Published in final edited form as:

Surg Obes Relat Dis. 2016 May ; 12(4): 778–782. doi:10.1016/j.soard.2015.11.012.

Roux-en-Y Gastric Bypass 10 Year Follow-up: The Found Population

J. Hunter Mehaffey, MD*, Florence E. Turrentine, PhD, RN*, Michael S. Miller, MS*, Bruce D. Schirmer, MD*, and Peter T. Hallowell, MD*

*Department of Surgery, University of Virginia, Charlottesville, VA, USA

Abstract

Background—The long-term durability of Roux-en-Y Gastric Bypass (RYGB) remains ill defined in the American population secondary to poor follow-up after bariatric surgery.

Objective(s)—This study evaluated the lost population to better define the long-term durability of RYGB for weight loss and comorbidity amelioration.

Methods—All patients (n=1,087) undergoing RYGB at a single institution between 1985-2004 were evaluated. Univariate differences in preoperative comorbidities, post-operative complications, annual weight-loss and 10-year comorbidities were analyzed to compare outcomes between patients with routine follow-up and those without. Using Electronic Medical Record (EMR) review for all encounters at our academic medical center and telephone survey we obtained data for patients lost to follow-up.

Results—Among 1,087 RYGB patients, 151 (14%) had consistent 10-year follow up in our prospectively collected database with yearly clinic visits beyond 2 years postoperatively. EMR review and telephone survey data was collected on an additional 500 (46%) patients resulting in 60% of patients having 10-year follow-up after RYGB. There was no statistical difference in any preoperative or postoperative variables between the two groups. We demonstrated no difference in comorbidity prevalence preoperatively or at 10 years between groups. Examination of percent excess BMI lost at yearly intervals revealed no difference between the groups at each interval to 10 years ($p=0.36$).

Conclusions—We demonstrated there is no difference in 10-year outcomes including weight loss and comorbidity reduction between patients with routine clinic visits and those lost to follow-up. These 10-year data address the gap in knowledge resulting from poor long-term follow-up after bariatric surgery.

Dr. J. Hunter Mehaffey MD, University of Virginia, Box 800709, Charlottesville, Virginia 22903, P: 828-779-3929, F: 434-243-5791, jhm9t@virginia.edu.

Disclosures: The Authors have no disclosures or conflicts of interest.

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Keywords

Bariatric; Roux-en-Y Gastric Bypass (RYGB); Long-term Follow-up; Found Population

Introduction and Objectives

Bariatric surgery has become a standard treatment for morbid obesity evidenced by more than 124,000 patients who underwent weight loss surgery in 2008.¹ Numerous studies have shown the benefits of bariatric surgery in terms of weight loss and co-morbidity reduction with good short-term (<2 years) follow-up approaching 99%.^{2,3} A large retrospective review found 83% of patients undergoing Roux-en-Y gastric bypass (RYGB) had improvement or remission of their diabetes at 12 months.⁴ While other smaller studies have demonstrated that RYGB can treat dyslipidemia, obstructive sleep apnea, and gastroesophageal reflux disease in the short-term.⁴⁻¹⁰ A recent National Institute of Health (NIH) symposium issued a workshop summary indicating “high-quality evidence” supports improved weight reduction and diabetes amelioration for surgical treatment of morbid obesity. In addition they report more information is needed about the long-term durability of comorbidity control that “will most likely come from carefully designed observational studies”.¹¹

The long-term durability of RYGB remains ill defined in the American population secondary to poor follow-up after bariatric surgery. This has long been a source of criticism in the bariatric surgery literature with opponents suggesting long-term outcomes were artificially inflated secondary to low follow-up selecting for patients with better results. However, there may still be validity in the studies because as a statistical example Gallup Polls report outcomes with high success based on sample size of 0.05% with a phone call response rate of only 50%.¹² Several theories have been proposed to explain the poor follow-up after bariatric surgery however there is limited evidence to substantiate these claims.¹³ The purpose of this study is to assess the lost population to better define the long-term durability of RYGB for the treatment of morbid obesity. We hypothesize there is no difference in weight reduction for patients with routine follow-up and those who are lost to follow-up. As a secondary outcome we hypothesize equivalent reduction in obesity related comorbidities between the groups.

Patients and Methods

Patients

A prospectively collected database approved by the Institutional Review Board (IRB# 17132) at the University of Virginia of all patients undergoing weight loss surgery was queried. We identified all patients undergoing RYGB performed for morbid obesity at our institution between 1/1/1985 and 1/1/2004. This database included the patient name, patient phone number, age, sex, pre-operative weight, pre-operative comorbidities (diabetes mellitus (DM), gastroesophageal reflux disease (GERD), obstructive sleep apnea (OSA), hypertension (HTN), osteoarthritis, pulmonary disease, and cardiac disease), post-operative complications/comorbidities (GERD, cardiac disease, osteoporosis, DM, OSA, HTN, pulmonary disease, myocardial infarction, stroke, cancer prevalence, and incisional hernia),

and weights from yearly follow-up appointments. Using Electronic Medical Record (EMR) review for all encounters at our academic medical center and telephone survey we obtained data for patients lost to follow-up in the database.

Telephone Follow-up

Trained medical personnel listed on the IRB protocol followed a standardized phone script to call the patients lost to follow-up. This was done to assess changes in comorbidities and weight as well as patient satisfaction with the surgery. Multiple attempts were made to contact patients on different days and times using phone numbers listed in their electronic medical record. If the numbers listed were disconnected, an online people search tool (Intelius People Search, Bellevue, WA) was used to locate patients using publically available records such as census data, property records, and telephone records.

Definitions

Comorbidity information was collected using a prospectively collected database for pre-operative data. Ten-year comorbidity data was collected through prospective database, retrospective chart review, and telephone survey. A patient was recorded as having a specific comorbidity if undergoing medical therapy for the disease during a clinical encounter at 10 years post-operative or through self-reporting during phone survey if no EMR data existed. During the phone interview patients were asked to rate their satisfaction with the operation on a 10 point Likert Scale with 0 being very dissatisfied and 10 being very satisfied. 25 kg/m² was used as ideal BMI to calculate percent reduction in excess BMI.

Statistical Analysis

The primary outcome was percent reduction in excess BMI over 10 years. Secondary outcomes included long-term comorbidity resolution in addition to patient satisfaction. Statistical analysis was performed using Mann-Whitney U test for continuous variables and χ^2 test for prevalence to calculate significance. A p-value of <0.05 was used for statistical significance.

Results

Preoperative Comorbidity Incidence

Among 1,087 patients undergoing RYGB at our large academic medical center between 1/1/1985 and 1/1/2004, 151 (14% Routine Follow-up) had consistent 10-year follow up in our prospectively collected database with yearly clinic visits beyond 2 years postoperatively. Through EMR review (41.8%) and telephone survey (58.2%) data was collected on an additional 500 (46% Found Population) patients resulting in 60% 10-year follow-up after RYGB. There was no statistical difference in any preoperative comorbidities between the routine follow-up and the found population, or the lost population and all patients with follow-up as demonstrated in Table 1. Additionally, there was no difference in age (41.4 vs 40.6 p=0.12) or preoperative BMI (53.1 vs 53.5 p=0.48) between all patients with follow-up and the lost population. Within the study population 335 patients (51.5%) underwent open RYGB and 316 (48.5%) had laparoscopic RYGB with no major difference between these groups as previously published.¹⁴

10-Year Weight Reduction

Examination of Total Body Weight Loss (TBWL) and Percent Excess BMI Lost (%EBMIL) at yearly intervals is listed in Table 2. Statistical significance was calculated using Mann-Whitney U test revealing no difference between the groups at each interval out to 10 years. Figure 1 illustrates the %EBMIL curves for the two groups.

10-Year Comorbidity Incidence

Table 3 demonstrates no difference in comorbidity prevalence at 10 years between groups for all comorbidities evaluated. There was no statistical difference in long-term complications including hernia occurrence and major adverse events. Of note there was no difference in the satisfaction scores between the two groups.

Discussion

The present study aims to characterize the population of patients who do not have yearly follow-up after RYGB. Through chart review and telephone survey we improved our rate of 10-year follow-up from 14% to 60% for patients undergoing RYGB during the study period. Comparing these groups we sought to determine the importance of complete follow-up to validate the long-term durability of RYGB. This study demonstrates no difference between outcomes, percent reduction in excess BMI and comorbidity amelioration, for patients with yearly follow-up and those lost to follow-up until 10 years. To our knowledge, this is the largest RYGB outcome study in the American population with 60% follow-up at 10 years.

We compared all pre-operative variables recorded to evaluate for selection bias between the groups. No statistical difference was found in pre-operative characteristics between the routine follow-up population the found population and the lost population in this study. Despite having no surgical follow-up for up to 9 years, the found population experienced similar rates of weight loss and comorbidity resolution. These finding refute the theory of poor follow-up negating durable follow-up data.

In our population, reduction in excess BMI peaked at 2 years for both groups with gradual weight regain averaging 1.2% of total body weight each year out to 10 years. Figure 1 illustrates this finding with no statistical difference between the curves. This data is similar to that reported in the literature by most groups examining the long-term reduction in excess BMI in patients after RYGB.^{7, 12, 13-16} Table 2 demonstrates the weight loss data for each year with the proportion of follow-up at each time point. The interval weights are calculated based on the limited follow-up data available through retrospective chart review for all inpatient and outpatient encounters at our academic medical center. There is a component of follow-up bias for the interval time points but this is negated by phone survey at 10 years.

No difference exists in long-term comorbidity amelioration data between the routine follow-up and the found population. While weight loss is an important metric following RYGB comorbidity reduction provides significant benefit to the patient resulting in decrease healthcare costs and an increase in quality life years.¹⁹⁻²¹ The present study reports no difference in these outcomes between patients who see their surgeon every year and those who seek follow-up with another physician. This is an important substantiation for studies

demonstrating durable outcomes at 10-20 years with poor follow-up.¹⁵⁻¹⁷ These results are more widely applicable than previously appreciated.

Poor follow-up is a common theme in the bariatric literature and has long been a criticism of studies reporting long-term outcomes in large populations with 10-20% follow-up. Several studies have explored this phenomenon and theories proposed include fear of disappointment with minimal weight loss and inability to remember appointments.¹⁸ However, encounters for other medical conditions in long-term follow-up have not convinced us that lack of return for visits denotes lack of success after surgery. Some argue that patient well-being is often a major reason why no follow-up is sought.²⁰⁻²¹ We found an average satisfaction score of 8.7/10 regardless of surgical outcomes with no difference between the routine follow-up and the found populations.

The limitations of this paper include the retrospective nature of the study and incomplete interval follow-up. The database we used to track all patients undergoing surgery has been prospectively collected for the past 30 years and is regularly updated when patients are seen in follow-up. There have been efforts to maintain yearly follow-up beyond two years but due to the large referral base, the geographic distance of many patients from our medical center, the role of primary care physicians in following these patients on a regular basis, and the cost and time of visits for the patient who feels well and in good health, achieving better follow-up in person has been challenging. Telephone follow-up improved the yield, but is limited by its lack of objectivity. However, telephone follow-up has been validated in the bariatric population as demonstrated by Harper et al.¹⁸

The major finding in the present study reports no difference in pre-operative comorbidities, long-term reduction in excess BMI, or post-operative outcomes between patients with routine follow-up and those lost to follow-up after RYGB. Outcome data for patients undergoing RYGB more than 10 years ago is sparse and incomplete outside of the Swedish Obesity Study. Several studies have published durable long-term outcomes but have been dismissed due to low follow-up and concerns about bias. We demonstrated no difference between these populations to support other long-term studies with poor follow-up.

Conclusion

This study represents the largest 10-year follow-up for RYGB in the American population. We demonstrated there is no difference in 10-year outcomes including weight loss and comorbidity reduction between patients with routine clinic visits and those lost to follow-up. These 10-year data address the gap in knowledge resulting from poor long-term follow-up after bariatric surgery.

Acknowledgments

Source of Funding: For all authors none were declared

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Figure 1.

The graph illustrates the 10 Year curves for Percent Reduction in Excess BMI for the routine follow-up population versus the found population.

Table 1
Preoperative Comorbidity Incidence: Routine Follow-up versus Lost Population

Preoperative Variables	Routine Follow-Up Incidence	Found Population Incidence	P-Value Routine vs Found	Lost Population Incidence	P-Value Lost vs All Follow-up
Gastroesophageal Reflux Disease	0.359	0.384	0.62	0.381	0.48
Cardiac Disease	0.214	0.248	0.45	0.252	0.45
Degenerative Joint Disease	0.624	0.613	0.83	0.618	0.52
Diabetes Mellitus	0.368	0.403	0.50	0.402	0.51
Obstructive Sleep Apnea	0.359	0.355	0.94	0.363	0.31
Hypertension	0.564	0.581	0.74	0.592	0.75
Pulmonary Disease	0.231	0.256	0.58	0.279	0.15
Psychiatric Disease	0.402	0.360	0.41	0.389	0.32

The table demonstrates preoperative comorbidity incidence for the routine follow-up versus the found population as well as the lost population versus the follow-up population. P-value is calculated by χ^2 test.

Table 2
Percent Reduction in Excess Body Mass Index and Percent Total Body Weight Loss between Routine Follow-Up versus Found Population

	Routine Follow-Up			Found Population			%EBMIL	
	% TBWL	%EBMIL	Follow-Up	% TBWL	%EBMIL	Follow-Up	p	p
1 month	8.9+/-3.6	16.7+/-14.0	149/151	8.6+/-4.1	17.9+/-12.2	250/500	0.62	0.62
2 months	13.7+/-7.6	27.9+/-19.9	105/151	14.5+/-4.4	30.1+/-12.0	136/500	0.63	0.64
3 months	18.1+/-5.6	36.9+/-13.1	142/151	18.9+/-4.8	38.5+/-13.5	168/500	0.79	0.76
6 months	27.3+/-5.4	54.9+/-16.6	136/151	27.4+/-7.0	55.0+/-17.9	194/500	0.38	0.34
12 months	34.2+/-9.9	69.1+/-23.9	127/151	36.3+/-8.7	71.7+/-20.6	183/500	0.95	0.73
24 months	34.6+/-9.3	69.7+/-25.6	97/151	38.2+/-10.3	76.0+/-21.7	117/500	0.98	0.90
36 months	34.6+/-7.6	71.0+/-20.3	71/151	35.5+/-10.6	68.3+/-21.7	78/500	0.54	0.61
48 months	32.0+/-9.7	63.5+/-22.5	72/151	34.3+/-11.7	65.9+/-26.1	65/500	0.77	0.53
60 months	30.6+/-10.7	62.8+/-27.1	98/151	35.7+/-11.5	70.1+/-24.7	61/500	0.96	0.80
72 months	28.7+/-11.0	64.0+/-32.8	88/151	32.3+/-12.0	64.3+/-26.0	64/500	0.85	0.34
84 months	26.3+/-9.3	57.8+/-22.2	61/151	33.1+/-12.1	65.8+/-31.4	53/500	0.95	0.75
96 months	25.1+/-10.4	51.0+/-25.0	72/151	33.2+/-13.3	64.3+/-26.9	57/500	0.99	0.96
108 months	28.7+/-14.2	54.8+/-26.7	87/151	31.5+/-12.4	62.5+/-28.3	68/500	0.69	0.81
120 months	26.3+/-31.4	52.2+/-77.7	151/151	28.3+/-20.5	52.8+/-56.8	500/500	0.73	0.36

Table 2 compares the Excess Body Mass Index Lost (EBMIL) and Total Body Weight Loss (TBWL) between the Routine Follow-Up versus Found Population at each time point out to 10 years. The fraction of follow-up for each group at each time is listed. The p value was calculated by Mann-Whitney U test.

Table 3
Postoperative Comorbidity Incidence: Routine Follow-up vs Found Population

10 Year Variables	Routine Follow-Up Incidence	Found Population Incidence	P-Value
Gastroesophageal Reflux Disease	0.248	0.299	0.29
Cardiac Disease	0.154	0.157	0.93
Degenerative Joint Disease	0.333	0.317	0.75
Diabetes Mellitus	0.145	0.187	0.31
Obstructive Sleep Apnea	0.154	0.165	0.77
Hypertension	0.462	0.472	0.84
Pulmonary Disease	0.128	0.131	0.94
Psychiatric Disease	0.248	0.299	0.29
Myocardial Infarction	0	0.005	0.43
Stroke	0.009	0.005	0.70
Cancer Prevalence	0.026	0.024	0.92
Major Vitamin Deficiency	0.120	0.096	0.46
Hernia Occurrence	0.111	0.077	0.25
Satisfaction Score (0-10)	8.7	8.8	0.59

The table demonstrates preoperative comorbidity incidence for the routine follow-up versus the found population. P-value is calculated by χ^2 test.