operative time, yr year

Table 4 (continued)

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needed in either arm of the study; however, they did show a reduction in overall 30-day complication rates from 13 to 8% [15]. In 2015, Anderin et al. used the Swedish nationwide prospectively collected registry to retrospectively analyze over 22,300 patients undergoing RYGB to determine if preoperative weight-reducing regimens affected postoperative complications within the first 6 weeks of surgery [16]. Grouping patients based on the magnitude of preoperative weight loss, there was a reduced risk of any postoperative complication although the magnitude of this reduction was greater for the modest weight losers compared to those who lost the most weight preoperatively [16]. Relative risk reduction for anastomotic leakage and deep infection were statistically significant for patients whose weight loss ranked in the 75-100th percentile, but there was no change in risk reduction for postoperative bleeding based on preoperative weight loss [16]. There was a decreased relative risk of conversion from laparoscopic to open surgery among patients with weight loss ranked from 25-100th percentiles [16]. Benotti et al. published a large retrospective case series in which over 800 patients undergoing both open and LRYGB at a single tertiary referral center [21]. Upon univariate analysis, increasing preoperative weight loss was associated with reduced overall complications and a trend towards decreased major complications. However, subset analysis of patients undergoing LRYGB revealed only a trend towards reduced complication rates with increasing preoperative weight loss [21]. Liu et al., in a retrospective chart review of 95 patients undergoing LRYGB, found that patients who had lost weight preoperatively had less intraoperative blood loss, had fewer operations that deviated from the "standard RYGB," and had surgeons less likely to report an enlarged liver intraoperatively. However, there was no difference in operative time, length of stay, or major complications [27]. Dividing 629 patients into three groups preoperatively before a LRYGB based on preoperative weight loss percentage, Giordano and Victorzon found patients with the least amount of weight loss preoperatively had the highest rate of early postoperative complications, particularly wound infections, ulcers, and strictures; however, the group with the largest amount of weight loss had lost an extreme amount of weight (22 kg) limiting the generalizability to other bariatric surgery practices [23].

Most studies have found no association between postoperative complication rate and preoperative weight loss [12, 13, 20, 24]. Alami et al. randomized 100 patients to either a preoperative required 10% weight loss group or a group with no weight loss requirement and followed patients prospectively [12]. The authors found no intraoperative or immediate postoperative complications, no anastomotic leaks, and no conversions to open procedures in either group [12]. Furthermore, the overall complication rate and estimated blood loss did not differ between the two cohorts [12]. Of note, there was significant attrition within the group required to lose weight that exceeded the permissive group: 24/50 (48%) of patients were lost within the weight loss group and 15/50 (30%) of patients were lost in the permissive group.

Researchers have also studied whether preoperative weight loss can improve operating room time or length of hospital stay with mixed results. Van Niewenhove. et al.in their randomized trial found no difference in operating room time based on whether patients adhered to a VLCD preoperatively [15]. Sherman et al. was the only author to look at these factors in patients undergoing SG [31]. In the author's retrospective analysis of 141 SG patients, they found no correlation between operating room time or length of stay with preoperative weight loss [31]. However, other groups have reported reduced operative time with preoperative weight loss [12, 20, 23, 24, 26]. Alvardo et al. found that an estimated weight loss of greater than 5% correlated with a decreased operating time of 36 min and Harnisch et al. found a decrease of 15 min when patients achieved a greater than 10-pound preoperative weight loss [20, 24]. Yet, the literature is further complicated by Riess et al.'s. findings that operating times averaged 10 min longer in patients who had who had lost 10 pounds preoperatively compared with patients who had no preoperative weight loss [30].

Likewise, preoperative weight loss's effect on hospital length of stay is unclear. In Cassie et al.'s. pooled metaanalysis, length of stay for patients who achieved preoperative weight loss was significantly less than those without preoperative weight loss (3.3 days vs. 4.0 days) [11]. Still et al. found that patients undergoing RYGB who had less than 5% preoperative weight loss were more likely to require a hospital stay greater than 4 days compared to patients who had successfully lost greater than 5% of excess body weight [19]. However, the authors included patients undergoing both open and LRYGB making interpretation on length of stay data challenging [19]. Lastly, Alami et al. found no difference in hospital length of stay in patient's undergoing RYGB who had been randomized preoperatively to either a weight loss or control group [12].

#### **Postoperative Weight Loss**

Although demonstration of preoperative acute weight loss is felt to be an indicator of elevated patient compliance and by inference maintenance of weight loss, after decades of investigation, the association between preoperative weight loss and postoperative weight loss remains inconclusive. Studies have reported both a positive relationship [12, 19, 20, 23, 28], no relationship [13–15, 18, 24, 29–32], and even a negative relationship [17, 30]. Few studies have shown a positive relationship between achieving preoperative weight loss and improved short-term postoperative weight loss. Alami et al. in their randomized trial of 100 patients found that

the group assigned to mandatory 10% preoperative weight loss achieved significantly greater percent excess weight loss at 3 months, but equivalent percent excess weight loss at 6 months compared to patients with no mandatory preoperative weight loss [12]. Mrad et al. performed a large retrospective chart review of 562 bariatric surgery patients undergoing a variety of different procedures including open RYGB, LRYGB, VBG, and LAGB [28]. The authors found that while early 3-month postoperative weight loss in men was greater for those patients who had preoperative weight loss, no correlation was found in either gender at 6 months, 12 months, or 24 months [28]. Giordano et al. found patients who achieved exceedingly high preoperative weight loss had greater postoperative weight loss at 1 year [23].

Two nonrandomized studies have found preoperative weight loss associated with improved long-term postoperative weight loss [19, 20]. Looking at patients who underwent LRYGB, Alvarado et al. determined that for every 1% increase in preoperative weight loss there was an associated 1.8% increased estimated weight loss at 1 year postoperatively [20]. Lastly, Still et al. found that patients who lost in excess of 10% of their body weight preoperatively were statistically more likely to achieve 70% loss of excess body weight at 1 year following both open and LRYGB [19].

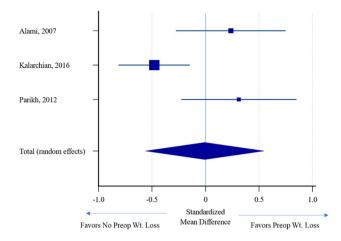
A mix of randomized control trials and prospective and retrospective cohort studies have found no relationship or even a negative relationship between pre-surgical weight loss and postoperative short-term and long-term weight loss. Parikh et al. performed a pilot randomized control trial that evaluated 55 patients who either underwent a mandatory 6-month medically supervised weight management program or "usual" care for 6 months [14]. At 3 months and 6 months postoperatively, the authors found no significant differences in weight loss, patient activation scores, medical adherence, or eating behavior between the two groups [14]. However, participation in the medically supervised weight management program was associated with a positive effect on postoperative physical activity [14]. Equivalent short-term weight loss results were also found by Kalarchian et al. After randomizing 240 patients to either a 6-month behavior lifestyle intervention or 6 months of usual presurgical care, the authors found comparable percent weight loss between the two groups at 6 and 12 months. Interestingly, there was a significantly decreased 24-month weight loss in patients randomized to mandatory behavior lifestyle interventions [13]. Kuwada et al. prospectively studied 440 patients undergoing either LRYGB or LAGB divided into two groups, patients required to complete a mandated medical program (6 months of standardized weight loss designed by medical bariatricians and nutritionists) and patients with no mandated preoperative medical program [18]. The authors found no significant differences in the percentage of excess weight loss between the two groups at 6 months or 12 months postoperatively, as well as no significant differences in weight loss on subset analysis for patients who either underwent LRYGB or LAGB [18].

Interestingly, Jamal et al. showed worse weight loss outcomes in 324 patients undergoing a 13-week mandatory preoperative dietary counseling [17]. The authors found that not only was the pre-surgery "dropout" rate 50% higher in the preoperative dietary counseling group, but also patients had statistically worse excess weight loss and higher BMIs at 1-year follow-up [17]. Ochner et al. sampled 94 patients required by their insurance company to complete preoperative medically supervised weight loss regimens (6-month physician-supervised weight loss program) and 59 patients with no preoperative requirement [29]. There was no difference in pre-surgical weight loss or 3-month post-surgical weight loss between the two groups [29]. In their cohort, patients who gained more weight preoperatively, actually lost more weight postoperatively, even after controlling for patient's initial weight [29]. With respect to SG, Sherman et al. found that the percentage of excess BMI lost at 1 year was not statistically different for patients who either lost weight, gained weight, or maintained weight preoperatively and concluded the preoperative weight loss was not a reliable predictor of postoperative weight loss for patients undergoing SG [31].

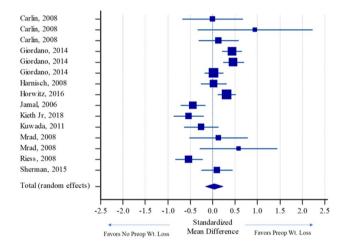
The most recent long-term data comes from Keith Jr. et al. Retrospectively examining 284 patients who either underwent a LRYGB or SG, the authors found that patients with no insurance-mandated physician-supervised diet had superior percent excess weight loss at 1 year and greater percent total weight loss at 24 months [1]. Harnish et al., in a retrospective analysis of 1629 patients, found no difference in the percentage of excess weight loss at 12 months or 24 months in patients who had a greater than 10-pound preoperative weight loss as compared to patients with preoperative weight gain [24]. Additionally, patients who experienced preoperative weight loss had equivalent resolution rates of diabetes, hypertension, and continuous positive airway pressure discontinuation at 1 and 2 years postoperatively [24]. Similarly, Carlin et al. showed that preoperative weight loss was not correlated with postoperative weight loss 12 months following surgery for 295 patients undergoing LRYGB [22].

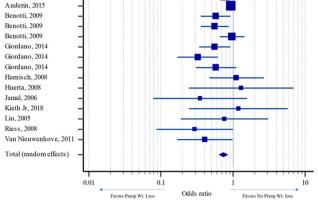
#### **Meta-Analysis**

Meta-analysis of the three randomized control trials evaluating the use of a structured preoperative weight loss regimen compared to the standard of care was evaluated for impact on postoperative weight loss. Kalarchian et al. measured weight loss outcomes up to 24 months, and Alami et al. and Parikh et al. followed patients for 6 months. On meta-analysis, there were no differences in %EWL between the two



**Fig. 1** Forest plot and random effects meta-analysis of randomized control trials measuring mean excess weight loss with a structured preoperative weight loss program as compared to standard care. SD, standard deviation; N, number; SMD, standardized mean difference; CI, confidence interval





Anderin, 2015

Anderin, 2015

**Fig. 3** Forest plot and meta-analysis of studies evaluating perioperative complications (perioperative to 90 days) for cohorts undergoing preoperative weight loss versus no preoperative weight loss

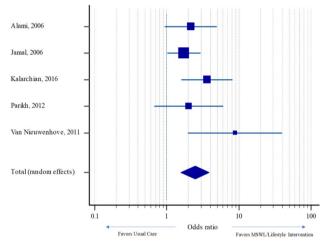


Fig. 2 Forest plot and meta-analysis of prospective and retrospective cohort studies included evaluating mean percent excess weight loss (%EWL) at 12 months for cohorts undergoing preoperative weight loss versus no preoperative weight loss

Fig. 4 Forest plot and meta-analysis of studies reporting patient attrition rates when randomized or enrolled in medically supervised weight loss (MSWL) programs or lifestyle interventions as compared to the standard of care

groups (SMD: -0.007; CI: -0.561 to 0.546; p = 0.98) (Fig. 1). Similarly, meta-analysis was completed for both prospective and retrospective cohort studies evaluating %EWL at 12 months for cohorts undergoing preoperative weight loss versus no preoperative weight loss. Again, there was no difference in %EWL in the cohorts where patients lost weight preoperatively (SMD: 0.035; CI: -0.163 to 0.233; p = 0.73) (Fig. 2).

The risk of perioperative complications based on patients achieving preoperative weight loss was also reviewed. Meta-analysis found that patients achieving greater preoperative weight loss had a reduced risk

of developing perioperative complications (OR: 0.73; CI: 0.64 to 0.97; p < 0.001) up to 90 days after surgery (Fig. 3). Although statistically significant, the overall complication event rates for each cohort were similar (preoperative weight loss cohort: 2206/24278 [9.1%]; no preoperative weight loss cohort: 2492/24,088 [10.3%]).

Lastly, meta-analysis of the risk for patient attrition showed that enrollment in a lifestyle program or a MSWL program was heavily associated with an increased risk of attrition (OR: 2.50; CI: 1.57 to 3.89; p < 0.001). Cumulatively, patients enrolled in MSWL programs were lost 27.6% of the time as compared to only 15.6% of patients undergoing standard of care (Fig. 4).

## Discussion

Bariatric surgery is the only treatment for morbid obesity that has proven sustained long-term weight loss success and demonstrated cost-saving benefits [5, 33]. However, individual procedures are expensive and require patients to rely on third party payer support. While most patients at the time of surgeon consultation meet NIH criteria for weight loss surgery, many insurance companies require completion of mandatory physician-supervised weight loss and nutrition programs for coverage approval. While most studies, and clinicians, would agree that even modest preoperative weight loss can benefit both the patient and the surgeon, it remains key to distinguish whether [1] mandatory preoperative nutrition programs actually lead to clinically beneficial preoperative weight loss on their own and [2] patients who achieve preoperative weight loss, regardless of participation in a preoperative mandated program, achieve better postoperative outcomes. The data reviewed here, aimed at addressing this debate, is unquestionably mixed in terms of results, and most studies represent a low quality of evidence. While it remains clear that any amount of preoperative weight loss likely poses little to no risk for patients, the data suggests that preoperative weight loss programs and mandates do not reduce mortality nor improve long-term weight loss results. Preoperative weight loss programs may have a small beneficial effect on perioperative performance. There does appear to be support for preoperative weight loss's ability to reduce liver volume size and operative times. The impact of perioperative complications is mixed and of small magnitude. While meta-analysis of perioperative complications did suggest that patients achieving greater preoperative weight loss had a reduced risk of perioperative complications, the total difference in complication rates of the two cohorts was exceeding small (1%), suggesting this outcome difference was not clinically relevant.

The impetus for strict insurance-mandated preoperative weight loss programs include reduction in perioperative complications, the ability to confirm a surgical candidate's incapacity to lose weight by conventional treatments, or to test a patient's weight loss motivation and adherence to diet modifications in the belief that these programs will correlate with long term weight loss [29]. At this time, not enough high-quality evidence exists for insurance companies to justifiably deny a patient coverage for weight loss surgery based solely on whether they have completed a preoperative weight loss program or have achieved a mandatory set amount of weight loss with the intent of reducing perioperative complications. Additionally, the literature does not support inclusion in insurance-mandated clinical programs or preoperative weight loss's ability to produce improved postoperative weight loss over the usual care [17, 33]. Some studies, including one of only a handful of randomized control trials, even suggest that mandated programs may actually lead to worse postoperative weight loss outcomes. Based on the data available, a preoperative weight loss mandate would be harmful for many patients and not an effective surgery screening strategy.

Participation, specifically in an insurance-mandated program, cannot predict improved postoperative weight loss [17, 18, 33]. Furthermore, our meta-analysis suggests that mandatory programs increase patient attrition and continue to represent a significant reason patients are excluded from obtaining weight loss surgery [34]. Given the evidence presented, the authors feel that mandatory preoperative weight loss programs are not an effective tool in predicting motivated or acceptable surgical candidates and may, in turn, exclude otherwise qualified patients from a beneficial surgical procedure. Preoperative weight loss will benefit patients regardless of surgical intervention and surgeons should continue to encourage patients to lose weight during their preoperative evaluation. However, utilizing compliance in a preoperative acute weight loss attempt as a screening criterion which ultimately excludes a patient from receiving bariatric surgery will condemn the patient to a much worse health outcome with persistence of morbid obesity and obesity-related comorbidities. Even in the studies we reviewed showing the greatest effect of preop weight loss on postop complications and long-term weight loss, the effects were modest in degree and would be dwarfed by the reduction in health care outcomes among the increased proportion of patients denied surgery due to attrition within such programs. Ultimately, the factors determining whether surgical candidates will be able to achieve acceptable postoperative weight loss, follow postoperative diet restrictions, and have acceptable perioperative surgical outcomes are not affected by or well-predicted by preoperative weight change. The decision to proceed with surgery should lie with the health care team and not with insurance providers.

## Conclusions

Preoperative weight loss mandates do not improve long-term weight loss outcomes, have small beneficial effects on perioperative conduct, and significantly increase patient attrition in obtaining bariatric surgical care. As all these patients have been unsuccessful with non-surgical weight loss in the past, many bariatric surgery candidates would be unable to meet a pre-surgical weight loss mandate rendering them ineligible to receive an intervention that would otherwise improve their health and would delay the treatment of their obesity-related comorbidities [1, 33, 35]. Furthermore, bariatric surgery is not a limited resource akin to transplant surgery with its

limits on organ availability. Provision of bariatric surgery does not need to be limited only to those with the best outcome relative to other patients. It should be provided to any whose health outcome would be better than the outcome in the absence of bariatric surgery. Patient's access to care is already affected by race, socioeconomic status, and education level. We should not add to this list ephemeral ability to lose weight preoperatively when there is minimal demonstrable benefit and clear potential harm by limiting access to health-improving and life-extending procedures.

#### Declarations

**Ethics Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Consent for Publication Informed consent does not apply.

**Conflict of Interests** Dr. Kushner and Dr. Eagon have no conflicts of interest or financial ties to disclose.

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