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Weight Loss During Medical Weight Management Does Not Predict Weight Loss After Bariatric Surgery: A Retrospective Cohort Study

Short title: Medical weight management and post-op weight loss

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40 **Abstract**

Background

Many bariatric surgical centres mandate achieving weight loss targets through medical weight management programmes prior to offering bariatric surgery, but the evidence for this is unclear.

45

Setting

Multi-centre community- and acute-based medical weight management (MWM) services referring to one regional bariatric centre, United Kingdom (UK)

50 **Objectives**

To examine the relationship between weight changes during (1) MWM and (2) pre-operative low-energy-diet (LED), and weight changes at 12 and 24 months post-surgery.

55 **Methods**

A retrospective cohort study of patients who attended MWM and then underwent a primary laparoscopic bariatric procedure (adjustable gastric banding (LAGB), or Roux-en-Y gastric bypass (RYGB)) in a single bariatric centre in the UK between 2013 and 2015. Data were collected from patient electronic records.

60

Results

208 patients were included (LAGB n=128, RYGB n=80). Anthropometric data were available for 94.7% and 88.0% of participants at 12 and 24 months, respectively.

There was no relationship between weight loss during MWM and post-surgery at either 12 or 24 months. Weight loss during the pre-operative LED predicted greater weight loss following LAGB (β= 0.251, p=0.006) and less weight loss after RYGB (β= -0.390, p=0.003) at 24 months, after adjusting for age, gender, ethnicity, baseline weight and LED duration.

Conclusions

Weight loss in MWM does not predict greater weight loss outcomes up to 24 months following LAGB or RYGB. Greater weight loss during the pre-operative LED predicted greater weight loss post-LAGB and less weight loss post-RYGB. Our results suggest that patients should not be denied bariatric surgery due to not achieving weight loss in MWM. Weight loss responses to pre-operative LEDs as a predictor of post-surgical weight loss requires further investigation.

Keywords: weight loss, pre-operative weight loss, post-operative weight loss, medical weight management, low energy diet

1.0 Introduction

Obesity is a global epidemic and rates of obesity have almost doubled globally since 1980 [1]. In the United Kingdom (UK), 28.7% of adults have obesity (defined as a body mass index (BMI) ≥ 30kg/m^2) [2]. The National Institute for Health and Care Excellence (NICE) recommends bariatric surgery as a treatment option for patients with a BMI ≥ 40kg/m^2; a BMI ≥ 30kg/m^2 with new onset of Type 2 Diabetes (T2D); or a BMI ≥ 35 kg/m^2 with T2D or other obesity-related complications [3].

Although bariatric surgery results in significant and long-term sustained weight loss [4], there is considerable heterogeneity in the maximum excess weight loss (EWL) achieved following surgery ranging from 12% to 143% [5]. In a large registry cohort study, 35% and 60% of patients who underwent RYGB and LAGB, respectively, achieved <50% EWL at 3 years post-operatively [6]. Hence, it is important to identify pre-surgical predictors of post-bariatric surgery weight loss to aid patient selection and help patients make informed decisions.

One possible predictor of post-bariatric surgery weight loss is weight loss before surgery, as a marker of "intrinsic motivation" [7]. As a result, some MWM services mandate ≥ 5% weight loss before allowing the patient to be referred for bariatric surgery. However, the evidence to support such practice is limited. Two systematic reviews and some studies [8–12] have examined the relationship between mandatory pre-bariatric surgery weight loss and post-operative weight losses. These studies largely did not include patients with LAGB and did not include patients receiving support from MWM programmes.

Therefore, the question of whether weight loss pre-bariatric surgery, particularly in the setting of MWM, is a predictor of weight loss post-bariatric surgery remains unclear. Hence, we conducted a study that aimed to investigate whether weight change during MWM predicts 12 and 24 month weight loss in patients undergoing LAGB and RYGB. The secondary aim was to investigate whether weight change in the immediate pre-operative liver shrinking low-energy-diet (LED) phase can predict 12 and 24 month post-surgery weight loss.

2.0 Material and methods

We conducted a retrospective cohort study of weight loss outcomes for all consecutive patients who were accepted for bariatric surgery and underwent a primary LAGB or RYGB procedure at our bariatric centre over a 2 year period between 1st January 2013 and 1st January 2015. Data were collected from electronic patient records. Baseline data included anthropometrics, demographics, and T2D status. Anthropometric measurements were also recorded at the following timepoints: initial surgical assessment appointment prior to surgery, day of surgery, and post-surgery at 12 and 24 months. Percentage weight change at each timepoint was defined as the following:

- Weight loss during MWM

  (weight at initial MWM appointment) – (weight at initial surgical assessment appointment) / (weight at initial MWM appointment) *100

- Weight loss during LED pre-operative phase

  (weight at initial surgical assessment appointment) – (weight on day of surgery) / (weight at initial surgical assessment appointment) *100

- Weight loss 12 months post-surgery

  (weight on day of surgery) – (weight at 12 months post-surgery) / (weight on day of surgery) *100

- Weight loss at 24 months post-surgery

  (weight on day of surgery) – (weight at 24 months post-surgery) / (weight on day of surgery) *100

Therefore, negative values indicate weight gain and positive values indicate weight loss.

We did not include patients undergoing a primary sleeve gastrectomy procedure, owing to small patient numbers at that time in our centre. Patients were excluded if they became pregnant, underwent revisional surgery or died during the 24 month follow-up period.

At our centre, similar to the rest of the UK, to qualify for public NHS funding for bariatric surgery patients must have attended a MWM service for 12 months (or 6 months in patients with BMI ≥ 50 kg/m^2) prior to referral for surgery. The composition of MWM varies in the UK; but commissioning guidelines recommend that patients have access to a dietitian, psychologist and a physician. We accept bariatric surgery referrals from five different MWM services from across the Midlands region of the UK and do not mandate a specific weight loss target as a condition to referral for bariatric surgery. At our centre, patients are asked to follow a LED of 800-1000 kcals for between 2 and 6 weeks prior to their surgery date, depending on their baseline BMI. All patients receive dietetic advice during their pre-surgery diet. Patients attend post-surgery follow-up appointments with a dietitian, starting with a group session at 6 weeks post-surgery and then one-to-one every 3 months for a 24 month period. All patients are recommended to take multivitamin and mineral supplementation and undergo blood monitoring, as per British Obesity and Metabolic Surgery Society guidelines [13].

This project was conducted as part of a health service evaluation using routinely collected measures to assess the outcomes of bariatric surgery at our centre and

was approved by the department governance lead at University Hospitals Birmingham NHS Foundation Trust (#5037).

2.1 Statistical Analysis

All analyses were performed using IBM SPSS Statistics 25.0. Data were presented as frequencies, mean (±SD) or median (IQR), depending on data distribution. Differences between LAGB and RYGB groups at baseline were assessed for continuous variables using the Independent Student's t-test or the Mann Whitney test, depending on data distribution, and the chi-squared test was used for categorical variables. The relationship between pre- and post-surgery weight loss was assessed using Spearman's rank correlation as the data were not normally distributed based on Shapiro-Wilk test. Data were analysed, stratified by the surgical intervention performed (i.e. LAGB or a RYGB) due to the difference in weight loss mechanisms between these two procedures. To assess whether weight changes during MWM or the pre-operative phase predicted post-surgery weight losses, linear regression analyses were performed. Linear regression assumptions of homoscedasticity and multicollinearity were assessed and not violated. Independent variables included in the model were age, gender, ethnicity, baseline weight, T2D status and time in the MWM or pre-operative LED phase and were chosen based on biological plausibility. Analyses were also conducted to explore whether the attainment of 5% weight loss in MWM as a binary covariate predicts post-surgical weight loss. A p-value of <0.05 was considered significant.

3.0 Results

185 271 patients were referred from five Tier 3 MWM services from across the Midlands region of the UK and underwent a primary LAGB or RYGB procedure. 63 patients were excluded due to pregnancy (n=4), death (n=1) and missing anthropometric data at baseline in MWM (n=58). A total of 208 patients were therefore included in the analysis (LAGB n=128, RYGB n=80). 197 participants (94.7%) (LAGB n=128, RYGB
190 n=69) attended follow-up at 12 months and 183 participants (88.0%) (LAGB n=19, RYGB n=64) attended follow-up at 24 months. There was no significant difference in the baseline characteristics of the LAGB and RYGB study population, as summarised in Table 1. The weight changes during MWM, pre-operative LED and post-surgery are summarised in Table 2.

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3.1 Relationship between weight loss during MWM and 12 months post-surgery

The relationship between MWM weight loss (%) and post-surgery weight loss (%) was not significant at 12 months for LAGB (r= -0.073, p=0.413) or RYGB (r= -0.136,
200 p=0.265). Using linear regression, there was no significant relationship between weight loss (%) in MWM and post-surgery weight loss (%) after undergoing LAGB or RYGB (Table 3). After adjustment for age, gender, baseline weight, time in MWM, T2D and ethnicity, the relationship between weight loss (%) in MWM and post-surgery weight loss for either LAGB or RYGB was still not significant (Table 3).
205 However, age (β= -0.272, p=0.034) and identifying as of South Asian ethnicity (β= 0.247 p=0.038) predicted less weight loss (%) at 12 months for patients post-RYGB.

The relationship between attainment of 5% weight loss in MWM and post-operative weight loss was not significant at 12 or 24 months, with and without adjustments (Table 3). There was no significant difference (p=0.087) in post-surgery weight loss (%) at 12 months between those who achieved (median 8.9%, IQR 2.7 to 14.2) compared with those that did not achieve (median 10.9%, IQR 6.0 to 16.0) ≥5% weight loss during MWM for LAGB (Figure 1). There was also no significant difference (p=0.949) in post-operative weight loss (%) at 12 months between those who achieved (median 28.2%, IQR 23.4 to 32.0) compared with those that did not achieve (median 27.5% IQR 22.1 to 32.8) ≥ 5% weight loss during MWM for RYGB (Figure 1).

3.2 Relationship between weight loss during MWM and 24 months post-surgery

The relationship between MWM weight loss (%) and post-surgery weight loss (%) at 24 months was not significant for LAGB (r= -0.035, p=0.708) or RYGB (r= -0.128, p=0.312). Unadjusted and adjusted analyses did not show a significant relationship between weight loss (%) in MWM and post-surgery weight loss (%) at 24 months for either LAGB or RYGB.

The relationship between attainment of 5% weight loss in MWM and post-operative weight loss was not significant at 24 months (Table 3). There was no significant difference (p=0.095) between weight loss (%) at 24 months post-surgery between those who attained (median 7.0%, IQR 2.0 to 15.7) compared with those that did not attain (median 11.3%, IQR 4.5 to 19.7) ≥ 5% weight loss during MWM for LAGB

(Figure 2). There was also no significant difference (p=0.681) between weight loss (%) at 24 months post-surgery between those who attained (median 30.9%, IQR 22.2 to 35.7) compared with those that did not attain (median 29.9%, IQR 24.0 to 38.0) ≥ 5% weight loss during MWM for RYGB (Figure 2).

3.3 Relationship between weight loss during pre-operative LED phase and 12 months post- surgery

The relationship between pre-operative LED weight loss (%) and post-surgery weight loss (%) at 12 months was not significant for RYGB (r=0.161, p=0.187), but there was a significant positive correlation for LAGB (r=0.215, p=0.015). Pre-operative LED weight loss (%) predicted 12 month post-surgery weight loss (%) for LAGB (β=0.179, p=0.043), which was no longer significant in the adjusted analysis (β= 0.174, p=0.058) (Table 4). No significant relationship was found between pre-operative weight loss (%) and weight loss (%) at 12 months post-RYGB. Analysis using the attainment of a 5% weight loss, instead of weight loss (%), during the pre-operative LED period was not a significant predictor of 12 month post-surgery weight loss (%) for LAGB or RYGB (Table 4).

3.4 Relationship between weight loss during pre-operative LED phase and 24 months post-bariatric surgery

There was no significant relationship between weight loss (%) during the pre-operative LED phase and weight loss (%) post-RYGB (r=-0.123, p=0.334), but greater weight loss during the pre-operative LED phase did have a significant positive correlation with weight loss (%) post-LAGB (r=0.200, p=0.029) at 24 months.

Using linear regression, pre-operative LED weight loss (%) predicted weight loss (%) at 24 months post-LAGB (β= 0.251, p=0.006); which remained significant after adjustment (Table 4). These findings indicate that greater weight loss in the pre-operative LED phase predicted greater weight loss at 24 months post-LAGB.

There was no significant relationship between pre-operative LED weight loss (%) and weight loss (%) at 24 months post-RYGB, however after adjustment, pre-operative weight loss (%) did inversely predict weight loss (%) at 24 months post-RYGB (β= -0.390, p=0.003). Time spent in the pre-operative LED phase (β= -0.251, p=0.039) and identifying as a South Asian ethnicity (β= -0.357, p=0.004) were also significant predictors of weight loss (%) at 24 months post-RYGB. These results indicate that greater weight loss in the pre-operative period, longer time in the pre-operative LED phase and being South Asian were associated with less weight loss 24-months post-RYGB. Using the attainment of a 5% weight loss, instead of weight loss (%), in the pre-operative LED phase did not alter the findings for either LAGB or RYGB (Table 4).

4.0 Discussion

While several studies [9,10,14] have examined the relationship between weight loss attainment during the pre-operative liver shrinking period and weight loss post-surgery, to our knowledge our study is the first to examine the relationship between weight loss during a MWM programme and weight loss up to 24-months post-bariatric surgery. This study has found that weight changes during a MWM program did not predict weight changes following LAGB and RYGB for up to 24 months post-surgery. Our findings suggest that patients should not be denied access to bariatric surgery based on their change in weight in MWM. However, our results showed that greater weight loss during the pre-surgery LED phase predicted greater weight loss in LAGB and less weight loss after adjustment in RYGB at 24 months. Therefore, our results suggest that weight loss during the pre-operative LED phase might help predict post-surgery weight loss response.

4.1 Weight loss in MWM and post-surgery weight loss

Our study shows that weight loss within a structured MWM program does not predict weight loss at up to 24 months after bariatric surgery, regardless of undergoing a RYGB or LAGB. This is consistent with our previous study [15] which showed that weight loss induced by glucagon-like peptide-1 (GLP-1) receptor agonists in patients with T2D did not predict post-LAGB or post-RYGB weight loss. These findings support the hypothesis that weight loss after bariatric surgery is due to biological factors and mechanisms and not due to a patient's "intrinsic motivation", will-power or adherence. This is further supported by the study by Dixon et al. [16] which showed

that LAGB weight loss outcomes were similar regardless of patients' readiness to change.

While in the United States, some insurance companies require a preoperative > 5% weight loss prior to approving surgery, pre-surgery weight loss is not a funding requirement for bariatric surgery in the UK. In fact, NICE guidance [3] states that a patient must have tried all appropriate non-surgical measures and have *not* achieved or maintained "adequate, clinically beneficial weight loss" to be considered for bariatric surgery. Despite this, some local protocols at bariatric centres across the UK mandate a > 5% weight loss during MWM. In the absence of any funding requirement and without clear evidence of the clinical benefits of mandated MWM weight loss [17], these findings do not support using attainment of an arbitrary weight loss target during MWM as a criterion to determine the suitability of a patient as a candidate for bariatric surgery.

4.2 Weight loss during the pre-operative LED phase

Our results show that greater weight loss in the pre-operative LED phase, which includes a 2 to 6-week LED (800-1000 kcals per day), was associated with greater weight loss up to 24 months after undergoing LAGB. R^2 was 0.125, suggesting that the model explained 12.5% of the variance in weight loss at 24 months post LAGB. Two prior studies [11,12] have examined the same relationship, but for very-low-energy-diets (VLEDs) (< 800kcals per day) prior to LAGB procedures, and had different findings. Results from one small study [11] of 36 patients found an inverse relationship between pre-operative weight loss during a 6-week VLED and 12 and 36

320 month weight loss post-LAGB, while another study [12] of 127 patients found no relationship between weight loss attained using a two week VLED and 24 month weight loss post-LAGB. Some of the differences between others' studies (using VLED) and ours (using a LED) may be explained by evidence that LEDs (800-1000kcals) do not lead to significant reductions in hunger compared to the ketogenic
325 state achieved with VLEDs (< 800kcals) [18].

However, our results showed that greater weight loss in the pre-operative LED phase predicted less weight loss at 24 months post-RYGB, with an R^2 of 0.343 suggesting that the model explained 34.3% of the variance in weight loss at 24 months post-
330 RYGB. This study adds to the existing body of conflicting evidence investigating the relationship between weight loss in the immediate pre-operative liver shrinking period and weight loss after RYGB [9,14]. Our findings are consistent with a previous study [19] that found greater excess weight loss post-RYGB in patients who had less weight loss prior to RYGB surgery. In addition, the findings of our study are consistent with
335 another study of our group [15] which showed greater weight loss (via lifestyle or GLP-1 receptors agonists) was negatively correlated with weight loss following RYGB at 12 months. These findings might be explained by the different mechanism of weight loss between RYGB and the LED, and the inability to predict who will produce better incretin responses post-RYGB. In addition, it is plausible that the amount of weight
340 loss that can be achieved by RYGB in any individual may be pre-determined by several biological factors, known as the weight 'set-point' [15,20].

4.3 Limitations and Strengths

Our study has several limitations primarily related to the retrospective nature of this study. Although we included important variables in the regression analysis, the R^2 were largely modest (<35%), suggesting that un-measured predictors of post-surgery weight loss existed within our study population. The lack of sleeve gastrectomy is another weakness, but at the time of data collection the number of sleeves was very limited in our centre and its popularity has increased significantly since then.

Our study has several strengths. We included patients referred from multiple MWM centres, rather than a single centre. We also had a very low proportion of loss to follow-up and we utilised a well-structured and established database at our bariatric centre. We also examined the above-mentioned relationships utilising different approaches (general lifestyle and behavioral intervention during MWM, and the liver shrinking LED).

5.0 Conclusion

Our study suggests that greater weight loss in MWM programmes is not associated with greater weight loss post-surgery for either LAGB or RYGB procedures. The extent of weight loss or attainment of an arbitrary 5% weight loss in MWM should not be used as an indicator of potential post-surgery weight loss ‘success’ or as a barrier to referral for bariatric surgery. Weight loss during a mandated 2-6 week pre-operative LED may be associated with weight loss up to 24 months post-LAGB, but this requires further investigation.

Conflicts of interest disclosure: All authors report no competing interests.

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Legends:

445 Table 1: Baseline characteristics

Table 2: Weight loss during medical weight management, pre-op phase, 12 months and 24 months post-bariatric surgery

450 Table 3: Uni-variate and multi-variate analysis for the relationship between weight loss in medical weight management and 12 and 24 months post-bariatric surgery

Table 4: Uni-variate and multi-variate analysis for the relationship between weight loss in pre-operative phase and 12 and 24 months post-bariatric surgery

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Figure 1: Clustered box-plot of weight loss (%) at 12-months post-bariatric surgery by attainment of weight loss during medical weight management

Figure 2: Clustered box-plot of weight loss (%) at 24-months post-bariatric surgery by

460 attainment of weight loss during medical weight management

Abbreviations:

BMI	body mass index
EWL	excess weight loss
GLP-1	glucagon-like peptide-1 receptor agonist
LAGB	laparoscopic adjustable gastric banding
LED	low energy diet (800 – 100kcals per day)
MWM	medical weight management
RYGB	Roux-en-Y gastric bypass
T2D	Type 2 Diabetes
VLED	very low energy diet (<800kcals per day)
WL	weight los