Superior Gastric Reduction Procedure for Morbid Obesity

A Prospective, Randomized Trial

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A prospective randomized clinical trial was undertaken to compare the effects of gastric bypass with Roux-en-Y gastrojejunostomy and a gastric partitioning procedure. Operative groups were comparable, with regard to preoperative weight, age, sex, historic findings and operative complications. Postoperative weight loss was followed for one year. Patients receiving the gastric partitioning procedure showed significantly poorer weight loss as early as three months postoperatively than did those receiving gastric bypass. This poorer performance persisted throughout the study period.

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INTRACTABLE, SEVERE OBESITY constitutes the most serious nutritional disorder affecting Americans. It is clear that individuals with just 30% excess weight are at an increased risk of early death.[5] Young men 60% overweight have a 60% increased likelihood of death.[3] In morbidly obese veterans, those in their twenties were 12 times as likely to die as their normal weight peers. Numerous other studies confirm the increased risk of morbidity and death of the obese.

Medical treatment including various diets, group therapies and behavior modification techniques, afford successful weight loss of 20 pounds or more in only 25% of patients and weight loss of at least 40 pounds in about 5%.[2] Of the fortunate minority who lose weight, only 10–30% maintain the weight reduction over a protracted period. These results are quite discouraging to the physician and the patient prompting recourse to surgical forms of therapy. This report documents our experience with a prospective, randomized trial of two forms of gastric alteration: gastric bypass with gastrojejunostomy and a gastric partitioning procedure.[6–8]

Methods

Patient Selection

To qualify for operation, patients were required to be mature adults, usually under the age of 50. Minimal acceptable weight was considered to be twice ideal weight for medium frame individuals from the Metropolitan Life Insurance scale. Associated disorders, such as hypertension, diabetes, low backache, chronic venous stasis, degenerative joint disease, encouraged operative intervention. Patients were required to agree to follow-up examinations, to comprehend the implications and after-effects of operation; and they were fully informed of the randomization process. We attempted to exclude patients with aortic stenosis, ischemic heart disease, reflux esophagitis, or unrealistic expectations.

Preoperative Evaluation

Preoperative evaluation included an admission laboratory screen, a thyroid profile, three-hour glucose tolerance test, vitamin profile, lipid profile, electrocardiogram and x-rays of the chest, stomach, and gall bladder. No psychiatric consultation was obtained.

Treatment groups. Fifty-three consecutive patients were randomized into two treatment groups: Group A (27 patients) received a gastric bypass with Roux-en-Y gastrojejunostomy, and Group B (26 patients) received a gastric partitioning procedure after the manner of Pace and colleagues.[8]

Randomization was effected by preshuffled cards drawn in the operating room at the time of operation. The preoperative average weight for females was 136.62 kg, and for males it was 174.54 kg. Of these, 34% had hypertension, 58% had diabetic glucose tolerance tests, and 30% had hypertriglyceridemia. One patient had a high serum cholesterol. The randomized groups were comparable in age, sex distribution, weight, frequency of hypertension, hypertriglyceridemia and diabetes.

Operation

In both groups, an upper gastric pouch of about 30 cc was created by a single application of the TA-90

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containing 4.8 mm staples. In Group A 13–14 mm anastomoses were effected with the jejunum (Fig. 1). In Group B an opening of 8–9 mm was left by removing two staples from the upper row and one from the lower row. The orifice was then narrowed down around a #18 levin tube with 3-0 prolene sutures which were run from either side of the orifice to the gastric wall to reinforce the staple line.

Postoperative Evaluation

Patients were evaluated for length of postoperative hospitalization, early and late complications, and for weight loss. Weight loss results were arbitrarily assigned as follows: poor—20% or less; fair—greater than 20% up to 25%; good—greater than 25% through 30%; excellent—greater than 30%.

Statistical Methods

All computations were done using the Statistical Analysis System.[1] Groups were compared with respect to preoperative weight, age, sex, concurrent or related complications, laboratory studies, operative and postoperative complications and subsequent weight loss. All weights were expressed as the per cent of starting weight. Differences were tested by means of a t-test or chi-square statistic. The significance level was $p < 0.05$.

Results

Complications

Postoperative hospital time (7.7 days) was essentially the same following either procedure with the exclusion of one patient who developed a suture line leak following gastrojejunostomy and remained hospitalized 58 days. There was no death during hospitalization. The complications are enumerated in Table 1. The groups were compared by means of a chi-square statistic which was not significant for any complications observed.

TABLE 1. *Complications*

Patients	G-J (Gastrojejunostomy) 27	BAF (Baffle) 26
	(Early)	
Wound infection	1	—
Perforation	1	—
Pulmonary embolus	—	1
	(Late)	
Readmit. Vomiting	2	3
Stoma stenosis	1	1
Hypoglycemia	2	—
Wound hernia	1	—
Ureteral stone	1	—
Stomal ulcer	2	—

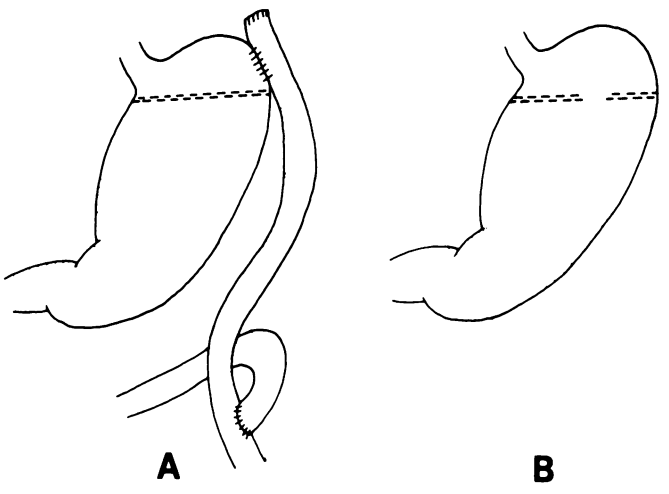

FIG. 1.

Weight Loss

Patients were followed in clinic at variable lengths of time after operation, generally at one, three, six, nine and 12 months. For the purpose of statistical analysis, follow-up examinations were grouped to the nearest three months. Graphs of average group weights at each followup time are illustrated in Figure 2. For each group the weight curve was fitted with a general linear model. For Group A $R^2 = 0.803$ and for Group B $R^2 = 0.800$. In each case the quadratic term (time^2) was highly significant ($p < 0.0001$) demonstrating the tendency of weight loss to level off at some point in time. The time to minimum weight was determined to be 287 days and 390 days for Groups A and B, respectively. This difference was statistically significant ($p < 0.01$).

Average weights in each group were compared for each follow-up examination. These results are in Table 2. Averages were compared by a t-test at each time. A significant difference in weight can be observed as early as three months, $p < 0.01$. This difference persists in its significance throughout the length of follow-up.

Discussion

Gastric bypass with gastrojejunostomy affords good-to-excellent weight loss in about 3/4 of patients, and we expect the average weight to stabilize at about 2/3 of the preoperative weight from our patient experience, prior to and including this trial. Our hope to achieve

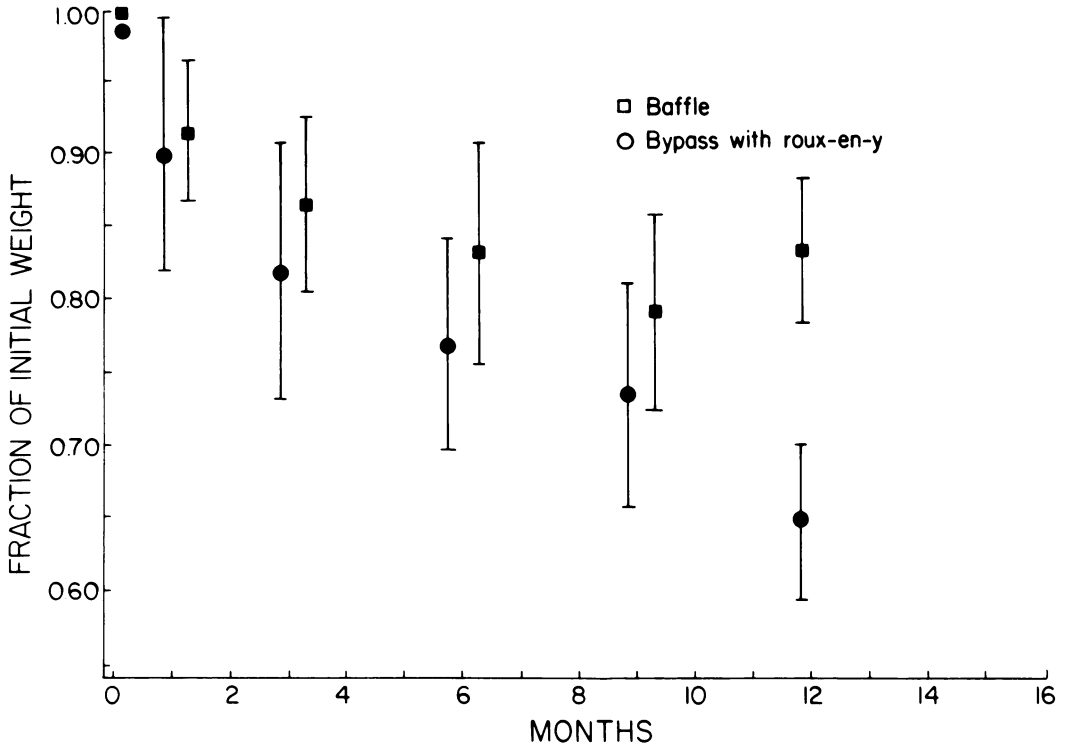

FIG. 2.

similar or better weight loss with a partitioning procedure was not realized in this prospective, randomized trial. In this small number of patients no significant difference in complications was apparent, but we feel an effective partitioning procedure would negate anastomotic leak, late episodes of reactive hypoglycemia, and the development of marginal ulceration. Gomez reports weight loss in his gastroplasties similar to what we have achieved with gastric bypass by employing sutures around the orifice which disallow enlargement.[4] Unfortunately, in our patients who had no external restraint of stomal size, the orifice enlarged sufficiently to allow maintenance of weight. Thus, it appears stomal size may be absolutely critical in gastric partitioning procedures. Anastomotic size may not be quite so critical with bypass procedures since exclusion of most of the stomach still allows some weight loss in most patients.

TABLE 2. *Fraction of Initial Weight*

Follow Up Time (Months)	Operative Group	Number of Patient Visits	Mean Weight/ Initial Weight	p Value
3	Bypass*	38	.82	0.0072
	Baffle†	36	.87	
6	Bypass	17	.77	0.012
	Baffle	24	.83	
9	Bypass	12	.73	0.05
	Baffle	11	.79	
12	Bypass	10	.65	0.0001
	Baffle	6	.84	

* Gastric bypass with Roux-en-Y gastrojejunostomy.
† Gastric partitioning procedure.

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