#### **ORIGINAL CONTRIBUTIONS**





# A Specialized Medical Management Program to Address Post-operative Weight Regain in Bariatric Patients

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#### Abstract

**Introduction** Although bariatric surgery results in massive weight loss, weight regain over time up to as much as 25% is not uncommon. Weight regain in this population often leads to long-term weight loss failure and non-compliance in clinical follow-up and program recommendations.

**Methods** We analyzed early weight outcomes at 3 and 6 months of 48 bariatric patients referred to an individualized, multidisciplinary medical management program at the Center for Obesity Medicine (COM) to address weight regain in 2015 and compared to a group of matched non-bariatric patients. The medical management center, under the direction of a medical obesity specialist and complementary to the surgical program and multidisciplinary team, addressed weight regain with intensive lifestyle (diet, activity, anti-stress therapy, behavioral counseling, sleep) and with medical intervention (one or more anti-obesity medications).

Results According to early findings, the average percentage post-operative weight regain of patients entering the weight management program was 20% above nadir and time since surgery averaged 6 years (range = 1 to 20 years) with a mean weight loss of -2.3 kg after 3 months and -4.4 kg at 6 months into the program. Individuals most successful with weight loss were those treated with anorexigenic pharmaceuticals. Weight and percent weight loss were significantly greater for the non-surgical than the surgical patients at 3 and 6 months (p < 0.05).

**Conclusions** A medically supervised weight management program complementary to surgery is beneficial for the treatment of weight regain and may prove important in assisting the surgical patient achieve long-term weight loss success.

**Keywords** Medical weight loss · Bariatric surgery · Weight regain · Anti-obesity drugs · Weight recidivism

# Introduction

Bariatric surgery is an effective surgical procedure for the treatment of severe obesity with overall improvement in medical comorbidities [1]. However, weight recidivism post-bariatric surgery has been noted among post-operative patients

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[2, 3] with 20–30% of patients either failing to reach targeted weight goals or failing to maintain a 20% weight loss over 10 years based on the type of operation [4–7]. Underlying factors which influence weight regain are multifactorial including nutritional, endocrine, anatomical, psychosocial, and lifestyle/behavioral components [3, 8]. After initial weight loss following the operation which influences mechanisms involved in appetite and body weight regulation, patients have reported increase in hunger, cravings, and eating behaviors which correlate with the weight regain [7, 9]. Previous small studies focusing on behavioral intervention to address weight regain post-bariatric surgeries have reported modest or little benefit [3, 10-12]. Given the challenges faced by these patients, there is a need for a multidisciplinary approach to addressing the weight regain. To date, little research has focused on pharmacological coupled with behavioral intervention to address post-operative weight regain. Thus, we report early outcomes of a multidisciplinary specialized medical obesity



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treatment center in the management of weight regain postbariatric surgery.

#### **Methods**

The qualitative evaluation study underwent formal approval by the institution board review. We analyzed de-identified clinical outcomes extracted from the electronic medical records for post-operative bariatric surgery patients treated for weight regain at the Center for Obesity Medicine (COM), Celebration, FL, a multidisciplinary outpatient specialized obesity care center affiliated with Florida Hospital. The center was directly co-located with the bariatric surgery team to allow increased collaboration and easier pathway for patient referrals. COM was under the direction of an obesity medicine specialist and affiliated with a dedicated team of medical ancillary experts including a dietitian, clinical psychotherapist, trained obesity nurse practitioner, and patient navigator. We retrospectively evaluated clinical weight outcomes of all 58 patients referred to COM during 2015 for management of weight regain post-bariatric surgery. Initial assessment at COM consisted of (1) anthropometrics measurements (weight with shoes off [Seca mBCA body composition analyzer] and height [Seca stadiometer], (2), laboratory evaluation including screening for vitamin and mineral deficiencies post-bariatric surgery, (3) nutrition, and (4) psychosocial evaluation. Lifestyle intervention included counseling on the following: (1) nutrition, (2) physical activity, (3) anti-stress therapy, (4) mal-behavioral patterns, and (5) sleep hygiene, including screening for recurrent sleep apnea. Patients were also prescribed one or more medications to treat weight gain (metformin, phentermine, topiramate, combination phentermine/ topiramate, combination bupropion/naltrexone, lorcaserin, zonisamide, and/or glucagon-like peptide-1 agonists). Vitamin deficiencies, if noted on laboratory screening, were addressed with appropriate respective oral or injectable supplementation. Post-operative weight regain patients were encouraged to take daily multivitamins and supplements as per bariatric surgery recommendations [13]. Follow-ups were recommended once a month for the first 3 months with the obesity medicine specialist and thereafter every 2–3 months. Data from the bariatric patients was also compared to non-bariatric, weight matched patients also enrolled in the medical weight management program. Statistical analyses were done using SPSS software. All variables were reported as frequency or percentages, mean  $\pm$  standard deviation (SD), or standard error of the mean (SEM). Repeated measures analyses were used to assess changes in weight pre- and post-medical intervention. Differences between medicine and non-medicine groups and between bariatric and non-bariatric patient data were determined using non-paired t tests. A p value less than 0.05 was considered significant.



### Results

A total of 58 patients were referred from the bariatric surgeons to COM in 2015 for management of weight regain post-operatively, of which 8 patients did not schedule their initial appointments (13.8% no show rate for bariatric referrals to medical weight management); 2 patients had missing data and could not be included in the analyses. Thus, 48 patients who presented for the initial visit were included in the final analyses along with 48 matched non-bariatric controls. A total of 25 patients (52.0%) underwent Roux-en-Y-gastric bypass surgery (RYGB); 14 patients (29.2%) underwent vertical sleeve gastrectomy (SG); 9 patients (18.8%) underwent abdominal gastric banding procedure (AGB).

## **Surgical Weight History**

Surgical weight history (Table 1) for these patients (mean  $\pm$  standard deviation [SD]) was as follows: preoperative weight 133.2  $\pm$  22.0 kg [average body mass index (BMI) 49.1]; nadir weight 86.1  $\pm$  16.4 kg (average BMI 31.8); surgical weight loss 47.1  $\pm$  17.9 kg (mean total % change in weight was 35.4% post-operatively); mean time since surgery was 6.1  $\pm$  4.6 years (1–20 years); initial weight upon presentation to COM was 103.6  $\pm$  18.6 kg (mean BMI 38.3). The initial weight of the bariatric patients when presenting to COM by procedure type did not differ significantly (p > 0.05; 103.16  $\pm$  3.43 kg RYGB; 102.10  $\pm$  4.15 kg SG; 104.2  $\pm$  4.41 kg AGB). At the initial visit, the proportion of surgical weight loss regained since nadir for the bariatric patients was 16.1 kg or 34% of surgical weight loss. The % increase in weight since nadir was 20.1%.

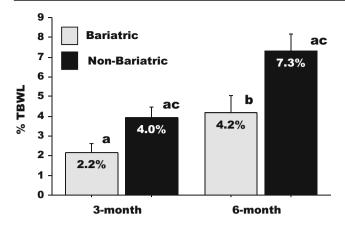
# Early Weight Loss Outcomes for Bariatric and Non-bariatric Patients

Initial program weight (kg) was  $102.91 \pm 2.55$  for bariatric and  $109.56 \pm 3.97$  for non-bariatric patients (p > 0.05). Average weight loss at 3 and 6 months respectively

**Table 1** Surgical weight history (n = 48 bariatric patients with weight regain)

	Mean ± SD
Pre-op weight	$133.2 \pm 22.0 \text{ kg (BMI = 49.1)}$
Nadir weight	$86.1 \pm 16.4 \text{ (BMI = 31.8)}$
Surgical weight loss	$47.3 \pm 17.9 \text{ kg}$
Total % change in weight	35.0%
Time since surgery	$6.1 \pm 4.6$ years (1 to 20 years)
Initial program weight	$103.6 \pm 18.6 \text{ kg (BMI} = 38.3)$
% weight gain nadir to program weight	20.1% (16.1 kg)
% surgical weight loss regained	34.0%

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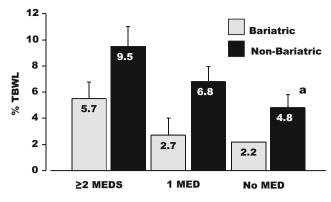
- <sup>a</sup> p<0.0001 from Baseline
- p=0.0005 from Baseline
- ° p<0.05 Bariatric vs. Non-Bariatric

Fig. 1 Percentage total body weight loss (%TBWL) for bariatric and non-bariatric patients

(Fig. 1) for the bariatric post-operative patients enrolled in the specialized medical obesity program was -2.3 kg (2.2%) and -4.4 kg (4.2%) (p < 0.0001 baseline vs. 3 months, p = 0.0005 baseline vs. 6 months). Outcomes for the different surgical approaches did not significantly differ (p > 0.05; data not shown). Average weight loss at 3 and 6 months for the non-surgical patients (Fig. 1) was -4.2 kg (-4.0%) and -7.7 kg (7.3%) (p < 0.0001 baseline vs 3 and 6 months). Weight and percent weight loss were significantly (p < 0.05) greater for the non-surgical than for the surgical patients at 3 and 6 months.

#### **Effectiveness of Weight Loss Medications**

Figure 2 illustrates the effectiveness of 2 or more types of medication as compared to one anti-obesity medication or none. As seen, for both the bariatric and non-bariatric patients, 2 or more meds were most effective in inducing weight loss at 3 and 6 months into the program. For the non-bariatric patients, the % change in weight at 6 months was significantly greater (p < 0.05) for the 2+ meds (9.5%) than for the patients taking only 1 med (6.8%) or no meds (4.8%). Within this group, there were no significant differences in 6-month weight loss between those taking one med as compared to those who were not on medication. A similar trend toward greater weight loss with 2 or more medications was found for the bariatric patients, as well, although these numbers did not reach statistical significance likely due to the small numbers and variability within this group. A trend was also apparent between the effects of medication on weight loss between the non-bariatric and bariatric patients, particularly as regards those individuals on two or more medications (p = 0.08).



#### <sup>a</sup>p< 0.05 No Medication vs. ≥ 2 Medications

**Fig. 2** Effect of anti-obesity medication(s) on weight loss outcomes in bariatric and non-bariatric patients. Additive effects of anti-obesity medications on weight loss outcomes to treat weight regain. Medications included metformin, phentermine, combination phentermine/topiramate, combination bupropion/naltrexone, lorcaserin, zonsiamide, topiramate, and glucagon-like 1 agonists; Med(s) = medication

#### Attrition

Among the different surgical types, the attrition rates at 3 months for the RYGB, SG, and AGB were 40, 36, and 33%, respectively. At 6 months, the attrition rates for the RYGB, SG, and AGB were 60, 79, and 78%. Attrition rates were greatest for those who had the SG and AGB procedures, at least, at 6 months. Overall attrition rate in the medical management program for all patients including non-bariatric controls was 23%. For the bariatric patients enrolled in the medical weight management program, attrition rate at 3 and 6 months was 37.5 and 68% respectively.

# **Discussion**

The comprehensive specialized obesity treatment program resulted in statistically significant weight loss in post-operative bariatric patients at 3 months that was subsequently maintained and greater at 6 months (-2.2% and -4.2% from baseline at 3 and 6 months respectively). The weight loss attained through the COM program was much higher than previous reported behavioral interventions in a meta-analysis which found positive but modest minimal differences between treatment and controls (1.6%) 6–12 months following the lifestyle intervention [10]. In addition, weight loss after weight regain was greater for bariatric individuals treated with > 2 antiobesity medications (-5.7%) but was less than non-surgical patients enrolled in the specialized obesity program ( $-9.5\% \ge$ 2 medications; Fig. 2), possibly related to less disease severity and earlier intervention in non-surgical patients. This finding also suggests that individuals with severe obesity, even though they might have surgery, manifest physiology and genetics



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causing them to resist weight loss. The early clinical outcomes reported from COM provide preliminary support for a multi-disciplinary approach that incorporates pharmacological intervention and use of anti-obesity medications for weight regain after bariatric surgery.

Overall, the program shows benefit in this sub-population of patients with weight regain post-bariatric surgery, though longterm data is needed. Notably, the patients continued to improve their weight losses 6 months into the program and approached nearly a mean 4% initial weight loss. Weight loss of 3-5% is clinically significant and has been shown to improve obesityrelated comorbidities [14]. Furthermore, though the intervention did not numerically evaluate hunger and satiety scores, decreased food cravings, decreased hunger, and improvement in eating behaviors were reported by all the patients, especially "decreased hunger" for those on anti-obesity medications. The patients also treated with  $\geq 2$  anti-obesity drugs had more weight loss compared to those who were not on any antiobesity medications (Fig. 2) though more robust studies are needed. This occurred despite the fact that there were no significant differences in % surgical weight responses, % weight regain from post-operative nadir, or initial program weight between those who were or were not on anti-obesity medication. Given the complex physiology involved with severe obesity including mechanisms influencing weight regain postbariatric surgery, it is interesting to note that these patients required more aggressive pharmaceutical intervention and that monotherapy with one anti-obesity medication may not be sufficient to treat weight regain post-bariatric surgery, suggestive also of poorer weight loss response. The bariatric patients also had higher attrition rates than the non-bariatric patients within the medical obesity program, likely related to previous numerous attempts at dietary intervention without success and meager weight loss outcomes within the medical program; all of whom dropped from the medical program were poor responders. These findings however do suggest that there may be some benefit in pharmacological treatment of weight regain postoperatively though more research is needed to better understand underlying physiological mechanisms leading to an improved weight loss outcome. These findings are also consistent with a previous multicenter study highlighting weight loss medications as a useful adjunct to inadequate weight loss or weight regain in bariatric patients [15]. Anti-obesity medications exert their effects through various pathways including the central nervous system and neuro-hormonal mechanisms affecting appetite and energy regulation and thus may positively influence physiological eating behaviors, hunger, and satiety cues postoperatively [16]. More recently, studies have shown that secretions of gut hormones differ in successful weight loss outcome compared to inadequate weight loss or weight regain [17, 18]. Further research is necessary to correlate effective pharmaceutical anti-obesity approaches targeting bariatric patients experiencing weight regain.

In addition to pharmacological strategies to combat weight regain, the program also incorporated sleep and stress management as part of intensive lifestyle modification. Sleep and stress have been associated with disturbances in circadian rhythm and insulin resistance promoting weight gain [19–23] while also exerting an effect on appetite, food cravings (hedonic activity), gut hormones, and other neurohormonal signals [24–28]. Future behavioral interventions targeting weight regain post-operatively need to explore this association further in post-operative bariatric patients.

The type of bariatric procedure did not appear to be a factor predicting the amount of weight lost after weight regain postoperatively in this study, although the variability was large and the numbers were small, particularly for those having an abdominal gastric banding and sleeve gastrectomy. Previous studies have shown distinct individual variability in response to bariatric surgery, with poor initial responders to weight loss also having more propensity to regain weight [29]. Identification of these poor initial responders to weight loss surgeries and insight into pre-surgical predictive clinical factors dictating weight loss response such as age of onset of obesity, high preoperative BMI, and presence of obesityrelated comorbidities [30] would be imperative to understand in order to treat these patients more effectively.

The outcomes highlighted in this study have limitations. This was a small retrospective study with variable bariatric surgeries and insignificant numbers for two of the surgical procedures; a multivariate analysis was not performed. Longer-term follow-up studies with more extensive numbers to examine the effects of comprehensive medical management for patients with weight regain who have had specific surgical procedures are needed. Bariatric patients need to be further queried as to reasons for reluctance in attending a medical weight management program postoperatively; previous bariatric studies evaluating attrition have cited inconsistent factors related to participant retention, aftercare attendance, and attrition [31, 32] though some qualitative factors have included inattention to aftercare after surgery, insufficient follow-up from the bariatric center, failure, shame, and vulnerability as reasons for irregular follow-up post-bariatric surgery [33]. Preoperatively, these bariatric patients might have trialed numerous medical weight loss programs, with only modest benefit [34], thus their reluctance in re-joining a similar program post-operatively. The medical weight management program studied was part of an overall comprehensive obesity care encompassing the bariatric center. Though only a small portion of all the medical weight management patients had received bariatric surgery, there were a number of bariatric patients who had regained significant weight post-operatively. Furthermore, though nutritional evaluation for vitamin and mineral deficiencies were addressed during the medical evaluation with appropriate supplementation prescribed, actual data on the prevalence of nutritional deficiencies among this population is important to note to determine adherence as a factor contributing to post-operative weight regain. More research and



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insights into modifiable factors, which may mitigate postoperative weight regain, are needed.

In general, though a medical weight management program can positively influence weight regain, not all hospital systems may have resources to invest in such a program. The establishment of COM was preceded by an almost 1-year designing and implementation phase. Hospital support and subsidy were garnered to provide adequate ancillary resources including dietitian and psychotherapy consultation services. Patients initially did not understand the value of a medical weight loss consultation when they had already undergone bariatric surgery and thus education and surgeon involvement was critical prior to the initial evaluation and assessment at COM. Because obesity-related medical comorbidities can recur overtime after bariatric surgery, involvement of a medical weight management team prior to the actual bariatric surgery and long-term follow-up may be integral component of comprehensive bariatric care. Though these measures were not quantified in the study, the main difficulties faced by the patients were lack of accountability and structure with continued lifestyle modification, along with lack of adherence to vitamin/mineral supplementation, and overwhelming increase in physiologic hunger, all of which the medical obesity intervention sought to address. Collaborative efforts by the bariatric surgeons with the medical weight management team are crucial to improved weight loss outcomes long term.

# **Conclusions**

A medically supervised weight management program, complementary to bariatric surgery, may be beneficial in stabilizing and alleviating weight regain experienced by patients post-operatively. Earlier identification, referral to medical weight management and pharmacological intervention may be valuable in the long term. Continued research targeting interventions to improve weight regain post-operative in bariatric patients and to understand recidivism is essential given the recurrence of obesity-related comorbidities and ill health effects associated with weight regain.

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**Contributions** GS and CB equally contributed to the contents of this manuscript.

#### **Compliance with Ethical Standards**

For this type of study, formal consent is not required.

**Conflict of Interest** GS serves as a consultant for Johnson and Johnson. CB declares no competing interests.

**Informed Consent Statement** Does not apply.

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