Long-limb Gastric Bypass in the Superobese

A Prospective Randomized Study

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This study was designed to determine whether greater diversion of bile and pancreatic secretions away from the functional gastrointestinal tract would produce greater weight loss in superobese patients (≥200 pounds overweight) in comparison with conventional Roux-en-Y gastric bypass (RYGB). During the past 7 years, two modifications of RYGB were prospectively compared in 45 superobese patients: RYGB-1, in which the length of defunctionalized jejunum measured 75 cm, and RYGB-2, in which the defunctionalized jejunum measured 150 cm. Respective mean preoperative weight/body mass indexes were 393 pounds/63.4 for 22 RYGB-1 patients and 404 pounds/61.6 for 23 RYGB-2 patients. Two patients (5%) had nonfatal early complications. There were six late incisional hernias. There were no cases of protein deficiency, hepatic dysfunction, or diarrhea after operation. Mean follow-up was 43 ± 17 months. Postoperative weight loss in pounds and daily calorie intake were compared at 6-month intervals. Weight loss stabilized by 24 months at a mean 50% excess weight lost in RYGB-1 patients and 64% excess weight lost in RYGB-2 patients. Nineteen of 23 RYGB-2 patients achieved at least 50% excess weight lost *versus* 11 of 22 RYGB-1 patients ($p \leq 0.03$). Weight loss was significantly greater at 24 through 36 months in RYGB-2 *versus* RYGB-1 patients ($p < 0.02$). There was no significant difference in either calorie intake or incidence of iron and vitamin B-12 deficiency between the two groups. These data show that gastric restriction and biliopancreatic diversion without intestinal exclusion resulted in significantly greater weight loss than conventional RYGB but did not cause additional metabolic sequelae or diarrhea. This long-limb modification of Roux-en-Y gastric bypass is a safe and effective procedure in patients who are 200 pounds or more overweight.

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THE MINIMUM WEIGHT limit for patients who are considered candidates for surgical treatment of obesity falls in the range of 100 pounds or 100% above so-called ideal weight as defined by standard life insurance tables.[1,2] The concept of "superobesity" has recently evolved to describe a smaller group of patients whose weight far exceeds the minimum weight criteria required for surgical treatment. Successful weight loss in these massive patients has been highly problematic after conventional gastric restrictive operations. This study was performed to determine whether a modification of Roux-en-Y gastric bypass (RYGB) in which bile and pancreatic secretions were diverted more distally in the functional digestive tract would result in greater weight loss in superobese patients than conventional RYGB.

Clinical Material and Methods

During the past 7 years, 45 superobese patients were prospectively randomized to receive one of two modifications of RYGB. Candidates for the study weighed at least 200 pounds more than ideal body weight at the time of their initial preoperative screening examination. All patients were independently evaluated by the surgeon and a clinical nutritionist, (Hallis A. Kenler, Ph.D., R.D.) at each outpatient visit before and after operation. Weight, blood pressure, and pulse rate were recorded at each visit. At the initial screening visit, the medical history was recorded and the clinical protocol was presented to prospective patients by the surgeon. Patients who were interested in participating in the study were given a consent form, which was reviewed again at the time of hospital admission. Patients usually signed the consent form on the evening before operation. Randomization was carried out on the day of operation.

The nutritionist obtained a detailed 1-day recall diet history from each patient at the initial screening visit and at each postoperative visit after the first month. The recall diet analysis included determination of each patient's total daily calorie intake and the relative percentage intake of protein, carbohydrate, and fat. The percentage of daily calories from milk products and sweets was also determined. Sweets intake was further subdivided into solid and liquid categories. Nutritional data were analyzed using the Nutritionist III computer program (N-Squared Computing, Silverton, OR) according to methods described previously.[3]

A chem-21 screen, lipid risk profile, urinalysis, chest x-ray, and electrocardiogram were performed in all patients before operation. A complete blood count; serum levels of vitamin B-12, folate, and iron; and iron-binding capacity were measured before operation and at each postoperative visit beginning at 6 months. Fasting serum glucose and lipid levels were followed at 6-month intervals in patients who had diabetes or hyperlipidemia before operation. Blood samples for measurements of liver function, albumin, and total protein were also obtained at 6, 12, and 18 months after operation. We had hoped to measure 24-hour fecal fat content after operation. However, compliance in obtaining the fecal specimens was so poor that these measurements were dropped from the study protocol.

The operative techniques are shown illustrated in Figure 1. All operations were performed by one surgeon (Robert E. Brolin, M.D.) at Robert Wood Johnson University Hospital. In each case, the volume of the upper gastric pouch was made as small as possible to allow for creation of an 11.4-mm–diameter gastrojejunostomy. Upper pouch volumes were measured in the range of 20 ± 5 mL. The distance between the gastrojejunostomy and jejunojejunostomy was measured on the antimesenteric border with the bowel on a stretch. In RYGB-2, the distance between the jejunojejunostomy and ileocecal junction was determined to be at least as long as the proximal

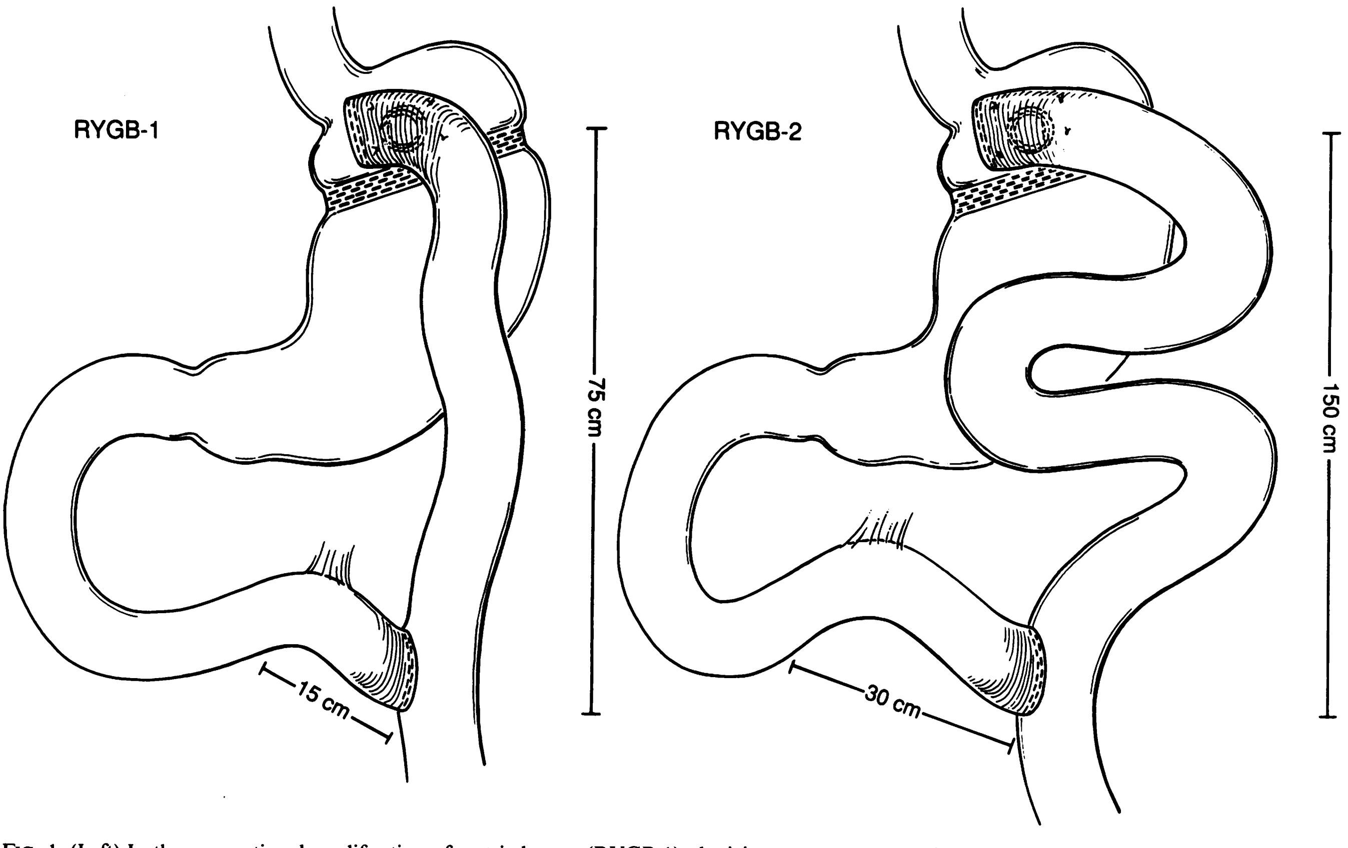

FIG. 1. (Left) In the conventional modification of gastric bypass (RYGB-1), the jejunum was transected 15 cm beyond the ligament of Treitz and the jejunojejunostomy was performed at a measured distance of 75 cm distal to the gastrojejunostomy. (Right) In the experimental group (RYGB-2), the jejunum was transected 30 cm distal to the ligament of Treitz and the jejunojejunostomy was created at a measured distance of 150 cm from the gastrojejunostomy.

measurement between the jejunojejunostomy and the upper gastric pouch. Other details of the operative technique of gastric bypass have been described previously.[4,5]

In the RYGB-1 group, there were 18 women and 4 men, ranging in age from 21 to 60 years, with a mean age of 38.7 years. The mean preoperative weight in RYGB-1 patients was 393 ± 64 pounds, and ranged from 324 to 586 pounds. The mean preoperative body mass index (BMI) was 63.4 ± 10 kg/m^2 and ranged from 48.8 to 94.6 kg/m^2. The mean age of the 8 men and 15 women in the RYGB-2 group was 36.5 years and ranged from 18 to 61 years. In RYGB-2 patients the mean preoperative weight was 404 ± 61 pounds and ranged from 320 to 592 pounds. The mean preoperative BMI was 61.6 ± 9 kg/m^2 and ranged from 51.8 to 89.9 kg/m^2.

After operation, a daily multivitamin supplement containing minerals was recommended for all patients. Patients were instructed to follow a modified liquid diet for the first 4 weeks.[3] At the 4-week visit, patients were given a new diet consisting of a variety of soft solid foods. Subsequent follow-up visits were scheduled at 3-month intervals during the first postoperative year, at 6-month intervals during the second year, and annually thereafter.

Statistical analysis of data was performed using Fisher's exact test, Student's t test and the Wilcoxon rank-sum test for comparisons between the two groups.

Results

Weight Loss and Calorie Intake

Postoperative weight loss in pounds is shown in Figure 2. Weight loss generally stabilized between 12 and 18 months after operation and had stabilized at 24 months after operation in all but one patient. This 33-year-old police officer became an avid weight lifter and occasional jogger after losing more than 150 pounds during the first 18 months after operation. A high level of physical activity probably contributed to his losing 50 more pounds during the third postoperative year. Although mean weight loss in RYGB-2 patients was greater than that in RYGB-1 patients at 6, 12, and 18 months after operation, this difference was not statistically significant. Mean weight loss at 24 and 36 months, however, was significantly greater in RYGB-2 *versus* RYGB-1 patients ($p \leq 0.02$ by unpaired Student's t test). At 24 months, the mean percentage of excess weight lost was 50% in RYGB-1 patients

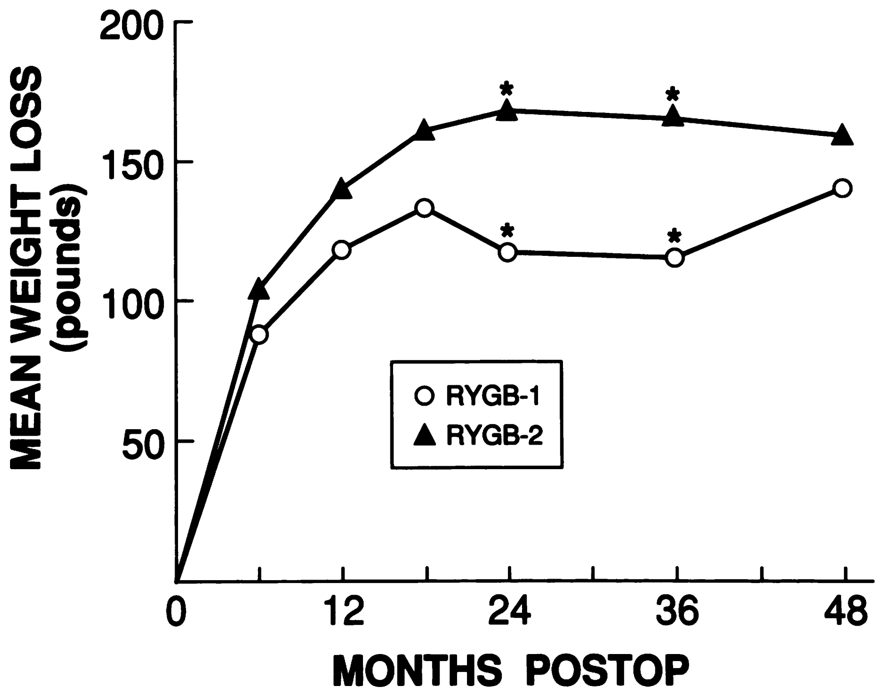

FIG. 2. Postoperative weight loss. The following values correspond with mean ± SD weight loss shown in the graph.

	6 mo	12 mo	18 mo	24 mo	36 mo	48 mo
RYGB-1	88 ± 23	118 ± 35	133 ± 40	117 ± 38*	115 ± 49*	140 ± 63
RYGB-2	104 ± 37	140 ± 41	161 ± 51	168 ± 52*	165 ± 50*	159 ± 70

* Significant difference between groups ($p \leq 0.02$ by unpaired Student's t test).

versus 64% in RYGB-2 patients. Nineteen of the 23 RYGB-2 patients lost at least 50% of their excess weight, whereas only 11 of 22 RYGB-1 patients lost 50% or more of their excess weight ($p \leq 0.03$ by Fisher's exact test).

Postoperative changes in BMI are shown in Figure 3. Body mass index changes in each group closely corresponded with weight loss. Mean BMI in RYGB-2 patients was significantly less than that in RYGB-1 patients at 24 months after operation ($p \leq 0.01$ by unpaired Student's t test). The difference in BMI between the two groups at 36 months approached statistical significance ($p = 0.06$).

Mean daily calorie intake before operation was 3621 ± 1677 calories in RYGB-1 patients *versus* 3828 ± 1120 calories in RYGB-2 patients. Postoperative daily calorie intake is shown in Figure 4. Postoperative calorie intake was significantly decreased *versus* preoperative levels in both groups throughout the duration of the study ($p < 0.001$ by paired Student's t test). Total calorie intake at 6 months after operation was significantly lower in RYGB-1 patients *versus* RYGB-2 patients ($p \leq 0.03$ by Wilcoxon rank-sum test). Daily calorie intake remained somewhat lower in RYGB-1 patients throughout the remainder of the study. The percentage of protein, carbohydrate, and fat in the diet was similar in RYGB-1 *versus* RYGB-2 patients after operation. There was also no significant difference in consumption of sweets or milk products between the two groups.

Improvement of Medical Problems and Lifestyle

There were 101 medical problems identified before operation in the two groups, as shown in Table 1. Only 3 of the 45 patients (6.6%) did not have obesity-related medical illnesses before operation. Hypertension, defined as a resting diastolic blood pressure of 90 mmHg or greater, was the most common problem and was recognized in 73% of these patients. Venous stasis was characterized by skin discoloration and brawny edema in the lower legs. Arthritis invariably involved weight-bearing joints. Congestive heart failure was typically associated

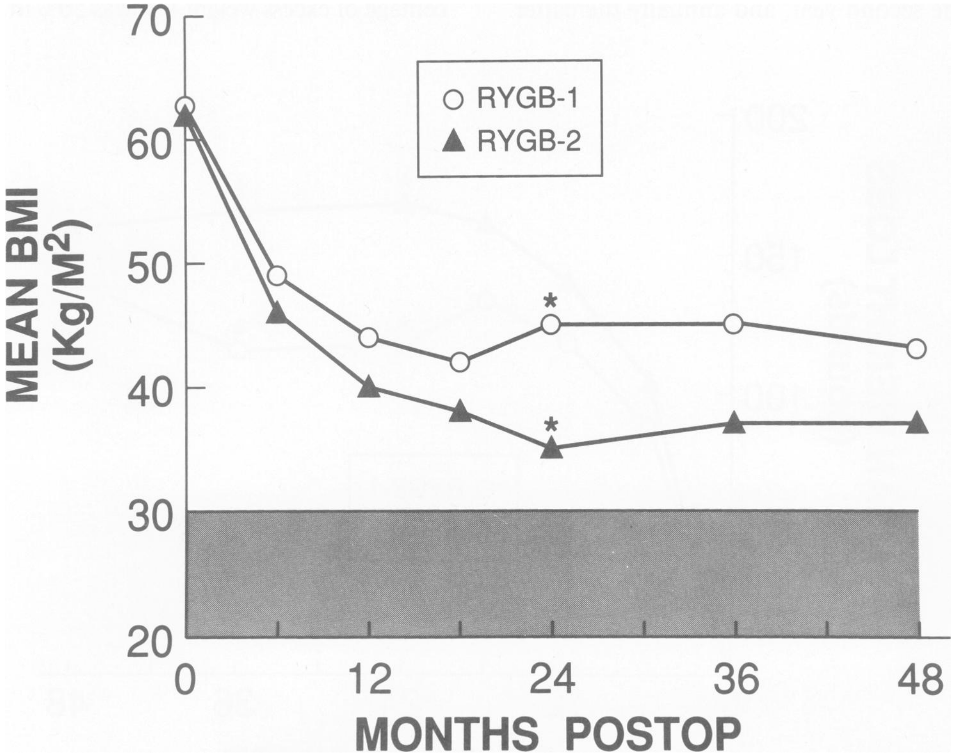

FIG. 3. Postoperative changes in BMI. The shaded area corresponds with the BMI range below Bray's minimum definition of obesity ($BMI \geq 30$). The following values correspond with mean ± SD BMI shown in the graph.

	6 mo	12 mo	18 mo	24 mo	36 mo	48 mo
RYGB-1	49 ± 9	44 ± 8	42 ± 11	45 ± 13*	45 ± 14	43 ± 10
RYGB-2	46 ± 8	40 ± 9	38 ± 7	35 ± 5*	37 ± 6	37 ± 11

* Significant difference between groups ($p \leq 0.01$ by unpaired Student's t test).

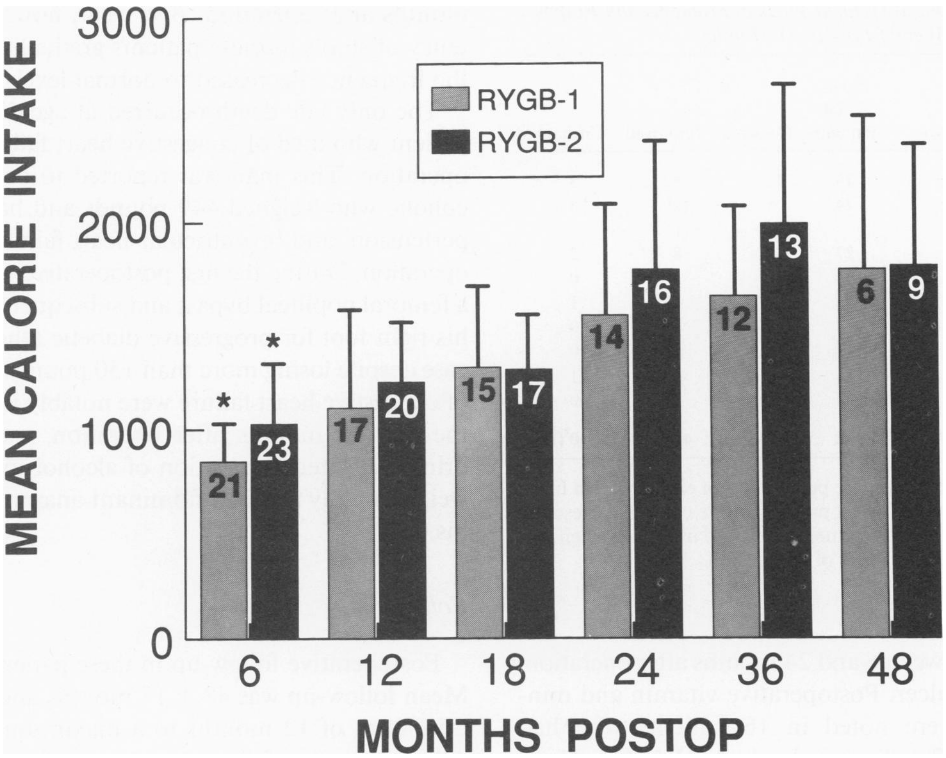

FIG. 4. Postoperative calorie intake. The numbers within bars represent the number of patients followed at each interval. The following values correspond with mean ± SD calorie intake in graph.

	6 mo	12 mo	18 mo	24 mo	36 mo	48 mo
RYGB-1	848 ± 181*	1102 ± 482	1296 ± 392	1549 ± 528	1643 ± 434	1722 ± 742
RYGB-2	1026 ± 290*	1225 ± 298	1285 ± 271	1770 ± 618	1990 ± 679	1789 ± 585

* Significant difference between groups ($p \leq 0.03$ by Wilcoxon rank-sum test).

with cardiomegaly, edema of the lower extremities, and elevated pulmonary artery wedge pressure measurements. All of the six diabetic patients were resistant to large doses of insulin. The five patients with asthmatic bronchitis were taking bronchodilators and had exertional dyspnea. Cardiac arrhythmias included multifocal premature ventricular contractions in three patients and atrial fibrillation in two patients. Patients with sleep apnea syndrome had elevated resting arterial carbon dioxide partial pressure levels and multiple apneic spells identified during polysomnographic studies.

Table 1 also shows the response of the 101 medical problems to weight loss at 24 months after operation. Improvement in congestive heart failure, arthritis, and asthmatic bronchitis included reductions in both symptoms and medications. Medical illnesses were either resolved or improved in all but four patients (9%). Each of these patients had unsatisfactory weight loss, with excess weight loss ranging from 33% to 47% at 24 months after operation.

Weight loss also had a positive socioeconomic effect on many of these patients. Seven of 11 patients (64%) who were receiving welfare or medical disability before operation subsequently became gainfully employed. Although most patients claimed greater satisfaction in their sex and social lives after operation, divorces among women outnumbered marriages by three to two. There was one divorce among the nine men who were married before operation. One man was married 18 months after RYGB-2. Two other men who were unmarried before operation remain single.

Postoperative Complications

There were three early postoperative complications in two patients. One patient had a major skin wound dehiscence that required operative closure. The other patient had a pulmonary embolus 10 days after a major wound infection developed. There were no perioperative deaths.

Late complications included six incisional hernias that

TABLE 1. *Incidence of Obesity-related Medical Problems and Response to Weight Loss at 24 Months*

Problem	No.	(%) of Total Patients	Resolved	Improved	Unchanged
Hypertension	33	73	22	8	3
Venous stasis	20	44	5	12	3
Congestive heart failure	10	27	2	8	2
Arthritis	11	24	3	8	0
Hyperlipidemia	6	13	1	4	1
Diabetes	6	13	3	3	0
Asthmatic bronchitis	5	11	4	1	0
Cardiac arrhythmia	5	11	0	4	1
Sleep apnea	3	7	3	0	0
Total no. (%)	101 (100)		43 (43)	48 (47)	10 (10)

Numbers in the third column are percentages of each problem in the entire series of 45 patients. Medical problems were considered resolved when they were controlled without medication and improved when they were controlled with reduced doses of medication.

were recognized between 6 and 24 months after operation, and one marginal ulcer. Postoperative vitamin and mineral deficiencies were noted in 16 patients who had RYGB-1 and in 17 patients who had RYGB-2. Three patients in each group had folate deficiency that was easily corrected by addition of a daily multivitamin supplement. Five patients in each group had vitamin B-12 deficiency. Nine of the ten vitamin B-12 deficiencies responded to additional oral B-12 supplements of 500 μg daily. Iron deficiency was noted in 11 RYGB-1 patients and in 13 RYGB-2 patients. All but 1 of these 24 patients were women. Nine of the 11 women with iron deficiency in the RYGB-1 group had a microcytic anemia. In the RYGB-2 group, iron-deficiency anemia was recognized in 6 of the 12 women with iron deficiency. Twelve of the 24 patients with iron deficiency responded to oral iron supplements of 600 or 900 mg daily. Two of the 12 patients who did not respond to oral iron administration were given intramuscular injections of Imferon (Fisons, Bedford, MA). Both of these women had moderately severe iron-deficiency anemia (hemoglobin $\leq$ 10 g/dL) and are still receiving Imferon injections. The remaining 10 patients with uncorrected iron deficiency are currently taking oral supplements.

There were no cases of postoperative protein deficiency or hepatic dysfunction. One RYGB-2 patient who was taking furosemide 80 mg daily for hypertension and congestive heart failure had transient hypokalemia that was corrected by increasing her oral potassium supplement. No patient had diarrhea after operation. Most patients reported having one small formed stool per day. Several patients in the RYGB-2 group reported having two or three semisolid stools during the first several months after operation. By 1 year, however, the consistency of stools in these patients gradually increased, and the frequency decreased to normal levels.

The only late death occurred at age 53 in a RYGB-1 patient who died of congestive heart failure 6 years after operation. This man was reported to be a reformed alcoholic who weighed 449 pounds and had diabetes, hypertension, and biventricular heart failure at the time of operation. During the first postoperative year, he required a femoral popliteal bypass and subsequent amputation of his right foot for progressive diabetic atherosclerotic disease despite losing more than 150 pounds. His symptoms of congestive heart failure were notably improved during the first 18 months after operation, until he resumed drinking. After resumption of alcohol intake, he gained weight rapidly and had fulminant anasarca at the time of his death.

Follow-up

Postoperative follow-up in these patients was difficult. Mean follow-up was 43 ± 17 months and ranged from a minimum of 12 months to a maximum of 86 months. All patients were followed in the outpatient clinic at Robert Wood Johnson University Hospital through their 6-month visit. The number of patients followed at each interval through 48 months is shown in Figure 4. Several patients missed interval visits but were not lost to follow-up. Three RYGB-1 patients did not return for follow-up at our medical center after the first postoperative year. One of these patients was subsequently followed through a medical clinic in Elizabeth, New Jersey, for 36 months. Another patient refused to keep numerous follow-up appointments after 6 months. Her weight after 18 months was provided by her gynecologist, and was recorded as 351 pounds because it exceeded the 350-pound limit of his office scale by an unknown amount. The remaining patient moved to Texas after 12 months and was followed locally by a physician who provided follow-up data for another 12 months. Another patient in the RYGB-1 group was withdrawn from the study after 24 months, when she was converted to a distal gastric bypass because of unsatisfactory weight loss. Two other patients (one in each group) were lost after moving out of state during the fourth postoperative year. One patient in the RYGB-2 group was excluded from the study after full-blown acquired immune deficiency syndrome developed 16 months after operation.

Three women became pregnant during follow-up, including a 35-year-old woman in the RYGB-1 group who became pregnant 6 months after operation, and two women in the RYGB-2 group, ages 19 and 29, who became pregnant during the latter part of the second postoperative year. During pregnancy, the weight of these three women was not entered in the study. Their weights were again recorded 3 months after delivery. The postpartum weight of each patient was less than the preconception weight. All three pregnancies were uncomplicated and ended with normal labor and delivery of four healthy infants (One woman had twins.).

Discussion

Defining Superobesity

Our arbitrary definition of superobesity at 200 pounds or more greater than ideal weight was chosen to reflect a minimum weight limit that corresponded to twice the minimum weight criterion (≥100 pounds overweight) that is used to define morbid obesity. In 1987, Mason et al.[6] classified patients who weighed 225% or more above ideal weight as "superobese," and suggested that these patients required a separate outcome analysis from their lighter morbidly obese patients, who weighed between 160% and 225% of ideal weight before vertical banded gastroplasty.[6] The basis of their recommendation was their finding that the heaviest patients lost a significantly lower percentage of their excess weight despite losing a significantly greater quantity of weight in comparison with the lighter patients. Benotti et al.,[7] Sugerman et al.,[8] Yale,[9] and MacLean, Rhode, and Forse[10] have subsequently used the Mason group's definition of superobesity (≥225% of ideal weight) in their reports of gastric restrictive operations. Each investigator likewise noted a lower percentage of excess weight loss in the superobese despite greater weight loss in pounds *versus* the lighter patients.[7-10]

The distinction between morbid obesity and superobesity can be justified on several grounds. First, the incidence of coexisting medical problems and overall health risk is substantially greater in the superobese.[2,5] Second, the likelihood of successful weight loss in the superobese is significantly lower than in the lighter patients after conventional gastric restrictive operations.[6,8] Hence, the distinction between morbid obesity and superobesity could be used to justify controlled prospective trials of operations that combine gastric restriction with malabsorption with the goal of improving weight loss without increasing the postoperative complication rate. It seems clear that the heaviest patients must lose more weight to achieve a level that would represent a valid reduction in their actuarial mortality risk.

The apparent paradox between differences in absolute quantity of weight loss and percentage of excess weight loss in superobese patients is readily explained by the criteria used to define successful weight loss after obesity operations. We have previously shown that the incidence of successful weight loss can be determined by both the patients' preoperative weight and the criteria used to define "success."[5,11] Our analysis affirmed that superobese patients lose more pounds but stabilize at a significantly greater percentage over ideal body weight than do the lighter morbidly obese patients. Moreover, there were statistically significant differences in the incidence of successful weight loss within the same group of patients that were solely determined by the criteria used to define "success." Loss of 50% of the excess weight has been used as a criterion to define "success" in several previous reports of bariatric operations.[5,7,12] Because the excess weight is the calculated difference between the ideal and preoperative weight, in the heaviest patients, excess weight loss is an intermediate outcome measure between weight loss calculated as a percentage of the preoperative weight *versus* a percentage above ideal weight.

The National Institutes of Health (NIH) Consensus Development Panel on obesity surgery recently recommended use of the BMI rather than a quantity or percentage of overweight in both preoperative patient selection and in reporting postoperative results.[13] The NIH panel established the minimum weight limit of "morbid" obesity at a BMI of 40 kg/m^2. Bray[14] has defined "obesity" at a BMI of at least 30 kg/m^2, which closely corresponds to 20% above the median of the recommended midpoint weight range for height according to the 1983 Metropolitan Life Insurance tables. Normal BMI has been calculated in the range of 21.6 to 24.4 kg/m^2, depending on frame size.[15] Because BMI expresses the magnitude of overweight for height as a single number, the variability inherent in expressing weight loss in terms of percentage of the preoperative weight or excess weight is avoided.

MacLean, Rhode, and Forse[10] and Benotti et al.[7] recently established a minimum BMI definition of superobesity at 50 kg/m^2.[7,10] The mean BMI at the point of maximum weight loss among superobese patients in the current study was 42 ± 11 in RYGB-1 patients and 35 ± 5 in RYGB-2 patients. Calculated BMI for patients who are approximately 50% overweight falls in the range of 34 to 36.5 kg/m^2. The BMI of 42 kg/m^2 recorded in RYGB-1 patients at 18 months after operation corresponds to approximately 85% overweight and exceeds the BMI limit of 40 kg/m^2 that was recently established by the NIH Consensus Development Panel as the minimum definition of morbid obesity. Only 7 (16%) of the 45 patients in the current series stabilized at a BMI less than or equal to 30 kg/m^2 (approximately 20% overweight), and only one reached a BMI of 25 kg/m^2 or less (normal weight) at the nadir of weight loss. These BMI data provoke the question of what are realistic and worthwhile weight loss goals for superobese patients after gastric restrictive procedures. It is probably unrealistic to expect that patients with a preoperative BMI of 50 kg/m^2 or greater should reach a BMI of less than 30 kg/m^2 after weight stabilization.

Combining Gastric Restriction With Malabsorption

In 1976, Scopinaro et al.[16] introduced biliopancreatic bypass (BPB), which combines a modest amount of gastric restriction with intestinal malabsorption. This group's early technique included transection of the small bowel at its midpoint and anastomosis of the proximal ileum to a 400-mL capacity gastric remnant after the distal stomach was removed. The jejunum is totally excluded from digestive continuity with the distal end anastomosed end-to-side to a "common channel" of ileum at a point 50 cm proximal to the ileocecal junction. The goal of biliopancreatic bypass was to provide temporary limitation of food intake caused by rapid emptying of the gastric remnant in conjunction with persistent malabsorption selective for fat and starch due to diversion of biliary and pancreatic secretions into the distal ileum.[16,17] Scopinaro et al. initially tested BPB in dogs and found that a 20-cm–long common tract consistently produced diarrhea, hypoproteinemia, and electrolyte imbalance, whereas a 35- to 40-cm–long common tract did not produce these sequelae.[17] Dogs with a 40-cm–long common channel, however, had a 35% weight loss and a 40% or greater increase in fat excretion *versus* control animals. Scopinaro and colleagues have subsequently modified their original operation by further reducing gastric capacity to approximately 200 mL in superobese patients (the so-called very little stomach modification) and have lengthened the common channel in less obese patients to decrease the incidence of malabsorption-related sequelae.[18]

Although weight loss with the Scopinaro group's BPB bypass has been excellent, it occurs at the expense of a variety of serious postoperative complications. Major perioperative complications have been reported in 8% to 10% of patients after BPB, including a mortality rate of between 1% and 2%.[16,18] The incidence of major metabolic complications during the first postoperative year has been alarmingly high, and includes a 30% incidence of anemia, a variety of vitamin and mineral deficiencies, and a 20% incidence of hospitalization for treatment of protein-calorie malnutrition.[16] Sugerman et al.[19] recently reported preliminary results of a prospective comparison of BPB with conventional RYGB in superobese patients.[19] Their 25 BPB patients had a 50% incidence of serious postoperative complications and metabolic sequelae, including two deaths. One of these deaths resulted from hepatic failure. Although weight loss at 1 year was significantly greater after BPB in comparison with conventional RYGB, Sugerman et al. concluded that the incidence and severity of complications after BPB was too great to justify its use as a primary operation for treatment of patients with superobesity.

The RYGB-2 modification of gastric bypass used in the current study differs substantially from the Scopinaro et al. BPB in that only 30 cm of small bowel is totally excluded from digestive continuity. This technique was designed to induce greater malabsorption of dietary fat without producing the protein malabsorption or clinically overt malnutrition that have been associated with the Scopinaro group's operation. Because mean calorie intake was consistently greater in RYGB-2 *versus* RYGB-1 patients, the superior weight loss in the RYGB-2 group may be attributed to greater fat malabsorption resulting from more distal diversion of bile and pancreatic secretions in the functional digestive tract. Unfortunately, our inability to measure fecal fat after operation coupled with the absence of an on-site clinical research center precluded verification of the fat malabsorption hypothesis. As an afterthought, we measured serum carotene levels in many of these patients. Although serum carotene levels in both groups were in the low normal to subnormal range, lack of parallel collection of samples throughout the entire study did not permit valid comparison of these data.

Risk–Benefit Analysis

A valid analysis of any obesity operation probably requires postoperative follow-up of at least 5 years. The pitfalls of assessing the effectiveness of operations with only 2 or 3 years' follow-up were clearly demonstrated by both jejunoileal bypass and horizontal gastroplasty in the early era of bariatric surgery. Hence, the results of this prospective series could be considered somewhat preliminary. Although the mean 43-month follow-up period is probably sufficient to validate the difference in weight loss between these two modifications of RYGB, there was a similar pattern of recidivism in RYGB-1 and RYGB-2 patients after weight stabilization. The loss of statistical significance in weight loss between the two groups at 48 months after operation was due to both the smaller number of patients followed at this interval and the fact that two of the most successful RYGB-1 patients were among the six patients in that group who were evaluated at 48 months. Weight loss maintenance in both groups was related to postoperative calorie intake in that recidivism generally occurred when calorie intake exceeded 1500 calories per day in women and 1800 calories per day in men. The lack of statistically significant differences in calorie intake between the two groups after 6 months following operation is primarily due to the large variation in daily calorie intake recorded among individual patients in both groups with longer postoperative follow-up (Fig. 4). Most of these added calories were in the form of either high-calorie liquids, soft junk food, or both, rather than as larger portions of mealtime foods. Patients who consciously restricted their intake of high-calorie liquids and soft junk food invariably maintained their weight loss.

Improvement of both coexisting medical problems and general lifestyle were dramatic among patients who lost substantial amounts of weight. The 90% incidence of improvement or resolution of medical problems in these patients was substantially greater than the incidence of successful weight loss, per se, in that 15 patients (33%) did not lose at least 50% of their excess weight. Moreover, there was virtually no regression of improved or resolved medical problems in patients who maintained satisfactory weight loss for the duration of the study. Conversely, improvement of medical problems was limited or transient in several patients who did not lose 50% of their excess weight. These results suggest that 50% excess weight loss is a useful measure of success in superobese patients, despite the fact that many of these patients remain 50% overweight after stabilization.

The 4.4% early complication rate in the current study compares favorably with the incidence of early postoperative complications reported by other surgeons in unselected series of gastric bypass patients.[7,9,20] This complication rate is also similar to the early morbidity rate previously reported in our lighter bariatric surgical patients.[5] Conversely, the 13% incidence of late incisional hernias in the current series is nearly twice as high as the incidence of postoperative hernias in our lighter bariatric patients. The 73% incidence of postoperative vitamin and mineral deficiencies in this study is somewhat higher than the overall incidence of these deficiencies previously reported in patients after conventional RYGB.[21,22] There is evidence, however, suggesting that the incidence of these metabolic deficiencies increases with longer follow-up after conventional RYGB.[23] There was no difference in the incidence of postoperative metabolic deficiencies between RYGB-1 and RYGB-2 patients. All of the postoperative vitamin and mineral deficiencies in this series were managed on an outpatient basis. Only two patients required injections rather than oral supplements. Patient noncompliance in regularly taking multivitamin supplements and in returning for scheduled follow-up visits contributed to the development and progression of many of these deficiencies.

In summary, this prospective study shows that gastric restriction combined with a modest degree of biliopancreatic diversion resulted in significantly greater postoperative weight loss in superobese patients than did conventional RYGB. Because only 30 cm of jejunum is excluded from the functional digestive tract, protein-calorie malnutrition and persistent diarrhea were not observed after the long-limb modification of RYGB. It appears that this long-limb modification of RYGB poses no greater risk of complications than the conventional technique.

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