A Randomized Prospective Trial of Gastric Bypass *Versus* Vertical Banded Gastroplasty for Morbid Obesity and their Effects on Sweets *Versus* Non-Sweets Eaters

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Vertical banded gastroplasty (VBGP) was compared with Roux-en-Y gastric bypass (RYGBP) in a randomized prospective trial that included preoperative dietary separation of "sweets eaters" *versus* "non-sweets eaters." Randomization was stopped at 9 months after 20 patients had undergone each procedure because a greater weight loss ($p < 0.05$) was noted after RYGBP than VBGP. This difference became more significant ($p < 0.001$) at each 3-month interval through 3 years, when patients who had VBGPs had lost 37 ± 20% of excess weight compared with 64 ± 19% for patients who had RYGBPs. The members of the groups were comparable with regard to age, sex, eating habits, morbidity rates before surgery, ideal body weight, and weight before surgery. Although there was no significant difference between the loss of excess weight in "sweets eaters" (69 ± 17%) or "non-sweets eaters" (67 ± 17%) after RYGBP at 1 year, "sweets eaters" who had VBGPs lost significantly less excess weight (36 ± 13%) than did "non-sweets eaters" who had VBGPs (57 ± 18%), $p < 0.02$, or "sweets eaters" who had RYGBPs, $p < 0.0001$. No significant differences were noted for electrolytes, renal or liver function tests, and most vitamins between patients who had VBGPs and RYGBPs; however, patients who had RYGBPs had lower ($p < 0.05$) serum vitamin B_{12} levels (286 ± 149 pg/dl) than did patients who had VBGPs (461 ± 226 pg/dl) at 2 years. By 3 years, the vitamin B_{12} levels were equal in members of the two groups. Five patients who had RYGBPs required endoscopic stomal dilatation for stomal stenosis and one had a marginal ulcer develop, which responded to cimetidine. RYGBP was clearly superior to VBGP for "sweets eaters," probably because of the development of dumping syndrome symptoms. However, RYGBP was associated with a larger number of correctable problems. Thus, it is important to evaluate a patient's eating habits before surgery for morbid obesity; "non-sweets eaters" probably should be treated with VBGP and "sweets eaters" with RYGBP.

MORBID OBESITY is associated with a decreased life expectancy[1-3] and a myriad of serious medical problems, including obesity hypoventilation syndrome,[4] obstructive sleep apnea syndrome,[4] adult onset diabetes,[5] hypertension and cardiovascular diseases,[2] pseudotumor cerebri,[6] chronic lower extremity venous stasis disease,[7] and degenerative osteoarthritis.[8] Morbidly obese patients also tend to have psychosocial problems, including job discrimination[9] and poor self-image.[10] Medical weight control programs have not had acceptable long-term success in the treatment of morbid obesity; the incidence of recidivism after dietary weight loss approaches 95%.[11] The previously popular jejunoileal (JI) bypass was associated with a high incidence of early[12,13] and late[14] complications. By comparison, a significantly lower incidence of complications after surgery, with little difference in weight loss, was noted with gastric bypass.[15-18]

Horizontal gastroplasty has been proposed as a simpler and safer procedure than gastric bypass.[19,20] However, several studies have shown that gastric bypass was more effective than horizontal gastroplasty with an unbanded stoma.[21-26] Suggested reasons for this difference include the inability to maintain a limited stomal size,[24,25] decreased duodenal carbohydrate absorption,[21] or dumping syndrome symptoms that cause a decreased ingestion of sweet foods and beverages.[26,27] This randomized, prospective study was designed to compare the newer vertical banded gastroplasty (VBGP), developed by Mason,[28] with the Roux-en-Y gastric bypass (RYGBP), as well as to evaluate the effectiveness of the two procedures for patients who were identified by dietary evaluation before surgery as being "sweets eaters" or "non-sweets eaters."

Methods

In this study, patients were considered to be morbidly obese if they weighed more than 100 lbs above ideal

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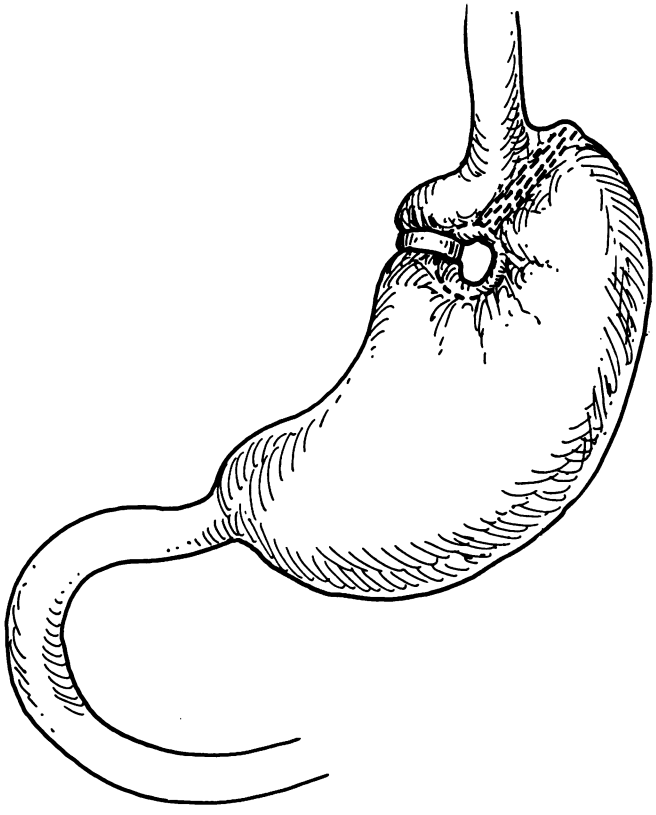

FIG. 1. Vertical banded gastroplasty.

body weight, as determined by the 1959 height/weight tables of the Metropolitan Life Insurance Company.[29] A detailed dietary history, including 24-hour recall and 2-day diary food frequency check,[30,31] was obtained by a registered dietitian. Patients were accepted for surgery if they (1) had failed to lose weight by supervised dietary program(s), or (2) had a significant medical problem related to obesity (*i.e.*, respiratory insufficiency, insulin-dependent adult onset diabetes, pseudotumor cerebri, *etc.*). The patient was classified as a "sweets eater" if he or she consumed more than 300 calories of sweet foods or beverages (*i.e.*, candy, ice cream, nondietetic carbonated liquids, Kool-Aid®, *etc.*) more than three times per average week. All other patients were considered to be "non-sweets eaters." After the conclusion of the study, the patients were re-evaluated with regard to the severity of their problem with eating sweets and reclassified according to the percentage of their total caloric intake in the form of simple carbohydrates, for example, "non-sweets eaters" (<10%), mild (10–15%), moderate (16–25%), or severe "sweets eaters" (>25%).

The risks and benefits of gastric surgery for morbid obesity were discussed in detail with each patient, as was the purpose of the randomized, prospective trial. Informed consent, approved by the Committee on the Conduct of Human Investigation at the Medical College of Virginia, was obtained before surgery for randomization to either operation. The feasibility of performing either procedure was determined at the time of laparotomy, and a randomized card was pulled that selected the operation to be performed. In order that approximately equal numbers of the two procedures would be performed concurrently, cards designating each operation were combined into groups of five each, "shuffled," and a card "blindly" pulled by the surgical secretary when called by the operating room circulating nurse.

Intermittent venous compression boots were applied to the lower legs in all patients before anesthetic induction. A midline incision, from xiphoid to umbilicus, provided adequate exposure with the assistance of a Gomez Polytrac® retractor (Pilling Co., Fort Washington, PA). The VBGP (Fig. 1) was performed according to the method of Mason.[28] The gastrohepatic omentum, lateral to the left gastric artery, was incised from the incisura angularis to the esophagus. The esophagus was bluntly mobilized and encircled with a soft rubber drain in order to identify the cardioesophageal junction and bring the stomach closer to the incision. A 1.5-cm opening was made in the lessor omentum immediately adjacent to the lesser curvature of the stomach, 4 cm distal to the gastroesophageal junction. A #30 Maloney dilator was inserted through the patient's mouth into the stomach and held tightly against the lesser curvature. A 28-mm anvil from an end-to-end anastamosing (EEA®) instrument (U.S. Surgical Corporation, Chicago, IL) was placed on the posterior gastric wall immediately adjacent to the dilator. The central rod of the EEA, attached to a specially designed needle,* was passed through the stomach. The needle was removed and the anvil attached. The EEA was screwed tight and fired, stapling the front wall to the back wall of the stomach and cutting out a 28-mm window. A large red rubber tube was then passed posteriorly from the angle of His through the gastric window, and a TA-90® (U.S. Surgical Corporation) with 4.8-mm staples was applied adjacent to the Maloney dilator and fired. Sponge sticks were used to pull the stomach to the left, creating as small a gastric pouch as possible. A second row of staples was applied as closely as possible to the first row. The pouch volume approximated 30 ml; however, it was not measured as suggested by Mason,[28] because it would not have been possible to make it any smaller. A strip of polypropylene mesh (Marlex®, C.R. Bard Inc., Billerica, MA), designed for reinforcement of hernia repairs, was cut 1.5 cm by 6 cm and inserted through the 1.5-cm lesser curvature opening, around the #30 Maloney dilator, and through the gastric window. The mesh was then sutured to itself with four 2–0 polypropylene sutures so

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that it was tightly applied to the dilator, constructing a stoma of 1 cm diameter. The mesh was marked at 5.0- and 5.5-cm lengths. In all but two cases, the 5-cm length was used. In these other two patients, the circumference was approximately 5.2 cm. The Maloney dilator was then removed, and a #18 nasogastric sump suction catheter was inserted through the patient's nose into the distal gastric pouch. Staple line integrity was tested with methylene blue dye under pressure. The greater omentum was then placed over the Marlex mesh and sutured to the cut edge of the gastrohepatic omentum.

The RYGBP was also constructed in a vertical direction (Fig. 2). The gastrohepatic ligament was incised and the esophagus mobilized. A 1.5-cm opening was made in the lessor omentum immediately adjacent to the lesser curvature of the stomach, 4 cm distal to the cardioesophageal junction. A large red rubber tube was passed through this hole, posterior to the stomach, and to the angle of His, in order to guide a TA-90 stapling device across the stomach. A "vertical" gastric pouch was created, with the use of a sponge stick to bring forth just enough stomach to perform a gastrojejunostomy. The volume of the pouch was approximately 30 ml and equivalent to that of the VBGP pouch. Two superimposed applications of 4.8-mm staples were made. The jejunum was transected with a GIA stapling device (U.S. Surgical Corporation) approximately 12 cm distal to the ligament of Treitz. A 5-cm segment of jejunum was excised with the use of a second application of the GIA in order to create a wide mesenteric opening, which would permit the distal jejunum to reach the stomach easily without tension. A 40-cm Roux limb was constructed with GIA® and TA-55® stapling devices with the use of 3.5-mm staples. The Roux limb was brought retrocolic and anastamosed to the small stomach pouch as a "side-to-side" anastamosis with an inner row of continuous, nonlocking, 2–0 polyglycolic acid (Dexon®, Davis and Geck, American Cyanamid Co., Danbury, CT) sutures and an outer row of interrupted vertical mattress, 3–0 silk sutures. The gastric and jejunal enterotomies were made with the use of electrocautery. The Dexon sutures were tied tightly around a #30 Maloney dilator, passed through the patient's mouth, in order to construct a 1-cm-diameter stoma equivalent to that of the VBGP. The anastamosis and staple lines were tested with methylene blue inserted via the nasogastric tube. Chromic catgut, 3–0, was used to sew the Roux limb to the mesocolon as well as to close the mesenteric defect at the Roux-en-Y anastamosis. A #18 mushroom catheter gastrostomy tube was inserted into the antrum of the distal gastric pouch and brought out through a stab wound on the patient's right side, so that it would not cross the Roux limb.

Patient care after surgery was similar in the two groups. The nasogastric tube was removed when drainage was less than 100 ml in 8 hours, which was usually the morning after surgery. The diet was advanced slowly: 30 ml "clear liquids" per hour, as desired, the second postoperative day; 60 ml per hour the third day; *ad libitum* the fourth day; and advanced to a blenderized diet on the fifth day. The large wound suction drain was removed when it drained less than 5 ml in 8 hours. For patients with RYGBPs, the gastrostomy tube was clamped 3 out of each 4 hours on the fourth postoperative day if it drained less than 300 ml per 8 hours, and then clamped continuously the next day.

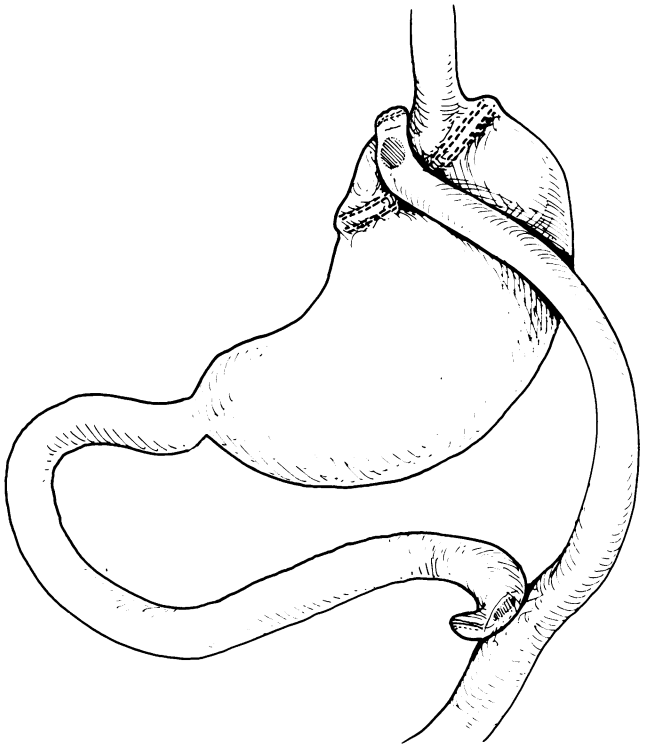

FIG. 2. Roux-en-Y gastric bypass.

The patient was given complete dietary instructions by a registered dietitian before discharge. Each patient was instructed to eat a blenderized diet for the next 6 weeks, with a minimum of 44 g of protein per day. In addition, each was to take a multivitamin capsule with minerals daily for the rest of his or her life. Supplemental calcium was added if dietary sources were inadequate. Initially, children's chewable vitamins with minerals were recommended until the patient felt comfortable swallowing an adult vitamin capsule. A dietary manual with detailed instructions was given to each patient. An upper gastrointestinal (UGI) radiographic study was obtained and used as a baseline, and the patient was usually discharged on the sixth or seventh postoperative day.

The patients were asked to return 2 weeks after discharge, at which time a thorough dietary interview was

TABLE 1. *Demographics and Weight Loss after Roux-en-Y Gastric Bypass (RYGBP)* Versus *Vertical Banded Gastroplasty (VBGP)*

	RYGBP	VBGP
Age (years)	38 ± 11	38 ± 9
Male/female	2/18	2/18
Black/white	5/15	10/10
Percentage ideal body weight		
Before surgery	213 ± 49 (20)*	225 ± 41 (20)
One year	138 ± 32 (19)†	176 ± 41 (18)
Two years	139 ± 32 (18)†	178 ± 41 (17)
Three years	142 ± 37 (18)†	180 ± 44 (16)
Weight loss (lbs)		
One year	96 ± 25 (19)‡	71 ± 24 (18)
Two years	96 ± 34 (18)‡	67 ± 27 (17)
Three years	91 ± 28 (18)†	60 ± 32 (16)
Percentage decrease in weight		
One year	33 ± 7 (19)‡	22 ± 8 (18)
Two years	33 ± 9 (18)‡	22 ± 9 (17)
Three years	32 ± 9 (18)†	20 ± 10 (16)

* Number of patients in parentheses.
† $p < 0.01$,
‡ $p < 0.001$.

conducted by a registered dietitian. The patients were weighed, examined, and interviewed by the surgeon, and blood was drawn for complete blood count (CBC) and SMAC. Patients who had RYGBPs had their gastrostomy tubes removed at this visit. Patients came for further follow-up visits, when possible, at 1½, 3, 6, and 9 months and 1 year after surgery and yearly thereafter. Evaluation at these visits included patient's compliance with prior dietary instructions, including daily use of vitamin/mineral supplementation; tolerance and use of sweets; problems with "nibbling"; estimated caloric intake; adequate protein, fiber, and calcium ingestion; and the presence or severity of constipation or diarrhea and other medical problems.

Exercise and psychosocial factors were also addressed at each visit. Blood was obtained at 1 and 2 years after surgery to test for CBC, SMAC (Sequential Multiple Analyzer Computer, Technicon Instruments Corp., Terrytown, NY), serum zinc (Zn), iron (Fe), magnesium (Mg), transferrin, folic acid, ascorbic acid (vitamin C), thiamine (vitamin B_1), pyridoxal phosphate (vitamin B_6), and cyanocobalomin (vitamin B_{12}). At 3 years, only blood for CBC, SMAC, vitamin B_{12}, and folic acid were obtained.

Data were evaluted using analysis of covariance with Statistical Analysis System (SAS) general linear models or Student's t-test for unpaired data, as appropriate. Weight loss ± SD was calculated as pounds lost, percentage of weight lost, percentage of excess weight lost, and percentage of ideal body weight achieved. At the outset of the study, it was determined that weight loss data would be analyzed at monthly intervals, beginning at 6 months after the start of the trial. Should one procedure be superior to the other, with a $p < 0.05$, the study would be stopped, because a number of patients would have only recently had their operations and would not have had time to achieve significant weight loss. If statistical significance less than 0.01 was not present when all patients had reached an equivalent time interval after surgery, the study would be reopened and continued until this level of statistical significance was noted.

Results

The randomized study started in June 1982 and was terminated 9 months later, when a statistically significant difference at $p < 0.05$ was noted in favor of the RYGBP. At this time, it was 5 months after surgery for nine patients with RYGBPs and nine patients with VBGPs. Twenty patients had been selected at random for each procedure when the study was stopped. No significant differences were noted between the two groups with regard to age, sex, ideal body weight, or percentage of ideal body weight (Table 1).

VBGP Follow-up

One patient with VBGP was lost to follow-up shortly after surgery, and all attempts to locate him were unsuccessful. One patient who had VBGP failed to lose weight and noticed the ability to eat without limit 2 months after surgery. UGI radiographic study confirmed a significant staple line disruption. She was subsequently converted to RYGBP. This patient was excluded from subsequent comparison with RYGBP but should obviously be considered as a VBGP failure. Thus, there were 18 patients with VBGPs available for comparison with RYGBPs at 1 year. A third patient with VBGP, who had severe respiratory insufficiency of obesity, had a transient initial weight loss with improvement in his breathing difficulties but subsequently had his VBGP procedure fail because he frequently ate sweets and high-starch foods; UGI and endoscopic studies confirmed an intact staple line and small (1 cm diameter) stoma. His severe obesity hypoventilation and obstructive sleep apnea syndromes[4] recurred, and he was converted to a gastric bypass 18 months after the VBGP was performed. A fourth patient with VBGP, who had lost only 8% of her excess weight by 2 years, was fatally stabbed by her husband 25 months after the VBGP was performed. A fifth patient with insulin-dependent adult onset diabetes and pseudotumor cerebri failed her VBGP, having lost only 15% of excess weight over 3 years, and was also converted to a gastric bypass at 38 months after the VBGP was performed. A sixth patient, who weighed 415 lbs before the VBGP was performed, lost only 22 lbs in the first 2 years after surgery. She admitted drinking 3,000 kcal of Kool-Aid per day and

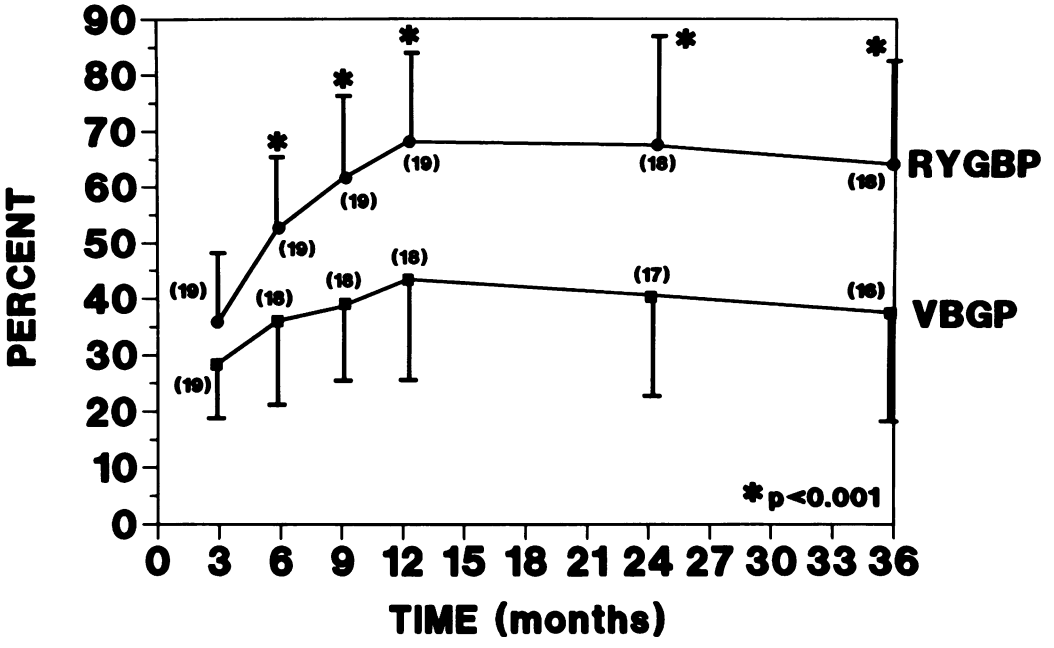

FIG. 3. The percentage loss of excess weight ± SD (N) over 3 years after Roux-en-Y gastric bypass (RYGBP) compared with vertical banded gastroplasty (VBGP).

claimed she became extremely nervous and angry if she couldn't have her sugar. Attempts at behavior modification were unsuccessful. She was then lost to follow-up for the next 14 months until she returned at 38 months after the VBGP was performed, weighing 405 lbs, and elected to undergo conversion to gastric bypass. Thus, 18 patients who had VBGPs were available for follow-up at 1 year, 17 at 2 years, and 16 at 3 years.

RYGBP Follow-up

One 470-lb patient who had RYGBP died suddenly on the fourth postoperative day. Postmortem examination did not reveal the cause of death, which was presumed secondary to an arrhythmia. A second patient who had RYGBP, with myotonic dystrophy and a permanent transvenous pacemaker for complete heart block placed before surgery for obesity, died suddenly 13 months after surgery. Autopsy again failed to reveal the cause of death, which was thought to be secondary to cardiac arrhythmia, known to occur in patients with myotonic dystrophy.[32] Thus, 19 patients with RYGBPs were available for follow-up at 1 year and 18 at both 2 and 3 years after surgery.

Comparison Overall of VBGP with RYGBP

When all patients in the randomized study had reached 6 months after surgery, the difference in loss of excess weight between VBGP and RYGBP became statistically significant at $p < 0.001$ and remained so through 3 years (Fig. 3). Patients with VBGPs lost 43 ± 18% excess weight at 1 year *versus* 68 ± 17% for patients with RYGBPs. The weight loss differences between the two procedures were also significant if evaluated as percentage of ideal body weight, absolute weight loss, or percentage of weight lost (Table 1). By 3 years, although three patients with VBGPs had already been converted to RYGBP, 11 patients with VBGPs still weighed more than 150% of their ideal body weight (Fig. 4), in contrast to five patients with RYGBPs (Fig. 5), and no patient with a VBGP weighed less than 130% of ideal body weight, in contrast to six patients who had RYGBPs.

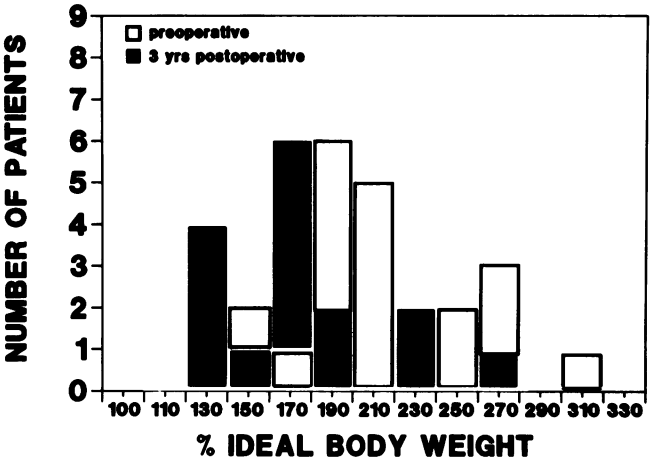

FIG. 4. Distribution of percentage ideal body weight (IBW) in patients before and 3 years after vertical banded gastroplasty (VBGP) for morbid obesity. Of the 20 patients who had VBGPs, 4 patients (percentage IBWs before surgery 201, 226, 254, and 268, respectively) were unavailable for 3-year follow-up (see text).

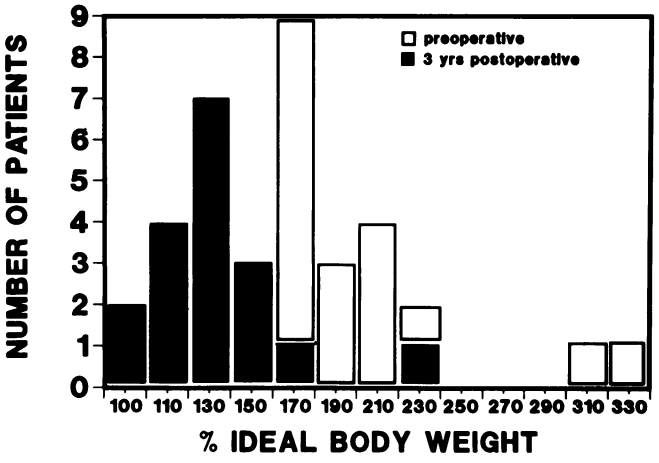

FIG. 5. Distribution of percentage ideal body weight in patients before and 3 years after Roux-en-Y gastric bypass (RYGBP) for morbid obesity. Of the 20 patients who had RYGBPs, 2 patients (percentage IBWs before surgery 185 and 320, respectively) were unavailable for 3-year follow-up (see text).

Sweets Versus *"Non-Sweets Eaters"*

At 1, 2, or 3 years after surgery, patients who had been identified before surgery as "sweets eaters" and had VBGPs were noted to have lost significantly less excess weight ($p < 0.05$) than "non-sweets eaters" with the same operation (Table 2). There was no significant difference at 1 year between "sweets eaters" and "non-sweets eaters" who had undergone an RYGBP (69 ± 17% *vs.* 67 ± 17%, respectively). The difference in loss of excess weight between "sweets eaters" with VBGPs *versus* RYGBPs was highly significant, $p < 0.0001$ (Table 2). Of the 12 patients who had VBGPs who were initially identified as "sweets eaters," nine were subsequently reclassified as severe (>25% of their total caloric intake was constituted of simple carbohydrates), two moderate (16–25%), and one mild (10–15%) "sweets eaters." Of the 12 patients with RYGBPs who were initially classified as "sweets eaters," seven were reclassified as severe, two moderate, and three mild "sweets eaters."

TABLE 2. *Percentage Decrease in Excess Weight in "Sweets Eaters" Versus "Non-Sweets Eaters" with Roux-en-Y Gastric Bypass (RYGBP) Versus Vertical Banded Gastroplasty (VBGP)*

	"Sweets Eaters"	"Non-Sweets Eaters"
RYGBP	(1) 69 ± 17 ⟨12⟩ (2) 62 ± 19 ⟨11⟩ (3) 59 ± 17 ⟨11⟩	67 ± 17 ⟨7⟩ 75 ± 19 ⟨7⟩ 71 ± 21 ⟨7⟩
VBGP	(1) 36 ± 13 ⟨12⟩ (2) 35 ± 14 ⟨11⟩ (3) 32 ± 18 ⟨11⟩	57 ± 18 ⟨6⟩ 53 ± 22 ⟨6⟩ 50 ± 21 ⟨5⟩
	$p < 0.0001$	NS
	NS	$p < 0.05$

( ) = number of year(s) since surgery; ⟨ ⟩ = number of patients; NS = not significant.

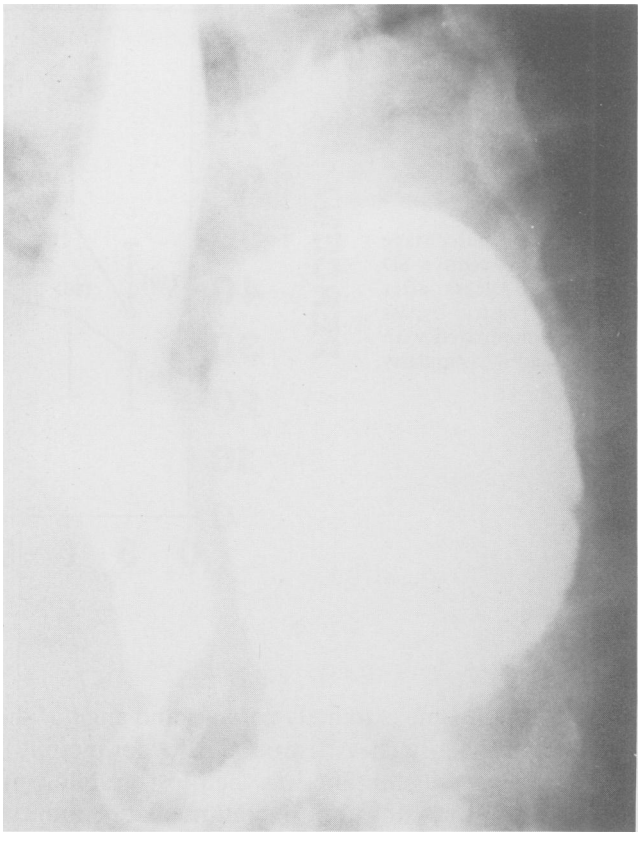

FIG. 6. Upper gastrointestinal series in patient who weighed 415 lbs before vertical banded gastroplasty showing 1-cm-diameter stoma connecting small proximal gastric pouch with remaining stomach.

Fifty per cent of the patients with RYGBPs stated that eating sweets made them feel "light-headed," nauseous, flushed, or sweaty or gave them severe watery diarrhea (*i.e.*, the "dumping syndrome"). Another 25% stated that they were either afraid to try sweets or had lost their taste for them. Three patients with RYGBPs never had dumping syndrome symptoms develop. Each patient with a VBGP who had lost less than 50% of his or her excess weight had a UGI examination 1 year after surgery to determine if his or her staple line had disrupted or the stoma had expanded. In addition, five patients also had endoscopic evaluation. Except for one patient who disrupted her staple line at 1 month after surgery, none of the other patients with VBGPs had evidence of staple line disruption, stomal dilatation, or excessive pouch expansion (Figs. 6 and 7). In the three patients converted to gastric bypass, the polypropylene mesh band was removed and the stoma stapled shut. In all three instances the band measured 5.0 cm in length (Fig. 8). In one patient without symptoms, the mesh band had eroded into the distal stomach at the EEA staple line, but the stomal channel was intact (Fig. 8).

At 2 and 3 years after surgery, there was a decrease in percentage excess weight loss for both the "sweets" and "non–sweets eaters" in the patients with VBGPs (Table 2), but this was not statistically significant. In the patients with RYGBPs at 2 and 3 years, the "sweets eaters" also appeared to not be doing as well as the "non–sweets eaters" (Table 2). However, this difference also was not statistically significant, possibly as a result of a small sample size creating a type 2 statistical error.[33] The five patients with RYGBPs who were 150% heavier than their ideal body weights at 3 years after surgery (Fig. 5) admitted to either the frequent ingestion of high-fat "junk foods," such as potato or corn chips (four patients), and/or that dumping syndrome symptoms did not follow the ingestion of simple carbohydrates (three patients). UGI studies in these patients, 2–3 years after surgery, did not reveal gastric pouch or stomal dilatation.

Laboratory Data and Complications

No significant deficiencies in either the patients with VBGPs or RYGBPs were noted for hemoglobin; transferrin; albumin; vitamins B_1, B_6, or C; folic acid; serum iron; total calcium; magnesium; or zinc levels at 1 or 2 years after surgery. No abnormalities in renal function tests (blood urea nitrogen or serum creatinine), liver function tests (serum bilirubin, alkaline phosphatase, serum glutamic–oxaloacetic acid transferase, or serum glutamic–pyruvic acid transferase), or standard electrolytes (sodium, potassium, chloride, or carbon dioxide) were noted in the patients with RYGBPs or VBGPs at 1, 2, or 3 years after surgery. Patients with RYGBPs had lower ($p < 0.05$) vitamin B_{12} levels (286 ± 149 pg/ml) than did patients with VBGPs (461 ± 226) at 2 years. Two patients with RYGBPs had values less than 100 pg/dl, one between 100 and 200 pg/dl, and four between 200 and 300 pg/dl. Only three patients with VBGPs had vitamin B_{12} values below 300 pg/dl. However, after an intensive patient educational program, there was no difference in vitamin B_{12} levels between the patients with

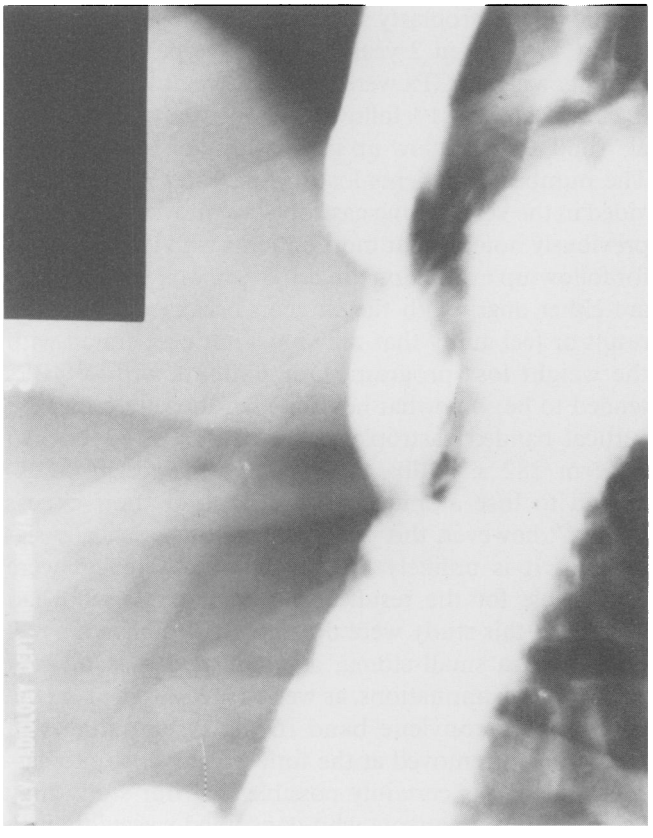

FIG. 7. Upper gastrointestinal series in same patient as in Figure 6 1 year after vertical banded gastroplasty after she had lost only 22 lbs, showing absence of either pouch or stomal dilatation. This patient admitted drinking approximately 3,000 kcal of Kool-Aid daily.

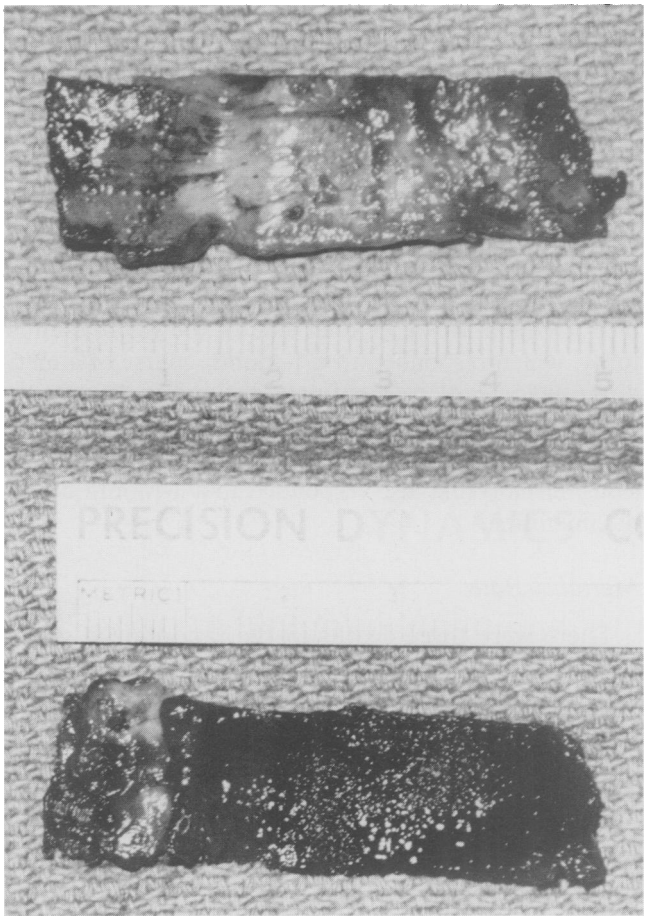

FIG. 8. Excised polypropylene mesh collars at the time of conversion to gastric bypass in two patients with vertical banded gastroplasties who had lost only 10% and 15% of excess weight, respectively, 3 years after surgery. In both instances, the mesh measured 5.0 cm in length, the same as when initially inserted. In addition, one collar had eroded into the distal stomach at the lateral portion of the EEA staple line (note darkened area of mesh in lower part of figure).

VBGPs or those with RYGBPs (411 ± 145 and 410 ± 331, respectively) at 3 years after surgery, although three patients with RYBGPs still had levels below 150 pg/ml. Furthermore, at this time three patients with RYGBPs were receiving vitamin B_{12} injections.

Five patients with RYGBPs had intractable vomiting develop and were found on endoscopic examination to have stomal stenosis. Each of these patients had endoscopic balloon catheter stomal dilatation with a 12-mm-diameter balloon.[34] One patient had a 0.5-cm marginal ulcer develop on the jejunal side of the gastrojejunostomy, which responded to a 1-month course of cimetidine (300 mg qid). As mentioned previously, one patient with a VBGP disrupted her vertical staple line 1 month after surgery and one patient had superficial stomal erosions develop that also responded to a 1-month course of cimetidine.

Mortality Rate

There were three deaths in the randomized study. These included a 470-lb woman who died suddenly 3 days after RYGBP and one patient with myotonic dystrophy who had a pacemaker, for complete heart block, placed before surgery for obesity. The latter patient died 1 year after RYGBP, having decreased her weight from 250 lbs to her ideal body weight. Autopsy in both patients failed to reveal the cause of death, which was presumed to be secondary to cardiac arrhythmias. A third patient was fatally stabbed by her husband 25 months after VBGP, having only lost 20% of her excess weight. Since the randomized study, an additional 254 patients have undergone primary gastric procedures for obesity, with two late sudden deaths. One patient with hypertrophic subaortic stenosis died 5 months after RYGBP, and one patient with severe obesity hypoventilation syndrome, biventricular heart failure before surgery with frequent multifocal premature ventricular contractions, died suddenly 5 weeks after RYGBP and also had an unrevealing autopsy. Thus, the total operative (<30 days) mortality rate was 0.4% and the overall disease-related mortality rate, 1.6%.

Discussion

All prior prospective studies have noted a significant weight loss difference in favor of the gastric bypass over gastroplasty procedures. This has been attributed to technical difficulties in maintaining a small gastroplasty stoma,[24,25] possible decreased carbohydrate absorption when the duodenum is bypassed,[21] or decreased ingestion of sweets with the gastric bypass as a result of the development of dumping syndrome symptoms.[26,27] It is currently thought that the VBGP is the best of the gastroplasty procedures[28,35,36]; however, this study still found a significantly better weight loss with RYGBP when compared with VBGP. This appeared to be primarily a result of the development of dumping syndrome symptoms after gastric bypass, because most patients stated that the ingestion of sweets made them flush, feel nauseous or light-headed, or have diarrhea. Absence of stomal and pouch dilatation were documented with UGI examinations after surgery in patients who had done poorly after either RYGBP or VBGP (Figs. 6 and 7). In three patients, the polypropylene mesh band was excised at the time of conversion to RYGBP and measured to be 5 cm or less in length (Fig. 8). It is also possible that patients with RYGBPs may have had decreased carbohydrate absorption as a result of distal gastric and duodenal bypass, although this would be difficult to validate. Makarewicz et al.[37] also noted that weight loss after VBGP was not as favorable in their experience as that claimed by Mason et al.[35] or Deitel et al.[36]

It is difficult to understand the reasons for the less favorable weight loss results after VBGP in this study, which averaged 43 ± 18% loss of excess weight at 1 year, when compared with the other vertical banded gastroplasty study, where the average loss of excess weight was 61 ± 23% and 68 ± 21%, respectively,[35,36] or a vertical silastic ring gastroplasty study,[38] where the loss of excess weight was 63% at 2 years. Ninety-five per cent of our patients with VBGPs were followed for at least 3 years, in contrast to an 81% follow-up in the study of Mason et al.[35] and a 90% follow-up in the study of Deitel et al.[36] The number of patients lost to follow-up was not provided in the vertical ring gastroplasty study.[38] It has been previously noted[23] that most patients who do not return for follow-up evaluation are not doing well because they are either angry with the surgeon because of the poor result or feel guilty that they have not cooperated with the weight loss program. Our patients with VGBPs tended to be somewhat heavier than those in either[35,36] vertical banded gastroplasty study (314 ± 57 *vs.* 286 ± 51 or 282 ± 48 lbs, respectively) and might be expected to lose a smaller percentage of their excess weight[39]; however, this difference is not statistically significant. It is unlikely that technical differences were responsible for the results, because patients who had failures in this study were documented to have a small pouch and a small stoma, as confirmed by UGI and endoscopic examinations, as well as measurement of the excised polypropylene band in the three patients in whom it was removed at the time of conversion to gastric bypass. It is certainly possible that our study may have had more patients who consumed sweets than in the studies from Iowa, Toronto, or Denver, which might explain the different results. Of interest, Deitel et al.[36] noted that 20% of their patients lost less than 50%, and

7% lost less than 30% of their excess weight at 1 year after VBGPs, confirming that there is a group of patients who will fail this procedure.

A significantly better weight loss was noted in patients who were identified before surgery as "sweets eaters" and subsequently had RYGBPs than "sweets eaters" who had VBGPs. This provides further evidence to support the dietary assessment technique.[30,31] Many patients with VBGPs admitted to the ingestion of sweet carbonated beverages or "ades" and candy and stated that these high caloric items caused no problems; this differed from the patients with RYGBPs who frequently noted unpleasant dumping symptoms with the ingestion of sweets. Furthermore, the patients with RYGBPs often stated that they were delighted with their loss of dependence on sweets. Three patients with VBGPs who denied a problem with sweets before surgery noted that "sweets went down easier" than other foods after the operation. More recently, Mason et al.[35] have suggested that the stomal banding be decreased to 4.5 cm circumference for the "superobese," that is, those weighing more than 225% of their ideal body weights. It is difficult to believe that a smaller stoma will prevent the ingestion of candy or carbohydrate beverages by superobese patients, who we have noted to frequently be addicted to sweets.

Although there was no difference between "sweets eaters" and "non-sweets eaters" at 1 year after RYGBP, the "sweets eaters" did not do as well as the "non-sweets eaters" at 2 and 3 years after RYGBP. This difference was not statistically significant; however, this may have been because of the small sample size and the result of a type 2 statistical error.[33] Five of the patients with RYGBPs weighed more than 150% of their ideal body weights 3 years after surgery and admitted to the frequent ingestion of small amounts of sweets or nibbling high caloric fatty foods or starches, such as potato or corn chips, buttered popcorn, *etc.*, which do not cause dumping syndrome symptoms. It is possible that these patients will require a malabsorptive procedure such as the partial biliopancreatic bypass procedure.[40]

In this study, no attempt was made to reinforce the gastric bypass stoma with a silastic ring, as others have suggested,[24] for fear of erosion of the silastic into the stomal lumen. Stomal dilatation was not a problem in our study; in fact, stomal stenosis was a greater concern, having occurred in 25% of the patients with RYGBPs. The high incidence of stomal stenosis may have resulted from the use of electrocautery to make the enterotomies. Stomal stenosis uniformly responded to endoscopic balloon catheter dilatation[34] and is a more acceptable complication than a stoma that is too large, because the latter requires reoperation to correct the problem.

No abnormalities were noted in electrolytes, liver or renal function tests, or any of the vitamins tested, except vitamin B_{12}, nor were there any significant differences in these values between patients with RYGBPs or VBGPs. The absence of electrolyte and vitamin deficiencies was probably related to our strong emphasis on daily supplementation with a multivitamin and mineral capsule, because it has been shown that surgery for morbid obesity, especially RYGBP, can lead to multiple vitamin deficiencies.[41,42] We did not note a problem in this study with iron deficiency anemia. However, others have noted iron deficiency anemia in patients after RYGBP that has been refractory to oral iron supplementation.[42] This has also been our experience in a few patients with dysfunctional uterine bleeding after RYGBP. There was a significantly lower level of vitamin B_{12} in patients after RYGBP, at both 1 and 2 years after surgery. This was rarely noted after VBGP. Most patients corrected their vitamin B_{12} deficiency with additional oral supplementation of 250 μg per day; three patients required monthly B_{12} injections.

There were three deaths in this randomized study, including two sudden deaths 3 days and 1 year after RYGBP and one homicide 25 months after VBGP. Since completion of the randomized study, 254 patients have had primary gastric surgical procedures for obesity, with two additional late sudden deaths, for a total operative (<30 days) mortality rate of 0.4% and an overall disease-related mortality rate (early plus late sudden deaths) of 1.6%. All but one of the sudden deaths were associated with severe cardiopulmonary problems associated with morbid obesity before their gastric procedures. Sudden death has been documented in patients after massive weight loss and may be associated with a prolonged QT interval on the electrocardiogram.[43]

In conclusion, RYGBP was associated with a significantly better weight loss than was the VBGP. However, this was at the expense of a 25% incidence of stomal stenosis, an occasional marginal ulcer, and a significantly greater incidence of vitamin B_{12} deficiency. Patients who were addicted to sweets before surgery did poorly with VBGP, because they were still able to eat high calorie sweets and drink nondietetic beverages. "Sweets eaters" had significantly better results with RYGBP, because this procedure was associated with unpleasant dumping symptoms with the ingestion of simple carbohydrates. These symptoms abated somewhat in the second and third year after RYGBP, with a moderate, but insignificant, weight gain in the "sweets eaters."

This study strongly suggests that surgical weight reduction procedures should be individually tailored to the eating habits of the patient in order to be maximally effective in weight control, while minimizing complications. Validation of this study will require a significant improvement in the VBGP results after selective assign-

ment of patients who are not addicted to sweets to the gastroplasty procedure.

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Discussion

DR. HERSCHEL A. GRAVES, JR. (Nashville, Tennessee): Dr. Sugerman is to be congratulated for his excellent series of cases and his pursuit of a patient-procedure selection. This is the first investigation of this patient selection of which I am aware, and I hope that it holds up in the long term. I do not disagree with anything he said, but I would like to talk a little bit about complications of the gastric bypass gastrojejunostomy procedure.

From 1978 until the spring of 1982, I performed 125 gastric stapling