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ORIGINAL ARTICLE

Psychological predictors of poor weight loss following LSG: relevance of general psychopathology and impulsivity

Giulia Testa[1,2,5] · Roser Granero[2,3] · Cinzia Siragusa[4] · Anna Belligoli[4,6] · Marta Sanna[4,6] · Maria Luisa Rusconi[5] · Paolo Angeli[4] · Roberto Vettor[4,6] · Mirto Foletto[6,7] · Luca Busetto[4,6] · Fernando Fernández-Aranda[1,2,8] · Sami Schiff[4]

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Abstract

Purpose After bariatric surgery (BS) a significant minority of patients do not reach successful weight loss or tend to regain weight. In recent years, interest for the psychological factors that predict post-surgical weight loss has increased with the objective of developing interventions aimed to ameliorate post-surgical outcomes. In the present study, predictive models of successful or poor weight loss 12 months after BS were investigated considering pre-surgery level of psychopathological symptoms, dysfunctional eating behaviors and trait impulsivity at baseline (pre-surgery).

Methods Sixty-nine patients with morbid obesity canditates for laparoscopic sleeve gastrectomy were assessed regarding metabolic and psychological dimensions. Successful post-surgery weight loss was defined as losing at least 50% of excess body weight (%EWL).

Results Logistic models adjusted for patient sex, age and presence of metabolic diseases showed that the baseline presence of intense psychopathological symptoms and low attentional impulsivity predict poor %EWL (<50%), as assessed 12-month post-surgery.

Conclusions The present findings suggest that intensity of general psychopathology and impulsivity, among other psychological factors, might affect post-surgery %EWL. Conducting adequate psychological assessment at baseline of patients candidates for BS seems to be crucial to orient specific therapeutic interventions.

Level of evidence Level III, case-control analytic study.

Keywords Psychological predictors of weight loss · Impulsivity · Psychopathology · Bariatric surgery · Laparoscopic sleeve gastrectomy

Introduction

Bariatric surgery (BS) is considered one of the most effective long-term weight loss treatments for morbid obesity, inducing a greater amount of weight loss compared to pharmacological or behavioral interventions [1, 2].

Despite this, not all patients benefit from long-term surgery outcomes, with a significant minority not reaching a successful weight reduction, generally considered as achieving at least 50% of excessive weight loss (%EWL) [3, 4]. The causes of this failure are complex and multi-factorial, and there is growing interest in identifying the possible

✉ Giulia Testa
testagiulia87@gmail.com

✉ Sami Schiff
sami.schiff@unipd.it

1 Department of Psychiatry, University Hospital of Bellvitge-IDIBELL, Barcelona, Spain

2 CIBER Fisiopatología Obesidad y Nutrición (CIBERobn), Instituto de Salud Carlos III, Barcelona, Spain

3 Department of Psychobiology and Methodology, Autonomous University of Barcelona, Barcelona, Spain

4 Department of Medicine—DIMED, University Hospital of Padua, Padua, Italy

5 Department of Human and Social Sciences, University of Bergamo, Bergamo, Italy

6 Centre for the Study and the Integrated Treatment of Obesity (Ce.S.I.T.O), University Hospital of Padua, Padua, Italy

7 Week Surgery, Department of Surgery, Padova University Hospital, Padua, Italy

8 Clinical Sciences Department, School of Medicine, University of Barcelona, Barcelona, Spain

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psychological factors implicated in positive or negative post-surgery outcomes.

Psychiatric symptomatology has been reported in patients with morbid obesity candidates for BS [5] even though there is currently no consensus over the possible effects of psychopathology on post-surgery outcomes. A negative relationship between preoperative psychiatric symptoms, especially depressive and anxiety disorders, and post-surgery weight loss has been suggested [6–10]. However, not all studies confirm preoperative anxiety or depression as having a negative effect on post-surgery outcomes [11–14].

On the other hand, dysfunctional eating-related attitudes and behaviors are frequently associated with obesity. In particular, the presence of binge eating disorder (BED) or subclinical binge eating behavior is high in bariatric population [15–18], thus binge status can be expected to affect post-surgery weight loss [see for a review: 12, 19]. By contrast, only few studies reported binge eating associated with higher body mass index (BMI) at long-term follow-up (i.e., 5 years) [20] and poorer dietary adherence [21].

Dysfunctional eating attitudes and behaviors other than binge eating have been related to obesity and are common among bariatric surgery patients. Food addiction, similar to other substance related disorders and behavioral addictions, is characterized by the loss of control over the consumption of certain foods (e.g., sugar, fat, carbohydrates) despite the adverse physical and psychological consequences [22]. Emotional eating refers to the tendency to eat in response to emotions (e.g., anger, sadness), possibly resulting in overconsumption of certain foods when facing with both positive and negative emotions. Others dysfunctional eating behaviors linked to overeating and obesity are restrained eating, which refers to continuous attempt to restrain food intake; and external eating, defined as the tendency to eat in response to external food-related cues in the environment. Among the bariatric population, the prevalence of food addiction and emotional eating has been shown to be even higher than in non-bariatric obese population [23, 24]. However, the impact of these factors on post-surgery weight loss has been explored only by few studies with contrasting findings [25–31]. Emotional eating has been shown to negatively predict weight loss in morbid obese patients following bariatric surgery [28] or weight loss programs [27]. By contrast, another study suggested that the presence of emotional eating did not predict weight loss among bariatric patients [30]. Regarding food addiction, one study showed that the presence of food addiction negatively predict weight loss 12-month post-surgery [28]. By contrast, the other two studies did not confirm food addiction as a significant predictor of postoperative weight loss [25, 31]. As for restrained and external eating, there is a lack of studies investigating the impact of these factors on weight loss following bariatric surgery.

Impulsivity is another factor that has been related to obesity [32–34], and that may be expected to influence post-surgery outcomes. A widely used questionnaire to assess impulsivity as a multidimensional personality trait is the Barratt Impulsiveness Scales [BIS-11; 35], which assesses the tendency to act without thinking (i.e., motor impulsiveness), the failure to plan ahead (i.e., non-motor impulsiveness), and difficulties in focusing attention or concentrating (i.e., attentional impulsiveness). Attentional impulsiveness has been more consistently related to overeating [36], and some studies have suggested a correlation between attentional impulsivity and food addiction in the obese population seeking BS [37–39]. To our knowledge, only two studies investigated impulsivity as predictor of weight loss after BS. The first showed that state impulsivity, as measured by an inhibitory control task, but not trait of impulsivity, as measured with BIS-11, predict changes in %EWL [40]. Despite this, the second study showed that trait impulsivity has an indirect impact on weight loss outcome after bariatric surgery, which is mediated by depression and transferred through pathological eating behavior [41].

Overall, clear psychological predictors of post BS outcomes are far from being fully identified. Taken together, most of the previous studies focused on some of the psychological factors which are supposed to influence post-surgery outcome (e.g., dysfunctional eating), rather than adopting a more comprehensive view, including different psychological dimensions as possible predictors in the model. In this direction, the present work aims at investigating multiple psychological predictors of successful %EWL at 12 month post Laparoscopic Sleeve gastrectomy (LSG) including: psychopathological symptoms of anxiety and depression, dysfunctional eating behaviors, and trait impulsivity.

Materials and methods

Participants

Sixty-nine patients with morbid obesity, who underwent Laparoscopic Sleeve Gastrectomy (LSG) at the Centre of the Study and the Integrated Treatment of Obesity (Ce.S.I.T.O). Participant's ages were in the range of 20–67 years, with a mean age of 42.6 years (SD = 11.6). The mean BMI at recruitment was 43.6 kg/m^2 (SD = 6.2) and the mean body weight was 118.0 kg (SD = 19.7).

The inclusion criteria were BMI ≥ 40 kg/m^2 or > 35 kg/m^2 with obesity-related comorbidities (e.g., type 2 diabetes mellitus, arterial hypertension, dyslipidemia, obstructive sleep apnea, severe osteoarthritis), which are necessary conditions to be considered for bariatric surgery.

Participants were informed about the experimental procedure and gave their written consent. The study was

performed in accordance with the Helsinki Declaration [42] and approved by the local Ethical Committee of the Padua University Hospital.

Pre-surgical assessment

Participants underwent complete pre-surgery clinical evaluation conducted by a highly trained interdisciplinary team including endocrinologists, surgeons and psychologists at the Centre of the Study and the Integrated Treatment of Obesity (Ce.S.I.T.O), of the Padua University Hospital. Demographic information (i.e., sex, age) was collected along with the assessment of pre-surgery metabolic diseases: hypertension, Type-2 diabetes, dyslipidemia, obstructive sleep apnea (OSA) and hypothyroidism. Anthropometric measures (i.e., height, weight, BMI) were collected prior to surgery and 12 months after LSG.

Preoperative psychological evaluation was performed by a short-structured interview oriented to assess history of eating and/or psychopathological disorders, and to evaluate the presence of clinical psychological conditions which may interfere with post-surgical weight loss. Patients did not systematically receive a pre-surgical psychological intervention. However, they received information about post-surgery implications and consequences, and recommendations for lifestyle changes aimed to improve diet and increase physical activity before surgery.

Psychometric measures

Psychometric tests were collected 1 month before LSG to further investigate these important factors including trait of impulsivity. Internal consistency in the sample of the study for the psychometric scales ranged between good and excellent (Table 1 contains Cronbach's alpha values, α).

Symptom checklist-90 items revised [SCL-90-R; 43, 44]

The SCL-90-R is a 90-item questionnaire widely used to assess the frequency of many psychopathological symptoms on 5-point Likert scales (0 = never; 5 = always) over the span of the previous week. In the present study, only the subscales assessing anxiety, depression and a total score indicating a global severity index (GSI) were considered as predictors in the model.

Barratt impulsiveness scale-11 [BIS-11; 35, 45]

This is a 30-item questionnaire used to assesses different facets of impulsivity as a personality trait, on a 4-point Likert scale (1 = rarely/never; 4 = very often). There are three subscales: attentional impulsiveness (i.e., tendency to a fast shift in attention); motor impulsiveness (i.e., tendency to rush, immediate actions); non-planning impulsiveness (i.e., a tendency not to plan ahead and to ignore long-term consequences of one's actions) and a total score ranging from 30 to 120, with higher scores indicating higher impulsiveness.

Binge eating scale [BES, 46, 47]

The BES is a 16-item questionnaire assessing behavioral characteristics, emotional and cognitive response related to binge eating. For each item, participants have to choose between 3 and 4 response statements corresponding to different symptoms severity. Scores range from 0 to 46, with scores higher than 27 indicating clinically relevant binge eating behavior.

Dutch eating behavior questionnaire [DEBQ, 48, 49]

This 33-item questionnaire assesses eating-related attitudes along three different dimensions: (1) "emotional eating"; (i.e., the tendency to eat in response to emotions); (2) "restrained eating" (i.e., the tendency to attempts to restrain food intake); and (3) "external eating" (i.e., the tendency to eat in response to external food-related cues which are present in the environment). For each subscale, items are distributed on a 4-point Likert scale to assess the frequency of each experienced dimension (1 = never; 5 = very often).

Yale food addiction questionnaire [50, 51]

The YFAS is a 25-item self-report measure to assess food addiction based on specific criteria resembling the symptoms for substance dependence in the DSM-IV-TR [52]. A continuous symptom-count score reflects the number of diagnostic criteria met and a food addiction threshold based on the number of symptoms and self-reported clinically significant impairment or distress.

Statistical analysis

According to standardized outcome measures [53], post-surgery weight loss was calculated in term of excess weight loss (%EWL) derived from the formula: %EWL = (weight loss/excess weight) × 100, with excess weight being the total preoperative weight minus the ideal weight (ideal weight is defined as the weight corresponding to a BMI of 25 kg/m2). Successful weight loss was defined as losing at least 50% of excess body weight, whereas poor weight loss was considered as %EWL outcome lower than 50%.

The statistical analysis was carried out with SPSS22 for Windows. Comparisons between groups (successful vs poor weight loss) were based on Chi square tests (χ^2) for categorical variables and analysis of variance (ANOVA) for quantitative measures. All comparisons for psychological

Table 1 Comparison between the groups

Metabolic disease at baseline	EWL < 50%; $n = 17$		EWL ≥ 50%; $n = 52$				
	n	%	*n*	%	$\chi^2(df = 1)$	*p*	|*d*|
Any metabolic disease	12	70.6	40	76.9	0.28	0.599	0.14
Hypertension	12	70.6	20	38.5	5.32	**0.021**[b]	**0.68**[c]
Type-2 diabetes	6	35.3	7	13.5	3.99	**0.046**[b]	**0.53**[c]
Dyslipidemia	8	47.1	23	44.2	0.04	0.839	0.06
Apnea-obstructive	7	41.2	9	17.3	4.10	**0.043**[b]	**0.54**[c]
Hypothyroidism	1	5.9	7	13.5	0.72	0.398	0.26
Sex							
Female	15	88.2	45	86.5	0.03	0.857	0.05
Male	2	11.8	7	13.5			
Age and BMI (kg/m^2)	Mean	SD	Mean	SD	F($df = 1/67$)	*p*	|*d*|
Age (years-old)	49.00	11.97	40.44	10.82	7.61	**0.007**[b]	**0.75**[c]
BMI baseline	47.28	6.75	42.40	5.66	8.65	**0.004**[b]	**0.78**[c]
Total weight loss (TWL%)	21.06	4.13	35.41	5.82	88.24	**< 0.001**[b]	**2.84**[c]
[a]Psychological profile at baseline:	*α*	Mean	SD	Mean	SD	F($df = 1/63$)	*p*	|*d*|
SCL-90-R depression	0.893	1.80	1.73	1.69	1.79	0.26	0.851	0.06
SCL-90-R anxiety	0.855	1.58	2.07	1.20	1.63	0.61	0.522	0.20
SCL-90-R GSI	0.976	1.90	1.95	1.75	1.97	0.43	0.828	0.07
BIS-11 motor	0.701	21.49	6.79	21.80	5.34	0.01	0.871	0.05
BIS-11 non-planning	0.707	23.93	3.83	27.04	5.52	2.59	0.079	**0.66**[c]
BIS-11 attentional	0.717	15.07	2.57	16.75	3.74	1.20	0.154	**0.52**[c]
BIS-11 total score	0.780	60.49	10.28	65.59	12.76	0.91	0.217	0.44
YFAS total score	0.899	2.85	1.78	3.07	1.80	0.05	0.700	0.12
DEBQ restrain	0.727	3.12	0.63	2.80	0.87	0.41	0.250	0.42
DEBQ emotional	0.740	2.54	1.04	2.96	1.22	0.36	0.271	0.37
DEBQ external	0.752	2.74	0.51	2.78	0.83	0.04	0.879	0.06
BES total score	0.887	14.14	9.23	14.63	9.21	0.13	0.876	0.05

EWL excess weight loss, *SD* standard deviation, *BMI* body mass index (kg/m^2), *TWL* total weight loss at 12 months after follow-up, *α* Cronbach's alpha in the sample

[a]Results adjusted by age, BMI at baseline and metabolic state at baseline

[b]Bold: significant comparison (0.05 level)

[c]Bold: effect size into the mild/moderate (|*d*| > 0.50) to large/good range (|*d*| > 0.80)

variables were adjusted for covariates patient age, BMI at baseline and the presence of metabolic diseases at baseline. Cohen's-*d* coefficient measured effect size for pairwise comparisons (|*d*| > 0.20 was considered low effect size, |*d*| > 0.50 mild–moderate effect size and |*d*| > 0.80 large-good effect size); [54]. Increases in Type-I error due to multiple statistical comparisons was controlled with Simes' correction method, a familywise error rate stepwise procedure which offers more powerful test than the classic Bonferroni correction [55].

Logistic binary regression in three block steps was used to explore predictive models of successful %EWL at 12-month follow-up after bariatric surgery (criterion: 0 = %EWL outcome lower than 50% versus 1 = %EWL outcome equal or higher than 50%). The first block added and fixed the covariates: sex, age, BMI at baseline and presence of metabolic diseases at baseline. The second block used a stepwise procedure to automatically select the statistically significant predictors of successful %EWL between the psychological measures registered at baseline/pre-surgery (psychological state measured with SCL-90-R scales, BIS-11 subscales, YFAS total, and DEBQ scales). The third block tested the potential interaction between selected psychological measures in the second block step with covariates: sex, age, BMI at baseline and the presence of metabolic diseases at baseline (only significant interaction parameters were retained into the final model). Goodness-of-fit for the final model was based on Hosmer–Lemeshow test ($p > 0.05$ was considered for good fitting), global predictive capacity was estimated with Nagelkerke's pseudo-R^2 coefficient and global capacity

to discriminate between the groups with the area under the ROC curve.

Results

Differences between the groups at baseline

Table 1 shows the distribution of clinical measures at baseline and the comparison between the groups who achieved successful and poor %EWL during the follow-up of 12 months after BS. Regarding metabolic diseases the probability of achieving %EWL outcome ≥ 50% was lower for patients who reported the presence of hypertension, Type 2 diabetes and apnea-obstructive syndrome pre-surgery. Other variables related to poor %EWL were older age, higher BMI at baseline, lower % of total weight loss (%TWL) and lower scores in the BIS-11 non-planning and attentional impulsiveness scales (although no significant result for these last measures, effect size estimated through Cohen's-*d* coefficient was into the moderate range).

Predictive models of successful weight loss (%EWL > 50%)

Table 2 contains the final predictive logistic regression of achieving %EWL outcome > 50% (binary criterion: 0 = %EWL outcome lower than 50% vs 1 = %EWL outcome of 50% or higher). The third block of the initial logistic regression was not considered, since no interaction parameters of the two selected predictors with the sex, age, or metabolic diseases were found (omnibus test for the block: $\chi^2 = 11.0$, $df = 6$, $p = 0.088$). The final model indicated that after entering and adjusting for covariates sex, age, BMI at baseline and presence of metabolic diseases at baseline, the significant predictors of achieving at least 50% of %EWL were a lower score in the SCL-90-R GSI scale and a higher score in the BIS-11 attentional scale. Final model achieved adequate fitting (Hosmer–Lemeshow: $p = 0.134$), global predictive capacity equal to $R^2 = 0.468$ and global discriminative ability equal to AUC = 0.852.

Discussion

The present study aimed at investigating multiple psychological predictors of successful or poor %EWL at 12-month post-LSG. Results suggested that age and baseline BMI negatively predicted %EWL. Thus, younger patients with lower pre-surgery BMI showed higher probability of achieving successful post-surgery weight loss, in accordance with previously published studies [19, 56–58].

As for pre-surgical general psychopathology, the SCL-90-R global severity index (GSI) negatively predicted %EWL, indicating that patients with more general psychopathology had lower probability of achieving %EWL > 50. Similarly, in a previous study, higher levels of psychopathology have been related with lower and slower trajectory of weight loss in BS patients [8]. By contrast, in the present study, nor anxiety or depression levels significantly predicted %EWL, although patients achieving successful weight loss were characterized by lower mean scores of anxiety and depressive symptoms. Thus, severity of psychopathological symptoms rather than a specific psychopathological condition (e.g., anxiety or depression) seems to affect post-surgery outcomes.

Moreover, it is remarkable that preoperative eating-related attitudes and behaviors were not significant predictors of post-surgery %EWL. Regarding binge eating, a large number of studies did not find association between preoperative BED or sub-clinical binge eating behaviors and post-surgery %EWL [12], although some evidence for

Table 2 Predictive model of the criterion good evolution in the EWL at 12-month follow-up after BS: logistic regression

	B	SE	Wald (*df* = *1*)	*p*	OR	95% CI (OR)	
First block							
Sex (0 = women; 1 = men)	0.168	1.107	0.023	0.879	1.18	0.14	10.36
Age (years-old)	−0.134	0.042	10.093	**0.001**[a]	0.88	0.81	0.95
Metabolic disease (at baseline)	1.432	0.979	2.137	0.144	4.19	0.61	28.54
Body mass index (at baseline)	−0.191	0.064	9.064	**0.003**[a]	0.83	0.73	0.94
Second block							
SCL-90R GSI	−0.382	0.270	1.997	**0.048**[a]	0.68	0.40	0.99
BIS-11 attentional	0.286	0.163	3.083	**0.047**[a]	1.33	1.01	1.83
Fitting statistics	Hosmer–Lemeshow: $\chi^2 = 12.40$, $df = 8$, $p = 0.134$ Nagelkerke's $R^2 = 0.468$; AUC = 0.852						

Good evolution was defined for patients with at least 50% of EWL during the 12-month follow-up after BS

OR odds ratio, *AUC* area under the ROC curve

[a]Bold: significant coefficient, Sample size: $n = 69$

negative relation between preoperative binge eating and weight loss exists [15, 18, 59]. The present finding did not suggest a significant association between preoperative binge eating symptoms, assessed by the BES scale, and %EWL 12-month post-LSG. Accordingly, previous studies showed that preoperative binge eating status assessed by BES scale was not predictive of post-surgery weight loss [60]. By contrast, when binge-eating episodes were investigated by a clinical interview, a negative association with weight loss has been reported [15]. Given this, combining clinical information to address the presence of binge episodes with a questionnaire to measure the severity of the symptoms is recommended to avoid misleading interpretations. Overall, the impact of preoperative binge eating on weight loss remains disputed, whereas evidence for a negative association between post-surgery eating behaviors (e.g., binge eating) and weight loss is more consistent in literature [61–64].

As for other maladaptive eating-related attitudes, emerging evidence emphasized the possible effect of emotional eating and food addiction on weight loss and post-surgery outcomes [28]. However, studies including these variables are limited; therefore, future studies with larger samples could help to clarify the relationship between pre-surgery dysfunctional eating and weight loss. To our knowledge, this is the first study evaluating preoperative restrained and external eating as possible predictors of BS outcome; our results did not show an effect of these variables over %EWL at 12 months following LSG.

Finally, pre-surgery level of attentional impulsivity positively predicted %EWL. Specifically, patients with impulsivity levels within normal range showed successful post-surgery %EWL, whereas patients with trait impulsivity below normative range [45] showed poorer %EWL outcomes at 12 months. It can be supposed that extremely low, as well as extremely high levels of trait impulsivity may negatively affected post-surgery outcomes. As for low levels of attentional impulsivity, individuals extremely attentional focused and over reflexive, may experience more anxiety when faced with the changes in eating behaviors required after BS. By contrast, optimal levels of attention and vigilance are possibly more effective in determining an adequate post-surgery weight loss. In general, impulsivity is expected to interfere with the achievement of successful weight loss, possibly because impulsive individuals may experience lower control over food intake. However, impulsivity is a complex and multifaceted construct, not limited to personality traits but also extending to state impulsivity (e.g., inhibitory control, reward sensitivity) [65]. Hence, different facets of impulsivity can be expected to differently affect post-surgery outcomes, as showed in a previous study in which inhibitory control, but not trait impulsivity, negatively predicted post-surgery weight loss [40].

Some limitations of the present study should be noted. First, the relatively short follow-up of post-surgery %EWL assessment. Indeed, higher risk of regaining weight may be expected at later follow-up (e.g., 24 months) [66]. Thus, the psychopathological symptoms, eating-related behaviors or personality traits considered here, could be expected to differently predict %EWL at a follow-up after more 12 months from surgery.

Another limitation is the lack of post-surgical assessment of psychopathological symptoms and eating-related maladaptive behaviors. Although these patterns are expected to improve following bariatric surgery, in some cases these maladaptive eating behaviors tend to persist and this has been linked to unsuccessful weight loss or weight regain [67]. There is evidence for persisting binge eating after surgery [64] or "grazing" (i.e., smaller subjective episodes of overeating accompanied by feeling of loss of control), which is a pattern often seen in post-surgery patients [61, 68]. Given this, investigating the link between preoperative and postoperative maladaptive eating, and their effect on weight loss, seems to be crucial and may help to develop specific psychological interventions prior to surgery.

Finally, the lack of some significant results may be due to the small sample size, which may represent the general population of morbid obese patients seeking surgical treatment at the Centre of the Study and the Integrated Treatment of Obesity (Ce.S.I.T.O). Thus, replication of the study in larger samples and in other countries is required and would permit to generalize these findings to other cultures. For instance, obesity is a growing phenomenon in some Asian countries, with bariatric surgery suggested as useful treatment [69, 70]. Similar to western countries, high prevalence of psychiatric disorders has been reported in Asian population seeking bariatric surgery [71]. However, little is known about psychological predictors of post-surgery outcomes in these countries and should be addressed in future studies to generalize the present findings.

In conclusion, the present study investigated multiple psychological predictors of successful or poor %EWL at 12-month post-LSG, including preoperative assessment of psychosocial variables, psychopathological symptoms, dysfunctional eating attitudes, and trait impulsivity. Younger age and lower baseline BMI predicted successful %EWL. As for psychological variables, higher presence and intensity of general psychopathological symptoms negatively predicted %EWL, whereas anxiety or depression alone did not affect %EWL directly. Dysfunctional eating attitudes assessed here did not appear to predict %EWL, although remission of some of these conditions such as binge eating, may be expected to follow restrictive BS procedures. Finally, levels of attentional impulsivity below normative range predicted poor %EWL outcomes, possibly suggesting that patients with low attentional impulsivity, experienced

more difficulties in adhering to nutritional and lifestyle recommended guidelines following BS. As clinical implication, bariatric surgery candidates could potentially benefit from psychological interventions aimed at ameliorating attentional mechanisms and regulating self-awareness. In this view, mindfulness-based interventions, may be particularly effective in reducing impulsive thought and behavior through the maintenance of attention on the present moment increasing self-awareness and acceptance [72]. Mindfulness-based interventions focused on eating behaviors have been proposed as effective treatment for overeating and obesity [73–75], although only a limited number of studies has been conducted in bariatric surgery patients [76, 77]. Despite the possible advantages, mindfulness alone may be too limited as it is a difficult state to fully achieve, which should be combined with traditional cognitive therapy [78].

Overall, the present findings allow the identification of multiple psychological factors affecting post-surgery %EWL, contributing to promote clinical interventions oriented at reducing poor post-surgery outcomes.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards 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.

Ethical approval The Ethical Committee of the Padua University Hospital (include name of committee + reference number) approved the study.

Informed consent All subjects gave their informed consent after we provided a full explanation of the study.

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