

Želodčni obvod: slovenske izkušnje – prvi rezultati našega dela

Gastric bypass: the Slovenian experience – preliminary results

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Izvleček

Opisujemo zgodnje rezultate operacije želodčnega obvoda pri prvih 100 bolnikih, ki smo jih spremljali 2–39 mesecev.

Prvih 100 bolnikov, ki so izpolnjevali IFSO kriterije (tj. kriterije mednarodne federacije za kirurgijo debelosti), smo operirali v času od februarja 2007 do marca 2010. Izdelali smo 30 ml vrečko, 60 cm dolgo biliopankreatično in 100 do 150 cm dolgo alimentarno vijugo. Delali smo s petimi trokarji in linearnim spenjalnikom.

Smrtnosti ni bilo, dvakrat smo izvedli konverzijo. EWL pri 12 in 24 mesecih je bila 69,6 % oz. 76,5 %. Do ozdravitve ali izboljšanja sladkorne bolezni je prišlo v 93,7 %, do ozdravitve ali izboljšanja povišanega tlaka pa v 97,0 %. BAROS ocena kakovosti življenja je bila v obeh skupinah (z in brez spremljevalnih bolezni) "prav do

Abstract

We evaluated the short-term outcomes for laparoscopic Roux-en-Y gastric bypass surgery in 100 patients with a follow-up of 2–39 months.

Consecutive patients who met the criteria for bariatric surgery set by the International Federation for the Surgery of Obesity were offered laparoscopic Roux-en-Y gastric bypass between February 2007 and March 2010. A 30-mL pouch, 60-cm biliopancreatic limb, and 100–150-cm Roux limb was created using a linear stapler using five trocar incisions.

No patients died. The prevalence of conversion to open gastric bypass was 2%. Excess weight loss (EWL) at 12 months and 24 months was 69.6% and 76.5%, respectively. Resolution or improvement of type-II diabetes mellitus and hypertension was 93.7% and 97.0%, respectively. The Bariatric Analysis and Reporting Outcome

bro": 6,5 oziroma 3,2. Prišlo je do 4 zgodnjih velikih komplikacij: puščanja na anastomozi, zapore črevesa, zožitve na entero-entero anastomozi in poškodbe tankega črevesa. Pozna komplikacija, notranja kila, se je pojavila enkrat. Želodčni obvod je učinkovita in varna operacija za izgubo odvečne telesne mase in izboljšanje spremljevalnih bolezni ter tudi kakovosti življenja.

System (BAROS) quality-of-life (QoL) score in the groups with and without comorbidities was evaluated to be "very good": 6.5 and 3.2, respectively. Four early major complications (leakage, ileus, stenosis of end-to-end anastomosis, iatrogenic lesion of the small intestine) were observed. A late complication of internal hernia occurred in one patient. Gastric bypass is effective and safe in achieving weight loss and improving comorbidities and QoL.

INTRODUCTION

Morbid obesity is a chronic, lifelong, multifactorial, congenital disorder characterized by excessive fat deposits as well as associated medical, psychological, physical, social, and economic problems. It is also a significant threat to health (1). Non-surgical treatment has a prevalence of relapse of $\leq 90\%$ irrespective of the choice of conservative treatment (2). As early as 1991, the US National Institutes of Health issued a statement recognizing the lack of success with conservative forms of treatment; they noted that surgeries to constrict or bypass the stomach were justified for fully informed and consenting patients, and constituted an acceptable risk (3,4).

In 1954, Kremen and Linner introduced jejunoileal bypass. Modifications to the original procedure and the development of new techniques led to three basic concepts for bariatric surgery: gastric restriction by gastric banding (vertical-banded gastroplasty and adjustable banding), gastric restriction with mild malabsorption (Roux-en-Y gastric bypass (GBP)), and a combination of mild gastric restriction and malabsorption ("duodenal switch") (5-7).

Bariatric surgery can be undertaken by open and laparoscopic techniques. The latter has become the more popular approach because of its proven (and

now well-known) advantages. GBP is currently the most popular procedure. More than 80% of bariatric procedures in the USA are GBP. It has earned the reputation of being the criterion standard against which other procedures are compared. The procedure has restrictive and malabsorptive components. GBP provides a substantial amount of dietary restriction. The restrictive element of the surgery consists of the creation of a small gastric pouch (~30 mL in volume) with a small outlet that, on distention by food, causes the sensation of satiety. In addition, GBP provides a small-to-moderate degree of intentional malabsorption due to the separation of food, which passes through the Roux alimentary limb of the Y, from the biliopancreatic secretions, which pass through the biliopancreatic limb of the Y. The degree of malabsorption can be adjusted by modifying the length of the alimentary and biliopancreatic limbs. For all bariatric procedures, pure reversal without conversion to another bariatric procedure is almost certainly followed by a return to morbid obesity. GBP can be reversed, though this is rarely required. GBP results in substantial weight loss and resolves >80% of cases of type-II diabetes mellitus (DM). Investigators suggest that this type of bariatric surgery should be considered the standard of care for morbidly obese patients with type-II DM (6).

The diversity of clinical- and occult obesity-related comorbidities necessitates a multidisciplinary-team approach in the preoperative evaluation of a morbidly obese patient: this evaluation enhances outcome. Preoperative cardiac, pulmonary, psychiatric, and endocrine evaluations may be necessary. These evaluations help to exclude patients who may not benefit from surgery. They simultaneously optimize those considered to be good candidates for this type of surgery. Patients should meet all necessary criteria for general surgery.

The contraindications specific to bariatric surgery are:

1. Absence of periods of identifiable medical management
2. A patient who cannot participate in prolonged follow-up
3. Non-stabilized psychotic disorders, severe depression and personality disorders (unless specifically advised by a psychiatrist experienced in obesity)
4. Alcohol abuse and/or drug dependencies
5. Diseases threatening life in the short-term
6. Patients who cannot care for themselves and have no long-term support from their family or social service that warrant such care.

The indications for bariatric surgery are: patients aged 18–60 years with a body mass index (BMI) >40 kg/m² or with a BMI 35–40 kg/m² with a comorbidity in which surgically induced weight loss is expected to improve the disorder (e.g., metabolic disorders, cardio-respiratory disease, severe joint disease, obesity-related severe psychological problems). The BMI criterion may be the current BMI or a documented previous BMI of identical severity. Bariatric surgery is indicated in patients who exhibit substantial weight loss in a conservative treatment program but who started to regain weight. To be considered for surgery, patients must have failed to lose weight or to maintain long-term weight loss despite appropriate medical care. Patients must have shown compliance with medical appointments. The indication for bariatric surgery for age >60 years or <18 years should be considered on an individual basis.

Preoperative consultation helps in obtaining a detailed diet history and in explaining preoperative and postoperative diet protocol. At our facility, patient preparation for surgery consisted of a detailed explanation (in written and oral form) of the developmental aspect of laparoscopic GBP and its benefits and risks. These included short- and long-term complications, side effects, nutritional sequelae, and the possibility of conversion to an open procedure. Antibiotics were administered perioperatively. Prophylaxis against venous thrombosis and pulmonary emboli consisted of perioperative pneumatic compression devices and low-dose heparin (s.c.).

After surgery, patients must remain on a high-protein, low-fat diet supplemented with multivitamins, iron, and calcium. Patients must modify their eating habits by avoiding “chewy” meats and other foods that may inhibit normal emptying of their stomach pouch. Nutritional and metabolic blood tests need to be carried out frequently (at 6 months after surgery, 12 months after surgery, and annually thereafter).

We have a monthly support group meeting in which evaluation of the results is monitored. The Bariatric Analysis and Reporting Outcome System (BAROS) was introduced to evaluate bariatric procedures and to compare them worldwide. It consists of a Moorehead Quality of Life (QoL) questionnaire, and documentation of excess weight loss (EWL), medical conditions, complications, and reoperations (Table 1). The total score is between 1 and 9 in the group with comorbidities and between 0 and 6 in the group without comorbidities (Table 2), each divided into five classes: bad, acceptable, good, very good, and excellent.

Outcomes related to changes in comorbidities, quality of life, and patient satisfaction was assessed for patients with 1 year or more of follow-up. Throughout the study the Moorehead-Ardelt Quality of Life Questionnaire specific for bariatric surgery was administered according to the protocol to assess quality of life changes.

Table 1: Bariatric Analysis and Reporting Outcome System (BAROS)

	points
Moorehead questionnaire of QoL	-3 to +3
EWL: weight gain	-1
0 – 24%	0
25 – 49%	+1
50 – 74%	+2
75 – 100%	+3
Medical condition:	
worsened	-1
unchanged	0
improved	+1
resolve a major comorbidity and improve others	+2
resolve all major comorbidities and improve others	+3
Complications: major	-1
minor	-0.2
reoperation	-1

MATERIAL & METHODS

Surgical procedures were undertaken at Slovenj Gradec General Hospital and Celje General Hospital (Slovenia). An extensive preoperative evaluation (history-taking and physical examination; nutritional and psychiatric evaluation; indicated specialty consultations) was undertaken on all patients. Laboratory evaluation included complete blood count, serum chemistries, and testing of thyroid function.

The surgical procedure was a modification of that described by Wittgrove et al (8). The patient was placed in a supine position. The surgeon was positioned between the legs of the patient; two monitors were placed above the patient’s shoulders. A carbon dioxide pneumoperitoneum (15 mmHg) was created using the Veress needle technique or entering the abdomen without gas. Using just the optic trocar, ports were placed at the level of mesogastrium. The first port was for the camera and was ~12 cm from the xiphoid. The operating table was placed in a steep reverse Trendelenburg position. To expose the esophagus and stomach, a liver retractor was placed

Table 2. Bariatric Analysis and Reporting Outcome System (BAROS) scoring

	Patients with comorbidities (total score)	Patients without comorbidities (total score)
bad	<1	<0
acceptable	1 – 3	0 – 1.5
good	3 – 5	1.5 – 3
very good	5 – 7	3 – 4.5
excellent	7 – 9	4.5 – 6

through the inferior right subcostal port, and the left lateral segment of the liver was elevated. A 30-mL gastric pouch was created. An endo-linear stapler (45-mm in length with 3.8-mm staples) was inserted and applied 3-4-times to staple and cut the gastric pouch with three rows of staples on each side. A gastroenteroanastomosis was then created 40-60 cm from the ligament of Treitz using a circular end-to-end anastomosis stapled technique (first 20 cases) or a linear stapled technique (last 80 cases). The Roux limb was then measured 100 cm distally (or 150 cm distally for superobese patients). A stapled side-to-side anastomosis was created with the proximal jejunal limb using the endo-linear stapler (45-mm in length with 2.5-mm white staples). The enterotomy sites were closed with a running suture. All anastomoses were tested with methylene blue. Lastly, the afferent loop close to the gastroenteroanastomosis was divided with a white cartridge of the linear stapler.

We carried out 100 (87 females and 13 males) laparoscopic GBP surgeries from February 2007 until March 2010 (i.e., 3 years and 2 months). The mean of patients was 42.2 years (range, 18.9-63.3 years). The mean age of the 87 females was 42.3 years (range, 18.9-63.3 years) and that for the 13 males was 41.5 years (range, 26.4-53.0 years). The mean BMI for the study population was 42.6 kg/m² (range, 33.4-72.3 kg/m²). The mean BMI for females was 42.7 kg/m² (range, 33.7-72.3 kg/m²) and was 42.1 kg/m² (range, 33.4-49.6 kg/m²) for males. Out of 100 patients, we followed up 53 patients for >1 year, 17 patients for >2

years, and 3 patients for >3 years. No patients were lost to follow-up.

BAROS is evaluated after 1 year. Hence, out of 100 patients we had 53 patients who were monitored for >1 year. Three out of 53 patients did not complete the BAROS evaluation, so 50 patients could be evaluated

Out of 100 patients, we detected 137 major and minor comorbidities. Eighty-six major comorbidities were analyzed: 34 cases of hypertension (HT), 22 orthopedic symptoms (degenerative joint disease), 16 type-II DM, 7 asthma, and 7 hyperlipidemia. Some patients had more comorbidities whereas others had none. We analyzed the resolution or improvement of the disease (not the number of patients who improved or those without the disease, which is why 86 comorbidities did not equal 86 patients). In the context of the present study, “resolved” meant that

patients did not need therapy now; “improved” means that they needed less therapy now.

RESULTS

The mean follow-up was 9.1 months (range, 2–39 months); 53 out of 100 patients had ≥ 1 year, 17 out of 100 patients had ≥ 2 years, and 3 out of 100 patients had ≥ 3 years of follow-up. We had one conversion because of adhesions and one because of bleeding from an injured mesentery (2% conversion rate).

One year after the surgery, 53 patients (48 females and 5 males) who were monitored for ≥ 1 year lost on average 32.8 kg (range 7.0 to 53.0). Female patients lost 31.8 kg on average (range 7.0 to 53.0) and male patients lost on average 43.0 kg (range, 37.0–47.5 kg). For the 17 patients who were monitored for ≥ 2 years, they lost on average 35.7 kg (range, 11.0–57.0 kg). For

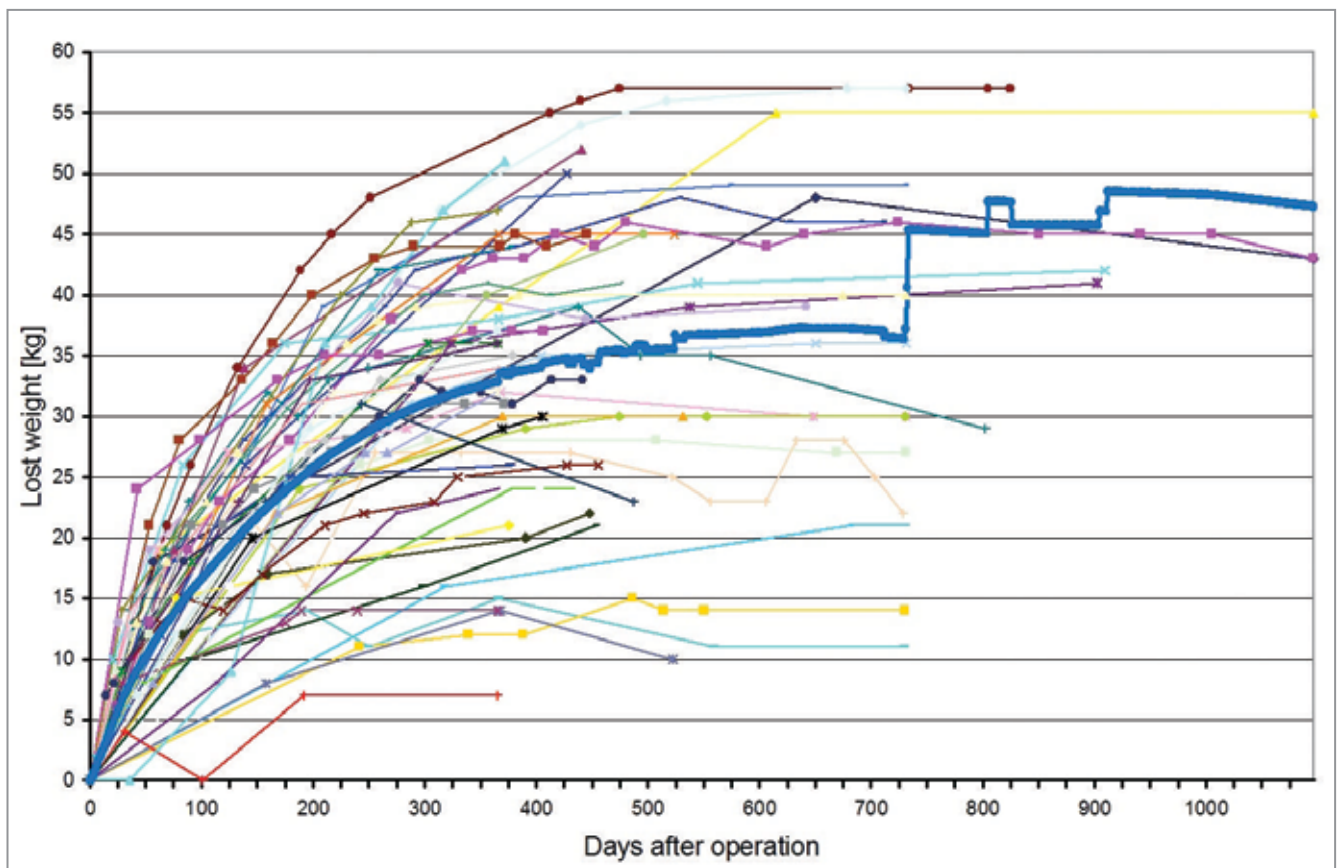


Figure 1: Weight loss (each line presents a patient; a dot in the line is the monitoring point; the thick line represents the mean value)

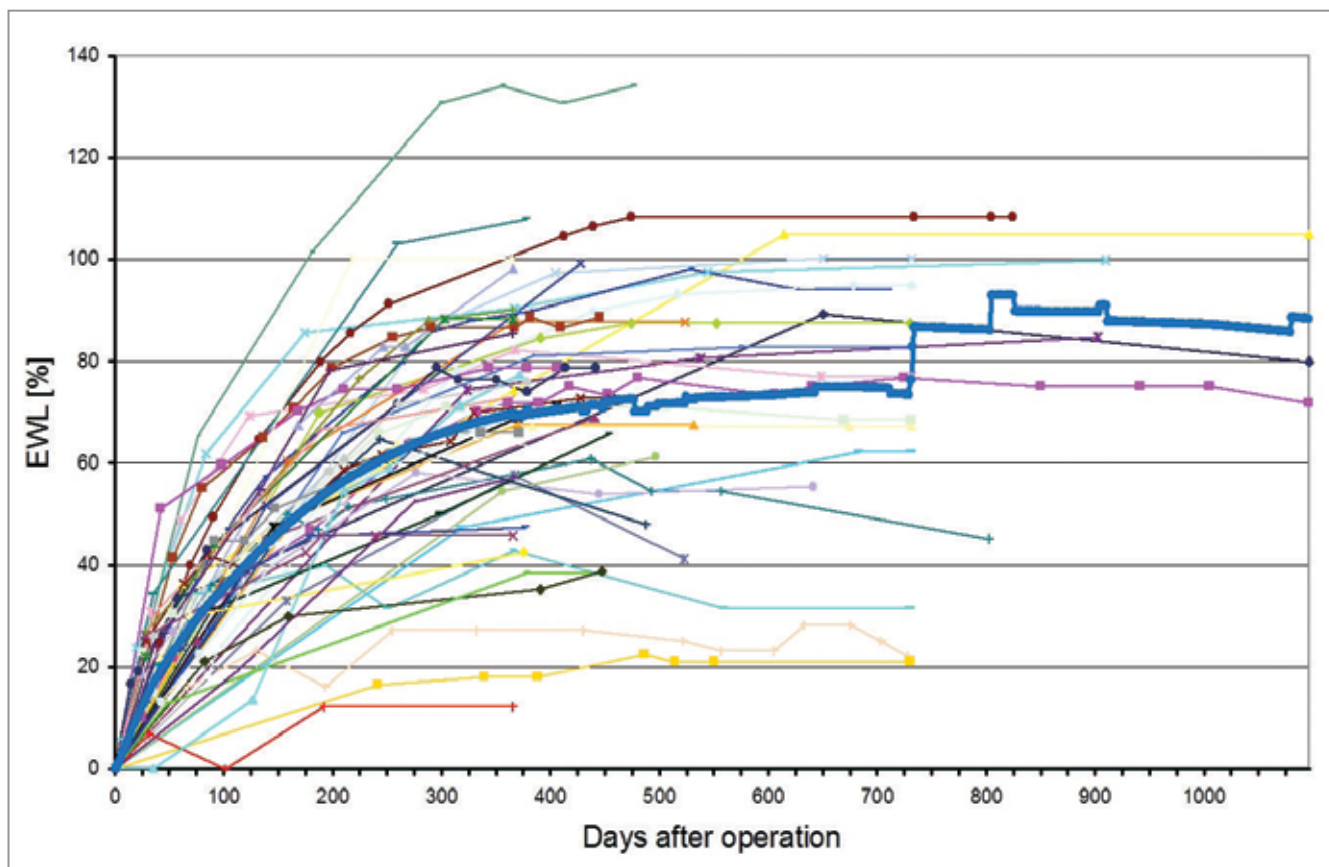


Figure 2: Excess Weight Loss – EWL (each line presents a patient; a dot in the line is the monitoring point; the thick line represents the mean value)

the 3 patients who were monitored for ≥ 3 years, they on average lost 47.3 kg (range, 43.0–55.0 kg) after 3 years (Figure 1).

EWL was 69.6% (range, 12.2–133.4%) after 1 year, 76.5% (range, 21.0–108.4%) after 2 years, and 86.0% after 3 years (range, 71.8–104.9%) (Figure 2). We used the following formula to calculate EWL:

$$EWL(t) = (\text{maximum weight} - \text{weight}(t)) / (\text{maximum weight} - \text{weight (BMI 25)})$$

where “t” is the time of the interest and weight (BMI 25) is the weight of the person at BMI=25 kg/m².

The BMI was reduced by 11.6 kg/m² from an average of 42.6 before surgery to 31.0 at 1 year after surgery (range, 21.4–59.5 kg/m²). The BMI was further reduced to 29.4 (range, 23.5–43.5 kg/m²) at 2 years

postoperatively, and to 27.4 at 3 years postoperatively (range, 24.1–31.2 kg/m²) (Figure 3, Table 3). We used the following formula to calculate the BMI:

$$BMI = \text{mass (kg)} / (\text{height, m})^2$$

Table 3: Results at 1, 2, and 3 years post-operatively out of 100 patients

	1 year- 53 pts	2 years- 17 pts	3 years- 3 pts
Lost weight (kg) (range)	32.8 (7.0–53.0)	35.7 (11.0–57.0)	47.3 (43.0–55.0)
EWL (%) (range)	69.6 (12.2–133.4)	76.5 (21.0–108.4)	86.0 (71.8–104.9)
BMI (kg/m ²) (range)	31.0 (21.4–59.5)	29.4 (23.5–43.5)	27.4 (24.1–31.2)

EWL—excessive weight loss

BMI—body mass index

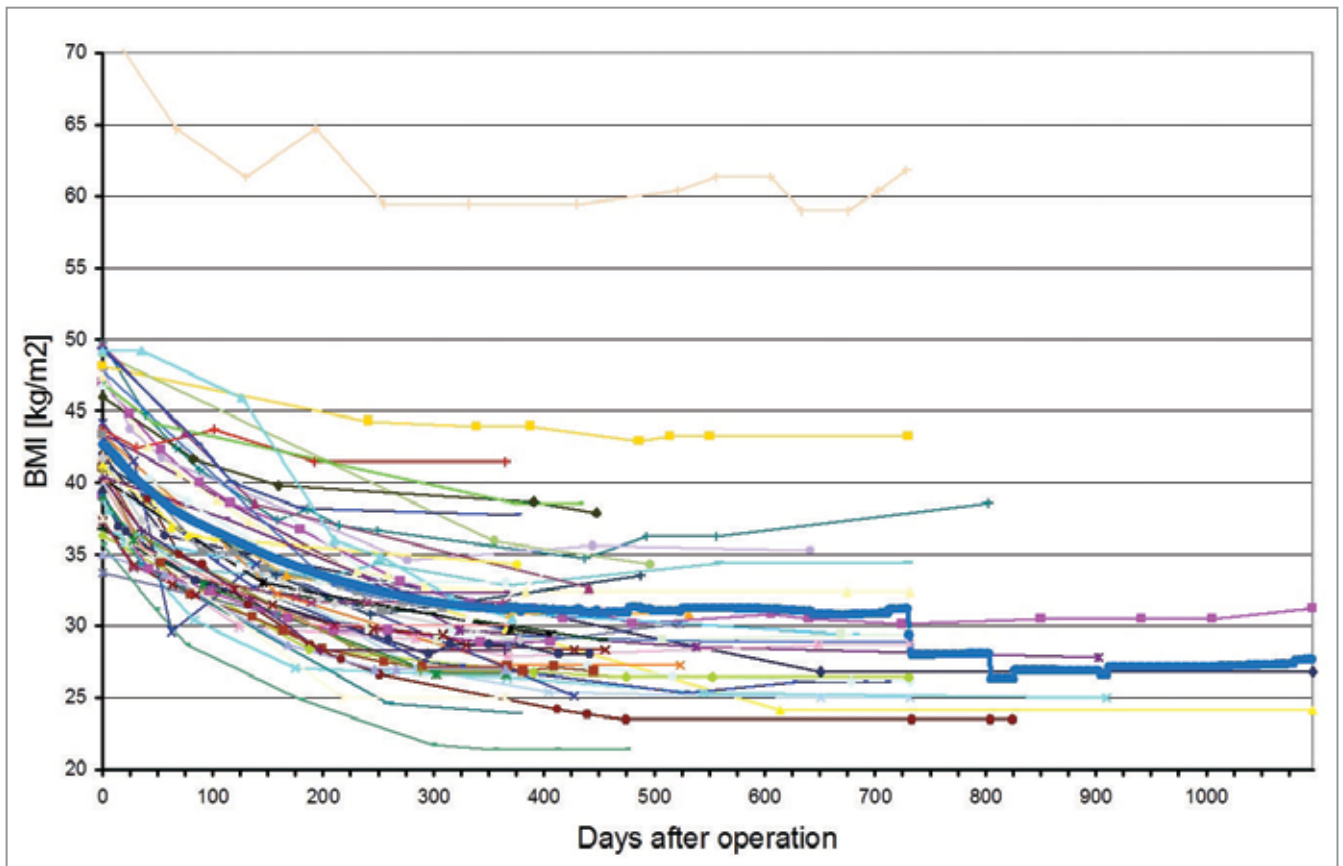


Figure 3: Reduction in the Body Mass Index (BMI) (each line presents a patient; a dot in the line is the monitoring point; the thick line represents the mean value)

The results of monitoring at 3 years are misleading because there are only 3 out of 100 patients. We included the data just as an example.

The comorbidities and their resolution are presented in Table 4. The resolution of DM with respect to therapy before GBP surgery is presented in Table 5.

Four out of 100 patients had early (<30 days) major complications: leakage, ileus, stenosis of entero–entero anastomosis, and small–bowel injury. All complications were treated with an additional laparoscopic procedure. Among the minor complications were two cases of bleeding from the mesentery due to mesentery suturing, and one case of intraluminal bleeding from the staple line. Blood transfusions were sufficient in

Table 4: Most frequent comorbidities out of 100 patients

	No. of pts	Improved No of pts (%)	Resolved No of pts (%)	No change No of pts (%)	No data No of pts
Orthopedic symptoms	22	9 (40.9%)	11 (50.0%)	1 (4.5%)	1
Hypertension	34	10 (29.4%)	23 (67.6%)		1
Diabetes	16	6 (37.5%)	9 (56.2%)		1
Hyperlipidemia	7	3 (42.9%)	4 (57.1%)		0
Asthma	7	2 (28.6%)	4 (57.1%)		1

Table 5: Resolution of diabetes with respect to therapy prior to surgery

	diabetic patients No. 15	Improved No of pts (%)	Resolved No of pts (%)	months to resolution
DM – diet	4	0	4 (100%)	< 1
DM – oral medication	7	3 (42.9%)	4 (57.1%)	10.2 (1–29)
DM – insulin	4	3 (75.0%)	1 (25.0%)	< 1

these cases. A port-site abscess occurred in one patient. One instance of Peterson’s hernia occurred 2 years after the first procedure when Peterson’s space was not closed. The problem was solved by repositioning the small bowel and closing the defect.

In our group of 100 patients, 3 had GBP surgery after insufficient weight loss after sleeve gastrectomy, and 4 patients had GBP surgery after gastric banding. One bypass was undertaken because of band migration. Two out of four major complications (ileus and small-bowel injury) occurred in redo procedures after failed bandings. Fifty out of 53 patients who were monitored for ≥1 year answered the Moorehead–Ardelt QoL Questionnaire. The total average BAROS score was 6.5 for the group with comorbidities (range 2.8 to 9.0), and 3.2 for the group without comorbidities (range 0.3 to 5.0) These scores were considered to be “very good” in both groups (Table 6).

DISCUSSION

Schirmer, Wise et al. and Miller (9–11) presented results stating that ~70% excess body weight loss can be achieved over 7–10 years. The correction of comorbid

conditions has been reported for DM (83%), HT (69%), gastric reflux (100%), urinary stress incontinence, and degenerative joint disease (12–15). Our results showed correction of DM in 93.7% of patients (improved in 37.5%, resolved in 56.2%) and correction of HT in 97.0% of patients (improved in 29.4%, resolved in 67.6%). In regards to DM with respect to its preoperative treatment, our results showed 100% resolution in patients who controlled their DM with diet alone, 57.1% resolution (42.9% improved) in patients on oral therapy, and 25.0% resolution (75.0% improved) in patients on insulin therapy before surgery. These are only the preliminary results of our relatively small study population. Flum and others have shown a significant improvement in survival for a group of patients treated with surgery compared with conventional treatment (16). Cost analyses have shown that recovery of the procedure cost is achieved in 12 months(17). In the present study, QoL (BAROS) evaluation showed “very good” results (grade 6.5 in the comorbidities group and 3.2 in the group without comorbidities).

GBP has become the surgical procedure of choice for morbid obesity because of its good long-term

Table 6: BAROS evaluation, 50 out of 53 pts monitored more than 1 year, 3 did not completed the evaluation

	Comorbidity group, 32 pts		Group without comorbidities, 18 pts	
	average score	range	average score	range
QoL	2.2	0.7 to 3.0	1.5	–0.7 to 3.0
EWL	2.6	1 to 3	1.9	0 to 3
Medical condition	1.9	1 to 3		
complications	–0.1		–0.1	
reoperations	–0.1		–0.1	
total	6.5	2.8 to 9.0	3.2	0.3 to 5.0

weight loss, excellent tolerance by patients, and acceptable short- and long-term prevalence of complications (18–28). A laparoscopic approach to Roux-en-Y gastric bypass was first described by Wittgrove et al. (8). Their technique involved the creation of a 15–30-mL gastric pouch isolated from the distal stomach, a 21-mm stapled, circular anastomosis, a 75-cm retrocolic, retrogastric Roux limb, and a stapled side-to-side jejunojunostomy. Our first 20 GBP surgeries were similar except for a 100-cm antecolic Roux limb. Wittgrove et al. presented their experience with 75 patients with 3–30 months of follow-up (29). Their operating time was 159–343 min. The mean duration of hospital stay and recovery time were 2.8 days (range, 2–75 days) and 15 days (range, 7–30 days), respectively. EWL at 12–30 months was 81–95%. The prevalence of major complications was 11%, and the prevalence of leaks was 4/75 (5%). There were no deaths. Most comorbidities (e.g., HT or DM) were eradicated or significantly improved. Wittgrove et al. recently presented their experience with 500 patients with a 5-year follow-up, demonstrating similar results and EWL in the 70–80% range (30). Other investigators have reported various laparoscopic approaches to GBP surgery with similar benefits but with a relatively short follow-up (31–33). In some long follow-up studies it is reported that DM can reoccur in ~50% of patients in late periods after surgery (34).

Unlike the gastroenteroanastomoses carried out by Wittgrove et al., the gastroenteroanastomoses carried out in the present study were done using a linear stapler. The Roux limb was longer: 100–150 cm. Our first 100 patients were followed up for 2–39 months after GBP surgery. One-hundred patients underwent laparoscopic GBP with an acceptable prevalence of early complications (4.0% major), a low prevalence of conversion (2%), and a short median hospital stay (4 days). EWL at 12 months and 24 months was 69.6% and 76.5%, respectively, and resulted in significant improvement in comorbidities and QoL. The overall prevalence of complications in the present study appears to be consistent with the literature.

These were preliminary results in a small study population with a short period of follow-up. Further analyses are needed with a larger study group and a longer monitoring period.

CONCLUSION

GBP is associated with a reduction in weight, BMI, mean systolic blood pressure, cholesterol, and the usage of medications for obesity-related conditions. A significant improvement in QoL was noted 1 year after surgery. After the initial learning curve, good results can be expected with a good interdisciplinary approach and sufficient frequency of carrying out this efficacious surgery.

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