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Gastrojejunal Stoma Diameter Predicts Weight Regain after Roux-en-Y Gastric Bypass

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Abstract

Background & Aims—Weight regain following Roux-en-Y gastric bypass (RYGB) is associated with reductions in health status and quality of life. We evaluated whether gastro-jejunal stoma diameter is a risk factor for weight regain after RYGB.

Methods—We examined data collected over 4 years from consecutive patients referred to a tertiary care bariatric center for upper endoscopy after RYGB. We used linear regression analysis to determine the association between the gastro-jejunal stoma diameter and weight regain. We applied a logistic regression model using clinical and endoscopic parameters to develop a prediction rule for weight gain after RYGB.

Results—Among 165 patients included in our study, 59% had significant weight regain ($\geq 20\%$ of maximum weight lost after the RYGB) and 41% did not. The mean percent of maximal weight lost after RYGB that was regained in the entire cohort was $30\% \pm 22\%$. Gastro-jejunal stoma diameter was significantly associated with weight regain after RYGB surgery in univariate analysis ($\beta = 0.31$, $P < 0.0001$). This association remained significant after adjusting for several known or purported risk factors for weight regain ($\beta = 0.19$, $P = 0.003$). We developed a simple prediction rule for weight regain after RYGB using a 7 point scoring system that includes the

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Authors Contributions:

Barham K. Abu Dayyeh: Study concept and design, acquisition of data, statistical analysis and interpretation of data, and drafting of the manuscript.

David B. Lautz: Study concept, critical revision of the manuscript for important intellectual content.

Christopher C. Thompson: Study concept and design, interpretation of data, critical revision of the manuscript for important intellectual content, and study supervision.

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gastro-jejunal stoma diameter, race, and percent maximal body weight lost after RYGB; a cut-off score ≥ 4 points had an area under receiver operating characteristic curve of 0.76 and a positive predictive value of 75%.

Conclusion—Increased gastro-jejunal stoma diameter is a risk factor for weight regain after RYGB and can be incorporated in a novel prediction rule.

Keywords

Weight loss; obesity; surgery; ROC; PPV

Introduction

Obesity and its associated conditions including type two diabetes and cardiovascular disease have reached epidemic proportions especially in the western world, and are associated with significant morbidity, mortality, and cost to the health care system.¹ Of the many treatment approaches for obesity and its complications, bariatric surgery shows the most promise in achieving significant and sustained weight loss and resolution of associated metabolic comorbidities, when compared to combinations of medications, dietary, and behavioral modifications.² Roux-en-Y gastric bypass (RYGB) is currently the weight loss surgical procedure of choice and results in excess body weight loss of 62% with an 84% diabetes resolution rate.^{3–4}

Despite its proven efficacy, the majority of patients undergoing RYGB regain about 30% of the weight they had lost, with about 20%–30% of patients regaining most of the weight that had been lost; thus, negatively impacting their health status and quality of life.^{5–6} The etiology of weight regain for those patients it affects is likely multifactorial and remains poorly defined. Risk factors cited include preoperative BMI at the time of RYGB, nutritional habits post surgery, self-esteem, mental health, socio-economic status, and the presence of gastrogastric fistula.^{7–10}

A long held concept in the bariatric surgical community has been that progressive dilatation of the gastrojejunal (GJ) stoma post-RYGB can contribute substantially to weight regain. This concern dates back to the era of the vertical banded gastroplasty and was the basis for reinforcing or “banding” the distal gastric pouch. The concern over GJ stoma dilatation has also been the reasoning behind the use of “banded” distal gastric pouches popularized by Fobi and Capella, who have among the highest post-RYGB weight loss results reported in the literature.^{11–12} More recently, dilatation of the GJ stomal diameter is increasingly an indication for revisional bariatric surgical procedures, which carry high rates of major complications.^{13–15} This has led to the development of a variety of less invasive endoscopic techniques and devices aimed at the reduction of the gastrojejunal anastomosis diameter and gastric pouch size. These include endoluminal suturing devices, tissue plication platforms, and sclerotherapy techniques.^{16–24} Despite these trends, the data to date are indirect, and no studies have directly evaluated the effects of GJ stoma diameter over time upon weight regain post-RYGB.

Thus, in this study, we sought to evaluate the influence of GJ stoma diameter on the risk of weight regain after RYGB. Furthermore, we sought to develop a predictive model based on endoscopic and clinical parameters that would stratify subjects at high risk for this costly complication. To address these questions, we studied a large, consecutive series of patients in which GJ stoma diameter was recorded, and serial weight measurements were available.

Methods

We reviewed data for all patients referred to our tertiary care bariatric center to undergo upper endoscopy post RYGB between 01/01/2006 to 09/01/2010. The indication for the upper endoscopy varied and included work-up for epigastric abdominal pain, nausea and vomiting, evaluation of possible gastric fistula and marginal ulcerations, as well as weight regain after RYGB. As a standard practice, all bariatric patients referred to our center for upper endoscopy post RYGB were examined by the same single expert endoscopist, who measured all GJ stoma diameters in an identical protocol using a novel direct reading endoscopic measuring instrument (Olympus, Center Valley, PA, USA). This flexible calibrated measuring instrument is introduced through the upper endoscope working channel and placed in proximity to the anatomical structure to be measured. Using this measurement, the endoscopist recorded the maximal diameter of the GJ stoma (figure 1).

165 consecutive patients, at least one year after RYGB, who underwent upper endoscopy with recorded GJ stoma diameter, and had documented post RYGB clinical profiles and weight data were included in the study. We excluded subjects with gastrogastic fistulae since the pathophysiology of their weight regain likely differs.

Statistical Methodology

Linear regression analysis was performed to determine the association between the GJ stoma diameter (in millimeters) and the percent of weight regained from maximal weight loss nadir after RYGB. In the multivariate analyses, we adjusted for known or purported risk factors for weight regain, including age, gender, race, percent of body weight lost at nadir after RYGB, time since the RYGB in years, type of the RYGB (open vs. laproscopic), diabetes status, selective Serotonin re-uptake inhibitors (SSRI) use, anti-psychotic medications use, and presences of marginal ulcers on upper endoscopy. Standardized β coefficients were reported and significant two-sided p-value was set at ≤ 0.05 . Pearson correlation was used to study the correlation between the length of the gastric pouch and the GJ stoma diameter.

We also used a logistic regression model to develop a prediction rule which consists of significant clinical and endoscopic parameters associated with weight regain after RYGB. For this, we divided the cohort in half, 82 subjects were used to derive the prediction rule and 83 subjects to valid it. We converted odds ratio estimates of different predictors used in the derivation model into a point system based on their strength of association with weight regain after RYGB. We compared the area under the receiver operating characteristic (ROC) curve for the derivation and validation models, as well as the positive predictive values (PPV) of weight regain associated with a score \geq to 4 points. Statistical significance was set at a two-sided p-value ≤ 0.05 . The Hosmer-Lemeshow test was used to assess the goodness-of-fit of the predictive model.

All statistical modeling was done using SAS version 9.2 software (Cary, NC, USA). Graphing was done using the JMP version 8 software (SAS Institute, Cary, NC, USA).

Results

Among the 165 patients included in our study, the average age of the population was 44 years with 91% females, 68% Caucasians, 16% Blacks, 16% Hispanics, 17.5% with a diagnosis of diabetes prior to the RYGB, 36% on SSRI therapy, 5% on anti-psychotic medications, 20% with known marginal ulcers or erosions, and 50% underwent an open RYGB procedure. The mean pre-RYGB BMI for the cohort was 49 (SD=8). After RYGB, the mean maximal percent total body weight lost was 38% (SD = 9), representing a maximal percent excess body weight lost (EBWL) of 73% (SD = 19). Fifty nine percent of the cohort

(97 subjects) had significant weight regain ($\geq 20\%$ of maximal weight lost after the RYGB), and 41% (68 subjects) did not. The mean percent of maximal weight lost after RYGB that was regained in the entire cohort was 30% (SD = 22). The average time between the RYGB surgery and endoscopic measurement of the GJ stoma diameter was 4.6 years (SD = 3).

Table 1 shows the univariate and multivariate associations between different variables and weight regain after RYGB. The GJ stoma diameter was significantly associated with weight regain after RYGB (standardized β coefficient = 0.31, $p = <0.0001$) in univariate analysis. This association remained significant after adjusting for multiple potential risk factors in a multivariate linear regression model (standardized β coefficient = 0.19, $p = 0.003$). Figure 2 shows a linear relationship with a positive slope between the GJ stoma diameter in millimeters and percent of maximal weight lost after RYGB that was regained. At 5 years after the RYGB each 10 mm increase in the GJ stoma diameter was associated with an 8% increase in the percent of maximal weight lost after RYGB that was regained (figure 3).

Other than the GJ stoma diameter, other variables that were significantly associated with weight regain after RYGB in the multivariate linear regression model included the time elapsed since the RYGB (standardized β coefficient = 0.65, $p = <0.0001$), and the presence of marginal ulcerations on endoscopy (standardized β coefficient = -0.17 , $p = 0.01$). The length of the gastric pouch was not associated with weight regain on both univariate and multivariate analyses.

In order to determine if the size of the gastric pouch correlates with the GJ stoma diameter, we calculated a Pearson correlation coefficient between them. The Pearson correlation coefficient was 0.1 ($p = 0.06$); indicating no correlation between these two measurements.

Given the positive association observed between the GJ stoma diameter and percent weight regain after RYGB in our linear regression model, we sought to develop a simple prediction rule based on clinical and endoscopic variables to estimate the probability of weight regain. In order to do so, we divided the cohort in half, 82 subjects were used to derive the prediction rule and 83 subjects to valid it in a multivariate logistic regression model. The area under the ROC curve for a prediction model including GJ stoma diameter, race, and maximal percent weight lost after RYGB was 0.76 (Hosmer-Lemeshow goodness-of-fit test = 0.6) (figure 4).

The odds ratio estimates of the different predictors used in this model were then converted to a simple 7 point system based on their strength of association with greater than 20% weight regain after RYGB (table 2). The positive predictive value (PPV) in predicting significant weight regain after RYGB for a cut-off score \geq to 4 points in this model was 75%. Scores lower than 4 points were indeterminate.

The performance of the predication rule in the validation cohort was similar. The area under the ROC curve was 0.70, and the PPV in predicting significant weight regain after RYGB for a cut-off score \geq to 4 points was 72%.

Conclusions

In this study, we demonstrate that an enlarged GJ stoma diameter is a significant risk factor for weight regain after RYGB; thus, establishing it as a legitimate delayed post-surgical complication that explains a significant proportion of variability in long term weight outcomes after RYGB surgery. Stoma dilation should thus be regarded in a manner similar to gastro-gastric fistulae or other postsurgical anatomic complications.

This finding is corroborated by earlier observations from vertical banded gastroplasty procedures^{11–12, 25}, previous data supporting the reinforcing or “banding” the GJ stoma in RYGB patients²⁶, and the early results of endoscopic procedures to narrow the GJ stoma in RYGB patients who have gained weight.^{16, 19–23}

Weight regain after RYGB is multi-factorial and likely involves a complex interplay between a permissive psychosocial environment, nutritional habits, and a complex genetic and anatomic milieu that effect many physiological regulatory pathways controlling food-intake behavior and energy metabolism after the procedure.^{5, 27–30} Some in the bariatric surgical community have claimed that weight regain post-RYGB is largely attributed to patient non-compliance, and as such, surgical or endoscopic revisional procedures in such patients should not be routinely considered. However, if a dilated GJ stoma results in early emptying of a gastric pouch and loss of post-prandial satiety, then such an anatomic alteration would present in the same manner as simple non-compliance. Thus, there is likely an interplay between the patient’s anatomy and the complex physiologic and psychosocial factors that regulate their eating behavior. The difficulty in treating such patients lies in the same difficulties that they face with non-operative measures to lose weight prior to their bariatric surgical procedure. Therefore, the ability to identify key modifiable risk factors for weight regain, and target them effectively with less invasive and cost-saving endoscopic approaches, could offer a substantial potential benefit to patients with this complication.

Mechanisms by which a dilated GJ stoma increases the risk for weight regain after RYGB are not yet clearly defined. However, a dilated gastrojejunal stoma may be a surrogate for a compliant gastric pouch. This permits accommodation of larger meal boluses prior to the activation of gastric wall mechanoreceptors and inhibition of the gastric hormone ghrelin, which is a 28-amino acid peptide secreted primarily by the A/X cells of the gastric fundus with strong orexigenic and adipogenic actions.^{31–36} A dilated GJ stoma may also alter the rate by which the gastric pouch empties partially digested nutrients to the jejunum, which in turn modulate the production of incretins from specialized enteroendocrine cells within the walls of the small bowel that modulate insulin secretion, energy expenditure, and body weight regulation.^{35, 37–38}

Other risk factors for weight regain after RYGB identified by our linear regression model include the time since RYGB surgery. Time since surgery includes in it many risk factors for weight regain that we could not measure and account for directly in our study, such as a permissive psychosocial environment, nutritional habits, physical activity, and genetic backgrounds of patients. Similar to others, our study did show an association between psychiatric medications use and weight regain. However, these associations were attenuated after multivariate adjustment.⁸

Since 1998 the number of bariatric surgery procedures has been on an exponential incline with an estimated 220,000 bariatric operations performed in the USA and Canada in 2008.^{39–40} With the continued projected increase in these procedures, identifying patients at increase risk for weight regain, with subsequent application of more aggressive behavioral, nutritional, and endoscopic interventions aimed at reducing the GJ stoma diameter is advisable to prevent or halt this outcome. To that end, our simple prediction rule based on clinical and endoscopic variables, had a positive predictive value of 75% in predicting weight regain at a cut-off score ≥ 4 points.

Our study has multiple strengths. First, this is the first study to directly correlate GJ stoma diameter with weight loss outcomes. Second, we included all consecutive patients who were referred to our center for upper endoscopy after RYGB to avoid confounding by indication. Third, the GJ stoma diameter in all subjects was measured in the same fashion by a single

endoscopist to minimize variability. Fourth, we had a reasonable sample size to examine our hypotheses, derive our prediction rule, and validate it.

Several limitations deserve comment. First, although the data was collected prospectively, the analysis was retrospective in nature. Second, we lacked information about nutritional habits and physical activity. Third, we only measured the maximal GJ stoma diameter. Finally, we lacked a reference group with no significant weight regain after RYGB, who also did not have an indication for upper endoscopy. However, the distribution of weight regain in our entire cohort was close to normal with a mean percent weight regain of 30%, which is similar to other studies that followed post RYGB subjects prospectively.⁶ Hence, it is unlikely that we had a significant selection bias.

All in all, as the obesity epidemic persists and more patients undergo surgical intervention there will be more patients at risk of weight regain and procedural failure. Thus, demonstrating that an enlarged GJ stoma diameter is a risk factor for weight regain after RYGB, and using it to develop a prediction rule for this complication, will enable us to more accurately stratify patients and employ a variety of early intervention strategies. If confirmed, these results suggest that endoscopic interventions designed to reduce gastrojejunal anastomosis aperture may be effective in treating or preventing weight regain. These devices and techniques, including endoluminal suturing devices, tissue plication platforms, and sclerotherapy techniques, have shown promise in managing weight regain after RYGB; however, they are yet to be validated in randomized controlled trials.^{18–24}

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Abbreviations

BMI	Body mass index
EBWL	Excess body weight lost
GJ	Gastrojejunal
PPV	Positive predictive value
ROC	Receiver operating characteristic
RYGB	Roux-en-Y gastric bypass
SSRI	Serotonin re-uptake inhibitors

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Figure 1. Endoscopic measurement technique of the gastrojejunal stoma diameter. A flexible calibrated measuring instrument is introduced through the upper endoscope working channel and placed in proximity to the GJ stoma. The endoscopist recorded its maximal diameter.

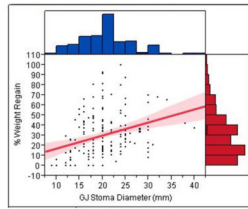


Figure 2. Scatter plot with best fit linear regression line and 95% confidence intervals of the association between the gastrojejunostomy diameter in millimeters and percent of maximal weight lost after RYGB that was regained. The normal distribution of each of the continuous variables is also shown.

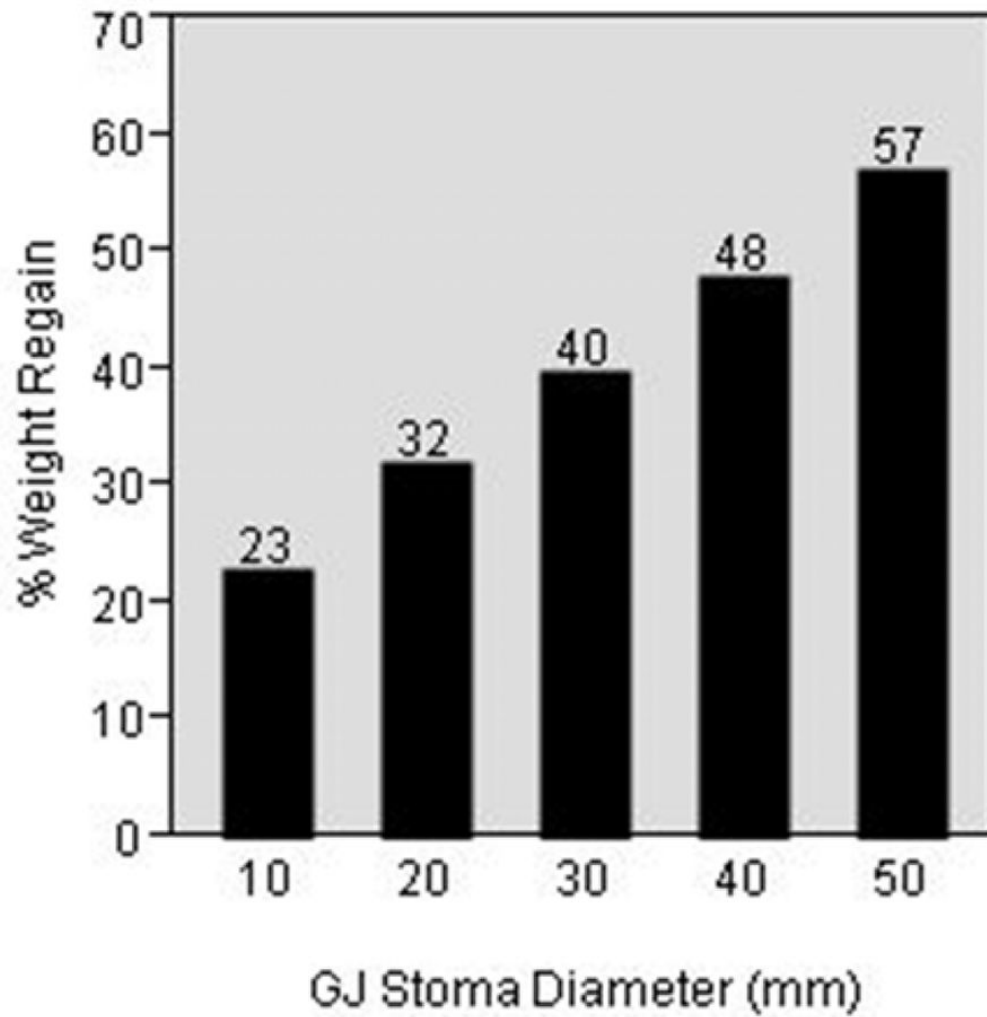


Figure 3. Predicted percent of maximal weight lost after RYGB that was regained in 5 years after the procedure at different gastrojejunostoma diameters based on the linear regression model.

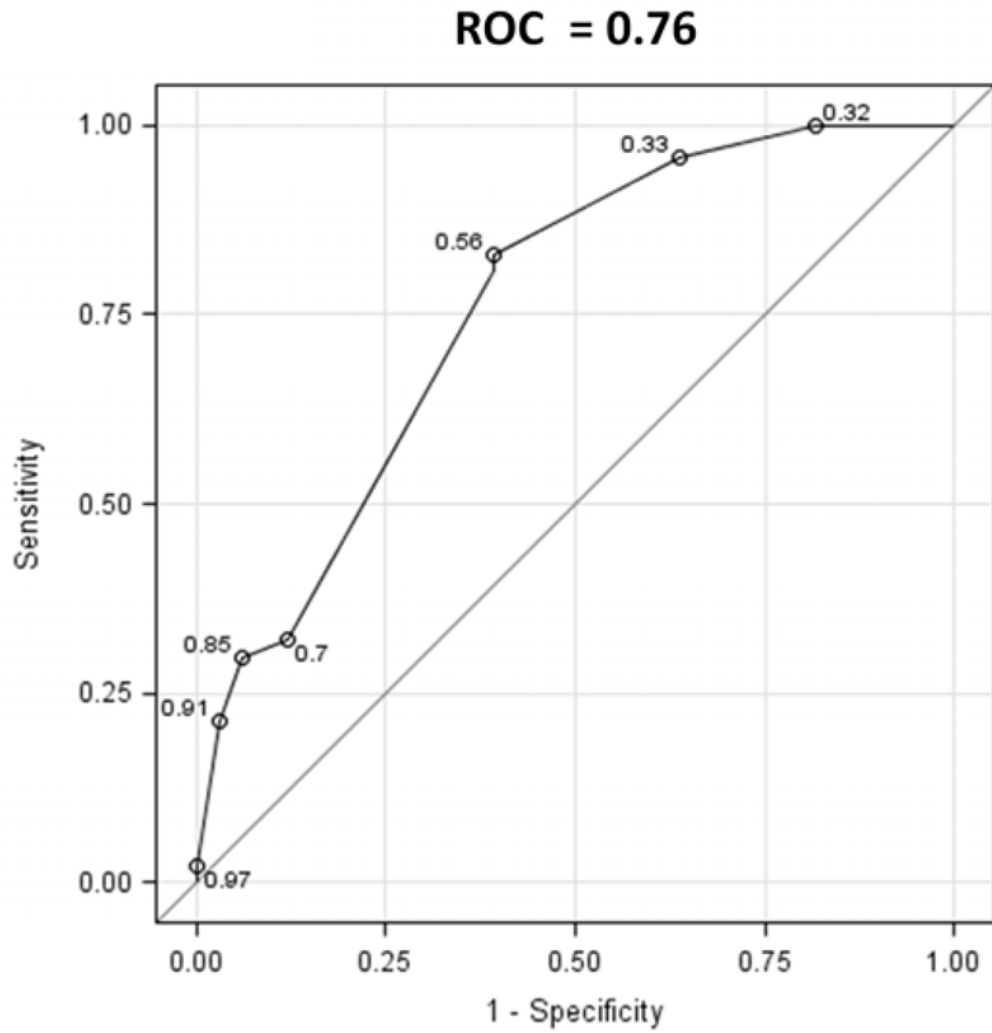


Figure 4. Area under ROC curve for weight regain after RYGB prediction model including gastrojejunal stoma diameter, race, and percent of maximal weight loss after RYGB.

Table 1

Univariate and multivariate analysis of variables associated with weight regain after RYGB in a linear regression model

	Univariate		Multivariate	
	Standardized β coefficient	P-Value	Standardized β coefficient	P-Value
Age (years)	0.04	0.62	0.02	0.8
Gen (Male vs. Female)	- 0.14	0.08	- 0.03	0.67
Race (Caucasians vs. African Americans and Hispanics with Caucasians as reference)	- 0.23	0.003	- 0.1	0.17
Maximal percent body weight lost after RYGB (%)	0.06	0.4	- 0.06	0.4
Time from RYGB (years)	0.66	<0.0001	0.6	<0.0001
Type of the RYGB (open vs. laproscopic with laproscopic as reference)	0.44	<0.0001	- 0.01	0.88
Diabetes	-0.09	0.26	0.09	0.15
SSRI use	0.21	0.008	- 0.01	0.86
Anti-psychotic medications use	0.18	0.02	0.07	0.23
Marginal ulcers presence	- 0.29	0.0002	- 0.19	0.004
Gastric pouch (cm)	0.09	0.27	- 0.003	0.95
Gastrojejunal stoma diameter in (mm)	0.31	<0.0001	0.19	0.003

Table 2

Prediction model for weight regain after RYGB

Risk Factors	Points	Cut-off point	Positive predictive value (PPV)
Gastrojejunal stoma diameter (mm)			
• ≤ 15	0	≥ 4 points	75 %
• 15–25	2		
• ≥ 25	4		
Race			
• Other	0		
• White	2		
Percent maximal body weight lost after RYGB (%)			
• $\leq 50\%$	0	< 4 points	Indeterminate
• $> 50\%$	1		
Maximum points	7		