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► To cite this version:

Paul Brunault, David Jacobi, Julie Léger, Céline Bourbao-Tournois, Noël Hutten, et al.. Observations regarding 'quality of life' and 'comfort with food' after bariatric surgery: comparison between laparoscopic adjustable gastric banding and sleeve gastrectomy.. Obesity Surgery, 2011, 21 (8), pp.1225-31. 10.1007/s11695-011-0411-4 . inserm-00686276

HAL Id: inserm-00686276

<https://inserm.hal.science/inserm-00686276>

Submitted on 9 Apr 2012

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Title: Observations regarding ‘quality of life’ and ‘comfort with food’ after bariatric surgery: comparison between laparoscopic adjustable gastric banding and sleeve gastrectomy.

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Short title: Quality of life and restrictive bariatric surgery

CONFLICT OF INTEREST DISCLOSURE: The authors declare that they have no conflict of interest.

ABSTRACT

BACKGROUND: Although laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG) are coexisting first-choice restrictive procedures for bariatric surgery candidates, it is possible, given their different modes of action, that these procedures have different effects on quality of life (QOL). We hypothesized that improvement of QOL and comfort with food could be better with LSG compared to LAGB.

METHODS: This cohort study included 131 obese patients who had either LAGB ($n=102$) or LSG ($n=29$). Patients were assessed during preoperative and at 6- and 12-month postoperative visits. Five QOL dimensions were assessed using the 'Quality Of Life, Obesity and Dietetics' rating scale: physical impact, psycho-social impact, impact on sex life, comfort with food, and diet experience. We compared QOL evolution between LAGB and LSG using linear mixed models adjusted for gender and body mass index at each visit.

RESULTS: Excess weight loss was $28.4 \pm 14.7\%$ and $34.8 \pm 18.4\%$ for LAGB, and $35.7 \pm 14.3\%$ and $43.8 \pm 17.8\%$ for LSG, at 6 and 12 months postoperatively, respectively. Both LAGB and LSG provided significant improvement in the physical, psycho-social, sexual, and diet experience dimensions of QOL. LSG was associated with better improvement than LAGB in short term (6-month) comfort with food.

CONCLUSIONS: Our results add further evidence to the benefit of LSG and LAGB in obesity management. Within the first year of follow-up, there is no lasting difference in the comfort with food dimension between LSG and LAGB.

Keywords:

obesity; bariatric surgery; quality of life; sleeve gastrectomy; gastric banding; cohort study

INTRODUCTION

Obesity is associated with decreased quality of life (QOL) [1]. Generic health-related QOL is lower in bariatric surgery candidates when compared to non-surgical obese patients, even after adjustment for body weight [2]. In obesity management, bariatric surgery is currently considered to efficiently produce long-term weight loss, improve comorbidities, and improve QOL [3]. Several studies have shown that improvement in QOL occurs as soon as three months after bariatric surgery. QOL then reaches a plateau after one to two years [4-6] and, in some cases, has been shown to match the data from a non-obese population [7]. With improvements in surgical techniques, QOL should be considered, in addition to weight loss, improvement in co-morbidities and postoperative risk, as a major outcome measure to guide the choice of surgical procedure.

With lower operative and nutritional risks compared to mixed and malabsorptive procedures, there is currently much interest in restrictive procedures. Laparoscopic adjustable gastric banding (LAGB), a procedure that has been in clinical use for 15 years [8], is gaining popularity in the United States [9], and laparoscopic sleeve gastrectomy (LSG) was recently proposed as a standalone bariatric approach [10].

Improvement of QOL is well documented following LAGB [11-16]. One and two years following LAGB, significant improvement in physical [11, 15, 16], psychosocial [11, 14-16], and sexual functioning [13] are documented for both obesity-specific and generic tools, such as the Moorehead–Ardelt Quality of Life Questionnaire and the 36-item Short Form Health Survey (SF-36), respectively. Although data for LSG are more limited, improvement of obesity-specific QOL following LSG has been also demonstrated [17-19]. Comparison of the evolution of QOL, food tolerance, and quality of eating with LAGB and LSG were studied in a single study by Schweiger et al. [20]. In this study, LAGB was associated with significantly lower scores in these dimensions when compared with LSG,

Roux-en-Y gastric bypass, and biliopancreatic diversion with a duodenal switch. However, this study did not provide any preoperative QOL data [20].

Although LAGB and LSG are coexisting first-choice restrictive bariatric procedures, it is possible that these procedures may have different effects on QOL. Indeed, low physical and psychological band tolerance has been reported [21] and recent data show that levels of plasma ghrelin, a hormone that stimulates hunger, are down-regulated with LSG but are up-regulated with LAGB [22]. Therefore, we hypothesized that improvement in the ‘comfort with food’ dimension of QOL could be better with LSG compared to LAGB.

The aim of this study was to compare the evolution of QOL, especially ‘comfort with food’, in patients following LAGB and LSG.

METHODS

Participants

This cohort study was conducted in the Nutrition Department of the University Hospital of Tours, France. We enrolled consecutive obese patients who had undergone restrictive bariatric surgery (either LAGB or LSG) between November 1999 and July 2009, with patients having a follow-up period of at least one year.

Measures

We assessed the patients preoperatively, and at 6 and 12 months postoperatively. At the preoperative visit, we collected data on demographics (age, gender, socio-professional category, marital status), previous maximal body-mass index (BMI), current BMI, preoperative obesity comorbidities, history of previous bariatric surgery, waist circumference, hip circumference, medications, and QOL. At 6 and 12 months, we recorded weight, waist circumference, hip circumference, incidence of surgical reoperations, postoperative gastric

fistula rate, use of medications, and QOL. The per cent excess weight loss was calculated at 6 and 12 months as follows: $\text{weight loss} * 100 / (\text{preoperative weight} - \text{weight if BMI was } 25 \text{ kg/m}^2)$.

The main outcome variable was QOL, assessed with the ‘Quality Of Life, Obesity and Dietetics’ (QOIOD) rating scale [23]. The QOIOD is a French tool derived from the ‘Impact of Weight on Quality Of Life Questionnaire’, which was the first instrument specifically designed to assess QOL in obesity [24, 25]. The QOIOD is a 36-item scale, each item being rated on a 5-point scale. This scale includes 5 subscales: ‘physical impact’ (11 items), ‘psycho-social impact’ (11 items), ‘impact on sex life’ (4 items), ‘comfort with food’ (5 items), and ‘diet experience’ (5 items). Ziegler et al. verified the construction validity and internal reliability of the questionnaire for each of the 5 dimensions, as well as its concurrent validity in relation to the 12-item Short Form Health Survey (SF-12). Reproducibility was satisfactory with an intraclass correlation coefficient greater than 0.8 [23].

Statistical analyses

We compared both groups’ characteristics using Wilcoxon and chi-squared tests. We used Fisher’s exact test when expected frequencies were too small. We compared QOL evolution between LAGB and LSG groups using linear mixed models. These models take into account intra-subject correlations due to longitudinal design and time-dependent covariates. Linear mixed models use all the available data, regardless of any missing data. Our models were adjusted according to gender and BMI (with the latter being a time-dependent covariates). The models were fitted with interaction terms between the type of surgery and the follow-up time. When the interaction term was not significant, the models were re-estimated without any interaction terms. Statistical analyses were performed with SAS Version 9.1 software for Windows (SAS Institute, Inc., Cary, NC, USA) and R 2.7.2 [26].

RESULTS

Participants

Figure 1 presents a study flow chart of the three questionnaire sessions. A total of 175 obese patients had either LAGB or LSG over the study period. Of these, 131 patients participated in the complete planned follow-up. Out of the 131 patients, 103 returned completed QOL questionnaires at the preoperative and at 6- and 12-month postoperative visits. Our analyses are based on 131 patients.

Descriptive data

Table 1 presents the patients' demographics. The two groups did not significantly differ regarding age, gender, socio-professional category, marital status, or preoperative obesity comorbidities. The LSG group had a significantly higher preoperative BMI, and a higher previous maximal BMI.

Weight loss and postoperative evolution

BMI was significantly decreased from baseline up to the 12-month visit in both the LAGB and LSG groups ($p < 0.0001$). The per cent excess weight loss was significantly greater in the LSG group compared to the LAGB group at 6 months ($p = 0.02$) and at 12 months ($p = 0.02$) (Table 2).

Surgical reintervention rate at 12 months was not different between the LSG and the LAGB groups ($p = 0.77$). The LSG group had higher postoperative gastric fistula rates than the LAGB group ($p = 0.01$) (Table 2).

Quality of life

Improvement in each of the five QOL dimensions was not better in the group who had prior surgery when compared to the group who had no prior bariatric surgery. Table 2 shows the descriptive data for the QOLOD subscale scores at the preoperative and at 6- and 12-month postoperative visits. Table 3 shows the fixed effects of the independent variables (time, gender, type of surgery, and BMI) on QOL. Except for ‘comfort with food’, we observed a significant time effect. A significant difference between the LAGB and LSG groups was observed for ‘psycho-social impact’ with a mean difference of 4.27 points in favor of the LSG group on a 55-point scale. A time-surgery interaction was observed for the ‘comfort with food’ scale, with a greater improvement in the LSG group compared to the LAGB group at the 6-month visit, but no longer at the 12-month visit.

DISCUSSION

In this study, data from the QOLOD questionnaire confirms that both LAGB and LSG provide significant improvement in the physical, psycho-social, sexual, and diet experience dimensions of QOL. ‘Comfort with food’ evolution was significantly better in the LSG compared to the LAGB group at the 6-month visit, but no longer at the 12-month visit.

Sex ratio, mean age, and preoperative obesity comorbidity rates (except for sleep-apnea syndrome) in our study population are comparable to that observed in Buchwald’s meta-analysis, which included a total 135,246 patients in 621 studies [27]. However, our population had higher preoperative BMIs and higher obstructive sleep-apnea syndrome rates. These data show that our population has characteristics close to those usually described for bariatric-surgery candidates.

Our study is the first to show with the QOLOD a significant increase after LSG in the physical, psycho-social, and sexual dimensions of QOL. Studies focusing on obesity-specific QOL following LSG are scarce, based on small samples and mainly measure QOL using the

Moorehead–Ardelt Quality of Life questionnaire [17-19], which is part of the Bariatric Analysis and Reporting Outcome System (BAROS). In line with these previous studies, our results support the hypothesis of a positive effect of LSG for improving physical, psycho-social, and sexual QOL. Conversely, the positive effects of LAGB on physical, psycho-social, or sexual QOL have already been widely demonstrated [11-17].

Thus, LSG seems to be at least as effective as LAGB in improving QOL. As LSG was also shown to be at least as effective as LAGB at improving weight loss and comorbidities [17, 28], our study adds further evidence to the benefit of LSG in obesity management.

Our study shows a significant improvement in ‘diet experience’ following both LAGB and LSG, and a significant increase in the short term ‘comfort with food’ dimension following LSG. This finding for LAGB seems surprising as digestive symptoms, such as heartburn and acid regurgitation, are commonly reported after LAGB [21, 29]. However, the QOLOD does not evaluate gastrointestinal symptoms themselves but rather their consequences on QOL. Indeed, QOL, defined as an individual's perception of their position in life, which encompasses physical, psychological, social, and spiritual dimensions, is a distinct concept from symptoms [30]. As QOL is an individual's perception, it can be hypothesized that, although gastrointestinal symptoms are frequent following LAGB, their consequences on eating and QOL are weak, and that the increase in QOL may be due to other variables that could be related to satisfaction from weight loss. This hypothesis is in line with Schweiger et al.'s findings, which show that, despite low food tolerance, LAGB patients had the same level of satisfaction as any other bariatric patients [20].

Improvement in ‘comfort with food’ and ‘diet experience’ following LSG was observed in the present study. The positive effects of LSG on ‘quality of eating’ and ‘food tolerance’ have been rarely studied. Only Schweiger et al. reported results similar to ours [20]. We additionally found that LSG patients showed significantly better ‘comfort with food’ than

LAGB patients at 6 months, but not at the 12-month visit. Studying ‘quality of eating’ and ‘comfort with food’ following bariatric surgery is a challenging area, as a decrease in ‘quality of eating’ may sometimes cause a gradual transition to eating soft and semi-liquid high-calorie foods, which would favour weight regain. Contrary to the notion that all restrictive procedures have poor digestive and food tolerance outcomes [31], our results suggest that the type of restrictive surgery could directly impact on ‘comfort with food’ and QOL evolution, with a better profile for LSG. Our results also show that although the LSG group had better comfort with food compared to the LAGB group at the 6-month visit, the difference was not significant any more at the 12-month visit. Although these results could be partly explained by loss of statistical power due to loss of follow-up, the data suggest that beneficial effects in comfort with food of LSG over LAGB tend to plateau within the first post-operative year.

Although validity and reliability of the QOLOD rating scale is documented in obese patients with a mean BMI of 35 kg/m² [23], it was not specifically validated in bariatric-surgery candidates and was not designed to investigate QOL following bariatric surgery. However, the evaluation of physical, psycho-social, and sexual QOL with the QOLOD is comparable to that of the Moorehead–Ardelt Quality of Life Questionnaire [32], a questionnaire issued from the BAROS, and the most widely used QOL questionnaire in the field of bariatric surgery [33]. For instance, psycho-social QOL was assessed in both questionnaires using questions regarding level of sadness, and sexual QOL was assessed using questions that focused on the level of pleasure related to sexual relations. Our statistical analyses used linear mixed models considering only two covariates (gender and BMI). Because of overfitting problems due to the limited size of our study [34] we did not take into account any other covariates (e.g. history of a previous bariatric surgery, preoperative obesity comorbidities). Despite loss of follow-up and the limitation of the 12-month postoperative

period, our study provides significant results on the evolution of QOL in both LAGB and LSG using a reliable obesity-specific QOL questionnaire.

In conclusion, our results show that both LSG and LAGB provide improvement in the physical, psycho-social, sexual, and diet experience domains of QOL. We also show that, within the first year of postoperative follow-up, there is no lasting difference in the comfort with food domain between the two procedures. Beyond weight loss, QOL should also be considered as a major outcome measure after bariatric surgery. Studies of the long-term differential effects of the various bariatric surgery procedures on QOL are warranted.

ACKNOWLEDGMENTS

We thank Vaïda Miknius, Jean-Pierre Chevrollier, and Martine Objois for their help in assessing the patients.

CONFLICT OF INTEREST DISCLOSURE

The authors declare that they have no conflict of interest.

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FIGURE LEGENDS

Figure 1. Study flow chart

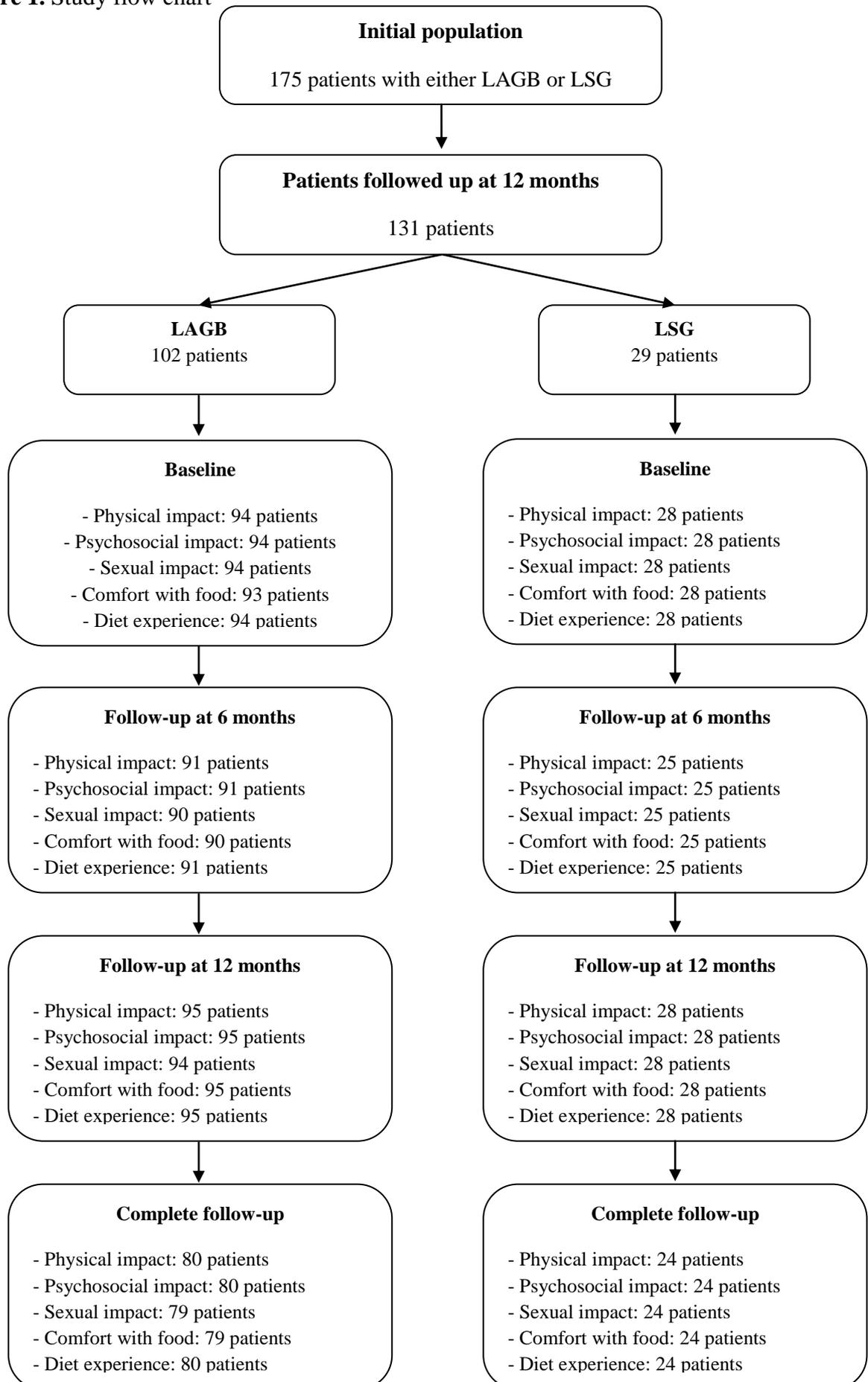


Table 1. Characteristics of study population

	Adjustable gastric banding (<i>n</i> =102)	Sleeve gastrectomy (<i>n</i> =29)	<i>p</i> -value
Age at baseline (years)	39.3 ± 9.6	41.0 ± 10.6	0.45
Gender			0.36
Male	17 (16.7%)	7 (24.1%)	
Female	85 (83.3%)	22 (75.9%)	
Socio-professional category			0.52
Farmers	3 (2.9%)	0	
Tradesmen, shopkeepers and business owners	5 (4.9%)	2 (6.9%)	
Managers and secondary/University teachers	2 (2.0%)	2 (6.9%)	
Intermediate professions	9 (8.8%)	2 (6.9%)	
White-collar workers	48 (47.1%)	11 (37.9%)	
Blue-collar workers	9 (8.8%)	1 (3.5%)	
Unemployed	26 (25.5%)	11 (37.9%)	
Marital status			0.24
Single	13 (12.8%)	5 (17.2%)	
Divorced	14 (13.7%)	1 (3.5%)	
Married or in a relationship	74 (72.5%)	22 (75.8%)	
Widowed	1 (1.0%)	1 (3.5%)	
Previous maximal BMI (kg/m ²)	49.6 ± 5.8	56.4 ± 10.6	0.0006
Preoperative BMI (kg/m ²)	48.1 ± 6.1	54.3 ± 10.1	0.0016

Preoperative obesity comorbidities

Hypertension	39 (38.2%)	10 (34.5%)	0.71
Diabetes	17 (16.7%)	6 (20.7%)	0.62
Dyslipidaemia	39 (38.2%)	17 (58.6%)	0.05
Obstructive sleep-apnea syndrome	30 (29.4%)	13 (44.8%)	0.19
Coronary arterial disease	2 (2.0%)	1 (3.5%)	0.53
Sterility	3 (2.9%)	1 (3.5%)	1.00
Active smoking	25 (24.5%)	6 (20.7%)	0.67
History of previous bariatric surgery	4 (3.9%)	6 (20.7%)	0.008

Data are means \pm standard deviations. We compared both groups' characteristics using Wilcoxon and chi-squared tests. We used Fisher's exact test when expected frequencies were too small.

Table 2. Evolution over the one year of follow-up

	Adjustable gastric banding			Sleeve gastrectomy		
	Baseline	6 months	12 months	Baseline	6 months	12 months
Weight (kg)	129.8 ± 21.0	111.6 ± 18.7	107.9 ± 18.9	149.7 ± 38,1	122.7 ± 33.7	117.2 ± 33.7
BMI (kg/m ²)	48.1 ± 6.1	41.6 ± 5.9	40.2 ± 6.1	54.3 ± 10.1	44.3 ± 9.0	42.2 ± 9.4
Excess weight loss (%)		28.4 ± 14.7	34.8 ± 18.4		35.7 ± 14.3	43.8 ± 17.8
Waist circumference (cm)	123.1 ± 13.6	111.9 ± 12.9	109.3 ± 13.3	141.9 ± 23.2	124.5 ± 21.7	121.8 ± 22.2
Hip circumference (cm)	143.7 ± 12.1	131.8 ± 12.2	129.4 ± 12.5	155.8 ± 20.5	137.9 ± 20.3	135.3 ± 21.1
Surgical reoperation (cumulative incidence)		9 (8.8%)	20 (19.6%)		5 (17.2%)	5 (17.2%)
Postoperative gastric fistula (cumulative incidence)		0	0		3 (10.3%)	3 (10.3%)
Medications						
Antidepressants	7 (6.9%)	5 (5.1%)	4 (4.0%)	5 (17.2%)	3 (10.7%)	4 (14.8%)
Anxiolytic or hypnotic	10 (9.9%)	9 (9.2%)	9 (8.9%)	3 (10.3%)	1 (3.6%)	2 (7.4%)
Quality of life scores						
Physical impact	31.3 ± 8.2	41.9 ± 7.1	43.1 ± 6.9	31.1 ± 7.8	42.7 ± 6.1	42.4 ± 7.1
Psycho-social impact	32.6 ± 8.3	39.9 ± 8.5	40.5 ± 8.3	36.7 ± 8.5	44.0 ± 8.5	42.7 ± 9.6

Sexual impact	13.4 ± 4.4	15.7 ± 4.1	15.9 ± 3.9	14.9 ± 4.6	17.0 ± 3.1	16.4 ± 3.5
Comfort with food	13.4 ± 4.2	14.4 ± 3.9	14.2 ± 4.3	14.2 ± 4.0	17.2 ± 3.9	15.4 ± 4.2
Diet experience	14.3 ± 4.3	16.9 ± 4.0	16.8 ± 3.9	16.0 ± 4.8	18.3 ± 5.4	16.9 ± 5.7

Data are means ± standard deviations. Per cent excess weight loss is calculated as follows: $\text{Weight loss} \times 100 / (\text{preoperative weight} - \text{weight if BMI was } 25 \text{ kg/m}^2)$

Table 3. Fixed effects of the independent variables on quality of life

Effect	Physical impact		Psycho-social impact		Sexual impact		Comfort with food		Diet experience	
	Estimation	<i>p</i> -value	Estimation	<i>p</i> -value	Estimation	<i>p</i> -value	Estimation	<i>p</i> -value	Estimation	<i>p</i> -value
Intercept	51.12 ± 3.42	<0.0001	45.68 ± 3.80	<0.0001	17.09 ± 1.85	<0.0001	13.39 ± 2.01	<0.0001	15.31 ± 2.10	<0.0001
Time		<0.0001		<0.0001		0.0009		<0.0001		<0.0001
T0	-	-	-	-	-	-	-	-	-	-
T6	7.72 ± 0.74	<0.0001	5.01 ± 0.79	<0.0001	1.50 ± 0.40	0.0002	1.12 ± 0.47	0.018	2.30 ± 0.47	<0.0001
T12	7.97 ± 0.87	<0.0001	4.92 ± 1.01	<0.0001	1.58 ± 0.48	0.001	0.76 ± 0.57	0.18	2.03 ± 0.56	<0.0001
Type of surgery										
Gastric banding	-	-	-	-	-	-	-	-	-	-
Sleeve	1.36 ± 1.35	0.32	4.27 ± 1.49	0.0048	1.13 ± 0.72	0.12	0.87 ± 0.93	0.35	1.20 ± 0.80	0.14
Gender										
Female	-	-	-	-	-	-	-	-	-	-
Male	1.90 ± 1.43	0.19	6.97 ± 1.57	<0.0001	3.33 ± 0.77	<0.0001	-0.40 ± 0.80	0.62	1.36 ± 0.85	0.11
BMI	-0.41 ± 0.07	<0.0001	-0.29 ± 0.08	0.0002	-0.08 ± 0.04	0.024	-0.002 ± 0.04	0.97	-0.02 ± 0.04	0.58
Surgery type*time								0.029		
Sleeve group*T6							1.95 ± 0.82	0.018		

Sleeve group*T12

0.46 ± 1.00 0.65

Results are based on linear mixed models adjusted for gender and BMI at each visit. Data are parameter estimation ± standard errors. T0, T6, and T12 are assessments at the preoperative and at 6- and 12-month postoperative visits, respectively. * Mean interactions between two variables.