# Prospective Evaluation of Biliopancreatic Diversion With Roux-en-Y Gastric Bypass in the Super Obese

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The aim of this study was to determine prospectively the efficacy and safety of the biliopancreatic diversion with Roux-en-Y gastric bypass (BPD with RYGBP) procedure used as the primary bariatric procedure in super obese patients. The main characteristics of the BPD with RYGBP procedure were a gastric pouch of 15 ± 5 ml, biliopancreatic limb of 200 cm, common limb of 100 cm, and alimentary limb of the remainder of the small intestine. From June 1994 through July 2003, 132 super obese patients (body mass index [BMI]:  $57 \pm 7$ ), with an incidence of comorbidities  $6 \pm 2$  per patient, underwent BPD with RYGBP and subsequent follow-up. Mean follow-up time was 29 ± 14 months. Maximum weight loss was achieved at 18 months postoperative with average excess weight loss (EWL) 65%, average initial weight loss (IWL) 39%, and average BMI 35 kg/m<sup>2</sup>. Thereafter, a decline was observed with EWL stabilizing at around 50%, IWL at around 30%, and BMI at around 40 kg/m<sup>2</sup>, respectively, by the end of the study period. The majority of preexisting comorbidities were permanently resolved by the 6-month follow-up visit. Early mortality was 1% and early morbidity was 11%. Late morbidity was 27%, half of which was due to incisional hernia. Deficiencies of microelements were mild and successfully treated with additional oral supplementation. The incidence of hypoalbuminemia was 3% and there were no hepatic complications. We conclude that BPD with RYGBP is a safe and effective procedure for the super obese with few metabolic complications. (J GASTROINTEST SURG 2004;8:479-488) © 2004 The Society for Surgery of the Alimentary Tract

KEY WORDS: Morbid obesity, super obesity, biliopancreatic diversion, distal gastric bypass, malabsorption

#### INTRODUCTION

Surgical treatment remains the only effective approach for the long-term management of morbid obesity. Bariatric operations have been defined as restrictive, malabsorptive, or a combination of both.<sup>2</sup> Super obesity has a more complicated clinical course following surgery, attributable to increased comorbidity, and a significant long-term failure rate associated with restrictive bariatric operations.<sup>3</sup> Many investigators suggest that surgical procedures in which malabsorption is the main component will result in better maintenance of weight loss and increased rate of success.4,5

It is generally accepted that biliopancreatic diversion (BPD) refers to a pathophysiological change based on an anatomic arrangement within the gastrointestinal (GI) tract that diverts bile and pancreatic secretions from their usual anatomic paths and not to a specific operation, thus BPD can be achieved in different ways. 4 Weight loss maintenance after these operations is primarily due to intestinal malabsorption.<sup>5</sup> In fact, the long-term weight loss results are remarkable; however, this is at the expense of a considerably high rate of metabolic complications.<sup>6,7</sup> The main representatives of malabsorptive procedures are the Scopinaro type BPD<sup>6</sup> and the duodenal switch modification described by Hess.<sup>8</sup> In addition, several forms of "distal gastric bypass" have been described. Actually, these procedures are modifications of the standard Roux-en-Y gastric bypass, where the mixing of bile and pancreatic juice with food takes place more distally in the jejunum or the terminal ileum with various lengths of intestinal limbs.<sup>5,7,9–11</sup>.

A particular type of BPD procedure is performed at our institution in an attempt to achieve acceptable weight loss results and resolution of comorbidities

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without the high rate of metabolic complications reported for other types of biliopancreatic diversion. The aim of this study is to report the effectiveness, complications, and long-term results of this surgical approach specifically in the super obese patient population.

#### MATERIALS AND METHODS

From June 1994, when the Morbid Obesity Clinic of the Department of Surgery was established at the University Hospital of Patras, through July 2003, 353 morbidly obese patients have undergone various bariatric procedures at our institution. In this study we present our experience with the use of biliopancreatic diversion with Roux-en-Y gastric bypass (BPD with RYGBP) in a super obese population.<sup>12</sup> From our bariatric database, the prospectively collected followup data of 132 super obese patients (BMI  $\geq$  50) who underwent biliopancreatic diversion with Roux-en-Y gastric bypass (BPD with RYGBP) were selected and studied. The patients' preoperative characteristics are shown in Table 1. Whenever a revision bariatric procedure was performed, follow-up results from these patients were not included thereafter in the study. A multidisciplinary team, including the surgeon, an endocrinologist, a cardiologist, a pneumonologist, a psychologist, and a nutritionist-dietitian, evaluated all patients preoperatively and postoperatively to assess and optimize their physical condition.

## Surgical Technique

The main characteristics of the BPD with RYGBP procedure were a gastric pouch of  $15 \pm 5$  ml, a biliopancreatic limb of 200 cm, a common limb of 100 cm, and an alimentary limb of the remainder of the small intestine. A detailed presentation of the procedure is as follows: under general and epidural anesthesia the abdomen was entered via a midline abdominal incision from the xiphoid process to just

**Table 1.** Preoperative patient characteristics

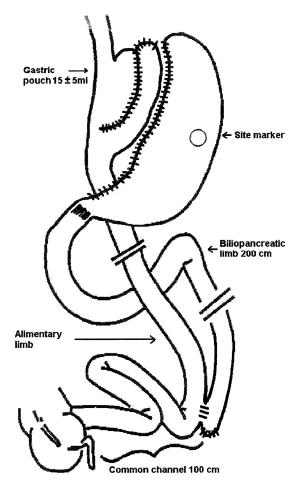
	BPD with RYGBP
Number of patients	132
Sex (male/female)	34/98
Age (years)	$36 \pm 10$
Height (cm)	$164 \pm 9$
Weight (kg)	$156 \pm 25$
Excess weight (kg)	$95 \pm 21$
BMI (kg/m <sup>2</sup> )	$57 \pm 7 \text{ (range: } 50-85)$

BMI = body mass index.

below the umbilicus. The small intestine was divided 200 cm distal to the ligament of Treitz with a linear stapler gastrointestinal anastomosis (GIA) (Tyco Healthcare, USSC, Norwalk, CT) using a 2.5-mm stapling cartridge thus forming the biliopancreatic limb. The jejuno-ileal enteroenterostomy was constructed 100 cm from the ileocecal valve with a linear stapler GIA in a side-to-side fashion creating a common channel of 100 cm. The mesenteric window was closed with 2-0 absorbable sutures. After mobilization of the gastroesophageal junction, a vertical 4cm long pouch of  $15 \pm 5$  ml was created at the lesser curvature of the stomach using a twice-fired TA90B (Tyco Healthcare) superimposed without complete anatomic separation from the bypassed gastric remnant.

Before the stapler was fired, the capacity of the pouch was measured by infusing 15 ml saline solution into it at a pressure of 70 cm  $H_2O$ . By the end of the first year, 5 of the first 69 patients had developed partial staple dehiscence (7%), thus creating a gastrogastric fistula. For this reason, in the remaining 63 patients of the present study, and in all patients thereafter, the gastric pouch was transected from the bypassed distal stomach with the use of EndoGIA staplers (Tyco Healthcare) and the Roux-Y limb interposed between the pouch and the bypassed stomach. In these patients the volume of the gastric pouch was visually estimated. The Roux-Y jejunal limb was brought through an opening in the transverse mesocolon, positioned in a retrogastric location, and an end-to-side anastomosis was performed between the gastric pouch and the jejunum using a single layer of running absorbable sutures polydioxanone (PDS) 3-0, creating an internal stoma of 1.5 cm. The defect in the transverse mesocolon was closed with a running 2-0 absorbable suture. A silastic round site marker was placed on the anterior wall of the gastric remnant and secured on the anterior abdominal wall (Fig. 1). A closed-suction drain was positioned near the gastrojejunal anastomosis.

Cholecystectomy was always added to the main procedure. Appendectomy was also routinely performed at the time of the main procedure to exclude the possibility in the future of confusing right-quadrant colicky pain due to lipid malabsorption with appendicitis. Furthermore, because fatty liver and nonalcoholic steatohepatitis are common in the super obese, liver biopsy was routinely performed to assess preoperative liver histopathology to be used as a baseline for comparison if a problem in hepatic function should arise in the future. The fascia of the abdominal wall was closed using continuous running double-stranded PDS-1 suture starting at both ends of the



**Fig. 1.** Diagram of biliopancreatic diversion with Roux-en-Y gastric bypass procedure.

wound and tied in the middle. Nonsubcutaneous sutures or drains were used. The skin was closed with staplers. Perioperatively, a second-generation cephalosporine and metronidazole were prescribed. Low molecular weight heparin (nadroparin 9500 IU anti-Xa) was administered subcutaneously daily and sequential compression devices were used perioperatively.<sup>13</sup>

# Postoperative Dietary Management

All patients underwent extensive nutritional counseling by our team's dietitian and followed a specific dietary protocol. On the fourth postoperative day, after uneventful upper GI radiologic evaluation, a liquid diet was started which was progressively increased to include blenderized foods before hospital discharge. Over the next 4–6 weeks, patients were gradually advanced to a more varied soft diet until regular foods were tolerated. During this time, all patients received high-protein dietary supplements.

After surgery all patients also received a daily multivitamin and mineral supplement and two grams of calcium. No additional fat-soluble vitamin supplementation was given other than that included in the multivitamin supplement prescribed to all patients which contained 4000 IU of vitamin A, 400 IU of vitamin D, and 10 mg of vitamin E. An oral iron supplement was prescribed for all premenopausal women at a dose of 80 mg/day. Starting at 6 months postoperatively, vitamin B<sub>12</sub> supplementation was given intramuscularly (IM) at a dose of 1000–3000 µg, as necessary, depending on measured values. <sup>14</sup>

## Postoperative Follow-up and Evaluation

Complete postoperative evaluation was performed at 1, 3, 6, 12, 18, and 24 months and yearly thereafter. Each follow-up visit included personal nutritional and medical evaluation by the team members and complete labs and evaluation by other medical personnel as necessary. In addition, at the first year follow-up visit a routine x-ray examination for staple-line disruption was performed in all patients and interim x-ray examinations were performed as necessary whenever there was clinical suspicion of disruption such as sudden unexplained weight gain.

# STATISTICAL ANALYSIS

All the values presented are expressed as mean  $\pm$  standard deviation, unless otherwise stated. Comparisons of observed values at various time periods during the study for cholesterol (CHOL), triglycerides (TRIG), low-density lipoprotein (LDL), high-density lipoprotein (HDL), glucose (GLU), and parathormone (PTH) were performed using one-way analysis of variance (ANOVA). When statistically significant differences were observed, the Tukey posttest was used for determination of the specific time points that contributed to this significance. All reported p values are two-sided and significant at a level of  $p \leq 0.05$ .

### **RESULTS**

For all patients, except for two who had undergone adjustable gastric band (AGB) in the past, BPD with RYGBP was their first bariatric operation. During the procedure 204 additional abdominal procedures took place, the majority of them cholecystectomies (59%). The mean operative time was  $205 \pm 41$  minutes. Two patients were admitted to the intensive care unit (ICU) postoperatively (2%), one for a 2-day period for application of continuous positive airway

pressure (CPAP) to treat hypoventilation syndrome and the other for 35 days due to multiple organ dysfunction after peritonitis due to leakage of the gastric remnant. The mean postoperative hospitalization time was  $9 \pm 6$  days. The mean follow-up time was  $29 \pm 14$  months. The rate of successful follow-up was 99% at 12 months, 99% at 18 months, 96% at 24 months, 93% at 36 months, 92% at 48 months, and 83% at 60 months. It should be emphasized that only 1 patient was lost completely to follow-up and that another patient, who lives permanently in Australia, had irregular follow-up. In four patients (3%) a revision bariatric procedure was performed and, in agreement with the study design, their subsequent follow-up results were not included in the analysis.

# Weight Loss

Weight loss results at each time period expressed as actual weight, BMI, percentage of excess weight loss (EWL %), and percentage of initial weight loss (IWL %) are presented in Table 2. Maximum weight loss was achieved at 18 months postoperative with average EWL 65%, average IWL 39%, and average BMI 35 kg/m². Thereafter a decline was observed with EWL % stabilizing at around 50%, IWL % at around 30%, and BMI at around 40 kg/m². Further analysis of the distribution of EWL % and IWL % is illustrated in Fig. 2 *A*, *B*, respectively.

## Comorbidities

The incidence of preexisting comorbidities was  $6 \pm 2$  per patient. The majority of these were permanently resolved by the first 6 months postoperatively with the remaining showing significant improvement. The preoperative prevalence and postoperative percentage of resolution and improvement of clinically significant comorbidities are presented in Table 3.

Hypercholesterolemia (cholesterol > 200 mg/dl) was present in 59 patients preoperatively. In these patients mean preoperative cholesterol levels (243  $\pm$  26 mg/dl) had decreased significantly (p < 0.001) by

the first postoperative month (156  $\pm$  26 mg/dl) and remained normal thereafter. Similarly, hypertriglyceridemia (triglycerides > 160 mg/dl) was present in the 36 patients preoperatively ( $226 \pm 79 \text{ mg/dl}$ ). From the first postoperative month triglyceride levels in these patients were significantly lower than preoperative levels (161  $\pm$  51 mg/dl, p < 0.001) and by the third month the mean value reached normal levels  $(128 \pm 46 \text{ mg/dl})$ . Also of interest is that mean HDL levels in all patients were significantly less than preoperative values up until 6 months postoperatively (p < 0.001), after which time they gradually increased reaching preoperative levels at 1 year and increasing progressively thereafter. This increase, however, did not reach statistical significance when compared to preoperative HDL levels.

There were 23 patients with diabetes (blood glucose >125 mg/dl) preoperatively. Of these patients, 18 were not on any type of medication either because they were unaware of the problem or because they were on conservative management with diet alone. Five patients were being treated with oral hypoglycemic agents (for a period of <5 years) and none were insulin dependent. Postoperatively, blood glucose levels had returned to normal in all patients by the first postoperative month and by the third month all 5 patients on oral hypoglycemic agents were able to discontinue treatment.

## **Complications**

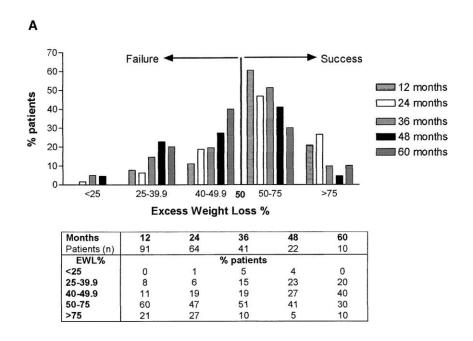
*Intraoperative Complications.* The only observed intraoperative complication that occurred was splenectomy, which was performed in, seven patients (5%) when conservative attempts to control hemorrhage from intraoperative injury to the spleen failed.

Early Mortality and Morbidity. There was one death that occurred in the early postoperative period (1%) in a patient who presented with peritonitis due to leakage of the gastric remnant on the second postoperative day. The patient died 35 days later in the ICU from multiple organ failure after three reoperations for abdominal sepsis.

Table 2. Weight loss results

		Postoperative years (followed-up patients)					
	Preoperative	1 (91)	2 (64)	3 (41)	4 (22)	5 (10)	
Weight	155 ± 25	95 ± 18	94 ± 16	99 ± 14	107 ± 15	111 ± 20	
BMI	$57 \pm 7$	$35 \pm 7$	$35 \pm 6$	$37 \pm 6$	$41 \pm 7$	$43 \pm 9$	
IWL %	_	$38 \pm 9$	$38 \pm 10$	$33 \pm 11$	$30 \pm 10$	$32 \pm 12$	
EWL %	_	$63 \pm 16$	$63 \pm 16$	$57 \pm 17$	$49 \pm 16$	$50 \pm 19$	
Patients (%) with ≥ 50% EWL	_	81	73	61	45	40	

BMI = body mass index; EWL = excess weight loss; IWL = initial weight loss.



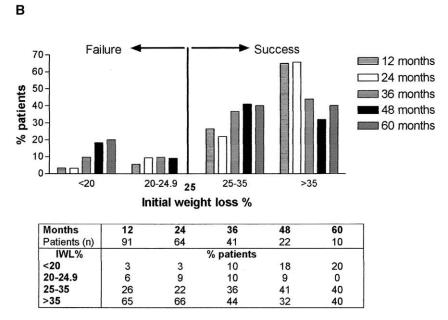


Fig. 2. Graphs representing analytical distribution of (A) excess weight loss % (EWL %) and (B) initial weight loss % (IWL %). The values in the tables below the graphs represent the percentages of followed-up patients in each weight loss category at each study period.

The overall rate of early morbidity (<30 days postoperative) was 11% and is presented in Table 4. The most serious complications were the two cases of anastomotic leakage, associated with the gastrojejunal anastomosis, which were treated conservatively without need for reoperation. The subhepatic abscess, drained percutaneously under CT guidance, developed as a result of bile accumulation due to an accessory bile duct at the gallbladder bed not recognized at the time of surgery, which also included a cholecystectomy. Major postoperative lung atelectasis, which presented in four patients, was resolved bronchoscopically.

Late Mortality and Morbidity. No deaths occurred during the late postoperative follow-up period. The overall rate of late morbidity was 27% and the details are shown in Table 4. More than half of

Table 3	3. ]	Incidence	of	comor	oic	lities	and	their	evolution	postoperativ	ely
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Comorbidity	Incidence (% of the total)	Follow-up time period	Resolved (% of the diseased)	Improved (% of the diseased)	Without change (% of the diseased)
Hypertension	48 (63/132)	24 months	68	28	4
Diabetes mellitus	17 (23/132)	3 months	100		
Glucose intolerance	17 (22/132)	1 month	100		
Hypercholesterolemia	45 (59/132)	1 month	100		
Hypertriglyceridemia	27 (36/132)	3 months	100		
Sleep apnea	15 (20/132)	1 month		100	
Hypoventilation syndrome	4 (5/132)	1 month		100	
Pickwick Syndrome	4 (5/132)	1 month		100	
Obstructive pulmonary disease	22 (29/132)	3 months	97		3
Hyperuricemia	24 (32/132)	6 months	100		
Osteoarthritis	36 (48/132)	6 months		100	
Depression	9 (12/132)	12 months	20	40	40

these late complications were incisional hernias, which almost always occurred during the first postoperative year. The six patients who presented with small bowel obstruction all underwent surgical exploration. Of these, three were treated with adhesiolysis, two were treated with enterotomy and removal of food bezoars, and the last was treated with enterectomy of 80 cm of small intestine, which was necessary because of necrosis of the obstructed portion of the intestine. Disruption of the gastric partition with formation of a gastro-gastric fistula occurred in five patients. In three of these patients the stoma of the gastro-gastric fistula was smaller than 1 cm and they were treated conservatively. Two of the patients continued to have favorable weight loss results. The

**Table 4.** Incidence of nonmetabolic postoperative complications

Complications	No. of patients	% of the total
Early (≤30 days)		
Anastomotic leakage	2	1.5
Subhepatic abscess	1	0.8
Evisceration	2	1.5
Incisional seroma	2	1.5
Pneumonia	4	3
Lung atelectasis	4	3
(clinically significant)		
Total	15	11
Late (>30 days)		
Incisional hernia	22	16.7
Small bowel obstruction	6	4.6
Gastro-gastric fistula	5	3.8
Stenosis of gastro-jejunal	2	1.5
stoma Stenosis of Roux-Y limb	1	0.8
Total	36	27

third, despite unfavorable weight loss results, did not opt for revision surgery. In the other two patients a fistula stoma of greater than 1 cm was discovered at 12 and 36 months postoperative, respectively. Both had ineffective weight reduction and both underwent conversion to a modified Scopinaro BPD. Another patient also underwent conversion to a modified Scopinaro BPD after resection of a stenotic Roux-Y limb, which was thought to have been caused by poor vascular perfusion. The two patients with stenosis of the gastrojejunal anastomosis were treated successfully with endoscopic dilatation. Diarrhea, defined as four or more loose stools per day, was not a major problem for most patients and there was a diminishing trend over the years. At the 12-month follow-up visit 8% of patients presented with diarrhea periodically and only 2% frequently. After this time there were no further complaints of frequent episodes of diarrhea. Fourteen patients (11%) presented anorectal complications during the entire follow-up period.

# **Metabolic Effects**

Anemia. The mean rate of postoperative anemia (hemoglobin: men < 13.5 mg/dl, women <12.5 mg/ dl) was 33%. For parameters correlated with anemia, the mean rates of postoperative deficiency were 13% for iron ( $<35 \mu g\%$ ) and 25% for vitamin B<sub>12</sub> (<200pg/ml). Additionally, the incidence of low ferritin levels (<9 ng/ml) was 20%. Folate deficiency did not occur at any time period during the study. The deficiencies were clinically mild, did not require transfusion, and were treated successfully with additional oral supplementation.

Calcium-Phosphorus Metabolism. Levels of calcium, phosphorus, and alkaline phosphatase (ALP) remained within the normal range throughout the study, whereas parathormone (PTH) values, after an initial drop immediately after surgery, steadily increased. Starting at the 2-year follow-up period, mean values of PTH surpassed preoperative values and continued to increase over the years without, however, reaching statistical significance. The percentage of patients presenting with postoperative PTH values greater than 90 ng/l was 15% and oral supplementation with 1α-OH-D<sub>3</sub> was initiated at this time. No spontaneous bone fractures occurred during the course of the study nor were there any signs and symptoms of metabolic bone disease based on clinical observation and the parameters studied.

Hypoalbuminemia. The occurrence of hypoalbuminemia was evaluated at every time period during the study. Mean serum albumin levels were always in the upper range of normal. Only 4 patients (3%) presented with a serum albumin level below 3 g/ dl at some time during follow-up. In 1 patient this occurred during the second postoperative year and was attributed to a very low dietary protein intake combined with an increased intake of fat causing diarrhea and therefore further protein malabsorption. The patient was hospitalized and received total parenteral nutrition for a three-week period and after further instruction and increased dietary protein intake there were no further complications or recurrence of the problem. Another patient experienced two episodes of hypoalbuminemia during the first and second postoperative year, both of which were treated successfully with a 3-week course of total parenteral nutrition. However, during the third postoperative year there was a recurrence of hypoalbuminemia and the decision was made to perform revision surgery with elongation of the common channel to 250 cm at the expense of biliopancreatic limb. This was the only case where revision surgery was necessary because of hypoalbuminemia, an occurrence rate of 1%. In the remaining two patients hypoalbuminemia occurred during the first postoperative months as a result of total patient noncompliance resulting in an extremely low dietary protein intake. Both patients were hospitalized and underwent placement of tube gastrostomy through the silastic site-marker under CT guidance and the hypoalbuminemia was resolved by the administration of high-protein enteral nutrition supplements.

#### **DISCUSSION**

Surgery is the only therapeutic option that offers permanent weight loss results in most morbidly obese patients.<sup>15</sup> Because of the high rate of weight loss

failure following gastric restrictive operations,<sup>3,9</sup> malabsorptive procedures are increasingly being performed all over the world.<sup>16</sup> Weight loss maintenance after procedures such as biliopancreatic diversion and the duodenal switch is primarily due to intestinal malabsorption.<sup>6,8,17</sup>

Similarly it has been reported that standard RYGB does not provide sufficient long-term weight loss in many super obese patients.<sup>3,18</sup> Adding malabsorption of macronutrients by elongating the Roux limb has proven satisfactory in weight control in this particular subgroup of patients.<sup>5,7,9–11</sup> There are only a small number of reports available in the literature regarding the use of different limb lengths in an attempt to increase the success rate in these patients.<sup>5,7,9–11</sup> To the best of our knowledge, the present study is one of the largest series to date of super obese patients treated with the same malabsorptive bariatric procedure with a thorough and very successful follow-up, which is greater than 80% throughout the 5-year study period.

Three digestive components contribute to weight loss in malabsorptive procedures: the volume of the functional stomach, the length of the common channel, and the length of the alimentary limb. 19,20 Fat is essentially absorbed in the common channel, but the digestion/absorption of protein and complex starch depends mainly on the total intestinal length from the gastroenteroanastomosis to the ileocecal valve. Alterations in functional gastric volume and intestinal limbs correlate with weight loss, its maintenance over time, and the occurrence of metabolic complications. 17,19,20 This study presents our experience in an exclusively super obese population using the particular biliopancreatic diversion procedure described above. This bariatric procedure is a malabsorptive procedure as a portion of the gastrointestinal tract—the 200 cm biliopancreatic limb—is excluded from digestion. Early weight loss is initiated by the small gastric pouch, which causes early satiety and anorexia.<sup>21</sup> Simultaneously, the entrance of nutrients directly into the jejunum, in addition to causing activation of the dumping effect, further promotes satiety and anorexia via chemical and mechanical receptors of the small intestine<sup>21</sup> and alterations in the secretion of gastrointestinal hormones.<sup>21–23</sup> After the first 6 postoperative months anorexia subsides, the dumping effect essentially disappears, and patients no longer experience significant limitations in food intake. From this time on, malabsorption becomes the main component of further weight loss and weight loss maintenance, although a relative increase in resting energy expenditure may also play an adjuvant role. 19,21,24 Generally, patients are able to eat a regular diet in desired

amounts with special attention paid to avoiding fibrous foods, which can lead to the formation of food bezoars and small bowel obstruction. Patients are also advised to avoid simple sugars and alcohol consumption as these calorie-rich non-nutritive substances are completely absorbed and may lead to a less successful outcome in terms of weight loss. However, the weight loss is still sufficient to achieve long-term improvement in preexisting comorbidities.

The construction of the small gastric pouch, initially measured to be  $15 \pm 5$  ml, is based on that described in previous reports.<sup>12</sup> Transection of the gastric pouch from the bypassed stomach, the volume of which from that time on was visually estimated, and the interposition of the Roux-Y limb between the pouch and the gastric remnant are also performed as previously described. 25,26 This resulted in elimination of the problem of gastro-gastric fistula. The avoidance of distal gastrectomy, which has its potential complications, makes the operation reversible. The addition of the silastic site-marker on the gastric remnant<sup>26</sup> makes it possible to perform an upper GI radiologic or endoscopic investigation or to create a gastrostomy for nutritional support, as was needed in 2 patients with refractory hypoalbuminemia. Because a small gastric pouch with small common channel and alimentary limb has been reported to result in significant mortality and morbidity, 7,27 we decided to combine a small gastric pouch with a longer common channel and alimentary limb in an attempt to decrease metabolic sequelae even though this would mean a compromise in terms of weight loss.

As shown in Table 3, the mean percentage of excess weight loss (EWL %) was maintained at around 50% through the fifth postoperative year, whereas the mean percentage of initial weight loss (IWL %) was always greater than 30%. Upon closer analysis of EWL %, as shown in Fig. 2, it can be seen that although a large number of patients were below 50% and would therefore be considered failures, the majority of them were able to maintain EWL % greater than 40%, which may be acceptable in this patient population. Superior weight loss results have been reported following biliopancreatic diversion with distal gastrectomy and duodenal switch; however, the published reports contain mixed populations of both the morbidly and super obese. <sup>6,17,28,29</sup> Therefore, results are difficult to interpret. Studies reporting exclusively on super obese patients are few. In one such study, Hess et al.8 presented very good long-term weight loss results following BPD with duodenal switch in a super obese subpopulation. Other authors have reported similar or even better weight loss results in the super obese following other malabsorptive procedures.<sup>5,7,10,11</sup> However, the results are hard to evaluate because the procedures are different in terms of common channel, alimentary, and biliopancreatic limb lengths. Furthermore, the number of patients in these series is smaller than in the present study and the follow-up is inadequate and often not carried out on a personal basis. <sup>7,10</sup>

It is well known that super obesity, due to increased comorbidity, has a more complicated clinical course than morbid obesity. In our study as well as in others, the incidence of preexisting comorbidities is very high in this patient population and the primary goal of bariatric surgery in the super obese should be the resolution or improvement of comorbidities rather than the achievement of normal body weight.<sup>30</sup> It has been reported that a reduction of 10– 20% of initial weight is sufficient for the resolution of comorbidities.<sup>31,32</sup> It has also been proposed that a more realistic goal of bariatric surgery in this population may be the long-term maintenance of 50% EWL or 25% IWL, which will ensure the resolution of most comorbidities without serious metabolic complications.<sup>30</sup> Based on the above observations, it is our opinion that the weight loss provided by our procedure can be considered acceptable in the super obese population. In agreement with results described by others, 8,17,19 in our patients the majority of preexisting comorbidities were permanently resolved or improved by the sixth postoperative month. As with other malabsorptive bariatric procedures, hypercholesteremia and hypertriglyceridemia, as well as glucose intolerance, were resolved from the first postoperative months, even though significant weight loss had not yet been achieved.<sup>6,8</sup> The potential of gastric bypass and biliopancreatic diversion in the treatment of diabetes mellitus type II has been described in detail in recent papers.<sup>32–35</sup>

Early mortality and morbidity were low and comparable to that found in other series. 5,10,17 Late morbidity was also comparable to that reported by others, 5,10,17,19 most of which was due to incisional hernia (17%). An interesting feature of our procedure was the absence of stoma ulcers in contrast to results reported by others.<sup>5,6,36</sup> The explanation for this may be the absence of acid-producing cells in the small gastric pouch near the esophago-gastric junction, which could also be the reason for the greater deficiency of vitamin B<sub>12</sub> observed in our study as compared to others.<sup>5</sup> In general, metabolic deficiencies are common after malabsorptive procedures; however, the percentage of metabolic deficiencies in our study was much smaller than that following biliopancreatic diversion with distal gastrectomy 19 or duodenal switch.<sup>8,17</sup> Metabolic deficiencies encountered in our study were more similar to those seen following

various types of "distal gastric bypass"<sup>5,10</sup> and, based on our own experience, similar to those found after the standard RYGBP.<sup>14</sup> All of the deficiencies encountered were mild and easily corrected with additional oral supplementation. Calcium deficiency, which has been stated in other reports, 5,8,17,19 did not occur, whereas postoperative measurements of calcium, phosphorus, and alkaline phosphatase were always within the normal range. Starting at the 2year follow-up period, mean values of PTH surpassed preoperative values and continued to increase over the years. However, the increase when compared to preoperative values did not reach statistical significance. Oral supplementation with  $1\alpha$ -OH-D<sub>3</sub> was prescribed for the patients who presented postoperative PTH values greater than 90 ng/l. It must be noted that levels of fat-soluble vitamins were not measured and, therefore, comments cannot be made based on the present study. However, no clinical symptoms of deficiency were observed and despite the fact that vitamin K is not contained in the multivitamin supplement prescribed, no patients presented with increased prothrombin time. Diarrhea was also not a major problem. It occurred in a smaller percentage of patients than has been reported by others<sup>6,7</sup> and was always resolved by the first postoperative year. The incidence of hypoalbuminemia was also very low in our series (3%). Furthermore, in only one patient (1%) was it necessary to perform revision surgery due to refractory hypoalbuminemia. This is in contrast to higher percentages reported for other types of BPD procedures. <sup>7,10,19,27</sup> The longer total alimentary limb and the lower incidence of diarrhea could explain this difference. Finally, in contrast to the reports of others,<sup>7,27</sup> no patient experienced liver failure or cirrhosis.

Overall, metabolic complications were relatively rare in our patients, therefore justifying the less impressive weight loss results. It is our opinion that weight loss should not be viewed as the ultimate measure of success, but only as a part of the total picture with the main focus on reduction in morbidity and mortality and improvement in quality of life.<sup>37</sup> On the other hand, the risk of metabolic complications after this type of malabsorptive bariatric procedure does exist, and, therefore, close medical and nutritional follow-up, as well as full patient compliance are essential to its overall success.

## **CONCLUSION**

Biliopancreatic diversion with Roux-en-Y gastric bypass as performed at our institution is an effective and safe surgical procedure for the treatment of super obese patients. Constructing a biliopancreatic limb of 200 cm and a common channel of 100 cm of the terminal ileum combined with a very small gastric pouch achieves acceptable weight loss maintenance, resolution of comorbidities, and significant improvement in quality of life without significant metabolic or nutritional complications. We recommend BPD with RYGBP as a primary procedure for super obese patients (BMI  $\geq$  50) with severe preexisting comorbidities and as a revision procedure for failed previous restrictive operations provided that the patients are well-educated and informed regarding the need for lifetime medical follow-up.

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