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Clinical Significance of Failure to Lose Weight 10 Years Following Roux-en-Y Gastric Bypass

Robert B. Hawkins, MD¹, J. Hunter Mehafeey, MD¹, Timothy L. McMurry, PhD², Steven K. Malin, PhD^{3,4}, Bruce Schirmer, MD¹, and Peter T. Hallowell, MD¹

¹Department of Surgery, University of Virginia, Charlottesville, VA

²Department of Public Health Sciences, University of Virginia, Charlottesville, VA

³Division of Endocrinology and Metabolism, Department of Medicine, University of Virginia, Charlottesville, VA

⁴Department of Kinesiology, University of Virginia, Charlottesville, VA

Abstract

Background—Although Roux-en-Y gastric bypass (RYGB) induces short-term weight loss and comorbidity amelioration, long-term data suggests a subset of patients return to their preoperative body mass index (BMI).

Objectives—Identify the clinical implications of 10-year weight-loss failure following RYGB.

Setting—Academic teaching hospital.

Methods—Adults undergoing Roux-en-Y Gastric Bypass (1985-2004) were included in this study (n=1087). Absolute weight-loss failure was defined as 0% reduction in excess BMI (%REBMI) 10 years after surgery. Univariate analyses compared comorbidity rates and resolution by weight-loss classification. Multivariable regression modeling analyzed preoperative predictors of 10-year %REBMI and weight-loss failure.

Results—Complete follow-up was available for 617 (57%) patients with a 10-year median %REBMI of 57.1% and 10.2% of patients had weight-loss failure. Prevalence of all comorbidities decreased, even in patients with weight loss failure (all p<0.05). Compared to patients with successful weight loss, patients with weight loss failure had similar rates of resolution of preexisting comorbidities, except for reduced resolution of apnea and cardiac comorbidities (both p<0.05). Risk factors for weight loss failure included lower BMI, non-governmental insurance,

Contact Information: Peter T. Hallowell, MD, University of Virginia, Department of Surgery, PO Box 800679, Charlottesville VA 22908, PTH2F@virginia.edu.

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longer travel time to hospital, and year of surgery. Non-governmental insurance (OR 2.03, $p=0.036$) conferred the highest adjusted odds of weight loss failure.

Conclusions—The vast majority of patients experience dramatic health improvement 10 years after RYGB, even though some patients fail to maintain their weight loss. Renewed focus should be placed on prevention and treatment of chronic disease, with further investigation of weight loss independent mechanisms of health improvement.

MeSH

Bariatric Surgery; Gastric Bypass; Weight loss; Prediction Models

INTRODUCTION

The epidemic of obesity in the United States continues to represent an alarming health burden with over half of the population overweight (Body Mass Index (BMI) 25–30 kg/m²) or obese (BMI >30 kg/m²).[1] While there were hints that the rate of obesity was stabilizing, the most recent figures suggest further increase with 37.9% of adults obese and 7.7% extremely obese (BMI >40 kg/m²).[1, 2] Several studies have demonstrated the early benefits of Roux-en-Y Gastric Bypass (RYGB) including reduction in cardiovascular risks and weight loss.[3–5] These results have been confirmed by several clinical trials demonstrating superiority of bariatric surgery to best medical therapy.[6, 7]

While the short-term success of RYGB has been well documented, long-term data has been sparse due to poor long-term follow-up.[8] The Swedish Obesity Study was the first to demonstrate durable remission of diabetes at 10 and 15 years with outstanding patient follow-up in their National Health Registry.[9] Recent reports show comparable long-term results with durable weight loss and comorbidity reduction in the American population.[10–12] Our group demonstrated that most patients reach maximum percent reduction in excess BMI (%REBMI) at 2 years (72% REBMI) with gradual weight regain and plateauing at 57% REBMI at 10 years.[11]

Despite the excellent overall results reported, there is a growing body of evidence that a small proportion of patients suffer large weight regain or weight-loss failure.[10, 11, 13] A small amount of weight regain can be expected, but the impact of large weight regain is poorly understood. The definition of failure is highly variable with no accepted classification due to the paucity of data.[12, 14, 15] The purpose of this study was to characterize the population with weight-loss failure after RYGB, determine the impact of weight loss failure on comorbidity amelioration, and identify predictors of weight-loss failure.

MATERIALS AND METHODS

Study Participants

Adults undergoing bariatric surgery at a single institution between 1985 and 2003 were included in a previously validated database ($n=1,087$).[11] Partial follow-up was available for 1,040 (96%) patients with at least one postoperative weight recorded and 10-year weights were available for 699 (64%) patients. All other analyses were performed on 617

(57%) patients with complete 10-year follow-up. Supplemental Figure 1 demonstrates the exclusion criteria; overall 108 (10%) patients were excluded due to mortality, 22 (2%) patients refused to participate, and 340 (31%) were lost to follow-up. Patients who underwent a revision to their RYGB were included. The University of Virginia institutional review board approved this study (IRB Protocol #17132).

End Points

Routine follow-up was completed for 151 of the 1,087 patients (14%). Additional follow-up on 500 patients was accomplished by surgical residents, medical students and study coordinators using standardized chart review alone (41.8%) or chart review and telephone interviews (58.2%) and was completed in 2015. Mortality information was obtained from the Centers for Disease Control National Death Index. Comorbid conditions were documented as present if the patient was actively undergoing treatment as previously described.[11] At 10-year follow-up, the same definitions were used, either documented in clinic visits or by telephone interview.

Patients were stratified by weight-loss failure, which was defined as 0% reduction in excess BMI (%REBMI) 10 years after surgery. The primary outcome of interest was a composite of comorbidities modeled after the Charleson Comorbidity Index, defined as the sum of comorbidities (apnea, cardiac, hypertension, pulmonary, type 2 diabetes, gastroesophageal reflux disease, degenerative joint disease, and psychiatric medication use) equally weighted for a maximum score of 8. Cardiac comorbidity included heart failure, coronary disease, and arrhythmia. Pulmonary disease included chronic obstructive pulmonary disease (COPD), asthma, and emphysema. Resolution of disease was calculated as the number of patients with a disease preoperatively who no longer have that diagnosis at 10 years.

Statistical Analysis

Patients were stratified by weight-loss failure and univariate analyses characterized baseline and operative characteristics along with late outcomes. The Mann-Whitney U test was used for independent continuous variables and the Wilcoxon signed rank sum test for paired ordinal data. The Chi-Square test was used for independent categorical variables, while McNemar's test was used for paired data. Multivariable linear regression was utilized to identify preoperative predictors of 10-year %REBMI. A priori the decision was made to include the six most statistically significant predictors in a multivariable logistic regression model for predicting weight-loss failure. Statistical significance was determined by two-sided α of 0.05. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

Study Participants

Of the 617 (57%) of patients with complete follow-up, the median age was 41 years, median BMI was 51.5 kg/m² and 82.7% were female. The median follow-up time point was equivalent between patients with weight-loss failure and success (14.4 vs 13.6 years, $p=0.19$). This group was similar to excluded patients for nearly all preoperative comorbid

conditions (Supplemental Table 1) and %REBMI for known interval time points (Supplemental Table 2). Baseline and operative comparisons are reported in Table 1 with significant differences in baseline BMI, cardiac comorbidities, gastroesophageal reflux disease (GERD), gender and insurance. There were no differences in operative characteristics with 43% of cases completed laparoscopically.

The trajectory of weight loss for all patients (n= 1,040) is demonstrated in Figure 1. The peak %REBMI was at 2 years postoperatively before plateauing with a 10-year median %REBMI of 57%. Weight-loss failure occurred in 67 of 699 patients (10%) at 10 years, and in 63 of 617 (10%) of patients with complete follow-up. The median %REBMI for patients with successful weight loss was 61.8 compared to -17.0 for patients with weight loss failure (Supplemental Table 3).

The weight loss success and failure groups had similar rates of most comorbidities at 10 years including the composite comorbidity index (median score 1 vs 1, p=0.29, supplemental Table 4). Only rates of obstructive sleep apnea were higher in patients with weight-loss failure (14.3% vs 12.3%, p=0.02). When compared to preoperative rates, patients with successful weight-loss at 10-years had significant reductions in every comorbidity measured (all p<0.0001; Supplemental Table 5).

As a measure of overall health, the percent improvement in comorbidity index was not statistically different between groups (67% vs 67%, p=0.760; Table 2). There were also no statistical differences in the rates of resolution for hypertension, pulmonary disease, type 2 diabetes, GERD, degenerative joint disease or psychiatric medication use between weight-loss failure compared to success (p>0.05). However, fewer patients with weight-loss failure had apnea (71.4% vs 87.1%, p=0.03) or cardiac comorbidities resolve (73.9% vs 90.8%, p=0.02).

Table 3 shows that female gender (p=0.008), travel time to the hospital (p=0.025), non-governmental insurance (p=0.006), preoperative BMI (p=0.015), and year of surgery (p=0.016) were independently associated with %REBMI at 10 years. A history of cholecystectomy trended towards significance (p=0.078). The model performance was poor with an R² of only 0.088.

Of these six variables, the preoperative risk factor conferring the highest odds of weight-loss failure was non-governmental insurance coverage (OR 2.03, p=0.036; Table 3). Both year of surgery (OR 0.94, p=0.029) and preoperative BMI (OR 0.90, p <0.0001) were independently associated with weight-loss failure. Every hour of increased travel time to the hospital conferred a 1.25 fold increased risk of weight-loss failure (p=0.015). Neither female gender nor prior cholecystectomy were statistically associated with weight-loss failure. The model performance was adequate with an area under the curve (c-statistic) of 0.767.

DISCUSSION

Mechanisms of Health Improvement

Using the stringent definition of weight-loss failure as any patient who was at or above their preoperative weight at 10 years, we demonstrate that 10% of patients had weight-loss failure. This is a larger percentage than previously reported in the male predominant Veterans Affairs health system.[12] Additionally, the finding of dramatic comorbidity resolution is consistent with prior work suggesting that multiple comorbidities improve after RYGB in the short-term.[3, 6, 7, 16] Herein we show that these same disease factors continue to exhibit significant improvement at 10 years post RYGB even in patients with weight-loss failure.[11] Both an index of comorbidities as well as every component comorbidity showed dramatic rates of improvement that ranged from 63% to 91% resolution. These rates of resolution were similar to a large meta-analysis performed by Buchwald and colleagues, except demonstrated to persist at 10 years.[5] Only apnea and cardiac comorbidities improved significantly more in patients with long-term weight loss compared to weight-loss failure. Collectively, our overall findings suggest minimal differences in health outcomes between patients with weight-loss failure compared to success.

There is clear evidence that weight loss is associated with resolution of chronic diseases, including type 2 diabetes, hypertension and hyperlipidemia.[10, 17] The comorbidity improvement in patients with weight-loss failure suggests that at least some portion of disease resolution may occur independent of weight loss. Alternatively, the initial weight loss seen in patients with eventual failure may result in persistent health improvement despite weight regain. The two exceptions we found were apnea and cardiac comorbidities. We hypothesize that resolution of apnea is unlikely to have a weight-independent mechanism of resolution due to the mechanical nature of the disease. The difference in cardiac comorbidity resolution may be related to the extremely high rate of resolution in those with successful weight loss (91%) who likely benefited from a synergy of cardiometabolic improvements from weight loss, increased exercise, and possibly improved sleep apnea.

While the evidence for weight-independent mechanisms is limited, it is well known that RYGB improves glucose tolerance before weight loss has occurred with multiple theories examining the impact of bypassing the duodenum.[18, 19] Other pathways may involve similar anatomic changes, secondary changes to the microbiome, or represent side effects from the long-term increased access to healthcare, psychological coaching, exercise and healthy diet. Shorter-term studies show a stronger correlation between amount of weight loss and comorbidity resolution, possibly suggesting that with time the weight-independent mechanisms become more important and may become a significant determinant of the long-term mortality benefit seen with RYGB.[20, 21] As a result of the dramatic health improvements seen in the weight-loss failure group, we contend that increased focus on health improvement after RYGB and not weight loss be a key discussion point with patients.

Predictors of Weight Loss

Patients undergo RYGB for multiple reasons, and an often cited priority is body image improvement through weight loss. In this patient cohort, multiple preoperative factors are associated with blunted long-term weight loss including female gender, non-governmental insurance, longer travel times to the hospital and lower BMI. However, predicting exact weight loss at 10 years is difficult and models perform poorly, as seen with our model accounting for only 9% of variability in %REBMI.

The preoperative factors that were associated with weight-loss failure in the present study include non-governmental insurance, increased travel time to the bariatric surgery center, preoperative BMI and year of surgery. These observations build on prior work and suggest that barriers to surgery and medical care may impede success rates long-term.[17] From a clinical perspective, these findings could aid counseling sessions with patients to minimize chances of possible weight-loss failure and maximize weight-loss success.

Policy Implications for Predictors of Weight-Loss Failure

The exact reason people regain weight after RYGB is controversial, and the impact must consider the health improvement even those with weight-loss failure achieve. Nevertheless, female sex is associated with poorer weight loss over time. This is consistent with prior literature, although the interactions with other socioeconomic factors is difficult to disentangle particularly with so few males undergoing RYGB.[22, 23] During follow-up these patients may benefit from focused efforts to maintain weight loss.[3, 5]

Higher preoperative BMI was associated with increased weight loss and was protective against weight-loss failure (OR 0.9 per 1 unit increase in BMI). These results are at odds with some recent literature, although a meta-analysis demonstrated significant variation with conflicting results.[17, 24] The effect size is small compared to other predictors and the model performance is poor, which along with heterogeneity in the meta-analysis suggests that BMI is not an important predictor of weight loss. Considering such minimal impact of BMI, a lower threshold for surgery for patients with multiple cardiometabolic risk factors should be researched further.[25]

The year of surgery was associated with both weight loss and weight loss failure, with every year later in the study period associated with reduced risk of weight loss failure (OR 0.94). Although not a high-impact predictor, the significance suggests that either improving surgical technique or non-surgical practices such as interdisciplinary care teams are having an impact on weight loss. As neither laparoscopic approach nor conversion to open surgery were associated with weight loss failure, the most likely reason will be non-operative. Despite a lack of high-quality prospective data, multidisciplinary teams likely have a wide range of potential benefits and are an essential component of consensus recommendations and accreditations [26, 27].

Finally, there are practical reasons for failure to achieve persistent weight loss. Increased travel distance from a patient's home to the bariatric surgery center is an independent risk factor for less weight loss and weight-loss failure. The current model where insurance policies restrict coverage to certified bariatric centers limits access to this procedure and

forces patients to travel farther.[28–30] This increased impediment likely prevents some patients from undergoing a needed surgery, and for others decreases frequency of follow-up that is proven to help maintain weight loss.[25] Efforts should be undertaken to expand access to RYGB while maintaining the high standards found at bariatric centers that include multidisciplinary care teams and specialty trained bariatric surgeons. Telemedicine represents a promising technology that could enable multi-disciplinary follow-up without costly and inconvenient travel.[31]

Also influencing access is insurance status, where non-Governmental insurance was associated with both less weight loss and weight-loss failure. The cause of this association is likely complex involving both preoperative criteria and socioeconomic characteristics of the patients. While requirements placed on patients to qualify for bariatric surgery are variable, there is evidence that governmental policies may be more stringent. Governmental insurance has been associated with longer wait times before surgery.[32] The intended effect is to only have motivated patients undergo the procedure, and for this the policies are effective with less weight-loss failure. Further supporting evidence for selection bias is the fact that private insurance patients are overrepresented in the bariatric surgery population (82%) compared to those eligible (65%).[33] This effect is also apparent by income level where 35% of patients eligible for bariatric surgery are in the lowest income quartile, but make up only 20% of the bariatric surgery population. Given the cardiometabolic benefits of bariatric surgery even in patients with weight-loss failure, further investigation is warranted to evaluate the potential benefits of increasing access to high-quality surgery.

While the retrospective nature of this analysis is a limitation of the study, the bariatric surgery database was created thirty years ago and data is prospectively collected. There have been efforts to maintain yearly follow-up after two years, although a geographically large referral area causes long travel times with higher costs, and therefore we emphasize close follow-up by primary care physicians. Additionally, our findings are limited by the subjectivity of patient reported information. Telephone interviews were utilized to increase the 10-year follow up rates as validated previously by Harper and colleagues.[8] In addition, we previously found no difference in %REBMI over time between patients with routine follow-up and those with medical record and telephone interviews suggesting minimal bias with self-reporting.[34] An additional limitation of partial retrospective follow-up is incomplete weights prior to 10 years. Future investigations into weight-loss independent health improvement would benefit from calculating duration of weight loss versus weight regain. Finally, we believe the risk for selection bias based on similar baseline characteristics and weight loss in excluded and included patients.

CONCLUSION

Our results suggest that approximately 10% of patients will regain all of their weight by 10 years post-surgery. Key factors explaining this weight regain appear linked to sex, travel time to the surgery center, insurance status and preoperative BMI. Thus, when physicians counsel patients, consideration of these factors may help inform the patient on potential risk for weight-loss failure. From a public health perspective, RYGB surgery promotes durable 10-year improvement of cardiometabolic health regardless of successful weight loss. This

data supports characterizing bariatric surgery as “metabolic surgery,” and by extension recruiting patients with a focus on health improvement. Further investigation is warranted to evaluate the potential weight loss independent mechanisms of health improvement and the impact of increasing access to RYGB through modification of requirements for surgery and increasing the number of highly qualified certified bariatric centers.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

The median and interquartile range of percent reduction in excess BMI (%REBMI) is plotted over time for the 67 patients with weight loss failure at 10 years (in black) and the remaining 973 patients (in gray).

Table 1

Baseline and operative characteristics among patients with 10-year weight loss success or failure

<i>Baseline characteristics</i>	Weight Loss Success (n = 554)	Weight Loss Failure (n = 63)	p-value
Age (years; median, IQR)	41 (35–48)	42 (38–48)	0.178
Female	452 (81.6%)	58 (92.1%)	0.037
Non-Caucasian	79 (14.3%)	12 (19.1%)	0.310
BMI (median, IQR)	51.8 (46.3–58.6)	45.3 (41.5–52.0)	< 0.0001
Travel Time (hours; median, IQR)	1.2 (0.7–1.7)	1.2 (0.8–1.7)	0.574
Comorbidity Index (median, IQR)	2 (1–4)	3 (1–8)	0.213
Apnea	193 (34.8%)	28 (44.4%)	0.132
Cardiac comorbidity [‡]	131 (23.7%)	23 (36.5%)	0.025
Hypertension	324 (58.5%)	37 (58.7%)	0.970
Pulmonary disease [†]	146 (26.4%)	22 (34.9%)	0.148
Type 2 Diabetes	223 (40.3%)	25 (39.7%)	0.930
Gastroesophageal reflux disease	202 (36.5%)	32 (50.8%)	0.026
Degenerative joint disease	335 (60.5%)	42 (66.7%)	0.339
Psychiatric medication use	207 (37.4%)	28 (44.4%)	0.273
Prior Appendectomy	47 (8.5%)	4 (6.4%)	0.560
Prior Bariatric Surgery	6 (1.1%)	1 (1.6%)	0.720
Prior Cholecystectomy	92 (16.6%)	14 (22.2%)	0.263
Prior Gynecologic Surgery	124 (22.4%)	18 (28.6%)	0.269
Non-Governmental Insurance	347 (62.6%)	50 (79.4%)	0.009
<i>Operative Characteristics</i>			
Cholecystectomy	232 (41.9%)	24 (38.1%)	0.564
Started Laparoscopically	267 (48.2%)	31 (49.2%)	0.879
Finished Laparoscopically	240 (43.3%)	28 (44.4%)	0.865

BMI = body mass index; IQR = interquartile range)

[‡]Cardiac comorbidity includes heart failure, coronary disease, and arrhythmia[†]Pulmonary disease includes chronic obstructive pulmonary disease (COPD), asthma, and emphysema

Table 2

Resolution of pre-existing comorbidities at 10-years among patients with weight loss success or failure

<i>Comorbidities</i>	Weight Loss Success	Weight Loss Failure	p-value
Comorbidity index (% decrease; median, IQR)	67% (0–100%)	67% (0–100%)	0.778
Apnea	168 (87.1%)	20 (71.4%)	0.030
Cardiac Comorbidity	119 (90.8%)	17 (73.9%)	0.020
Degenerative Joint Disease	252 (75.2%)	28 (66.7%)	0.232
Diabetes	190 (85.2%)	22 (88.0%)	0.707
Gastroesophageal Reflux Disease	156 (77.2%)	24 (75.0%)	0.781
Hypertension	205 (63.3%)	24 (64.9%)	0.849
Pulmonary Disease	121 (82.9%)	19 (86.4%)	0.683
Psychiatric Medication Use	163 (78.7%)	20 (71.4%)	0.382

IQR (interquartile range)

[†]Cardiac comorbidity includes heart failure, coronary disease, and arrhythmia[†]Pulmonary disease includes chronic obstructive pulmonary disease (COPD), asthma, and emphysema

Table 3

Predictors of weight loss at 10-years

<i>Predictors of %REBMI</i>	Parameter Estimate	95% Confidence Limits		p value
Age (years)	−0.28	−0.64	0.07	0.121
Female	−11.48	−20.00	−2.95	0.008
Non-Caucasian	−5.36	−14.23	3.50	0.235
Travel Time to Hospital (Hours)	−2.94	−5.51	−0.37	0.025
Non-Governmental Insurance	−9.19	−15.69	−2.68	0.006
Body Mass Index	0.41	0.08	0.75	0.015
Obstructive Sleep Apnea	−7.04	−15.64	1.57	0.109
Cardiac Comorbidity [‡]	−6.40	−18.68	5.88	0.306
Hypertension	3.54	−3.93	11.01	0.353
Pulmonary disease [†]	1.39	−9.86	12.64	0.808
Type 2 Diabetes	−1.09	−9.68	7.50	0.803
Gastroesophageal reflux disease	−5.26	−13.57	3.05	0.214
Degenerative joint disease	0.76	−6.22	7.74	0.831
Psychiatric medication use	3.52	−4.74	11.79	0.403
Prior Appendectomy	5.51	−6.04	17.05	0.349
Prior Bariatric Surgery	−0.63	−29.76	28.50	0.996
Prior Cholecystectomy	−7.70	−16.26	0.86	0.078
Prior Gynecologic Surgery	−3.02	−11.24	5.21	0.471
Open RYGB	4.34	−5.55	14.24	0.389
Conversion to open surgery	3.84	−11.00	18.69	0.611
Year	1.24	0.23	2.25	0.016
<i>Predictors of weight loss failure</i>	Odds Ratio	95% Confidence Limits		p value
Non-Governmental Insurance	2.03	1.05	3.94	0.036
Travel Time to Hospital (Hours)	1.25	1.05	1.49	0.015
Body Mass Index	0.90	0.87	0.94	<0.0001
Year	0.94	0.89	0.99	0.029
Female	2.42	0.92	6.38	0.075
Prior Cholecystectomy	1.15	0.58	2.27	0.685

%REBMI (Percent reduction in excess BMI); IQR (interquartile range)

[‡]Cardiac comorbidity includes heart failure, coronary disease, and arrhythmia[†]Pulmonary disease includes chronic obstructive pulmonary disease (COPD), asthma, and emphysema