

A behavioral rating system predicts weight loss and quality of life after bariatric surgery

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Author Disclosure: The authors declare that they have no conflicts of interest.

Funding Disclosure: None.

Short title: A rating scale predicts weight loss and HR-QoL

ABSTRACT

Background: Bariatric surgery represents the most effective intervention for severe obesity available today, however, significant variability in postoperative outcomes exists. Effective tools that predict postoperative outcomes are needed for decision-making and patient counseling.

Objectives: We hypothesized that a validated behavioral assessment tool, the Cleveland Clinic Behavioral Rating Scale (CCBRs), would predict excess weight loss (EWL), health-related quality of life (HR-QoL), depression, anxiety, and alcohol use after bariatric surgery.

Setting: Hospital in the United States

Methods: A prospective observational study with 2-year planned follow-up was conducted with patients who completed a psychological clinical interview, the Short Form 36 (SF-36) v.2 Health Survey and brief self-report questionnaires measuring depression (PHQ-9), anxiety (GAD-7), and alcohol use (AUDIT) preoperatively. At the conclusion of the pre-operative psychological evaluation, the psychologist completed the CCBRS. All questionnaires were re-administered at

6, 12, 18, and 24 months after surgery. Generalized estimating equations (GEE) were used to assess whether any CCBRS ratings predicted surgery outcomes.

Results: 179 patients (113 Roux-en-Y gastric bypass and 66 sleeve gastrectomy) were included in the analyses. SF-36 scores, PHQ-9 scores, and the AUDIT total scores improved significantly after surgery, while GAD-7 scores did not change appreciably. Higher pre-operative CCBRS ratings predicted higher SF-36 scores, and lower PHQ-9, GAD-7 and AUDIT scores. The CCBRS Social Support rating predicted higher postoperative %EWL.

Conclusion: A behavioral rating scale (CCBRS) completed prior to bariatric surgery predicted postoperative weight loss, quality of life, depression and anxiety. Therefore, this tool may prove useful in patient counseling and expectation management before surgery.

Key Words: Bariatric surgery; Quality of life; Behavioral rating system; Social support; Obesity

INTRODUCTION

Obesity continues to be of epidemic proportions, affecting as many as 12% of adults in the world and is a major cause of erosions in quality of life ^(1, 2). Bariatric surgery has been well established as an effective and durable intervention for severe obesity and co-morbid conditions ⁽³⁾. While there are prospective long-term studies that suggest health-related quality of life (HR-QoL) improves after bariatric surgery ⁽⁴⁾ it has been noted that these improvements have generally been less well established compared to weight loss and co-morbidity improvement/resolution due to the variations in reporting of QoL ⁽⁵⁾. Research on

the impact of bariatric surgery on anxiety and depression has led to mixed findings. The role of obesity in the cause of anxiety disorders is not fully established, based on a review and meta-analysis ⁽⁶⁾, and may follow a course different than that of depression after bariatric surgery ⁽⁷⁾. In recent years, there are data to show an increased risk for alcohol problems after bariatric surgery ⁽⁸⁾.

The psychosocial evaluation is an important part of the team effort to identify factors which may affect optimal post-surgical outcomes ⁽⁹⁾, though which outcomes are most important can vary by discipline ⁽¹⁰⁾. While efforts are made to identify the patients who are psychologically at risk prior to surgery, there is no algorithm to determine which patients may need additional preparation or even be denied. Just as the cause of obesity is multifaceted, contributions to successful weight loss post-operatively and subsequent weight regain are not well understood. Suspected behavioral and emotional contributions to poor outcomes have included binge-eating disorder ⁽¹¹⁾, grazing ⁽¹²⁾, non-adherence to taking vitamins and adequate hydration ⁽¹³⁾, poor impulse control ⁽¹⁴⁾, lack of persistence ⁽¹⁵⁾, depression ⁽¹⁶⁾, and possibly alcohol use disorders (see Parikh et al. for a review ⁽¹⁷⁾). One purpose of pre-surgical psychological evaluations presumably is to help predict probability for success, however, evidence for predictive validity is limited.

One of the more systematic approaches to the psychological evaluation is the Cleveland Clinic Behavioral Rating Scale ⁽¹⁸⁾. This is a clinician rating of eight domains that can affect success and adjustment to bariatric surgery, plus an overall impression score: consent, expectations, social

support, mental health, chemical/alcohol abuse/dependence, eating behaviors, adherence, coping/stressors.

The CCBRS ratings were hypothesized to be predictive of bariatric surgery outcomes. We hypothesized that patients who receive bariatric surgery will not only show significant weight loss by post-op month 6, but also experience clinically meaningful improvements in HR-QOL, and show reductions in anxiety and depression.

MATERIALS and METHODS

Participants and Procedures: After the Institutional Review Board approved the study, 380 patients were seen from October 2012 to October 2013 for their pre-surgical psychological evaluation. All psychological evaluations were performed by one of two psychologists using the instruments described in the measures section below and a diagnostic interview.

During the course of the psychological evaluation and chart review, it was determined if the patient met the inclusion criteria of being at least 18 years of age, was fluent in English, cognitively able to give consent, and willing to participate. As a result, 314 patients were enrolled. Of these, 184 patients underwent bariatric surgery. Data from five patients were excluded because they were either revisions or band placement, therefore the final analytical sample included data on 179 participants.

Weight, height, SF-36v2, PHQ-9, GAD-7, and AUDIT data were collected pre-operatively, as well as for 2 years post-operatively at an interval of six months, during the patients' regularly scheduled clinic visit. BMI was calculated using the standard formula: $\text{weight (kg)} / [\text{height (m)}]^2$. We calculated %EWL as follows:

$$\%EWL = [Initial\ weight - Postoperative\ weight] / [Initial\ weight - Ideal\ weight] * 100$$

Ideal weight was considered to be equivalent to each patient's weight at BMI=25⁽⁵⁾. The pre-operative BMI entered for each participant was taken on the day of the initial surgical consultation.

Of 181 patients, there were 126 (69.6%) with at least one follow-up visit in which data were collected. SF-36v2 data were not used for that visit if there were any omitted responses. About 39.2% of the patients were followed-up 6 months after surgery, 47.5% 12 months after surgery, 31.5% 18 months after surgery, and 22.7% 24 months after surgery.

Measures: The Short Form 36 item Health Survey (SF-36)⁽¹⁹⁾ was chosen due to its broader relationship to comorbidities associated with obesity⁽⁵⁾. It yields two component scores, the Physical Component Score (PCS), and the Mental Component Score (MCS). The PCS includes items assessing general health, mobility and self-care, pain, and the extent to which physical problems affect the ability to fulfill roles. The MCS has items assessing social functioning, vitality, emotional distress, and the extent to which mental health affects the ability to fulfill roles. The CCBRS⁽¹⁸⁾ is shown to have internal consistency (Chronbach's alpha = 0.88) with good inter-rater reliability (r=0.82) and was developed for use with preoperative psychological assessment of bariatric patients. The CCBRS includes eight content areas plus one overall impression score: consent, expectations, social support, mental health, chemical/alcohol abuse/dependence, eating behaviors, adherence, coping/stressors, and overall impression were evaluated for all the patients in the sample. These areas were rated by the evaluating psychologist using a Likert scale ranging from 1 (poor) to 5 (excellent). See Heinberg et al.⁽¹⁸⁾ for the descriptors for each of the five rating scores. The Patient Health

Questionnaire 9 item (PHQ-9)⁽²⁰⁾ and the Generalized Anxiety Disorder 7 item (GAD-7)⁽²¹⁾ are both brief measures originally developed for use in primary care to assess depression and anxiety, respectively, but now widely used due to their acceptable psychometric properties and ease of use. The Alcohol Use Disorders Identification Test (AUDIT)⁽²²⁾ was used to measure alcohol use, with a suggested cut-off total score of eight or above on this 10 item questionnaire identifying possible hazardous alcohol use.

Statistical Analysis: We used generalized estimating equations (GEE) to examine if any CCBRS rating predicts the physical component summary score (PCS), mental component summary score (MCS), total depression score (PHQ-9), total generalized anxiety disorder score (GAD-7), total AUDIT score, and % excess weight loss (%EWL). Since the probability of observing the dependent variables was independent of observing all of the domains of CCBRS ratings, we assumed missing variables to be completely at random while applying -xtgee- command to report the unbiased estimates. The GEE models were using linear link function. An exchangeable correlation specification was used in the GEE models to account for the effect of within-subject correlation for all models except with %EWL. Percent EWL was calculated from baseline at all-time points. We used an independent structure, assuming that the excess weight loss in different follow-up time point is independent of one another. We verified the correlation structure using quasi-likelihood under the independence model criteria⁽²³⁾, smaller the better fit to the model. Akaike's information criteria (AIC) works but only with maximum likelihood approaches. However, GEE uses quasi-likelihood methods without making any assumption about the distribution of the responses. Therefore, QIC was used to select the best working-correlation structure for GEE models. The level of significance was set at 0.05 and

coefficients with 95% confidence intervals were estimated. Stata 14.2 ⁽²⁴⁾ was used in all analysis.

RESULTS:

Out of 179 patients in the study sample, 63.1% underwent a Roux-en-Y gastric bypass (RYGB), while 36.9% underwent the sleeve gastrectomy. There were no significant differences in gender and race at baseline between the RYGB and sleeve gastrectomy surgeries (Table 1). Patients undergoing the RYGB had a higher BMI and were younger.

Bariatric surgery led to significant weight loss by month 6 and this improved to 12 months and remained steady at 18 and 24 months (Table 2). Improvements in health-related quality of life were assessed using 5 T score points as the minimally clinically important difference (MCID) on the SF-36. For the Physical Component Score, 52 (80.0%) patients achieved MCID within six months, 59 (80.8%) at 12 months, and 40 (74.1%) at 18 months, and 31 (77.50%) at 24 months. For the Mental Component Score, 25 (38.5%) patients achieved MCID within 6 months, 24 (32.9%) at 12 months, 17 (31.5%) at 18 months and 9 (22.5%) at 24 months.

In general, the univariate analyses with Tukey's adjustment for multiple comparisons of this study indicate that the SF-36 Physical Component Summary Score showed improvement by 6 months and stayed improved up to 24 months after bariatric surgery. The mean PHQ-9 score at baseline reveals that the sample had mild symptoms of depression. This score decreased (improved) over time. Total AUDIT score also decreased from baseline to 6 months after surgery. Time did not seem to have a similar effect on GAD-7 scores.

Results from the multivariable analysis to examine the relationship of each baseline (pre-op) CCBRS domain rating with HR-QoL, depression, anxiety, alcohol use, and excess weight loss in patients undergoing bariatric surgery and being followed up for 6, 12, 18, and 24 months are presented in Table 3. All of these models controlled for gender, age, race, initial BMI, and the type of surgery. Patient's capacity to consent, surgical outcome expectations, mental health, and overall impression ratings at baseline predicted both physical and mental component scores (PCS, MCS) across all time points. Each unit increase in the ratings for consent, expectations, mental health, and overall impression at baseline independently predicted, on an average, higher ratings on the PCS across all time points. All of the CCBRS domain ratings significantly predicted the MCS score and GAD-7 score. Except for the Chemical/Alcohol Abuse/Dependence rating, all of the CCBRS ratings significantly predicted the PHQ-9 scores – the higher (more favorable) the ratings on the CCBRS, the lower the depression score. The CCBRS Chemical/Alcohol Abuse/Dependence rating significantly predicted the total score on the AUDIT – the higher this CCBRS rating was, the better (lower) the AUDIT score. Only the CCBRS social support domain rating significantly predicted percent excess weight loss ($p=0.036$). Thoughts of suicide or death did not increase after bariatric surgery (Fisher's exact test, $p=0.168$).

We are grateful for a reviewer raising the question as to whether or not the CCBRS might also predict patient retention. While not part of our original hypotheses, we used bivariate association and found that social support (Est. Odds Ratio=1.88, $p<0.011$), coping (Est. Odds Ratio=1.87, $p<0.005$), and overall impression (Est. Odds Ratio=1.66, $p<0.03$) ratings predicted 24 month retention.

DISCUSSION

The purpose of the study was to determine if a validated behavioral assessment tool, the CCBRS, could predict outcomes after bariatric surgery. Outcome areas examined were excess weight loss (EWL), health-related quality of life, depression, anxiety, and alcohol use after bariatric surgery. The data show that each outcome measure was predicted by at least one CCBRS domain rating.

Patients' capacity to consent, surgical outcome expectations, mental health, and overall impression ratings at baseline predicted both physical and mental health-related quality of life (PCS, MCS) over the two year follow-up period. All of the CCBRS domain ratings significantly predicted the MCS score and GAD-7 score, and all but one of the CCBRS ratings predicted PHQ-9 scores. The fact that more CCBRS domains were predictive of changes in mental health QoL than of physical health QoL is not surprising given that the CCBRS was designed to be used in a behavioral health assessment to help explore psychosocial variables ⁽¹⁸⁾.

The present results are consistent with the initial development of the CCBRS in that it shows predictive validity. Previous work showed that patients rated as guarded were more likely to withdraw from the program, and those that did undergo surgery spent more time in the hospital, for example ⁽¹⁸⁾. In the present study, the CCBRS Chemical/Alcohol Abuse/Dependence rating significantly predicted the total score on the AUDIT (the higher this CCBRS rating was, the better the AUDIT score), while no other scale did. The CCBRS social support domain rating was the sole predictor of weight loss. Greater social support, as rated by the clinician, appears to have a beneficial effect on weight loss in patients undergoing bariatric

surgery, as well as being associated with a greater likelihood of keeping their 24 month post-op visit. The coping and the overall impression ratings also predicted whether participants kept their 24 month post-op visit.

Limitations of the study include low retention, raising the issue of self-selection over time. However, retained patients may not be as selective as previously thought. For example, no differences in weight loss and co-morbidity reduction in patients with routine clinic visits vs. “found” patients were seen 10 years post-surgery ⁽²⁵⁾. In the present study, retention is low for a shorter period of time (two years of follow-up). Probable contributions to this involved changes to the program, which include a location change for the clinic potentially creating greater geographic distance for some patients. Secondly, the study period encompassed a time during which the complement of surgeons changed and this could have influenced patients’ desire for continued follow-up as well as they may no longer be seeing their original surgeon. Since these additional barriers would occur randomly to our patients, we still have confidence in our findings with the smaller number of retained participants. Another limitation is that this was a single-center study, potentially limiting generalizability of the findings.

CONCLUSIONS

A behavioral rating scale (CCBRS) completed prior to bariatric surgery predicted postoperative weight loss, quality of life, alcohol use, depression and anxiety. The real world significance is that this tool may prove useful in expectation management before surgery. Further, it may identify patients requiring more intensive preoperative therapy and closer postoperative follow-up in order to maximize their chance of success after bariatric surgery. Social support was once again found to be a critical factor in weight loss, consistent with previous research ⁽²⁶⁾

and clinical observations. One mediating factor may well be that patients with sufficient social support are more likely to keep their clinic follow-up visits. The complexities and importance of social support merits further research.

Conflicts of Interest

The authors have no conflicts of interest to declare.

Table 1: Sample characteristics at baseline (N=179)

Characteristics	Total sample	RNY	Sleeve	p-value
Gender, %(N)				0.08 [‡]
Female	84.92 (152)	88.50 (100)	78.79 (52)	
Male	15.08 (27)	11.50 (13)	21.21 (14)	
Race, %(N)				0.061 [‡]
White	82.68 (148)	86.73 (98)	75.76 (50)	
Others	17.32 (31)	13.27 (15)	24.24 (16)	
Age, mean (SD)	45.8	44.4 (11.2)	48.3 (12.3)	0.031 [*]
BMI, mean (SD)	48.3	49.4 (8.8)	46.4 (7.9)	0.023 [*]

‡ Fisher's exact test between categorical variables;

* Pairwise comparison of the means with Tukey's adjustment for multiple comparisons between RNY and Sleeve

Table 2: Trends for HR-QoL, depression, anxiety, alcohol dependence, BMI, and excess weight loss in the entire sample (mean T scores for the PCS and MCS, raw scores for PHQ-9, GAD-7 and AUDIT)

Indicators	Baseline N=179 (100%)	6 months N=70 (40%)	12 months N=86 (48%)	18 months N=57 (32%)	24 months N=41 (23%)
SF-36 – Physical Component Score****	36.82	48.33	50.33	50.34	48.52

SF-36 – Mental Component Score****	47.72	54.07	51.90	51.18	50.05
Total PHQ-9 score****	6.20	3.00	3.46	3.86	4.32
Total GAD-7 score	3.62	3.29	3.83	3.74	5.12
Total AUDIT score***	0.97	0.39	0.56	0.92	0.63
BMI****	48.28	34.72	31.89	31.59	31.37
Change in BMI from baseline*	-	13.43	16.93	19.59	18.17
% Excess Weight Loss**	-	60.72	73.56	76.19	75.55
% Total Body Weight Loss**	-	26.98	33.72	36.78	35.11

**** p≤0.001 between baseline and six months, *** p≤0.01 between baseline and six months,

** p≤0.001 between six and twelve months, *p≤0.05 between six and twelve months PHQ-9: 9-

item Patient Health Questionnaire; GAD-7: 7-item Generalized Anxiety Disorder; AUDIT: Alcohol

Use Disorders Identification Test

Table 3: Multivariable analysis of CCBRS domain with HR-QoL, PHQ-9, GAD-7, AUDIT, and excess weight loss in sample

CCBRS domain	PCS	MCS	PHQ9	GAD7	A
	Coeff. [95% CI]	Coeff. [95% CI]	Coeff. [95% CI]	Coeff. [95% CI]	Coeff.
Consent	3.54 [1.35, 5.74]**	3.14 [0.92, 5.36]**	-1.32 [-2.29, -0.34]**	-1.02 [-1.94, -0.1]*	0.1
Expectations	3.25 [1.32, 5.18]**	4.06 [1.9, 6.22]**	-1.58 [-2.49, -0.68]**	-1.53 [-2.35, -0.71]**	-0.0
Social Support	0.6 [-1.01, 2.21]	3.33 [1.71, 4.96]**	-1.5 [-2.26, -0.73]**	-1.29 [-2.1, -0.48]**	-0.
Mental Health	2.35 [1.01, 3.7]**	6.3 [4.75, 7.85]**	-2.35 [-3, -1.69]**	-2.22 [-2.89, -1.55]**	-0.1
Chemical/Alcohol					
Abuse/Dependence	0.65 [-1.06, 2.36]	2.99 [1.39, 4.58]**	-0.61 [-1.32, 0.1]	-0.96 [-1.75, -0.18]*	-0.43 [
Eating Behaviors	1.62 [0, 3.23]*	3.31 [1.56, 5.06]**	-1.74 [-2.5, -0.99]**	-1.39 [-2.15, -0.64]**	0.0
Adherence	1.48 [-0.25, 3.21]	2.96 [1.27, 4.64]**	-1.25 [-2, -0.5]**	-1.43 [-2.12, -0.75]**	-0.
Coping/Stressors	0.75 [-0.96, 2.46]	4.95 [3.3, 6.6]**	-1.77 [-2.47, -1.06]**	-1.57 [-2.32, -0.83]**	-0.0
Overall Impression	2.63 [0.85, 4.41]**	5.48 [3.91, 7.05]**	-2.35 [-3.04, -1.66]**	-2.12 [-2.87, -1.36]**	-0.0

Note: All of these models were controlled for gender, age, race, initial BMI, and the type of surgery they underwent.

*** $p < 0.001$; ** $p < 0.01$; * $p < 0.05$

PCS: Physical Component Summary score; MCS: Mental Component Summary score; PHQ9: 9-item Patient Health Questionnaire; GAD7: 7-item Generalized Anxiety Disorder; AUDIT: Alcohol Use Disorders Identification Test; %EWL: Percent Excess Weight Loss

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