

Article

Psychological Predictors of Poor Weight Loss Following Endoscopic Sleeve Gastropasty

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Abstract

Endoscopic sleeve gastropasty (ESG) does not produce homogeneous results, with some patients showing little weight loss after the procedure. The aim of the present study was to evaluate the ability of pre-procedural psychometric questionnaires to predict insufficient weight loss after ESG in patients with obesity. Patient candidates for ESG were requested to complete the following psychometric questionnaires: Short Form-36 (SF-36), Symptom Checklist-90 Revised (SCL-90-R), Binge Eating Scale (BES), Yale Food Addiction Questionnaire (Y-FAS), Eating Attitude Test-26 (EAT-26), and Barratt Impulsiveness Scale-11 (BIS-11). The results of the psychometric scores were then compared with the ESG outcome, which was considered a therapeutic failure if the %EWL was less than 30% at 12 months after the follow-up. Thirty-five patients (8 males and 27 females, mean age 49 years, range 21–75 years) were included in this study. At the one-year follow-up, the mean %EWL was $40 \pm 43\%$. Male sex and higher preoperative BMI were identified as risk factors for poor weight loss. A logistic regression analysis adjusted for sex and preoperative BMI showed that low scores on the SF-36 (Subscale Mental Health), high scores on the SCL-90-R, and an elevated BES score were predictors of therapeutic failure. The results of the present study seem to confirm the usefulness of the SF-36, SCL-90R, and BES questionnaires in the selection of patients eligible for ESG.

Keywords: endoscopic sleeve gastropasty; endosleeve; bariatric surgery; psychometric questionnaire; SF-36; SCL-90-R; BES; Y-FAS; EAT-26; BIS-11



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1. Introduction

Obesity is a worsening pandemic with significant social and economic impacts [1]. In fact, obesity is a risk factor for disabling diseases, such as cardiovascular and metabolic diseases. The prevalence of obesity is increasing, reaching over 40% of adults in the USA in 2021 [2]. For a variety of reasons, diet, lifestyle modification, psychological support, and pharmacotherapy are, in many cases, not enough to alleviate obesity.

In such cases, bariatric surgery is considered an effective treatment, although it is still invasive with a risk of complications. For this reason, new, less invasive endoscopic

bariatric procedures have been conceived to help patients achieve effective weight loss with a lower risk of complications. One of the most effective bariatric procedures is the endoscopic sleeve gastroplasty (ESG) [3]. ESG is performed with the OverStitch™ endoscopic suturing system (Boston Scientific, Marlborough, MA, USA). This device allows for volumetric restriction of the gastric body using full-thickness sutures performed on the large curve. A multi-center, randomized, open-label controlled trial (MERIT trial) including 209 participants (85 in the ESG-plus-lifestyle-modification arm versus 124 in the lifestyle-modification-alone arm) demonstrated $13.6 \pm 8.0\%$ Total Weight Loss (TWL) in the ESG-plus-lifestyle-modification group compared to $0.8 \pm 5.0\%$ in the lifestyle-modification-alone group after 52 weeks [4]. Safety is one of the major advantages of this procedure. A meta-analysis of 1772 patients reported a pooled AE rate of 2.2%, which includes severe pain or nausea requiring hospitalization (1.08%), gastrointestinal bleeding (0.56%), and perigastric leak or fluid collection (0.48%). In most cases, complications are managed conservatively [5].

Unfortunately, not all patients have a satisfactory outcome after ESG, and according to some series, up to 50% of patients report an insufficient result in terms of weight loss [6]. For this reason, it is essential to identify risk factors for failure before referring patients for the procedure. Previous studies demonstrated that some psychological patterns have demonstrated to predict poor weight loss after laparoscopic sleeve gastroplasty [7], but so far, similar studies on patients undergoing ESG are lacking. The aim of the present study was to evaluate the ability of pre-procedural psychometric questionnaires to predict insufficient weight loss after ESG.

2. Materials and Methods

In this prospective study, all patients eligible for endoscopic sleeve gastroplasty in the period between March 2019 and August 2023 were enrolled. Indications for ESG were as follows:

- Primary intervention in overweight patients (BMI between 27 and 29.9 kg/m²) with an obesity-related medical condition that was not controlled by medical therapy [8];
- Class I obesity (BMI between 30 and 34.9 kg/m²) with at least one comorbidity;
- Class II obesity (BMI between 35 and 39.9 kg/m²);
- Class III obesity (BMI > 40 kg/m²) in patients who are not suitable candidates for metabolic and bariatric surgery [9].

These subgroups include the following:

- Patients who are considered high risk for bariatric surgery due to age or comorbidities;
- Those who refuse bariatric surgery due to fear of associated risks and complications;
- Those who have already undergone at least one complex abdominal surgery, making bariatric surgery technically difficult and increasing the risk of intra- and postoperative complications.

The indications for ESG were discussed and then validated in a multidisciplinary team conference involving surgeons, internists who deal with metabolic diseases, physicians practicing bariatric endoscopy, nutritionists, dietitians, and psychologists. These consultation meetings took place in an accredited center, authorized to perform bariatric and metabolic surgery, with experience in the management of obesity, and the capability to offer all types of bariatric management.

2.1. Psychometric Measures

Psychometric tests were administered prior to the ESG intervention as part of the standard evaluation for patients with obesity who are candidates for bariatric surgery. The

purpose was to investigate the presence of psychopathological symptoms, dysfunctional eating behaviors, traits of impulsivity, and subjectively perceived quality of life.

Short Form-36 (SF-36) [10]

Quality of life was evaluated by two subscales of SF-36, Physical Health (PH) and Mental Health (MH), which are the most suitable for measuring quality of life in patients with obesity.

Symptom Checklist-90 Revised (SCL-90-R) [11,12]

The SCL-90-R is a 90-item questionnaire widely used to assess the frequency of many psychopathological symptoms on a 5-point Likert scales (0 = never; 5 = always) over the span of the previous week. The questionnaire comprises nine subscales: Somatization (SOM), Obsessive–Compulsive (OC), Interpersonal Sensitivity (IS), Depression (DEP), Anxiety (ANX), Hostility (HOS), Phobic Anxiety (PA), Paranoid Ideation (PI), and Psychoticism (Psy). In addition, the questionnaire includes three global indices that offer an overarching assessment of symptom severity: Global Severity Index (GSI), Positive Symptom Distress Index (PSDI), and Positive Symptom Total (PST).

Barratt Impulsiveness Scale-11 (BIS-11) [13]

This is a 30-item questionnaire used to assess 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, motor impulsiveness, and non-planning impulsiveness; and a total score ranges from 30 to 120, with higher scores indicating higher impulsiveness.

Binge Eating Scale (BES) [14,15]

The BES is a 16-item questionnaire assessing behavioral characteristics as well as emotional and cognitive responses related to binge eating. Scores range from 0 to 46, with higher scores correlating with more frequent and severe binge-eating behaviors.

Eating Attitude Test 26 (EAT 26) [16]

The EAT26 is a widely used test to measure symptoms and concerns characteristic of eating disorders. It consists of 26 questions with a score ranging from 0 to 3.

Yale Food Addiction Questionnaire (Y-FAS) [17,18]

The Y-FAS is a 25-item self-report measure designed to assess food addiction based on specific criteria resembling the symptoms of substance dependence in the DSM-IV-TR.

2.2. ESG Procedure

ESG was performed as previously reported [19]. First, the patients were intubated, and general anesthesia was administered. Carbon dioxide insufflation was used during ESG. The usual position was in the left lateral, except for those with specific anesthesiologic risks; for example, pulmonary disease required a supine position. A gastroscopy was performed to exclude contraindications. Patients were treated with Overstitch (Apollo Endosurgery, Austin, TX, USA), mounted on a double-channel gastroscope (Olympus Optica, Tokyo, Japan), after positioning an overtube under endoscopic guidance or with the Apollo Sx mounted on a single-channel gastroscope. The gastric body was reduced by performing endoplication on the greater curvature using multi-bite interrupted sutures. Full-thickness 2-0 polypropylene sutures were placed endoluminally by grasping the stomach wall via the helix. The pattern of the suture was transverse monolinear. The number of sutures varied according to the length of the gastric body so as to suture the entire greater curve of the gastric body.

After the procedure, the patients were prescribed a proton pump inhibitor (PPI), metoclopramide, and ondansetron treatment, if needed. On the first postoperative day (POD1), the patients underwent an upper gastrointestinal series after swallowing a water-soluble contrast medium to evaluate the endoplication and voiding of the stomach. If the test result was normal, they were placed on a soft diet. After the procedure, regular

follow-up examinations were scheduled for 1, 6, and 12 months later. The patient's weight was assessed during the follow-up visit, along with TWL and %EWL (excess weight loss) after 6 months and 1 year. %EWL was calculated as follows: $(\text{Pre-op Weight} - \text{Follow-up Weight}) / (\text{Pre-op Weight} - \text{Ideal Body Weight}) \times 100$. Meetings were arranged with dietitians for dietary advice during hospitalization and at follow-up visits.

Patients with a follow-up of less than 1 year or who refused to participate in the study were excluded.

According to results in the literature, a %EWL less than 30% at the 1-year follow-up was considered a treatment failure. This number was calculated considering the ASGE (American Society for Gastrointestinal Endoscopy) and the ASMBS (American Society for Metabolic and Bariatric Surgery) definition of thresholds for endoscopic bariatric therapies [20,21].

According to the above definition, an endoscopic bariatric therapy intended as a primary obesity intervention in Class II/III obese individuals (body mass index [BMI] > 35 kg/m²) should achieve a mean minimum threshold of 25% excess weight loss (%EWL) measured after 12 months.

Considering that this study also includes many patients with BMI < 35 kg/m², we decided to increase the cut-off to 30% EWL at the 12-month follow-up.

2.3. Statistical Analysis

The results are reported as the mean and standard deviation (SD) for quantitative variables and as the count and percentage for categorical variables.

Logistic regression analysis was applied to identify psychometric scores as potential predictors of poor weight loss at the 1-year follow-up (%EWL < 30%), adjusting for sex and BMI prior to the ESG intervention. The results of the logistic regression analyses are presented as *p*-values, odds ratio (OR) estimates, and their 95% confidence intervals (CIs), calculated with the Wald method. Odds ratios and 95% CIs for continuous variables are expressed per-unit increase. The linearity assumption for the continuous variables was evaluated with the Hosmer and Lemeshow goodness-of-fit test. Statistical significance was declared for *p* < 0.05.

Due to the limited sample size, a multivariate model, considering the psychometric scores, resulted in statistical significance at the 5% level, but was not built up.

Statistical analyses were conducted using SAS ver. 9.4 (SAS Institute Inc., Cary, NC, USA) for Windows.

3. Results

From March 2019 to August 2023, 50 patients underwent ESG. Thirty-five (8 male and 27 female, mean age 49 years, range 21–75 years) patients, who had filled out the questionnaires before the procedure and had regular follow-up visits for at least one year, were considered for this analysis.

The mean BMI before the procedure was 35.5 (range 28.1–60.8).

After 1 year, the mean TBWL and %EWL were 10 ± 9 kg and 40 ± 43 , respectively. For twenty patients, the treatment was deemed effective (%EWL $\geq$ 30%). In the univariate analysis, male patients and patients with higher preoperative BMI had a higher rate of procedural failure (Table 1).

Table 1. Effects of gender, age, and initial BMI on EWL results.

	EWL > 30%			Univariate Logistic Regression Results	
	No (N = 15)	Yes (N = 20)	Total (N = 35)	Odds Ratio (95% CI)	p-Value
M/F, n (%)					
F	9 (33.3%)	18 (66.7.0%)	27 (77.1%)	1	
M	6 (75.0%)	2 (25.0%)	8 (22.9%)	6.000 (1.003; 35.908)	0.0497
Age (yrs)					
N	15	20	35		
Median (Range)	50.0 (21.0, 75.0)	49.5 (29.0, 73.0)	50.0 (21.0, 75.0)	1.020 (0.965; 1.078)	0.4870
BMI (Kg/m²)					
N	15	20	35		
Median (Range)	37.8 (29.0, 60.8)	34.2 (28.1, 41.0)	35.5 (28.1, 60.8)	1.288 (1.020; 1.627)	0.0337

Among the psychometric tests used, SF 36 (subscale MH), SCL-90 (subscales IS, DEP, ANX, HOST, PI, PSY, and GSI), and BES were identified as predictors of insufficient weight loss (sex- and BMI-corrected logistic regression; see Table S1).

4. Discussion

ESG is an incisionless weight-loss procedure that has been demonstrated to be safe and effective for the treatment of obesity. First described in 2013, the procedure utilizes the Overstitch endoscopic suturing device (Boston Scientific, Marlborough, MA, USA) to create a tubular stomach that mimics sleeve gastrectomy by means of multiple full-thickness suturing [22].

In practice, ESG cannot be compared to laparoscopic sleeve gastrectomy, since it leaves the gastric fundus intact and does not involve removing part of the stomach, but it represents a valid alternative with reduced invasiveness.

Numerous studies have shown that ESG is effective not only in achieving weight loss in patients [4,23,24], with EWL of up to 53% at 12 months [20], but also in reducing obesity-related metabolic diseases [25].

Unfortunately, not all patients achieve the expected weight loss. In the study by Frey et al. [6], the primary outcome of 15% TWL was obtained in 48.7% of the patients.

According to previous studies, predictive factors for weight loss after ESG include BMI < 40 kg/m², extension of plication for at least 1/3 of the whole gastric length [19], and nutritional and psychological interactions after the procedure [26].

The present study aimed to investigate multiple psychological predictors of poor %EWL 12 months post-ESG.

The results of the present study suggest that male sex and higher preoperative BMI negatively predicted %EWL after ESG. A higher preoperative BMI has been reported to be a negative factor for weight loss after ESG [19]. Interpreting the finding regarding gender is beyond the scope of our study, and, given the limited sample size, it should be regarded with caution. Moreover, this result has not been confirmed by larger sample studies [27].

It was not surprising to find fewer males than females in our study, given that the latter are more likely to undergo surgery for obesity in the absence of complications.

In any case, the analysis of the impact of psychometric measures on weight loss has been corrected on the basis of these two factors, initial BMI and gender, to avoid any confounding effect.

As for pre-surgical general psychopathology, higher SCL-90 (in the categories IS, DEP, ANX, HOST, PI, and PSY) and Global Severity Index (GSI) scores negatively predicted %EWL, indicating that patients with more psychopathological symptoms had a lower probability of achieving satisfactory weight loss after ESG. High Binge Eating Scale scores also correlated with sub-optimal weight loss after the operation.

In a meta-analysis, Dawes AJ et al. [28] found depression in 19% and binge eating disorders in 17% of patients seeking and undergoing bariatric surgery.

A relation between preoperative Binge Eating Scale score and weight loss after surgery has been previously reported for patients treated with gastric bypass [29,30].

By contrast, other studies failed to find a negative association between preoperative BES score and postoperative weight loss [7,31], while the evidence for a negative association between weight loss and post-surgery eating behaviors is more consistent [32–35].

Obviously, identifying predictive indicators of postoperative outcome is particularly important during patient recruitment in order to treat those who are likely to benefit. Psychological support may also be considered for some patients, thereby increasing their likelihood of successful surgery.

In a previous study analyzing psychological predictors of insufficient weight loss following LSG [7], BIS was identified as a consistent risk factor for poor %EWL outcome after 12 months. On the contrary, in this study, we did not find an association between the BIS and %EWL after ESG.

To our knowledge, this is the first study evaluating preoperative psychometric scales to predict weight loss after ESG.

This is probably because ESG is a more recent operative procedure than sleeve gastrectomy. Although ESG is a minimally invasive procedure, performed endoscopically, it is still important to conduct an adequate preoperative study and a multidisciplinary evaluation of the patients. Psychometric tests can be a useful part of this evaluation.

The results presented here are consistent with the fact that patients who have psychological problems before surgery, such as depression, anxiety, or eating disorders, have more difficulty losing weight because they do not change their eating habits.

This finding should be taken into consideration both in the selection of patients to undergo endoscopic bariatric surgery and in the management of postoperative follow-up.

This is a pilot study, with the aim of preliminarily evaluating which psychometric indices would be most suitable for a preoperative evaluation of patient candidates for ESG. The limitations of the present study are its small sample size, the risk of type I error due to multiple analyses, its observational nature, and the lack of post-procedural psychological assessment.

Thus, it must be emphasized that the results of this preliminary study need to be confirmed in a larger sample and with multivariate analysis, keeping in mind the psychometric indices found to be predictive of the endoscopic bariatric procedure outcome.

If confirmed, the results of this study demonstrate the importance of an appropriate psychological assessment for patients undergoing ESG. As this procedure is certainly less invasive but also less effective than laparoscopic surgery for weight loss, patient compliance could be even more important for good outcomes.

Although ESG is safe, considering its elevated costs, an adequate preoperative evaluation is advisable in order to offer this procedure to patients who can best benefit from it.

It is also possible to hypothesize, where indicated, the use of psychological support strategies in order to optimize the results of the procedure.

5. Conclusions

According to the results of the present study, the psychometric tests SF 36 (subscale MH), SCL-90 (GSI and most subscales), and BES were predictors of insufficient weight loss 12 months after ESG.

Some limitations of this study are represented by the small sample size and the high number of variables analyzed. If confirmed by a larger study, the routine use of these psychometric tests in the preoperative setting could help physicians select patients who are likely to respond to the ESG procedure or, if indicated, plan psychological support strategies.

Supplementary Materials: The following supporting information can be downloaded at <https://www.mdpi.com/article/10.3390/obesities6010011/s1>, Table S1: Preoperative psychometric scores and EWL <30% at 1 year.

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Data Availability Statement: The raw data supporting the conclusions of this article will be made available by the authors on request.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

ANX	Anxiety
BES	Binge Eating Scale
BIS-11	Barratt Impulsiveness Scale-11
BMI	Body Mass Index
CI	Confidence Interval
EAT-26	Eating Attitude Test-26
ESG	Endoscopic Sleeve Gastropasty
EWL	Excess Weight Loss
GSI	Global Severity Index
HOS	Hostility
IS	Interpersonal Sensitivity
MH	Mental Health
OC	Obsessive–Compulsive
OR	Odd Ratio
PA	Phobic Anxiety
PH	Physical Health
PI	Paranoid Ideation
POD	Postoperative Day
PPI	Proton Pump Inhibitor

PSDI	Positive Symptom Distress Index
PST	Positive Symptom Total
PSY	Psychoticism
SCL 90-R	Symptom Checklist-90 Revised
SD	Standard Deviation
SF36	Short Form-36
SOM	Somatization
TWL	Total Weight Loss
Y-FAS	Yale Food Addiction Questionnaire

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