ORIGINAL ARTICLE

Predictors of Complication and Suboptimal Weight Loss After Laparoscopic Roux-en-Y Gastric Bypass

A Series of 188 Patients

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Hypothesis: An analysis of patients undergoing laparoscopic Roux-en-Y gastric bypass (RYGB) may identify factors predictive of complication and of suboptimal weight loss.

Design: Inception cohort.

Setting: Metropolitan university hospital.

Patients: One hundred eighty-eight consecutive patients with severe obesity who met National Institutes of Health consensus guidelines for bariatric surgery.

Interventions: Laparoscopic RYGB.

Main Outcome Measures: Complications requiring therapeutic intervention and percentage of excess body weight lost at 1 year after surgery.

Results: Of the 188 patients who underwent laparoscopic RYGB, 50 (26.6%) developed complications that required an invasive therapeutic intervention, including 2 deaths. The average follow-up was 351 days (range, 89-1019 days). Multivariate analysis by stepwise logistic regression identified surgeon experience, sleep apnea ($P=.003$; odds ratio, 3.0; 95% confidence interval, 1.3-7.1), and hypertension ($P=.07$; odds ratio, 2.0; 95% confidence interval, 1.0-4.0) as predictors of complications. The most common complication requiring therapeutic intervention was stricture at the gastrojejunal anastomosis, occurring in 27 patients (14.4%). Of the 115 patients who underwent surgery more than 1 year previously, 1-year follow-up data were available for 93 (81%). The body mass index (weight in kilograms divided by the square of height in meters) decreased from 53±8 preoperatively to 35±6 at 1 year. The mean±SD percentage of excess body weight lost at 1 year was 61%±14%. Diabetes mellitus was negatively correlated with percentage of excess body weight lost at 1 year ($P=.06$).

Conclusions: Surgeon experience, sleep apnea, and hypertension are associated with complications after laparoscopic RYGB. Diabetes mellitus may be associated with poorer postoperative weight loss.

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OBESITY IS a major health problem in the United States, estimated to account for approximately 280 000 deaths per year.[1] Obesity, which is associated with multiple life-threatening comorbidities, is defined as a body mass index (BMI; calculated as weight in kilograms divided by the square of height in meters) greater than 40. Surgical intervention has been proven to be the most effective therapeutic option for the morbidly obese patient. Of the most commonly offered surgical procedures, Roux-en-Y gastric bypass (RYGB) appears to offer the best long-term results.[2,3]

In an effort to decrease both postoperative length of stay and the complication rate associated with RYGB, the procedure has been adapted for a minimally invasive approach.[4-6] Since the introduction of laparoscopic RYGB, there has been a rapid increase in the volume of bariatric surgery. Several large series have been reported, with weight loss as well as improvements in comorbidities similar to those seen with earlier reports of open gastric bypass.[7-10] We present data on our initial series of patients who underwent laparoscopic RYGB, with multivariate analyses to identify factors predictive of complication and of inadequate weight loss.

METHODS

This is a case series from a tertiary care academic hospital in a metropolitan setting. Information on all patients who underwent bariatric surgery from July 21, 1999, to January 30, 2002, were entered into a database. Data included sex, age, weight, BMI, comorbidities,

Table 1. Patient Demographics

	Present Study	Higa et al[9]	Schauer et al[7]	DeMaria et al[10]
No. of subjects	188	400	275	281
Mean age (range), y	44 (22-66)	43 (13-70)	42 (17-68)	42 (15-71)
Sex, % F	83.5	82.5	81	87
Mean weight (range), kg	144 (97-293)	NA	NA	131 (77-201)
Mean BMI (range)	52 (38-82)	46 (35-78)	48 (35-68)	48 (40-71)
Mean EBW (range), kg	81 (42-214)	NA	NA	NA
Hypertension, %	44	NA	52	42
Diabetes mellitus, %	26	NA	22	28.5
GERD, %	34	NA	51	70
Arthritis, %	65	NA	64	NA
Sleep apnea, %	22	NA	36	22
Asthma, %	14	NA	16	NA

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EBW, excess body weight; GERD, gastroesophageal reflux disease; NA, not available.

Table 2. Perioperative Data

	Present Study	Higa et al[9]	Schauer et al[7]	DeMaria et al[10]
Mean OR time (range), min	163 (75-420)	NA	260 (105-734)	NA
Conversion or planned open procedure, No. (%)	3 (1.6)	12 (3)	3 (1.1)	8 (2.8)
Mean length of stay, (range), d	3.8 (2-32)	NA	3.4 (1-84)	4.3

Abbreviations: NA, not available; OR, operating room.

length of operation, postoperative length of stay, complications, readmissions, and weight recorded in follow-up visits. All patients qualified for surgery under published National Institutes of Health consensus guidelines for treatment of the morbidly obese patient,[11] including evaluation and approval by a multidisciplinary team. Patients' charts were reviewed with their permission. This was in accordance with the institutional review board at the University of Massachusetts Medical School, Worcester.

All complications were categorized according to the Clavien et al scale.[12] Ideal body weight, as determined by the Metropolitan Life Insurance tables, was used to calculate excess body weight (EBW). Follow-up data regarding weight loss were recorded as percentage of EBW lost at various points postoperatively. Multivariate statistical analyses were performed to identify factors associated with complications that required invasive therapeutic intervention (Clavien et al category 2b and above) or with percentage of EBW lost at 1 year postoperatively.

Associations between each independent variable and each dichotomous outcome were evaluated by simple logistic regression and likelihood ratio tests. When multiple factors were found to be significantly associated with a dichotomous outcome, stepwise multiple logistic regression was used to develop a multivariate model using the likelihood ratio test as a stepping metric and the significance of the improvement in the model as a stopping rule. For the continuous outcome (percentage of EBW lost), the univariate associations with continuous independent variables were evaluated by the Spearman rank correlation coefficient, and for the dichotomous independent variables by the *t* test. Multivariate models were developed for the continuous outcomes by means of multiple linear regressions.

The technique for constructing an RYGB is a modification of that described by Lonroth et al.[6] Whereas they described an antecolic loop gastrojejunostomy with an omega loop enteroanastomosis, we transect the loop to fashion an antecolic Roux-en-Y gastrojejunostomy. Enoxaparin sodium and cefazolin sodium are routinely administered for prophylaxis.

The phrenicogastric peritoneal reflection is divided and the gastric fundus is mobilized. At a point approximately 3 cm from the esophagogastric junction on the lesser curvature, a retrogastric plane is developed by means of blunt dissection and hook cautery until the lesser sac is entered. With the ultrasonic dissector, a very small anterior gastrotomy is made on what is to become the stomach pouch. A larger anterior gastrotomy is made on what is to become the remnant stomach, and a 25-mm end-to-end anastomosis (EEA) anvil is inserted into the abdomen via the left upper quadrant port; this requires dilation of the port site. The port is replaced with a balloon-tip trocar to prevent air leakage. The anvil is then passed through the remnant stomach gastrotomy so that the spike exits the stomach pouch through the gastrotomy. The gastrotomy on the remnant stomach is closed with a gastrointestinal anastomosis stapler (EndoGIA; US Surgical, Norwalk, Conn). The stomach is transected sequentially from the lesser curve to the angle of His with multiple fires of the gastrointestinal anastomosis stapler reinforced with bovine pericardium strips (Cardio-Medical, Rockaway, NJ), completing the pouch. The distal edge of omentum is divided with the ultrasonic dissector up over transverse colon to the greater curve of the stomach. A loop of jejunum 20 to 30 cm distal to the ligament of Treitz is identified and a 50% circumference transverse enterotomy is made with the ultrasonic dissector. A 25 EEA stapler (US Surgical) is brought in through the left upper quadrant port site and into the small bowel enterotomy, entering proximal bowel and advancing distally away from the ligament of Treitz. The loop is swung up to the gastric pouch, the anvil and the stapler are docked together, and the stapler is fired. The stapler is removed through the left upper quadrant port. The small-bowel enterotomy used for stapler entry is resected after the Roux limb and the biliary limb ends are stapled off, truncating the loop gastrojejunostomy. The Roux limb is marched distally approximately 120 cm. A side-to-side jejunojejunostomy is created at this point with a gastrointestinal anastomosis stapler. The enterotomy is closed transversely with a gastrointestinal anastomosis stapler. Silk stitches proximal and distal to the anastomosis are placed to prevent torsion at the anastomosis. The mesenteric defect is closed with 2-0 silk suture. A drain is left alongside the gastrojejunostomy.

RESULTS

Table 1 and **Table 2** include demographics and perioperative data, respectively, on the 188 patients who underwent laparoscopic RYGB. The mean age of the patients was 44 years, and most of the patients were female (83.5%). The average BMI in this series was 52; the average patient would be considered superobese. The average time in the operating room was 163 minutes and was not corrected for any additional procedures performed. In addition, this series documented our learning curve, and operative times decreased as experience was gained (**Figure 1**). The average operating time for the last 50 cases was 140±28 minutes.

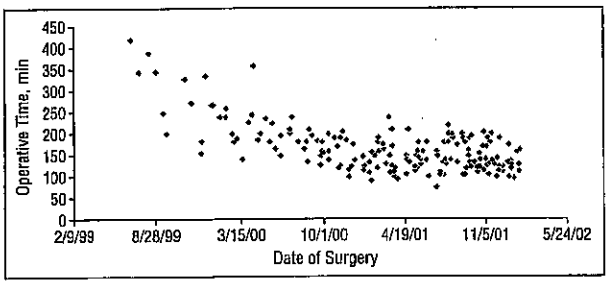

Figure 1. Operative times required to perform laparoscopic Roux-en-Y gastric bypass. A trend toward lower operative times is apparent. Times are not adjusted for procedures performed in addition to laparoscopic Roux-en-Y gastric bypass.

In 3 patients, open laparotomy was performed. In 2 cases the procedure was converted to open laparotomy, and 1 case was planned open. One of the conversions was due to splenic hemorrhage. The second patient had had a previous attempt at RYGB that was aborted. When she underwent reexploration for laparoscopic RYGB, a gastrotomy was made inadvertently because this plane had been obliterated by previous dissection. Finally, 1 case was planned open because of a large incisional hernia, which was repaired at the time of surgery. The mean postoperative length of stay was 3.8 days.

The most common postoperative complication requiring invasive therapeutic intervention was stenosis at the gastrojejunal anastomosis, occurring in 14.4% of all patients (**Table 3**). This accounts for more than half of all of the complications listed. The complications with the next highest frequency, staple line hemorrhage and bowel obstruction due to adhesions, each occurred in only 3.2% of all patients. Of particular note, leak from the gastrojejunal anastomosis was relatively rare (1.6%).

The univariate analysis identified experience, hypertension, and sleep apnea as being predictive of complication (**Table 4**). The most important factor after multivariate analysis was experience. A significant decrease in the complication rate was recognized only after 120 procedures had been performed (**Table 5**). Sleep apnea and hypertension also appeared to be independent predictors of complications, with odds ratios of 3.0 and 2.0, respectively.

Weight loss at the time of most recent follow-up is included in **Figure 2**. We analyzed the outcomes with respect to weight loss at 1 year after surgery. Twenty-two (19%) of the 115 patients who had surgery more than 1 year ago were lost to follow-up. In the remaining 93 patients, weight decreased from a mean±SD of 148±30 kg to 100±21 kg. The BMI in these patients decreased from 53±8 to 35±6. The mean±SD percentage of EBW lost was 61%±14%. The only variable inversely correlated with percentage of EBW lost at 1 year was a preoperative diagnosis of diabetes mellitus (P=.06; **Table 6**). When patients were stratified according to whether or not diabetes was present, no other factor was significantly correlated with weight loss.

COMMENT

This series corroborates several others in demonstrating that a laparoscopic approach to RYGB is feasible, even in superobese patients. Furthermore, results with regard to weight loss appear to be similar to those reported in the open literature. Laparoscopic gastric bypass should be accepted as at least the equivalent of open gastric bypass as a bariatric procedure. The percentage of patients who require open RYGB, whether planned or as a result of intraoperative complication, is quite low (1.1%-3.0%).

Table 3. Complications Requiring Invasive Therapeutic Intervention

Complication	Present Study		Rate in Previous Studies, %		
	No.	Rate, %	Higa et al[9]	Schauer et al[7]	DeMaria et al[10]
Stenosis at gastrojejunal anastomosis	27	14.4	5.25	4.7	6.6
Staple line hemorrhage	6	3.2			
Bowel obstruction due to adhesions	6	3.2			
Upper GI hemorrhage, postoperative	4	2.1			
Roux limb obstruction at jejunojejunostomy	3	1.6			
GJ leak	3	1.6	0	0.72	4.3
Nausea	2	1.1			
Infected hematoma	2	1.1			
Incarcerated hernia	1	0.5			
OR bleeding splenectomy	1	0.5			
Bile leak	1	0.5			
Gastrogastric fistula	1	0.5			
GOO/bezoar	1	0.5			
Wound infection	1	0.5			
Gastric perforation	1	0.5			
Left upper quadrant pain, unspecified	1	0.5			
Mortality	2	1.1	0	0.4	0
Total	63	25.5*			

Abbreviations: GI, gastrointestinal; GJ, gastrojejunostomy; GOO, gastric outlet obstruction; OR, operating room.
*Complications occurred in 25.5% of patients. Some patients had more than 1 complication.

Table 4. Univariate Analysis to Identify Demographic Factors Associated With Complications Requiring Invasive Therapeutic Intervention

Variable	*P* Value
Age	.13
Asthma	.40
BMI	.98
Diabetes mellitus	.48
Hypertension	.007
Osteoarthritis	.83
Sleep apnea	.03
GERD	.52
Sex	.18
Weight	.55
Experience	.003

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); GERD, gastroesophageal reflex disease.

Table 5. Significance and Odds Ratios for Hypertension, Sleep Apnea, and Surgeon Experience in a Multivariate Model to Predict Complications

Variable	*P* Value	Odds Ratio (95% Confidence Interval)
Hypertension	.07	2.0 (1.0-4.0)
Sleep apnea	.01	3.0 (1.3-7.1)
Surgeon experience		
Cases 1-40		1
Cases 41-79	.48	0.70 (0.26-1.90)
Cases 80-120	.86	1.10 (0.43-2.80)
Cases 121-159	.01	0.21 (0.065-0.690)
Cases 160-188	.004	0.091 (0.018-0.470)

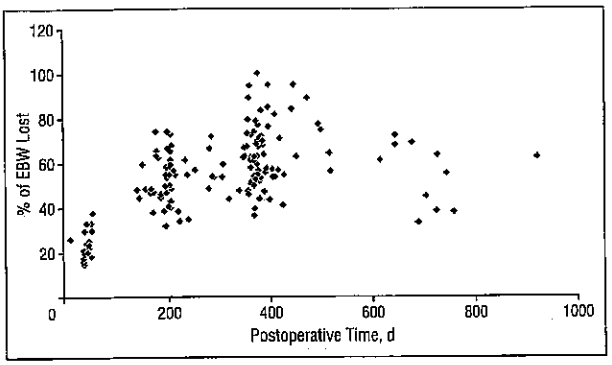

Figure 2. Percentage of excess body weight (EBW) lost at most recent follow-up visit for all patients in this series.

Table 6. Univariate Analysis Showing Correlation Between Independent Variables and Percentage of Excess Body Weight Lost at 1 Year

Variable	*P* Value
Age	.09
Asthma	.62
BMI	.25
Diabetes mellitus	.06
Hypertension	.12
Osteoarthritis	.52
Hypercholesterolemia	.42
GERD	.52
Sex	.47
Weight	.50
EBW	.29
Operating time	.51

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EBW, excess body weight; GERD, gastroesophageal reflux disease.

Patients who undergo laparoscopic or open RYGB can have adverse outcomes in 2 different respects. First, the surgery may be associated with several complications, some of which may be life threatening. Indeed, Pories et al[13] reported an early complication rate of 25.5% and a mortality rate of 1.5% in a series of open gastric bypasses. Second, some patients experience suboptimal weight loss after gastric bypass. Wittgrove and Clark[8] noted that 15% to 22% of patients will have lost less than 50% of excess body weight by 36 to 54 months postoperatively.[8]

An analysis of the complications in this series has to be tempered by the increased incidence of gastrojejunostomy stricture. This occurred in 14.4% of cases. This rate should be contrasted to the 4.7% to 6.6% reported by Schauer et al,[7] Higa et al,[9] and DeMaria et al.[10] It is possible that the factors we identified as predictive of complication (experience, sleep apnea, and hypertension) may be specific for the complication of gastrojejunal stenosis.

A possible explanation for the high rate of gastrojejunal stricture, as compared with the other series mentioned, is that whereas we bring the Roux jejunal limb anterior to the transverse colon, the other groups noted tunnel the Roux limb in a retrocolic fashion. Another possible explanation involves the use of a circular stapler to create the anastomosis. Although our stricture rate was 17% for the first 100 cases, it decreased to less than 4% for the next 100 cases, with no change in our operative technique. Therefore, any theory about the cause of gastrojejunal strictures that we can formulate by comparing this series with others would be flawed, as it would not explain the drop in our stricture rate. Gastrojejunal strictures may be one of the indicators for learning curve. Experience may cause subtle improvements that surgeons are not able to identify except for objective decreases in morbidity.

The most significant factor associated with complications requiring invasive intervention was surgeon experience. In this series, all the operations were performed by one surgeon (J.J.K.), trained in advanced laparoscopic surgery. The complication rate did not decrease until after 120 cases. This finding is similar to reports by Schauer et al[14] and Oliak et al[15] suggesting that the complication rate does not decrease until after 100 cases. Laparoscopic RYGB is a challenging procedure, demanding a long learning curve. In addition to surgeon experience, hypertension and sleep apnea also were independent predictors of complication. To our knowledge, this is the first series that has implicated either as factors associated with complications after laparoscopic RYGB.

With follow-up data available for 81% of all patients more than 1 year after surgery, the mean±SD percentage of EBW lost was 61%±14%. Values of 69%, 69%±22%, and 70%±5% were reported by Higa et al,[9] Schauer et al,[7] and DeMaria et al,[10] respectively. The only factor inversely correlated with percentage of EBW lost 1 year postoperatively in this series was a preoperative diagnosis of diabetes mellitus or impaired glucose tolerance ($P=.06$, t test). This should not discourage surgeons from performing bariatric procedures on diabetic patients. Indeed, Pories' group[13,16] demonstrated that one of the greatest health benefits of gastric bypass in severely obese patients is the ability to cure diabetes. More than 80% of obese diabetic patients become euglycemic after gastric bypass. More importantly, this translates into a significantly reduced mortality for obese diabetic patients who undergo gastric bypass compared with control obese diabetic patients (1.0% per year vs 4.5% per year). Weight loss in and of itself is too simplistic a mea-

sure of success for bariatric surgery programs; other outcomes to be considered are improvement in quality of life, resolution of comorbidities, and, ultimately, improvement in life expectancy. A valid criticism of this analysis is that we did not quantify degree of insulin resistance. We simply characterized as "diabetic" all patients who were previously diagnosed as diabetic, whether they required medication or their condition was controlled by diet.

Thirty-six patients (19.1%) had a preoperative BMI greater than 60. We found no objective reason to consider excessive BMI or weight a contraindication to laparoscopic approach to RYGB. The most difficult cases involved patients with central obesity and a large left lateral hepatic lobe; these cases occurred across all BMI categories.

Previous upper abdominal surgery also adds to the degree of difficulty in performing a laparoscopic RYGB. This should not be considered a contraindication to the laparoscopic approach. Four of the patients included in this series had undergone previous open vertical banded gastroplasties. In all cases, we were able to convert to RYGB laparoscopically. Three of these patients had uneventful postoperative courses. One patient had a gastrogastric fistula requiring reoperation.

In summary, this series confirms that a program in laparoscopic RYGB can be successful in an academic medical center. The procedures were performed in an acceptable length of time (163 minutes). Patients with routine courses were discharged in 3 days. Complications that required invasive therapeutic intervention occurred in 25.5% of patients. The most significant predictor of complication was surgeon experience, with the rate of complication decreasing after treatment of 120 patients. A preoperative diagnosis of hypertension or of sleep apnea was also associated with postoperative complications. Postoperative weight loss was comparable with that seen in a series of open RYGB (61%±14% of EBW at 1 year postoperatively). Diabetes mellitus may be inversely correlated with percentage of EBW loss at 1 year postoperatively.

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DISCUSSION

Padiath Aslam, MD, Augusta, Me: After doing several hundred open cases and starting to do laparoscopic, I cannot agree with you more that the surgeon experience is a good predictor of complication. I agree also after doing 50 retrocolic and about 125 antecolic, antecolic will have less complications because of the fewer number of steps involved. Also the visibility is better laparoscopically that way. I would suggest that the stricture rate in the initial cases when doing antecolic might be due to the tension and also to the fact that with the EEA intraluminal stapler, you crush a lot of tissues when you have tension. I would suggest doing it with a linear stapler. The stricture rate, even though still present, will be less. One of the silver linings about the complication rate, if it is a nonfatal complication, is that patients are happier because the restriction—for example, if there is a stricture, weight loss is better and patients are happier [laughter].

Jeffrey Cohen, MD, Hartford, Conn: I want to congratulate Dr Perugini and his coauthors on a very impressive study, especially with the learning curve for laparoscopy, which we are all interested in for various procedures. What I was wondering about, working at the other end of the GI tract, the EEA-25 stapler we find creates significant strictures in the lower intestinal tract and I am wondering, speculating that maybe that is responsible for the stricture formation that you saw at 14% and whether it is necessary to use such a small aperture for the overall success of the patients.

Lastly, could you comment on what you do to maintain the success of the body weight? What is the support system a year out that you have for these patients?

David Butsch, MD, Barre, Vt: I certainly compliment the authors on a wonderful paper, but I cannot help but ask the question, when you see all these patients in your office and have them on your operating table, especially the 650-pounder, do you ever have any other ideas at the end of surgery that might

help these people? In a serious way I would like to ask that question. Thank you.

Dr Perugini: I would like to address the idea of the stricture rate at the proximal anastomosis. This has been troubling us for some time and we thought we had some answers—again, antecolic vs retrocolic, maybe EEA stapler vs linear staplers—but the fact that this complication has basically disappeared in our practice really leaves us at a loss as to why this was happening. We have not changed our technique whatsoever. We are still using a 25-EEA stapler. We are possibly getting subtly better with doing our proximal dissection around the gastric pouch, maybe maintaining some more blood supply, but I do not have a good idea. I do not know that anything that has been addressed, advanced today, really—we have thought about it all and it has not helped us understand it better.

In terms of support systems postoperatively, the patients are seen by the surgeon on a routine postoperative schedule at 2 weeks, 6 weeks, 6 months, 1 year, and every year thereafter. They are also seen by the nutritionist on a scheduled basis too. If either the surgeon or the nutritionist identifies any issues, they are quickly referred back to either nutrition, behavioral medicine, whatever other support system it takes to help with their postoperative outcome. A lot of this has to do with how compliant the patient is.

Finally, a good point that was brought up was antecolic vs retrocolic. Most of the series that I was talking about are switching to an antecolic approach for other reasons as was mentioned. The initial surgery is much easier. The reexplorations are much easier also, as the Roux limb is right in front, basically the first thing to be seen on exploring the abdomen.

Finally, how to get better quicker? I am someone who has gone through a laparoscopic fellowship program, so luckily during my training I have had the privilege of doing a good 80 cases. I am hopeful that my learning curve is going to be much shortened because of that. I do not have any other helpful tips other than a lot of practice. The learning curve of 120 patients has pretty much been verified by both Schauer and by Ballantine in Hackensack, who noted that their complication rate did not decrease until after 100 cases.