

# Gastric banding outcomes are better if patients participate in the support group

Rezultati operacije želodca s prilagodljivim trakom so boljši, če bolniki obiskujejo klub operiranih

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## Abstract

**Introduction:** We analyzed our first five years of performing gastric bandings. We monitored weight reduction in patients with regard to their participation in the support group. Based on our experience, gastric banding is successful only with thorough assessment and treatment before surgery, as well as methodical, professional support after it. Those who participated in the support group more often had a greater weight reduction than those who were present less frequently.

**Patients and methods:** We performed 264 gastric bandings between May 2005 and May 2010 (66.5 % of all bariatric procedures). On average, patients were 41.0 years old and had a BMI of 42.4 kg/m<sup>2</sup>. There were 224 female (84.8 %) and 40 male patients (15.2 %). We followed 192 patients for more than one year. 155 patients (80.7 %) were evaluated with BAROS. We excluded patients with hormonal disorders and other pathologies preoperatively. Because gastric banding is not suitable for every patient, we made a thorough psychological evaluation of the patients before the procedure. We offered preoperative and postoperative psychological and dietary support when needed.

**Results:** Patients lost on average 23.4 kg, 31.4 kg and 33.7 kg after the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> year, respectively (EWL average of 50.3 %, 65.6 % and 69.8 %, respectively).

We monitored the resolution of comorbidities and complications. Both the “comorbidity” and “without comorbidity” groups achieved a grade of “good” on the BAROS quality of life scale (4.85 and 2.64 respectively).

Given the Pearson coefficient of  $r = 0.58$  ( $p < 0.001$ ), we concluded that there is a “moderate to strong” correlation between the number of visits in the support group and EWL.

**Conclusions:** Weight reduction is greater when patients participate in the support group after bariatric surgery.

## Izveček

**Uvod:** Analizirali smo rezultate prvih 5 let nameščanja prilagodljivega traku želodca pri bolnikih. Spremljali smo izgubo telesne teže glede na njihovo sodelovanje oziroma obiskovanje kluba operiranih. Po naših izkušnjah je prilagodljivi želodčni trak uspešna metoda zdravljenja le ob hkratnem spemljanju ter zdravljenju pred operacijo in po njej. Pri bolnikih, ki so redno obiskovali klub operiranih, se je telesna teža zmanjšala bolj kot pri tistih, ki so na sestanke prihajali redkeje.

**Bolniki in metode:** Od maja 2005 do maja 2010 smo 264 bolnikom namestili prilagodljivi želodčni trak (66,5 % vseh bariatričnih operacij). V povprečju so bili stari 41,0 let, njihov ITM pa je v povprečju znašal 42,4 kg/m<sup>2</sup>. 224 je bilo žensk (84,8 %) in 40 moških (15,2 %). 192 bolnikov smo spremljali več kot leto dni. 155 bolnikov smo anketirali za BAROS. Izključili smo bolnike s hormonskimi motnjami in drugimi bolezenskimi spremembami, ki izključujejo bariatrično operacijo. Ker tehnika prevezave želodca s prilagodljivim trakom ni primerna za vsakogar, smo bolnike pred operacijo natančno psihološko ovrednotili. Omogočili smo jim tudi psihološko in dietično podporo, če so jo potrebovali.

**Rezultati:** V povprečju so v prvem letu shujšali za 23,4 kg, v drugem letu za 31,4 kg in tretje leto za 33,7 kg (EWL v povprečju 50,3 % prvo leto, 65,6 % drugo leto in 69,8 % tretje leto).

Spremljali smo tudi hkrati prisotne bolezni (komorbidnost). Po oceni BAROS sta obe skupini (skupina z komorbidnostjo in skupina brez nje) dosegli oceno »dobro« (4,85 oz. 2,64).

Izračunana vrednost Pearsonovega koeficienta  $r = 0,58$  ( $p < 0,001$ ) je pokazala, da je povezanost med številom obiskov na klubu in EWL zmerna do močna.

**Zaključek:** Ugotovili smo, da bolniki shujšajo več, če pogosteje obiskujejo klub operiranih.

**Table 1:** Patients

	All	Female	Male
No	264	224	40
Age	41.0 (17.2–68.8)	41.0 (19.5–68.8)	41.2 (17.2–61.9)
BMI	42.4 (34.5–59.0)	42.0 (34.5–59.0)	44.0 (34.8–55.7)

## Introduction

Morbid obesity is a chronic, lifelong, multifactorial, hereditary disorder characterized by excessive fat deposits and associated medical, psychological, physical, social, and economic problems. It is also a significant health threat.<sup>1</sup> An extra weight puts outstanding stress on all parts of the body. It raises one's risk of diabetes, stroke, heart disease, kidney disease, and gallbladder disease. Conditions such as high blood pressure and high cholesterol, which were once thought to mainly affect adults, are often seen in children who are obese. Obesity may also increase the risk of some types of cancer. Obese people are more likely to develop osteoarthritis and sleep apnea. Obesity is the second leading cause of preventable death. A combination of genetics, environmental issues and behavioral factors may contribute to the condition.

Nonsurgical treatment has relapse rates of up to 90 %, irrespective of the choice of conservative treatment.<sup>2</sup> As early as in 1991, the U.S. National Institute of Health issued a statement recognizing the known lack of success with conservative forms of treatment, noting that operations to constrict or bypass the stomach were justified for fully informed and consenting patients and constituted an acceptable risk.<sup>3,4</sup>

Patients are considered candidates for surgery if they meet one of the following criteria: body mass index (BMI) > 40, BMI of 35–40 plus one of the obesity-associated co-morbidities (diabetes, hypertension, heart disease, sleep apnea, osteoarthritis, asthma...). To be considered for bariatric surgery, patients should have attempted, without success, to lose an appropriate amount of weight through supervised diet changes. Patients must also be able to comply with postoperative diet and exercise.

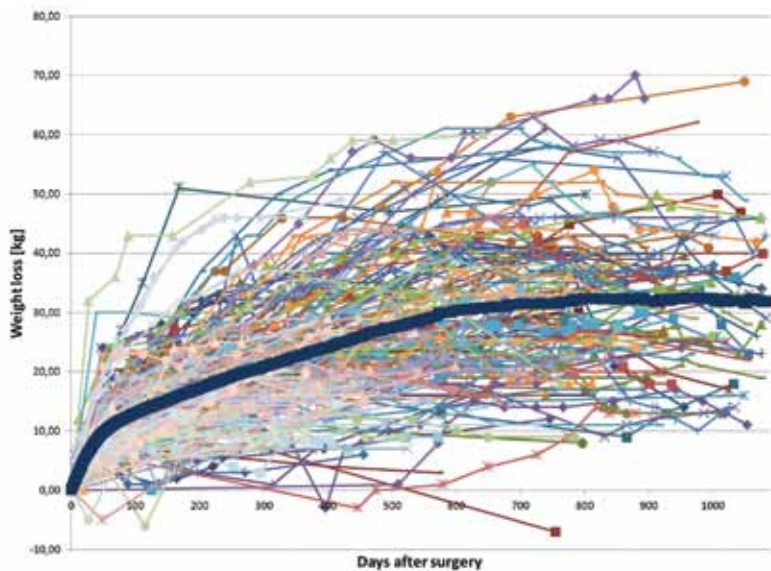
Contraindications for bariatric surgery include: substance abuse, major psychiatric disorder, end-stage organ disease (e.g. hepatic, cardiac, pulmonary...).

Gastric banding consists of an adjustable inflatable band placed around the proximal part of the stomach. This creates a small gastric pouch (approximately 15 ml in volume) and a small stoma. The degree of restriction is adjustable by adding or removing radioopaque solution from the inflatable band. A reservoir system, which is fixed to abdominal fascia and filled or emptied transcutaneously, is connected to the band via tubing. Adjustment of the band through an access port is an essential part of laparoscopic adjustable gastric banding therapy. Appropriate adjustments, performed up to 6 times annually or even more often, are critical for successful outcomes. Patients must chew food thoroughly to allow food to pass through the band. Adjusting the inflation of the cuff changes the size of the opening through which the food passes, but does not change the size of the gastric pouch; deflation of the cuff is useful when the outlet is obstructed.

On average, weight loss after laparoscopic adjustable gastric banding is about 50–

**Table 2:** Monitoring

Year of surgery	Pts	With band	Without band	Lost
1 <sup>st</sup>	11	4 (36.4 %)	6 (54.5 %)	1 (9.1 %)
2 <sup>nd</sup>	76	68 (89.5 %)	8 (10.5 %)	0
3 <sup>rd</sup>	49	46 (94 %)	1 (2 %)	2 ( 4 %)
4 <sup>th</sup>	75	74 (99 %)	0	1
5 <sup>th</sup>	53	53 (100 %)	0	0
ALL	264	245 (92.8 %)	15 (5.7 %)	4 (1.5 %)



**Picture 1:** Weight loss

60 % of excess body weight in approximately 2 years.<sup>5</sup> AGB can be completely reversed with removal of the band, tubing, and port.

Laparoscopic adjustable gastric banding is a safe and feasible procedure with specific indications in moderately obese patients and, secondarily, in highly obese patients who are unfit for more invasive techniques. A recent study suggests that in patients with mild-to-moderate obesity, laparoscopic adjustable gastric banding appears to be significantly more effective than nonsurgical therapies in producing weight loss, resolving the metabolic syndrome, and improving quality-of-life outcomes.<sup>6-8</sup>

### Patients & methods

A clinical study was conducted at Slovenj Gradec General Hospital, Slovenia. We performed 264 gastric bandings (66.5 % of

all bariatric procedures) between May 2005 and May 2010. On average, patients were 41.0 years old (range 17.2–68.8) and had a BMI of 42.4 kg/m<sup>2</sup> (range 34.5–59.0). There were 224 female patients (84.8 %) with an average age of 41.0 years (range 19.5–68.8) and a BMI 42.0 kg/m<sup>2</sup> (range 34.5–59.0) – Table 1. Out of 264 patients, 15 had to have the band removed because of either insufficient weight loss (6 patients, 2.3 %), slippage (4 patients, 1.5 %), migration (1 patient, 0.4 %), band leakage (1 patient, 0.4 %), intra abdominal abscess (1 patient, 0.4 %), outlet obstruction (1 patient, 0.4 %), and personal reasons (1 patient, 0.4 %). 4 patients (1.5 %) were lost to follow up – Table 2 and 3. We followed 192 patients for more than one year. 155 patients (80.7 %) were evaluated with BAROS – Bariatric Analysis and Reporting Outcome System, which is a questionnaire assessing the quality of life (QoL), excessive weight loss (EWL), medical conditions, and complications. Scoring is divided into 5 grades ranging from bad to excellent. There are 2 different scoring groups: a group with comorbidities (1–9 points) and a group without comorbidities (0–6 points). 155 of our patients (80.7 %), 101 with- and 54 without comorbidities, responded and answered the BAROS questions.

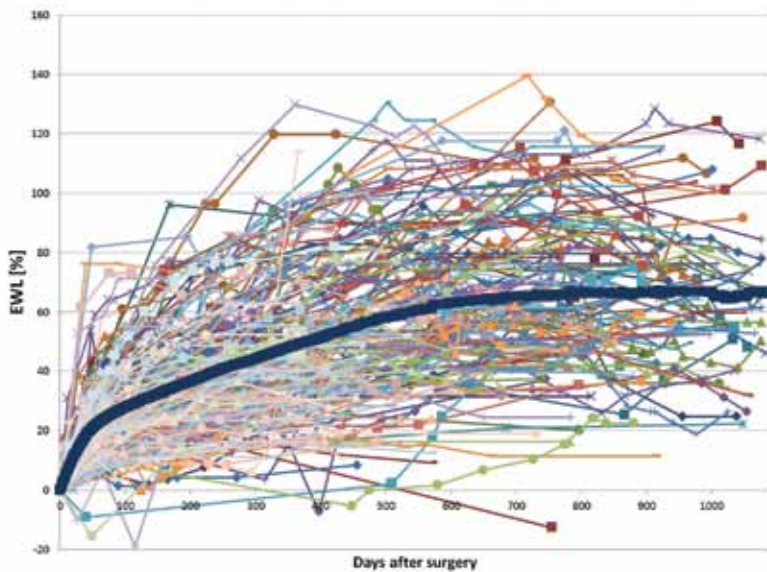
We excluded patients with hormonal disorders and other pathologies preoperatively. Because gastric banding is not suitable for every patient, we performed a thorough psychological evaluation of all the patients. Patients were offered preoperative and postoperative psychological and dietary support when needed.

**Table 3:** Reasons for removing of the band

Year of surgery	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	TOTAL
migration		1				1 (0.4 %)
Slippage/dilatation	1	2	1			4 (1.5 %)
Insufficient weight loss	3	3				6 (2.3 %)
Outlet obstruction	1					1 (0.4 %)
Band leakage	1					1 (0.4 %)
Personal reasons		1				1 (0.4 %)
Intra abdominal abscess		1				1 (0.4 %)

**Table 4:** Background data of the patients participating the support group

Characteristics	Patient group (N=192)
EWL	50.3 ± 24.2
Gender (%)	
male	12.4
female	87.6
Age in years	41.7 ± 12.2
Number of visits	2.8 ± 2.0



Picture 2: EWL

We performed the operation using a pars flaccida technique and secured the band with 1–3 stitches (fundus to the left crus and pouch).

To determine a possible correlation between EWL and participation in the support group, we performed a statistical analysis on the 192 patients who were monitored for more than 1 year. Background data statistics included frequency and percentage distributions for categorical variables, along with mean values and ranges for continuous variables. Pearson correlation coefficient was calculated to conduct univariate strength association between EWL and the number of visits in the support group. We used the linear regression method for calculating the EWL value (dependent variable) in relation to the number of visits, adjusted for age and gender (Table 3). Statistical analysis was performed with the SPSS 15.0 software (SPSS Inc., Chicago, IL). P value < 0.05 was marked as statistically significant.

Table 5a: Results—all

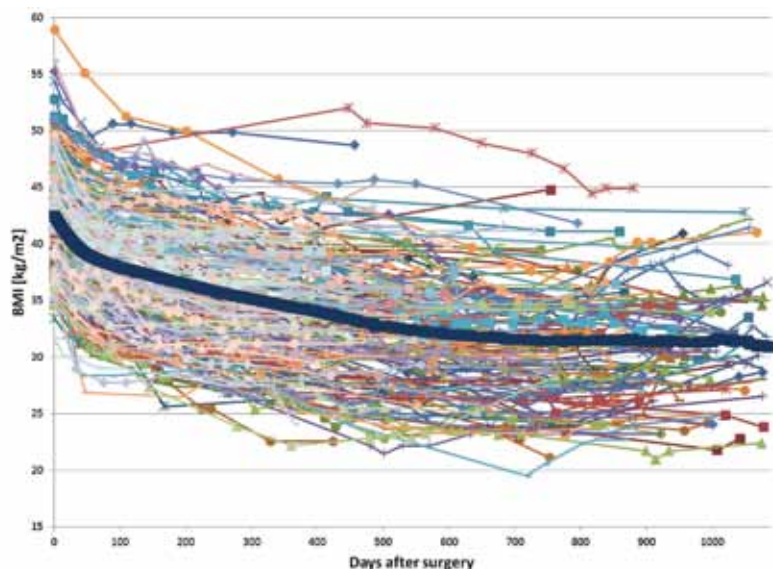
Monitored years/ No. of patients	Weight loss(kg)	EWL(%)	BMI(kg/m <sup>2</sup> )
> 1/192	23.4 (-1.1–52.9)	50.3 (-2.0–145.3)	34.0 (21.9–51.2)
> 2/118	31.4 (-6.3–63.8)	65.6 (-11.2–135.9)	31.4 (20.2–47.9)
> 3/72	33.7 (6.2–69.0)	69.8 (17.0–134.9)	30.8 (22.4–44.0)
> 4/4	35.1 (25.1–51.7)	82.2 (69.0–97.3)	27.6 (25.4–29.7)

Table 5b: Results–female

Monitored years/ No. of patients	Weight loss(kg)	EWL(%)	BMI(kg/m <sup>2</sup> )
> 1/172	23.3 (-1.1–52.9)	51.7 (-2.0–145.3)	33.6 (21.9–51.2)
> 2/106	31.4 (-6.3–63.8)	68.0 (-11.2–135.9)	31.0 (20.2–47.9)
> 3/67	33.7 (6.2–69.0)	71.6 (19.5–134.9)	30.3 (22.4–41.6)
> 4/4	35.1 (25.1–51.7)	82.2 (69.0–97.3)	27.6 (25.4–29.7)

Table 5c. Results–male

Monitored years/ No. of patients	Weight loss(kg)	EWL(%)	BMI(kg/m <sup>2</sup> )
> 1/20	24.6 (8.4–47.7)	38.3 (12.4–79.7)	37.4 (29.0–45.5)
> 2/12	29.9 (11.0–51.9)	43.9 (19.0–62.5)	36.4 (31.8–43.0)
> 3/5	33.5 (12.2–51.2)	45.0 (17.0–60.6)	36.2 (30.9–44.0)
> 4/4			



Picture 3: BMI reduction

## Results

192 out of 264 patients were monitored for more than one year after the procedure (172 females and 20 males).

### Weight loss

In the first year, patients lost 23.4 kg on average (-1.1–52.9); (females 23.3 kg, range -1.1–52.9; males 24.6 kg, range 8.4–47.7).

Two years after surgery, 118 patients (106 females and 12 males) lost 31.4 kg on average, range -6.3 to 63.8 (females 31.4 kg, range -6.3–63.8; males 29.9, range 11.0–51.9).

Three years after surgery, 72 patients (67 females and 5 males) lost 33.7 kg on average, range 6.2 to 69.0. Fig. 1.

### EWL

One year after surgery, EWL was 50.3 % on average, range -2.0–145.3 % (females 51.7 %, range -2.0–145.3 %; males 38.3 %, range 12.2–51.2 %).

Two years after surgery, EWL was 65.6 % on average (-11.2 to 135.9 %); (females 68.0 %,

range -11.2–135.9 %; males 43.9 %, range 19.0–62.5 %).

Three years after surgery, EWL was 69.8 % on average, range 17.0 to 134.9. Fig 2

### BMI

The average BMI of all patients before the operation was 42.4 kg/m<sup>2</sup> (range 34.5–59.0), 42.0 kg/m<sup>2</sup> for females (range 34.5–59.0), and 44.0 kg/m<sup>2</sup> for males (range 34.8–55.7).

One year after the procedure, the average BMI was 34.0 kg/m<sup>2</sup> for all patients (range 21.9–51.2), 33.6 kg/m<sup>2</sup> for females (range 21.9–51.2), and 37.4 kg/m<sup>2</sup> for males (range 29.0–45.5).

Two years after the procedure, the average BMI was 31.4 kg/m<sup>2</sup> (range 20.2–47.9), 31.0 kg/m<sup>2</sup> for females (range 20.2–47.9), and 36.4 kg/m<sup>2</sup> for males (range 31.8–43.0).

Three years after the procedure, the average BMI of all patients was 30.8 kg/m<sup>2</sup> (range 22.4–44.0) Fig. 3, Table 5a-c.

### Reoperations

We performed 15 reoperations: 4 (1.5 %) bands were removed due to dilatation of the pouch and slippage, 6 (2.3 %) due to insufficient reduction of body weight, and one each (0.4 %) due to migration, outlet obstruction, band leakage, intra abdominal abscess, and personal reasons.

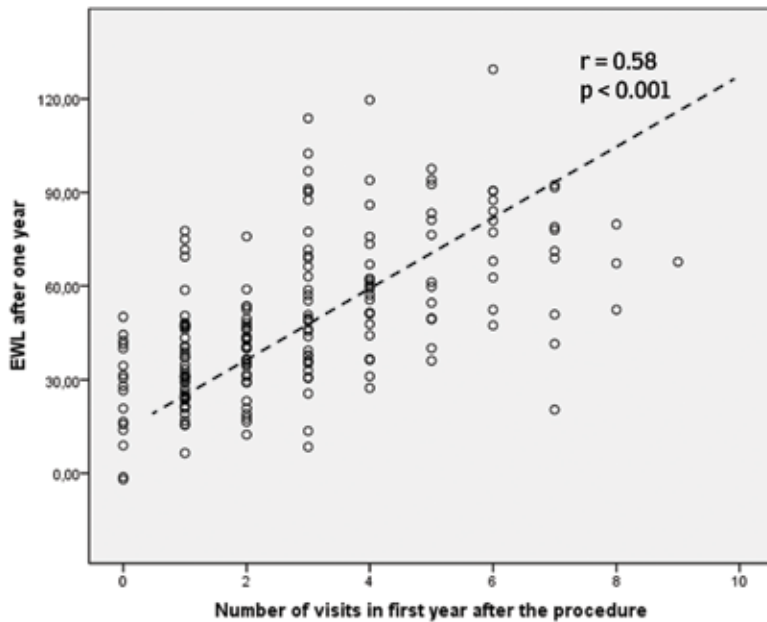
### Resolution of comorbidities

The main obesity-related comorbidities resolved as shown in Table 6. We had 31 patients with diabetes; 13 of them (41.9 %) improved, 17 (54.8 %) had complete resolution of the disease, and one patient (3.2 %) was lost to follow up. Out of 51 patients with hypertension, 21 (41.2 %) improved, 28 (54.9 %) had complete resolution of the disease, one patient (2.0 %) showed no change,

Table 6: Resolution of comorbidities

	all	improved	resolved	No change	No data
Diabetes	31	13 (41.9 %)	17 (54.8 %)		1 (3.2 %)
Hypertension	51	21 (41.2 %)	28 (54.9 %)	1 (2.0 %)	1 (2.0 %)
Hyperlipidemia	17	6 (35.3 %)	9 (52.9 %)	1 (5.9 %)	1 (5.9 %)

**Table 7:** Relation between number of visits and EWL after one year



and one patient (2.0 %) was lost to follow up. Out of 17 patients with hyperlipidemia, 6 (35.3 %) improved, 9 (52.9 %) had complete resolution of the disease, one patient (5.9 %) showed no change, and one patient (5.9 %) was lost to follow up.

**Complications**

There was no perioperative mortality, no pulmonary embolism, no stomach wall lesions, and no hemorrhage.

Early complications among 264 patients (within 1 month after the procedure): 1 (0.4 %) intra abdominal abscess and 1 (0.4 %) outlet obstruction.

Late complications among 264 patients (more than 1 month after the procedure): 1 (0.4 %) band migration, 4 (1.5 %) slippages/dilatations, and 1 (0.4 %) band leakage (follow up 1–60 months, 22 months on average).

**Table 8:** Linear model to calculate EWL

	Beta	t	p
Number of visits	0.56	9.32	<0.001
Age	-0.03	-0.57	0.571
Female gender	0.09	1.45	0.148

R2 = 0.341

**Statistical analysis of support group visits and EWL**

With the Pearson coefficient of  $r = 0.58$  ( $p < 0.001$ ), we can conclude that there is a “moderate to strong” correlation ( $r > 0.5$  is usually interpreted as a strong correlation) between the number of visits in the support group first year after the procedure and EWL after one year. The distribution between EWL and the number of visits is shown by a scatter plot in Table 7.

Table 8 shows that the number of visits has a statistically significant impact on EWL, while age and gender do not significantly correlate with EWL.

**Quality of life evaluation**

The average BAROS score was a grade of “good” in both groups: 4.85 in the group with comorbidities and 2.64 in the group without comorbidities. 155 out of 193 patients (80.7 %) answered the QoL questionnaire. In the group of 54 patients with comorbidities, the average score for QoL was 1.83 (range -0.4–3.0), 1.53 for EWL (range 0–3), and 1.66 for medical condition (range 0–3). In the group of 101 patients without comorbidities, the average score for quality of life (QoL) was 1.72 (range -2.5–3.0), and 1.48 for EWL (range 0–3), Table 9.

**Discussion**

Our results are comparable to the ones published in the literature.<sup>9-12</sup> In our case, there is a noticeable difference between the early results, when we did not have enough experience to decide which patients are appropriate for the band and which are not, and the more recent results. Several of our first 20 cases were not really successful, probably because of insufficient psychological and dietary treatment before surgery; our first patient had psychological problems, which we failed to recognize. She was willing to cooperate, but she did not tell us about her son, who used drugs and her husband, who was an alcoholic. There were periods of significant stress and depression in her life, during which she ate compulsively. Two years after she had gastric banding, we per-

formed LSG on her. Our second patient was unable to change his eating habits, which resulted in slippage of the band. With greater dietary support before and in the early period after the procedure, he would have a greater chance to succeed. Another patient ate too much and too fast from the very beginning—an outlet obstruction occurred 4 weeks after surgery and we had to remove the band. More education before the procedure could have prevented the complication.

Many failures can be prevented with a proper psychological evaluation of the patients. AGB is a method that requires very motivated patients who are willing to cooperate. If one's personality has many of the obsessive-compulsive elements, we cannot expect good results. Frequent monitoring in a support group after surgery is very important, as is immediate emptying of the band if necessary. Our statistics prove that there is a strong correlation between the number of support group visits and EWL; the exact reason for this correlation is yet to be determined. Perhaps only the more successful patients choose to participate in the support group more often. Nevertheless, if we can add any kind of support to morbidly obese patients after their weight loss surgery, the outcomes can only improve. The importance of good monitoring can also be found in the literature.<sup>13</sup>

AGB is usually reported to be associated with a low perioperative complication rate and a very low mortality. The mean excess weight loss after 2 or more years is between 45 % and 65 %;<sup>14-21</sup> in our study it is 65.6 %. Commonly reported long-term complications are band slippage with or without pouch dilatation, band erosion (migration of the band into the stomach), band or port

infection, and leaks from the band, port, or connecting tube. Overall, late morbidity affects between 6 % and 25 % of the patients in series including more than 100 patients. The frequency of each of these complications varies among the series. For instance, band slippage occurs at rates between 0.6 % and 20 %, band erosion at rates between 0 % and 11 %, and leaks at rates between 1.4 % and 26 %.<sup>22-24</sup> In our study, we had 4 slippages and 1 migration. These late complications lead to reoperations in up to 20 % of the patients.<sup>25,26</sup> Our reoperation rate was 5.7 %. We did not have any fatalities, stomach wall lesions, pneumothoraces, or hemorrhages (reports in the literature include up to 2.1 % fatalities, up to 3.5 % stomach wall lesions, up to 2.0 % hemorrhages, and up to 10.4 % port or band system complications).<sup>5,26</sup>

We found a positive correlation between patients' participation in the support group and their EWL. It is well known that AGB requires patients to be very cooperative. The support group is one of the essential ways of monitoring and following the patients post-operatively.

## Conclusions

Bariatric surgery has proven to be the best treatment for morbid obesity. AGB is a bariatric procedure with the least complications, but it is not suitable for everyone. Good preoperative psychological evaluation has proven to be as necessary as good post-operative monitoring.

Good results can be expected with an interdisciplinary approach. The outcomes are significantly better when patients participate in the support group guided by a psychologist.

**Tabele 9:** BAROS

	QoL	EWL	Medical condition	Total score
Comorbidity group	1.83 (-0.4-3.0)	1.53 (0-3)	1.66 (0-3)	4.85 (0.2-8.4)
Without comorbidity	1.72 (-2.5-3.0)	1.48 (0-3)		2.64 (-2.5-5.9)

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