Gastric Surgery for Morbid Obesity

The Adelaide Study

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The efficacy of three gastric restriction operations were compared in a prospective randomized study of 310 morbidly obese subjects. The median patient age was 34 years (range, 18 to 62 years). They were predominantly female (13:1) and had a median preoperative weight that was 198% of their ideal weight (range, 160% to 318%). There was an equitable dispersion of perceived risk factors between the groups under study and there were no deaths during the perioperative period. Compliance with follow-up at 3 years was 91%. When success was defined as a loss of more than 50% of excess weight or a current pregnancy, the success rates at 3 years were 17% for gastrogastrostomy, 48% for vertical gastroplasty, and 67% for Roux-en-Y gastric bypass ($p < 0.001$). Although the gastric bypass operation took longer to perform, there were similar outcome patterns for the three groups during the postoperative period. We conclude that the Roux-en-Y gastric bypass is the preferred procedure for the surgical treatment of morbid obesity.

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THE QUALITY OF LIFE of morbidly obese individuals tends to be poor. Besides being afflicted by a number of psychosocial problems,[1] they are prone to health risks that contribute to a shortened lifespan.[2,3] Unfortunately few morbidly obese patients achieve long-term weight loss after dietary or behavioral therapy, and techniques that use mobile incarceration (jaw wiring and the endoscopic insertion of intragastric balloons) are associated with high rates of initial failure or recidivism.[4–7]

Although the operation of jejunoileal bypass resulted in satisfactory weight loss, with a reversal of many of the psychosocial and physical disorders associated with massive obesity, the metabolic consequences were considerable.[8–10] Attempts to avoid these problems have resulted in the creation of various gastric restriction operations. During these procedures, stapling devices are used to form a small proximal pouch of stomach that is confluent with the esophagus, and a narrow stoma is constructed to drain this pouch into either the distal stomach or a segment of small bowel. In general these operations result in similar patterns of weight loss but fewer complications than occur with jejunoileal bypass.[11–14] Both the jejunoileal bypass and gastric reduction procedures produce better patterns of weight loss than dietary therapies.[15,16]

Several gastric procedures have been recommended as the best forms of bariatric surgery. However there is a lack of clinical trials that have evaluated different forms of surgery. The Adelaide Study is a clinical trial designed to investigate the effect of Roux-en-Y gastric bypass, gastrogastrostomy, and vertical gastroplasty on weight loss in patients with morbid obesity. This report details the results 3 years after surgery.

Methods

We decided prospectively to enter more than 300 patients into the study so that we could reliably detect or reject a 20% difference in the success rates after surgery using a two-tailed test and assuming a probability of a type I error of 5%, a power of 90%, and a failure rate of 10% after 1 year for the control group (gastric bypass).[17] At the time of the study closeout in December 1984, 310 patients had been entered at an accrual rate of 9.1 patients

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per month. The study protocol was approved by the Human Ethics Committees of the participating institutions.

Patients

All patients referred to the participating surgeons for bariatric surgery were considered for entry into this study providing that they weighed more than 160% of their ideal weight,[18] were over 18 years of age, had no prior abdominal surgery for obesity, had undergone vigorous attempts at weight reduction by conservative means, and resided within the Adelaide metropolitan area. Patients who fulfilled these criteria entered the study providing that the patient gave their informed consent, a physician and psychiatrist had reviewed the patient to exclude the presence of an underlying endocrinopathy or psychotic disorder, and the surgeon was satisfied that the operation was desirable and that any one of the three procedures was technically feasible.

Patients were counseled at length about the possible outcome of surgery and were provided with a 24-page information booklet that outlined the basic features of the operations, gave an indication of the anticipated weight loss, detailed the events that might occur during the perioperative period, gave an account of the probability of a significant complication or death after surgery, advised about food intake after surgery, and provided information about the local Gastric Stapling Support Group. Therefore the study complied with published recommendations about information dissemination before bariatric surgery.[19]

Entry Procedure

Entry into the trial was initiated by a telephone call to the Trial Secretary. The patient was interviewed by a research nurse and then randomized into one of the three treatment groups. At this stage information was collected about prognostic factors to be used in the randomization procedure, psychosocial and demographic variables, and the existence of comorbid conditions.

A stratified randomization technique was used, with a block size of six with allocation of operations within each block determined by computer-generated pseudorandom numbers. There were 32 strata, *i.e.*, sex (male, female); age (18 to 27 years, 28 to 37 years, 38 to 47 years, older than 47 years); and percentage of ideal weight (160% to 190%, 191% to 220%, 221% to 250%, more than 250%). We also wished to have an equitable dispersion of the three operations between the participating surgeons. Because increased stratification would have been self-defeating in a trial of this size, we ensured an even balance of this prognostic variable by using the baseline adaptive randomization procedure advocated by Pocock and Simon.[20]

Standardization of Operations

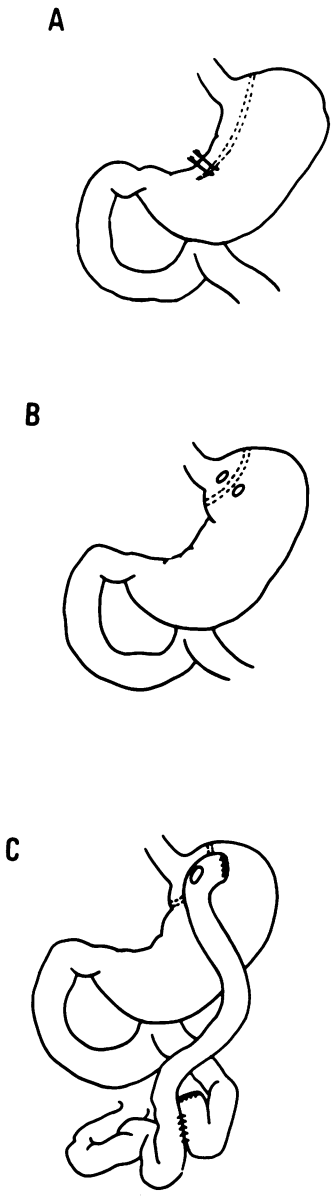
Before beginning this study, the participating surgeons visited their colleagues's operating theatres to standardize their techniques. During the course of the study discussions about standardization of operative techniques took place during each of the three-monthly trial-review sessions. The protocol for the operative procedures remained unchanged throughout the course of the study. The nature and duration of each operation was recorded by the surgeon on an operative data sheet. The patients were interviewed again by a research nurse before leaving the hospital.

There were several features common to each of the three operations (Fig. 1): Laparotomies were performed through an upper midline incision that was repaired by mass-closure with 1 nylon; prophylactic antimicrobials that were active against facultative aerobes and anaerobes were administered at the time of induction of aneasthesia; proximal gastric pouches less than 50 mL were created with the aid of a nasogastric tube; stomachs were partitioned using staples (TA 90, Auto Suture Australia Pty Ltd, Kingsgrove, New South Wales, Australia); stomas measured between 10 and 12 mm at the time of construction; and drain tubes were not used routinely.

When performing a vertical gastroplasty, the staples were inserted from a point adjacent to the left margin of the esophagogastric junction to the edge of a bougie occupying the lesser curve of the stomach. The resultant stoma was then reinforced with two encircling sutures of No. 1 Ethibond (Ethicon Mechanical, Sydney, New South Wales, Australia) placed at and 1 cm proximal to the caudal end of the staple line. When identified the pin holes in the stomach were closed with an absorbable suture. Anterior gastrogastrostomies were constructed around a 36F bougie (diameter of 11.5 mm) in two layers using inner 3/0 absorbable and outer 3/0 nonabsorbable sutures. When performing a gastric bypass, the proximal pouch of the partitioned stomach was anastomosed side-to-side with a 40-cm retrocolic Roux-en-Y segment of upper jejunum in two layers using inner 3/0 absorbable and outer 3/0 nonabsorbable sutures.

Assessment of Outcome

The research nurse interviewed and weighed each patient in the hospital before surgery, at home 10 weeks after discharge from hospital, and thereafter each year. Patients were encouraged to contact the research nurse or their surgeon when any perceived problems arose. The problems of loss to follow-up in clinical trials were discussed with the patients before surgery, and each patient who entered the trial provided the names and addresses of two friends or relatives to act as contact persons if they became lost to follow-up (only one patient supplied fic-



FIGS. 1A–C. The three gastric restriction operations under study: (A) vertical gastroplasty, (B) gastrogastrostomy, and (C) Roux-en-Y gastric bypass.

titious contacts). Patients who shifted interstate were contacted by telephone and local doctors were asked to provide information about the patient's present weight.

Weight loss was the main study endpoint. We have adopted the convention of expressing this variable as the percentage of the excess weight that had been lost, *i.e.*, (weight lost) · 100 / (initial weight − ideal weight). Treatment failure was defined as either a failure to lose 50% of excess weight,[21] death, loss to follow-up, or revision or reversal of the operation. Patients who were pregnant within 3 months before the time of assessment have been classified as a success. Thereafter such patients were assessed on their current weight.

Comorbidity Status and Nutritional Assessment

Comorbidity was deemed to be present when an independent clinician reviewed the patient before surgery and decided that there was a clinical indication for drug therapy in the management of diabetes mellitus, hypertension, asthma, or an arthropathy. In addition assessment by an independent clinician determined the need for medication at the time of each annual review.

Iron and multivitamin supplementation were prescribed for all patients during the first year after surgery. Each surgeon has assumed responsibility for the long-term monitoring of nutritional status for their patients.

Statistical Analysis

We have used nonparametic descriptive statistics to describe the data. The interquartile range (IQR) describes values between the 25th and 75th percentiles. Success rates between the groups were compared using the chi square test for overall trend. Statistical significance was set as a probability of a type I error of less than 5% using a two-tailed test.

Results

Success of Stratified Assignment

Of the 350 eligible patients who were referred to the participating surgeons during the accrual period, 40 were excluded from study (Table 1). The most frequent reason for exclusion was inadequate communication that resulted in a failure to randomize the patient before surgery. The stratified assignment of patients resulted in an equitable dispersion of demographic variables and perceived risk factors between the groups under study (Table 2). A previous jaw wiring had failed to control morbid obesity in 18% of the patients (55 of 310 patients).

Perioperative Events

No patients died during the perioperative period. Although it took longer to perform a gastric bypass than

TABLE 1. *Eligible Patients Excluded from Study*

Reason	Number of Patients
Failure to be randomized	16
Surgeon's Decision	9
Concern about access (8)	
Duodenal tumor (1)	
Physician's Decision	5
Pulmonary disease (3)	
History of thromboembolism (1)	
Pregnancy (1)	
Patient Refused Consent	7
Noncompliance by Surgeon	3
Total	40

TABLE 2. *Dispersion of Baseline Variables*

Baseline Variable	Gastroplasty (n = 106)	Gastrogastrostomy (n = 105)	Gastric Bypass (n = 99)
Age (years)			
Median	34	34	35
IQR	29–39	28–40	29–44
Absolute range	18–59	18–62	19–57
Sex			
Male/Female	8/98	9/96	5/94
Percentage Ideal Weight			
Median	198	194	198
IQR	186–219	180–215	181–224
Absolute range	164–318	162–284	160–269
Surgeon			
A	34	36	34
B	22	20	20
C	18	19	16
D	18	17	17
E	9	8	8
F	5	5	4
Prior Cholecystectomy	16	20	11
Prior Attempts at Weight Loss			
Weight reduction programs	99	98	90
Prescription drugs	94	83	86
Hypnotherapy	33	39	35
Acupuncture	38	30	34
Jaw wiring	22	19	14
Psychiatric Problems Requiring Medication			
Current	5	0	2
Previous	25	17	13
Marital Status			
Married	67	65	60
Single	39	39	39
Socioeconomic Status in Household			
Professional/managerial	13	11	10
Own Business/clerical	19	15	14
Skilled labor	17	24	23
Unskilled	57	57	50

either of the other two procedures, each of the groups of patients spent an equivalent time in the hospital and had similar patterns of perioperative morbidity (Table 3). The three patients who had a pulmonary embolus had each undergone a gastric bypass operation. There were six intraoperative complications: Three occurred in patients undergoing a gastroplasty (nasogastric tube stapled to the stomach, staple-gun malfunction, and an incidental splenectomy), two patients had complications during the course of a gastrogastrostomy (one a pouch hematoma and the other laceration of the splenic vein), and an incidental splenectomy was performed in one patient undergoing a gastric bypass.

Events During Follow-up

Two patients died within the 3-year review period. One patient had an adenocarcinoma of the colon and the other had hemorrhagic complications after a subsequent cholecystectomy. In all, 89 obesity-related surgical procedures, exclusive of reversal or revisional operations, were performed within the 3 years after bariatric surgery (Table 4). The most common operations performed were trimming procedures to remove excess skin from abdomen, breasts, thighs, and arms. Ten per cent of the women younger than 40 years (21 of 214 patients) became pregnant within 3 years of bariatric surgery.

Weight Loss

Table 5 lists data about the absolute weight of each of the groups under study. These figures demonstrate that patients in the gastrogastrostomy group have performed relatively poorly at the time of each annual review. Unlike the patients in the other groups, patients in the gastrogastrostomy group weighed more at the end of the second year than they did at the end of the first year. The median weight of all of the groups was higher at the end of the third year than it was at the end of second year. There were no marked differences in outcome between the participating surgeons.

Table 6 lists the percentage of the excess weight that was lost at the end of the third year. The cumulative results are presented over the full range of values so that the

TABLE 3. *Perioperative Data*

Data	Gastroplasty (n = 106)	Gastrogastrostomy (n = 105)	Gastric Bypass (n = 99)
Operating Time (minutes)			
Median	70	90	120
IQR	60–90	75–105	105–140
Absolute range	30–130	45–175	70–310
Duration of Postoperative Stay in Hospital (days):			
Median	8	8	8
IQR	7–9	7–10	7–10
Absolute range	5–68	5–20	6–29
Concomitant cholecystectomy (n = 55)	16	21	18
Postoperative Complications (number of patients)			
Wound infection	4	6	4
Atelectasis/pneumonitis	2	5	3
Delayed pouch emptying	1	6	2
Pulmonary embolus	0	0	3
Phlebitis	0	0	3
Hematemesis	0	2	1
Crisis reaction	2	0	0
Subphrenic abscess	1	0	0
Small bowel necrosis	0	0	1
Wound dehisence	1	0	0
Deep vein thrombosis	0	0	1
Respiratory failure	1	0	0
Urinary tract infection	0	0	1

consequences of selecting different criterion levels can be evaluated. Regardless of which criterion level is selected for analysis, the proportion of patients who can be classified as a success is greatest in the gastric bypass group and least in the gastrogastrostomy group. When the criterion used in this study is employed, these differences are significantly different ($p < 0.001$).

Comorbidity

We observed an improvement in comorbidity patterns associated with weight loss (Table 7). The amount of medication required to manage patients with obesity-related illnesses tended to decrease as the patients lost weight. Sixty per cent of the patients who initially had an obesity-related comorbid condition (50 of 84 patients) were free of specific medication when reviewed 3 years after bariatric surgery.

Discussion

In this study we found that the Roux-en-Y gastric bypass operation was more effective in weight reduction than either vertical gastroplasty or gastrogastrostomy. Although this procedure took longest to perform, it was associated with a similar perioperative morbidity when compared with the other operations, and it resulted in more weight loss during the first 3 years after surgery.

Since this study was started, various forms of gastroplasty have been promoted as the optimum form of gastric

TABLE 4. *Obesity-related Events in the First 3 Years After Bariatric Surgery*

Event	Gastroplasty (n = 106)	Gastrogastrostomy (n = 105)	Gastric Bypass (n = 99)
Nongastric Operations			
Trimming procedures (n = 68)	19	14	35
Cholecystectomy (n = 18)	4	7	7
Incisional hernia (n = 3)	0	1	2
Total (n = 89)	23	22	44
Pregnancy			
Year 1 (n = 8)	3	3	2
Year 2 (n = 7)	1	4	2
Year 3 (n = 6)	4	1	1
Total (n = 21)	8	8	5

TABLE 5. *Body Weight (kg) During the Period of Study*

Time	Gastroplasty	Gastrogastrostomy	Gastric Bypass
Baseline	(n = 106)	(n = 105)	(n = 99)
Median	112	110	115
IQR	100–125	100–126	104–125
Range	88–157	78–162	83–170
Year 1	(n = 99)	(n = 95)	(n = 95)
Median	76	81	73
IQR	65–87	74–95	63–84
Range	50–115	56–132	53–128
Year 2	(n = 89)	(n = 80)	(n = 92)
Median	75	86	71
IQR	66–89	75–98	63–83
Range	49–121	58–132	49–140
Year 3	(n = 80)	(n = 67)	(n = 85)
Median	79	93	76
IQR	70–94	79–106	65–86
Range	44–125	60–156	55–140

The number of patients decreases during each subsequent year because of the exclusion of patients who are either pregnant or have been classified as failures.

TABLE 7. *Comorbidity Status 3 Years After Bariatric Surgery*

Disease	Proportion of Patients Off Medication
Diabetes mellitus	6 of 8 (75%)
Arthropathy	16 of 25 (64%)
Hypertension	22 of 39 (56%)
Asthma	6 of 12 (50%)

restriction. However gastrogastrostomy has failed to gain credibility and is now rarely discussed in the surgical literature. In the Greenville Study,[22] 87 morbidly obese patients were randomized to receive either a gastric bypass or a gastrogastrostomy. Gastric bypass patients lost 21% more of their original weight at 18 months than did the patients who received a gastrogastrostomy. When Buckwalter and Herbst[23] concluded that gastrogastrostomy was the preferred operation for the treatment of morbid obesity, this statement was based on the observation that gastrogastrostomy was associated with a low incidence of stomal obstruction rather than on considerations relating to the extent of weight loss. That impression has not been confirmed in our study.

A number of prospective studies have concluded that gastric bypass is more effective than various forms of unbanded gastroplasty.[24–27] Furthermore Flickinger et al.[28] have reviewed the Greenville experience of gastric bypass in 210 patients who had an average age of 35 years and an initial mean ideal weight of 214%. Twenty of the twenty-six patients reviewed at 3 years (77%) had lost more than 50% of their excess weight. In the Greenville Study, as in this study, there was uniformity in the methods used to construct both the proximal gastric pouches and the anastomoses. Therefore it is tempting to speculate that the superiority of the gastric bypass is related to distal gastric and duodenal exclusion. It may be that the gastric bypass operation contains the benefits of a gastroplasty plus the added advantages of maldigestion associated with bypassing the upper gut. The possible mechanisms are a decreased carbohydrate absorption resulting from duodenal exclusion,[22] an earlier onset of satiety, and the de-

TABLE 6. *Assessment of Outcome 3 Years After Bariatric Surgery*

Outcome Event	Gastroplasty (n = 106)	Gastrogastrostomy (n = 105)	Gastric Bypass (n = 99)
% Excess Weight Lost			
>100	1 (1%)	0 (0%)	2 (2%)
>90	3 (3%)	0 (0%)	6 (6%)
>80	10 (9%)	2 (2%)	15 (15%)
>70	23 (22%)	2 (2%)	36 (36%)
>60	33 (31%)	11 (10%)	53 (54%)
>50	47 (44%)	17 (16%)	65 (66%)
>40	52 (49%)	30 (29%)	75 (76%)
>30	66 (62%)	40 (38%)	82 (83%)
>20	76 (72%)	51 (49%)	84 (85%)
>10	78 (74%)	60 (57%)	85 (86%)
>0	80 (75%)	65 (62%)	85 (86%)
≦0	80 (75%)	67 (64%)	85 (86%)
Patients not Weighed			
Lost to follow-up	7	16	5
Revisional surgery	10	20	4
Reversal surgery	5	1	2
Dead	0	0	2
Pregnant	4	1	1
Successful outcome*	51 (48.1%)	18 (17.1%)	66 (66.7%)

* $X^2 = 52.2$, d.f. = 2, $p < 0.001$ (success is more than 50% loss of excess weight or pregnancy).

velopment of an aversion to foods containing high carbohydrate loads because of the dumping syndrome.[29,30]

The vertical banded gastroplasty[31] was introduced after the commencement of our study. Sugerman and associates[32] have compared the vertical banded gastroplasty with a gastric bypass procedure in a randomized trial. Entry into this trial ceased after 40 patients had been evaluated because of a statistically significant weight loss pattern in favor of the gastric bypass group. The average amount of excess weight lost at 3 years was 64% for the gastric bypass compared with 37% for the vertical banded gastroplasty. In addition these investigators compared the performance of "sweets eaters" with "nonsweets eaters". The subgroup analysis suggested that vertical banded gastroplasty may have a role in management of patients who are not addicted to sweets. In addition it should be noted that the patients who received a vertical banded gastroplasty in the study by Sugerman et al.[32] lost less weight than did patients in a longitudinal study conducted by Deitel et al.,[33] *i.e.*, an average loss of excess weight at 1 year of 43% *versus* 68%. Besides avoiding the dumping syndrome, vertical banded gastroplasty is less likely to result in malnutrition than is a gastric bypass.[34] A later study by Sugerman et al.[35] found that patients who were not addicted to sweets lost more weight after gastric bypass than after vertical banded gastroplasty. There is an evident need for a long-term comparative study of these two operations that incorporates large numbers of patients.

In this clinical trial, we evaluated groups of patients who were twice their ideal weight, had made vigorous attempts to lose weight by more conservative means, and were afflicted by a range of obesity-related comorbid conditions. We included 160% of ideal weight as a minimum entry criteria so that the study would include the full range of patients who are referred for bariatric surgery. Close contact with the patients was promoted by issuing an information booklet before entry into the study, having a nurse visit the patients at home during the immediate postoperative period and at yearly intervals thereafter, and promoting the use of the telephone as a medium for counseling throughout the period of review. These interactions aided patient compliance with the follow-up regimen and, after 3 years, 91% of patients had been successfully reviewed.

A blocked stratification technique was used to randomize patients into groups at the time of entry into the study. This ensured that there was an unbiased allocation of patients into the groups under study and resulted in an equal dispersion of putative risk factors relating to bariatric surgery. Potentially one of the greatest confounding influences that may affect the outcome of bariatric surgery is the surgeon, not only because surgeons differ in their operative skills but also because surgeons vary in their interpersonal communication techniques and this may influence long-term weight loss by behavioral modification. We have recognized the possibility of confounding factors relating to the surgeon by including a cell relating to the surgeon in the blocked stratification technique, thus insuring that all of the surgeons were familiar with each of the operations before the commencement of the study, and holding regular meetings to insure that the protocol for the operative procedures was adhered to during the entire period of patient accrual.

There are variations in the way that authors express the extent of weight loss after bariatric surgery. The results of our study are valid regardless of the expression that is used to record weight loss, *i.e.*, loss of percentage ideal weight, loss of absolute body weight, or percentage excess weight lost. We have chosen to use the latter because it provides a standardized expression of weight loss, and we have adopted the 50% level recommended by Reinhold[21] as the criterion of a good result. However, because the criteria used to define success are both subjective and arbitrary, we declared the percentage excess weight lost using a complete range of criterion levels. Raising or lowering this figure would have altered the total number of patients classified as successes but would not have influenced any relative comparison of the three operations.

Factors other than the recorded weight of patients were considered when determining the success rate. The need for revisional surgery has been classified as a treatment failure, although it is recognized that after an additional operation the patient may indeed have a good weight loss record. Nevertheless, for the purposes of this study, we have regarded any form of revisional or reversal surgery as an indication of failure of the initial bariatric operation. Loss to follow-up precludes objective statements, but it is interesting that there is an inverse correlation when extent of weight loss is compared with loss to follow-up or the incidence of revisional surgery. Also, although there is no obvious relationship between the original choice of operation and both of the deaths that occurred during the review, we prospectively decided that all deaths should be regarded as treatment failures. With regard to patients who were pregnant at the time of assessment, we believe that this indicates a favorable event and have classified such patients as having a successful outcome for that study period. Patients who had conceived during the previous 3 years were assessed on their current weight.

There is unequivocal evidence that weight loss after bariatric surgery has a beneficial effect on obesity-related comorbidity.[36–41] Patients with hypertension, diabetes mellitus, asthma, or an arthropathy have a greater than 50% chance of being free of medication 3 years after bariatric surgery. An additional finding relates to fertility. The high incidence of fertility is one pleasing aspect of

weight reduction that has not achieved prominence in the surgical literature. In this study 10% of the women under 40 years of age became pregnant within 3 years of bariatric surgery.

There are also penalties associated with bariatric surgery. Like other investigators, we observed a high incidence of subsequent obesity-related operations for revision or reversal of the initial procedure, the trimming of excess skin folds, and the management of gallstones.[42,43] Further demands are created by the need for close monitoring of nutritional status,[44] the frequent requirement of upper gut endoscopy, and the heavy use of various counseling services. These factors, when combined with the transient value of bariatric surgery for many patients, make it imperative that the surgical community continues to evaluate the role of bariatric surgery within the structured format provided by long-term clinical trials.[45]

In this large randomized clinical trial that evaluated patients 3 years after bariatric surgery, the Roux-en-Y gastric bypass produced a clearly superior pattern of weight loss when compared with vertical gastroplasty and gastrogastrostomy. At the present time, the Roux-en-Y gastric bypass should be regarded as the established procedure of choice in the surgical management of patients who are morbidly obese. Newer operations should be considered as experimental until their use has been validated in appropriately designed clinical trials that evaluate patients during a long period of time and include the Roux-en-Y gastric bypass as the control group. We intend to follow the patients included in this study for at least 5 years after their bariatric surgery.

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