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Original article

Improvement in health-related quality of life in first year after laparoscopic adjustable gastric banding

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Abstract

Background: We analyzed the health-related quality of life (HRQOL) and its determinants in the first year after laparoscopic adjustable gastric banding (LAGB). The setting was 10 Italian public and private bariatric surgery centers.

Methods: Data collected in an ongoing, prospective, 3-year multicenter Italian study on the changes in HRQOL after LAGB were used. HRQOL was investigated using the Medical Outcomes Study Short-Form 36 questionnaire. Hunger, satiety, and the self-perceived effects of LAGB were recorded.

Results: A total of 334 patients were enrolled. The follow-up rate was 92.2%. The percentage of excess weight loss was 39.6% ± 25.8%, with very few side effects or complications. Hunger in the morning (0–10 scale) was 4.5 ± 2.7 before surgery and 3.8 ± 2.4 after 1 year (P <.001). Satiety after a meal (0–10 scale) was 7.1 ± 2.7 before surgery and 8.2 ± 1.9 at 1 year (P <.001). The self-perceived effect of LAGB on caloric intake (0–10 scale) was 8.4 ± 1.9 after 1 year. The scores for the 8 Medical Outcomes Study Short-Form 36 subscales were significantly improved after surgery. The physical component summary score was 52.6 ± 11.9 at baseline and 79.1 ± 15.6 after 1 year (P <.001). The corresponding mental component summary scores were 52.2 ± 12.3 and 76.5 ± 17.2 (P <.001). Greater physical component summary improvement was independently associated with a low initial physical component summary (P <.001), high satiety (P = .002), a high percentage of excess weight loss (P = .013), and a high self-perceived effect of the LAGB (P = .026). Greater mental component summary improvement was associated with a low initial mental component summary (P <.001), high satiety (P <.001), a low frequency of heartburn (P = .004), and a high percentage of excess weight loss (P = .012).

Conclusions: Significant improvements in HRQOL were observed in the first year after LAGB. A poor baseline HRQOL, a high efficacy of the banding in eating control, and better weight loss might influence HRQOL changes. (Surg Obes Relat Dis 2012;8:260–268.) © 2012 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Health-related quality of life; Morbid obesity; Gastric banding

Laparoscopic adjustable gastric banding (LAGB) is one of the most frequently performed procedures worldwide [1]. LAGB has been proved to be associated with successful weight loss and weight maintenance [2,3], improvement of obesity-related comorbidities [2,4], and reduced all-cause mortality [5,6]. Initial observations also reported an improvement in health-related quality of life (HRQOL) after LAGB [7–11].

Members and institutions of the Italian Group for Lap-Band (Gruppo Italiano Lap-Band [GILBPLUS]) are listed in the Appendix.

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Several studies investigating HRQOL in morbid obese candidates for bariatric surgery uniformly confirmed that these patients have HRQOL levels significantly lower than the corresponding national norms [8,9,12–16]. HRQOL is a complex item and refers to the overall effects of medical conditions on physical, mental, and social functioning and well-being, as subjectively evaluated and reported by the patient [17]. The entity of the impairment of HRQOL in obese patients has been found to be related to obesity levels [18] but is also influenced by the presence of somatic complaints and co-morbidities [16,19,20], mental disorders [20,21], and unfavorable socioeconomic factors [22,23]. The entity of the improvement in HRQOL observed after LAGB might be only partly explained by the degree of weight loss [7,10,11], and it might also be influenced by preoperative co-morbidities [7] and the interval after surgery [10]. However, LAGB can also cause adverse upper gastrointestinal side effects in some patients [24]. The relative weight of these symptoms (an inability to consume solid foods, moderate dysphagia, occasional regurgitation) on overall patient satisfaction has been reported to be low in a cross-sectional analysis of obese subjects treated with LAGB [24]. However, the role of gastrointestinal side effects in determining postoperative HRQOL after LAGB has never been prospectively analyzed.

The objective of our study, therefore, was to prospectively analyze the weight loss, rates of complications and upper gastrointestinal side effects, and changes in HRQOL in the first year after surgery in a large series of morbidly obese patients enrolled in a prospective 3-year multicenter Italian study on the changes in HRQOL in patients treated with LAGB. In the present study, HRQOL was analyzed using the 36-item Medical Outcomes Study Short-Form Health Survey (SF-36) questionnaire.

Methods

Patients and procedures

The Italian Group for Lap-Band (Gruppo Italiano Lap-Band [GILBPLUS]) is a centralized electronic database that collects operative and follow-up data from Italian surgical centers using the Lap-Band System (Allergan Medical, Irvine, CA) as a LAGB procedure. Participation of the centers to the database is voluntary. In 2008, GILBPLUS designed an ongoing prospective 3-year observational study on the changes in HRQOL in patients treated with LAGB. Participation of the GILBPLUS centers in the present study was on a voluntary basis, and participating centers agreed to comply with a minimal follow-up rate of 75% to maintain their right to participate. The general design of the study and baseline data have been previously described [25]. In brief, the inclusion and exclusion criteria were in accordance with standard international guidelines for bariatric surgery [26,27]. From June 2008 to December 2009, 383 morbidly obese candidates for LAGB (82 men and 301 women) were originally enrolled in 13 Italian bariatric surgery centers participating in the GILBPLUS study and underwent LAGB surgery [25]. Each patient gave written informed consent for study participation. Two centers were subsequently excluded from the study because of an inability to provide acceptable follow-up rates. Also, 1 center withdrew its participation for personal reasons. Finally, 334 participants (74 men and 260 women) were enrolled at 10 Italian bariatric surgery centers. Their mean age was 38.9 ± 10.1 years (range 19–60), and they had a mean body mass index (BMI) of 41.7 ± 5.6 kg/m^2 (range 35.0–77.0). No significant differences were found in the baseline characteristics of the patients finally included in the study or in the excluded patients (data not shown). Only data collected during the first year of the study were used in the present report.

A preoperative multidisciplinary assessment was performed at all centers. The basic multidisciplinary assessment included clinical history, physical examination, psychological evaluation, blood tests, electrocardiography, chest radiology, spirometry, abdominal ultrasonography, and esophagogastroduodenoscopy. Additional tests and consultations were scheduled if clinically appropriate. All clinical data were electronically stored in a centralized electronic database.

All LAGB procedures were performed on an inpatient basis using the LAP-BAND AP Adjustable Gastric Banding System (Allergan Medical, Irvine, CA). At discharge, the patients were instructed to follow a modified liquid diet for 4 weeks. Thereafter, a solid diet was followed, with an inventory of permitted foods and a list of rules specifically developed for patients with gastric restriction. Both the liquid and solid diets were arranged to fit a 24-hour energy intake of 2.5 MJ (40% protein. 25% fat, 35% carbohydrate). Physical activity was encouraged. Patients were seen on an outpatient basis 1, 3, 6, and 12 months postoperatively and yearly thereafter. Band adjustments were performed with the barium swallow test under fluoroscopy and the levels of band filling were recorded as the volume of saline solution progressively inflated into the band after surgery.

No further efforts for the standardization of patient care management among participating centers were made for the specific purpose of the present study. However, both preoperative and perioperative clinical pathways and surgical technique were relatively uniform among the GILBPLUS centers.

Study measurements

The study measurements were performed at baseline and 6 and 12 months after surgery.

All anthropometric measurements were made with the subjects wearing only light clothes without shoes. Height was measured to the nearest .01 m using a wall-mounted stadiometer. The body weight was determined to the nearest

.05 kg using a calibrated balance beam scale. The BMI was calculated as the weight in kilograms divided by the height in meters squared. The systolic and diastolic blood pressure were measured with the patient in the sitting position, after a 5-minute rest, with an appropriately sized cuff. Venous blood sampling was drawn early in the morning, after a 12-hour overnight fast. The fasting blood glucose, glycated hemoglobin, total cholesterol, high-density lipoprotein cholesterol, triglycerides, and the liver enzymes aspartate transaminase and alanine transaminase were determined using standard methods by local laboratories.

Specific questions about preoperative co-morbidities were included in the GILBPLUS database. Diabetes was defined as a fasting plasma glucose level of ≥126 mg/dL or the use of any antidiabetic drug [28]. Hypertriglyceridemia was defined as fasting triglycerides of ≥150 mg/dL and low high-density lipoprotein as a high-density lipoprotein cholesterol level of <40 mg/dL in men and <30 mg/dL in women [29]. Hypertension wad defined as blood pressure ≥140/90 mm Hg or the use of any antihypertensive drug [30]. Sleep apnea was diagnosed on the basis of the presence of subjective diurnal and/or nocturnal symptoms [31]. An instrumental registration of the breathing pattern during sleep was not mandatory. Osteoarthritis was clinically defined as the presence of chronic pain in the weight-bearing joints with or without the use of pain suppressant medications. As a part of the preoperative multidisciplinary assessment, eating behavior disorders, eating attitudes, and psychological symptoms were evaluated in all patients during a clinical unstructured interview performed by an experienced psychologist. Psychiatric consultation was not routinely performed, but it was requested in the case of suspected severe psychiatric co-morbidity. Patients with psychotic disorders, severe depression, and personality disorders were excluded [26]. Patients with a mild-to-moderate major depressive disorder or dysthymic disorder were included and simply categorized as affected by depression. The diagnosis of binge eating disorder was determined using standard diagnostic criteria [32]. Sweet eating was diagnosed when the patient craved simple carbohydrates, and carbohydrate craving could be continuously present or triggered by emotional (anxiety, stress) or physiologic (premenstrual phase) situations [33]. Nibbling was diagnosed when the patient ate small quantities of foods repetitively between meals, typically triggered by inactivity and/or loneliness [33].

Hunger in the morning after an overnight fast and satiety after a standard meal were graded by the patients using a 0–10 visual scale before and 6 and 12 months after surgery. At the 2 postoperative evaluations, the patients were also asked to rate the self-perceived effect of LAGB on their caloric intake using a 0–10 visual scale. The gastrointestinal symptoms were recorded with the use of a standardized brief questionnaire. Dysphagia, simply defined as difficultly swallowing any type of food, and reflux were categorized as absent or present. The frequency of episodes of food regurgitation during meals was categorized using a 0–3 scale (0, no episodes of vomiting during the previous month; 1, no >5 episodes of vomiting during the previous month; 2, no >than 20 episodes of vomiting during the previous month; 3, >20 episodes of vomiting during the previous month or daily vomiting) [34]. The frequency of heartburn or gastric pyrosis episodes were categorized using a similar 0–3 scale.

HRQOL was analyzed using the SF-36 questionnaire. The standard (4-wk) recall, version 2.0, of the SF-36 was used. The SF-36 measures the following 8 subscales: physical functioning, social functioning, role limitations due to a physical problem, role limitations due to an emotional problem, mental health, vitality, bodily pain, and general health perception. The 8 subscales form 2 distinct higher ordered summary scales: the physical component summary scale (PCS), mainly based on physical functioning, role limitations due to a physical problem, pain, and general health perception; and the mental summary component scale (MCS), mainly reflecting social functioning, role limitations due to an emotional problem, mental health, and vitality [35]. The SF-36 has an Italian validated version, and normative values have been published for the Italian adult population [36].

Statistical analysis

All statistical analyses were performed using the Statistical Package for Social Sciences, version 18.0 (SPSS, Chicago, IL). In all analyses, $P < .05$ was considered statistically significant. The frequencies, mean values, and standard deviations were used to describe the baseline characteristics of the patients. Differences in the values observed before and after surgery were evaluated using a paired Student's *t* test. Changes in HRQOL were quantified as the difference between the values of the 2 SF-36 summary scales (PCS and MCS) observed 12 months after surgery and those observed at baseline. The determinants of PCS and MCS changes were first analyzed by simple correlation analysis. Categorical covariates was coded as absent (0) or present (1). The tested variables were gender (0 = male; 1 = female), age at surgery, baseline BMI, baseline PCS and MCS scores, baseline physical co-morbidities (type 2 diabetes, hypertension, sleep apnea, osteoarthritis), baseline depression and eating behavior disorders (binge eating disorder, sweet eating, nibbling), resolution of physical co-morbidities at 12 months, dysphagia and reflux at 12 months, regurgitation and pyrosis scores at 12 months, morning hunger and after meal satiety at 12 months, self-perceived effect of LAGB on caloric intake at 12 months, BMI, and percentage of excess weight loss (%EWL) level at 12 months. Variables significantly associated with changes in the PCS or MCS scores on simple correlation analysis were finally entered in a stepwise multiple linear regression model to test their independent contribution to the variability of PCS or MCS changes. Predictors were selected at a significance level of $P < .05$. As a criterion

Table 1
Baseline characteristics of 334 morbidly obese patients

Baseline characteristic	Value
Male gender (%)	22.2
Age (yr)	38.9 ± 10.1
Body weight (kg)	113.8 ± 18.6
BMI (kg/m^2)	41.7 ± 5.6
Type 2 diabetes (%)	11.4
Hypertriglyceridemia (%)	11.1
Low HDL levels (%)	8.1
Hypertension (%)	27.5
Sleep apnea (%)	9.3
Osteoarthritis (%)	21.6
Binge eating (%)	3.9
Sweet eating (%)	.6%
Nibbling (%)	11.7
Depressive symptoms (%)	8.4

BMI = body mass index; HDL = high-density lipoprotein.
Data presented as mean ± standard deviation or percentages.

for removing variables in the stepwise regression, P for F of ≥ .10 was chosen.

Results

The baseline characteristics of the 334 morbid obese participants in the GILBPLUS prospective 3-year observational study on the changes of HRQOL in patients treated with LAGB are reported in Table 1. Our series included mainly young female patients with a relatively low BMI and co-morbidity burden. All but 1 surgical procedures were performed using a laparoscopic approach. The LAP-BAND AP was successfully positioned in all patients (AP small in 67.7% and AP large in 32.3%), with no perioperative mortality. Intraoperative complications were mild and rare (2.1%), and only 3 patients (.9%) presented with early postoperative medical or surgical complications. The mean operative time was 67.8 ± 33.1 minutes (range 20–240), and the mean hospital stay was 2.7 ± 3.8 days (range 1–9).

The anthropometric and biochemical data collected in the first year after surgery are reported in Table 2. The follow-up rate was 97.0% at 6 months (324 patients) and 92.2% at 12 months (308 patients). The %EWL was 29.2% ± 15.9% at 6 months and 39.6% ± 25.8% at 12 months. During the first year after surgery, 2 cases of pouch dilation (.6%) were observed, 1 of which evolved to slippage requiring band removal (.3%). No case of band erosion or infection was observed, and no additional band-related redo surgery was required. Five minor port complications were observed (1 port-tube leak, 3 port rotations, and 1 port infection), and 2 patients (.6%) required minor port-related surgery. One female patient became pregnant during the first year after surgery. The fasting blood glucose, total cholesterol, low-density lipoprotein cholesterol, triglycerides, and alanine transaminase levels were significantly reduced at the 6-month evaluation and remained substantially stable afterward. The glycated hemoglobin level in patients with type 2 diabetes at baseline was 6.3% ± 1.2% before surgery and 5.2% ± .9% at 6 months (P <.001) and 5.5% ±.7% at 12 months (P <.05) after surgery. The resolution of type 2 diabetes was observed in 79.4% of patients at 6 months and 85.3% at 12 months. The resolution of hypertension was observed in 77.3% of the patients at 6 months and 89.2% at 12 months postoperatively. Symptoms of sleep apnea had disappeared in 96.6% of patients at 6 months and 100.0% of patients at 12 months. Pain related to osteoarthritis had disappeared in 80.9% of patients at 6 months and 87.3% at 12 months.

Hunger in the morning after an overnight fast, satiety after a standard meal, the self-perceived effect of LAGB on caloric intake, and the band filling levels are reported in Table 3. Hunger in the morning after an overnight fast was graded as significantly reduced by the patients after surgery and satiety after a standard meal significantly increased. Patients graded the self-perceived effect of LAGB on caloric intake as high after surgery (8 on a 0–10 visual scale). The self-perceived effect of LAGB was found to strongly correlate with satiety after a meal at both 6 (r = .522; P <.001) and 12 (r = .501; P <.001) months. The self-perceived effect of LAGB correlated negatively with hunger in the morning at both 6 (r = −.216; P <.001) and 12 (r = −.143; P <.05) months. Moderate correlation levels were found between the self-perceived effect of LAGB and the %EWL (r = .132; P <.05 at 6 mo; and r = .166; P <.01 at 12 mo). No significant correlations were

Table 2
Anthropometric and biochemical data in first year

Variable	Baseline	6 mo	12 mo
Patients (n)	334	324 (97.0)	308 (92.2)
Body weight (kg)	113.8 ± 18.6	97.6 ± 17.5*	93.4 ± 17.9*†
Body mass index (kg/m^2)	41.7 ± 5.6	35.8 ± 5.5*	34.3 ± 5.7*†
%EWL (%)	—	29.2 ± 15.9	39.6 ± 25.8†
Fasting blood glucose (mg/dL)	94.0 ± 18.0	89.4 ± 13.5‡	89.7 ± 13.9‡
HbA1c (%)	5.1 ± 1.1	4.9 ± .8	5.0 ± .7
Total cholesterol (mg/dL)	200.8 ± 39.5	188.6 ± 36.7*	184.9 ± 37.2*
HDL cholesterol (mg/dL)	47.0 ± 10.9	43.2 ± 10.0§	43.3 ± 11.6
LDL cholesterol (mg/dL)	122.6 ± 35.4	118.0 ± 34.6‡	115.2 ± 33.0‡
Triglycerides (mg/dL)	155.5 ± 74.4	134.7 ± 39.9*	129.2 ± 39.8*
AST (U/L)	23.9 ± 12.4	24.1 ± 8.7	22.3 ± 8.3
ALT (U/L)	30.3 ± 22.3	24.6 ± 10.1‡	23.1 ± 9.7‡

HDL = high density lipoproteins; LDL = low density lipoproteins; AST = aspartate transaminase; ALT = alanine transaminase.

Data presented as numbers, with percentages in parentheses, or mean ± standard deviation.

* P <.001, paired Student's t test versus baseline.

† P <.001, paired Student's t test versus 6 months.

‡ P <.01, paired Student's t test versus baseline.

§ P <.05, paired Student's t test versus baseline.

Table 3
Hunger morning after overnight fast, satiety after standard meal, self-perceived effect of gastric banding on caloric intake, and band filling levels in first year

Variable	Baseline	6 mo	12 mo
Patients (n)	334	324 (97.0)	308 (92.2)
Hunger in morning	4.5 ± 2.7	4.0 ± 2.4*	3.8 ± 2.4†‡
Satiety after meal	7.1 ± 2.7	7.9 ± 2.1†	8.2 ± 1.9†§
Self-perceived effect of LAGB	—	8.0 ± 2.1	8.4 ± 1.9¶
Band filling volume (mL)	.0 ± .0	3.6 ± 2.1†	4.5 ± 2.3†¶

LAGB = laparoscopic adjustable gastric banding.
Data presented as numbers, with percentages in parentheses, or mean ± standard deviation.
* P <.01, paired Student's t test versus baseline.
† P <.001, paired Student's t test versus baseline.
‡ P <.05, paired Student's t test versus 6 months.
§ P <.01, paired Student's t test versus 6 months.
¶ P <.001, paired Student's t test versus 6 months.

found between the levels of band filling volume and hunger, satiety, or self-perceived effect of the band at any point after surgery. The levels of band filling volume correlated negatively with the %EWL at both 6 ($r = -.300$; P <.001) and 12 ($r = -.256$; P <.001) months.

The frequency of episodes of food regurgitation during meals and episodes of heartburn or gastric pyrosis are shown in Figure 1. No significant increases in the frequency of episodes of heartburn or gastric pyrosis were observed after surgery. In contrast, the frequency of episodes of regurgitation of food during meals significantly increased after surgery, at both 6 (P <.001) and 12 (P <.001) months. At the 6-month evaluation, 34.4% of the patients had no episodes of food regurgitation during the previous month, 49.5% had ≤5 episodes, 12.9% had ≤20 episodes, and

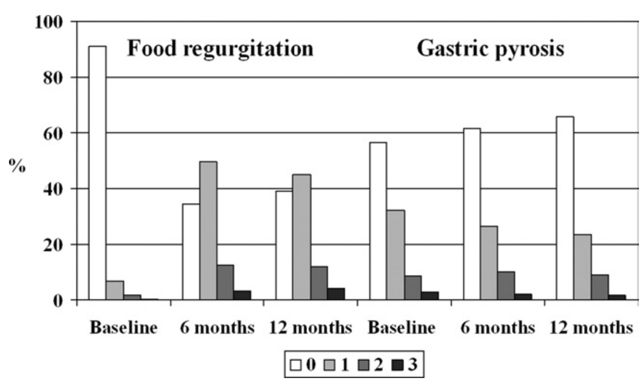

Fig. 1. Frequencies of episodes of food regurgitation during meals and episodes of heartburn or gastric pyrosis in first year of Italian Group for Lap-Band (GILBPLUS) prospective 3-year observational study on changes of HRQOL after LAGB: 334 participants enrolled in 10 Italian bariatric surgery centers. Follow-up rate was 97.0% at 6 months (324 patients) and 92.2% at 12 months (308 patients). Frequencies were categorized on a 0–3 scale (0, no episodes during previous month; 1, ≤5 episodes during previous month; 2, ≤20 episodes during previous month; and 3, >20 episodes during previous month or daily episodes).

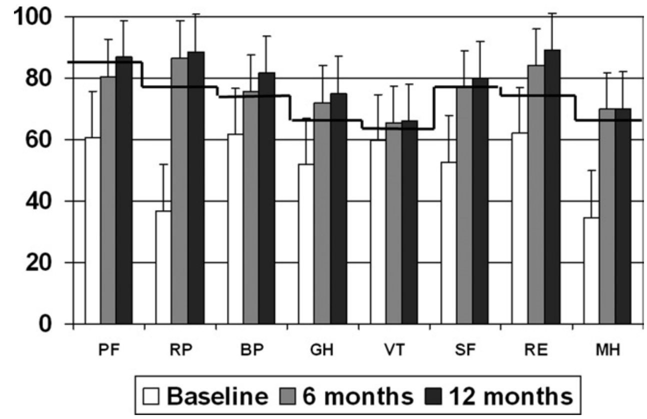

Fig. 2. Health-related quality of life (HRQOL) levels in the first year of the Italian Group for Lap-Band (GILBPLUS) prospective 3-year observational study on the changes of HRQOL after laparoscopic adjustable gastric banding: total of 334 participants enrolled in 10 Italian bariatric surgery centers. Follow-up rate was 97.0% at 6 months (324 patients) and 92.2% at 12 months (308 patients). Baseline (white bars), 6-month (gray bars), and 12-month (black bars) HRQOL levels reported. Eight subscales of SF-36 questionnaire indicated: PF = physical functioning; RP = role limitations due to physical problem; BP = bodily pain; GH = general health; VT = vitality; SF = social functioning; RE = role limitations due to an emotional problem; MH = mental health. Black line represents normative values in Italian adult population [36].

3.2% had >20 episodes or daily food regurgitation. At the 12-month evaluation, 39.1% of the patients had no episodes, 45.0% had ≤5 episodes, 11.9% had ≤20 episodes, and 4.0% had >20 episodes or daily food regurgitation. No significant interactions were found between the frequency of food regurgitation after surgery and the levels of hunger in the morning, satiety after a meal, self-perceived effect of LAGB on caloric intake, band filling levels, and %EWL (data not shown). A very small fraction of patients reported having dysphagia (1.5% at 6 mo and 2.0% at 12 mo) or reflux (2.0% at 6 mo and .3% at 12 mo) after surgery.

The HRQOL levels before and after LAGB are shown in Figure 2. Before surgery, the scores for the 8 SF-36 subscales were lower than those for the general adult Italian population. Compared with the baseline values, highly significant improvement (P <.001) was observed in all 8 SF-36 subscales at the 6-month evaluation. Compared with the 6-month values, an additional significant improvement in HRQOL levels was observed at the 12-month evaluation for physical functioning (P <.001), bodily pain (P <.001), general health (P <.001), vitality (P <.05), social functioning (P <.01), and role limitations due to an emotional problem (P <.01). The physical PCS was 52.6 ± 11.9 at baseline, 75.3 ± 19.9 at 6 months (P <.001), and 79.1 ± 15.6 at 12 months (P <.001 versus baseline and P <.001 versus 6 mo). The MCS was 52.2 ± 12.3 at baseline, 73.2 ± 18.2 at 6 months (P <.001), and 76.5 ± 17.2 at 12 months (P <.001 versus baseline and P <.001 versus 6 mo).

Changes in HRQOL have been calculated as the difference between the PCS and MCS values observed 12 months

Table 4
Variables significantly associated with changes in physical component summary score and mental component summary score in first year after surgery

Variable	Change in PCS	Change in MCS
Baseline PCS score	−.423*	−.154†
Baseline MCS score	−.245*	−.324*
Frequency of gastric pyrosis at 12 mo	—	−.126‡
Satiety after meal at 12 mo	.168†	.210*
Self-perceived effect of band at 12 mo	.199†	.191†
Excess weight loss at 12 mo (%)	.125‡	.129‡

PCS = physical component summary; MCS = mental component summary.

Simple linear correlations coefficients reported.

Changes in PCS and MCS calculated as difference between 12-month values and baseline values; variables tested reported in "Statistical Analysis" section.

* $P < .001$.
† $P < .01$.
‡ $P < .05$.

after surgery and those observed at baseline. A positive value was found in 94.3% of the patients for PCS and 91.6% for MCS. Determinants of PCS and MCS changes were analyzed by simple correlation analysis. The variables tested have been reported in the "Statistical Analysis" section, and the variables significantly associated with changes in the PCS or MCS scores are reported in Table 4. Improvements in both summary scales were more relevant in patients with poor HRQOL at baseline. Moderate levels of correlation were found between the PCS and MCS changes and the degree of weight loss (%EWL). Satiety after a standard meal and the self-perceived effect of LAGB on caloric intake were positively associated with both PCS and MCS changes after surgery. Finally, a negative correlation between the frequency of gastric pyrosis at 12 months and the change in MCS was observed. The independent contribution to these variables to the variability in PCS or MCS changes was tested in a stepwise multiple linear regression model analysis. High improvements in PCS were independently associated with low baseline PCS levels ($P = .000$), high satiety after a meal ($P = .002$), high %EWL ($P = .013$), and high self-perceived effect of LAGB ($P = .026$). High improvements in MCS were independently associated with low baseline MCS levels ($P = .000$), high satiety after a meal ($P = .000$), a low frequency of gastric pyrosis ($P = .004$), and a high %EWL ($P = .012$). However, our model explained only a moderate fraction of the PCS and MCS change variability. The explained variance was 27.6% for PCS change variability and 22.9% for MCS change variability.

Discussion

In the present study, we analyzed the changes in self-reported HRQOL in the first year after surgery in a large group of morbidly obese patients enrolled in a multicenter prospective study of the changes in HRQOL in patients treated with LAGB. We have confirmed previous observations reporting a significant improvement in HRQOL [7–11]. The improvement in HRQOL was greater in patients with a poor level of HRQOL before surgery and in patients with greater weight loss after surgery. We also confirmed that LAGB is not only able to increase satiety after meal, but also to reduce hunger after an overnight fast. Patients graded as high (8 on an 0–10 scale) the effect of LAGB on their caloric intake. High satiety after meal and a high self-perceived effect of the banding on caloric intake were both associated with greater improvement in HRQOL in the first year after surgery. Gastrointestinal side effects played a minor role in determining overall patient satisfaction.

The baseline self-reported HRQOL was very poor and lower than the national norms in our series, as well in several other studies involving morbidly obese candidates for bariatric surgery [8,9,12–16]. In the first year after surgery, we confirmed the highly significant rapid improvement in HRQOL observed in previous studies of LAGB [7–11]. Most of the improvement was seen in the first months after the procedure, but a small additional increment was also observed in the second postoperative semester. At the end of our observation period, the mean values for all 8 subscales of the SF-36 questionnaire were comparable to the Italian national norms (Fig. 2). Improvements in HRQOL were substantial and very consistent between patients, with >90% of participants showing better physical or mental HRQOL. Patients with the most impaired levels of HRQOL at baseline had the greater improvements of HRQOL after surgery. The role of the degree of weight loss on HRQOL changes after LAGB has been examined in several studies. Dixon et al. [7] analyzed the SF-36 data from 218 LAGB patients with paired preoperative and 1-year scores and demonstrated that the %EWL at 1 year was of little predictive value for improved HRQOL. Nguyen et al. [9], in a prospective randomized trial comparing gastric bypass and gastric banding, found an equivalent improvement of HRQOL in the first year after the 2 procedures, despite greater weight loss after gastric bypass. Similar results were reported by a study comparing LAGB and laparoscopic sleeve gastrectomy [10]. In our study, the %EWL in the first year after LAGB was only moderately related to improvements in the physical and mental summary scores of SF-36. Thus, we can conclude that highly successful weight loss seems to have a little role in predicting greater patient satisfaction after LAGB. If this is the case, what other factors might be involved? Dixon et al. [7] reported a role of preoperative co-morbidities in predicting the improvement in HRQOL after LAGB. In our studies, we did not observed any relationship between preoperative co-morbidities or the resolution of co-morbidites after surgery and the magnitude of HRQOL improvements. However, this might have resulted from the relatively low burden of co-morbidities observed in our series at baseline.

The analysis of prospectively collected hunger and satiety questionnaires demonstrated that patients in our study had increased satiety after a standard meal and, more surprisingly, reduced hunger in the morning after LAGB. These subjective reports might well have been influenced by a placebo effect. However, significantly greater fasting and postprandial satiety levels have been previously demonstrated in a randomized blind crossover study of LAGB patients with optimal or reduced restriction [37]. Plasma insulin, ghrelin, and leptin levels appeared unrelated to the prolonged satiety observed by LAGB patients with optimal restriction and displayed orexigenic compensatory changes [37]. Whatever the mechanisms involved, our patients graded as high (8 on a 0–10 scale) the self-perceived effect of the banding on their caloric intake, and we found a significant association between the self-perceived effect of the banding and satiety after a meal and hunger in the morning. More surprisingly, both satiety after a meal and the self-perceived effect of banding on caloric intake were positive independent predictors of the changes in the physical and mental components of HRQOL observed after surgery. We might hypothesize that the help the patients received from the LAGB in controlling eating behavior and caloric intake should be important in determining the subjective overall satisfaction of the patients with their procedure.

Since the very beginning of its use in clinical practice, gastric banding has been associated with the emergence of some gastrointestinal side effects, with the most frequent represented by episodes of food regurgitation during meals. Busetto et al. [34] analyzed the eating patterns in the first year after surgery of 80 morbidly obese patients undergoing gastric banding with open surgical access from 1992 to 1994. They first reported a high frequency of food regurgitation, with 11.5% of the patients having >20 episodes in the last month and an additional 21.7% having 5–20 episodes. Such a high vomiting frequency played a significant role in determining the global outcome, forcing the patients to avoid solid foods and to switch to the consumption of soft highly caloric processed foods [34]. The introduction of more modern bands adapted to the laparoscopic approach and the implementation of a more prudent strategy for postoperative band adjustments, might have permitted a reduction in vomiting frequency after surgery. However, in a recent cross-sectional analysis of 323 patients treated with LAGB from 2003 to 2007, Burton et al. [24] reported 9% of patients with daily food regurgitation and an additional 23% of patients having regurgitation more frequently than once per week. The inability to consume a range of foods because of the regurgitation was cited in their study as the most troublesome symptom or problem after surgery by 66% of patients [24]. A lower frequency of food regurgitation was observed in our study, with only 4.0% of patients having daily food regurgitation and an additional 11.9% having 5–20 monthly episodes. This might be partly attributed to the use in all patients of a large-volume low-pressure band with a wider adjustability range, because all band adjustments in our study were performed under radiologic guidance and control, or because of other unknown factors. Additionally, and in accordance with previous reports [24], we confirmed a low frequency of other gastrointestinal symptoms after surgery, reflux in particular. Moreover, episodes of gastric pyrosis did not seem to be increased after surgery. The role of gastrointestinal side effects in determining overall patient satisfaction has been reported to be marginal in a cross-sectional analysis of obese subjects treated with LAGB [24]. In our study, we prospectively confirmed no relationship between gastrointestinal symptoms (dysphagia, reflux, food regurgitation, and pyrosis) and the changes in HRQOL observed after surgery. In summary, the frequency of gastrointestinal side effects was low, and their occurrence had little effect on patient satisfaction after surgery. This observation has been attributed to the fact that patients undergoing LAGB might be prepared to accept some adverse symptoms as the price to pay for successful weight loss and food control [34].

Our study had several methodologic limitations that should be remembered in the interpretation of the results. The total number of follow-up visits in the first year of our study was 4, and this relatively low number of follow-up contacts might have had a negative effect on excess weight loss, which was lower than that reported in other studies [1–3]. The diagnosis of physical co-morbidities at baseline and after surgery was based on very simple clinical criteria, and co-morbidities have been simple classified in the GILB-PLUS database as present or absent, irrespective of their clinical severity. Therefore, the effects of co-morbidities on HRQOL changes could have been attenuated by some degree of missing the diagnosis or by the absence of a more precise staging of co-morbidity severity. The presence of depression and eating behavior disorders was also tested before surgery with the use of an unstructured clinical evaluation and without the application of any formal testing. Some gastrointestinal side effects observed after surgery (dysphagia and reflux) were also simply categorized as absent or present and not graded with the use of the more sophisticated scores applied in some recent reports [24]. The definition of dysphagia adopted in our gastrointestinal symptom questionnaire as difficultly in swallowing any type of food might have produced an underestimation of this symptom in our patients. Finally, in the present study, the HRQOL changes were analyzed using a single instrument, the SF-36 questionnaire. Obesity-specific instruments, such as the Impact of Weight on Quality of Life questionnaire or others, might be more sensitive to the effects of weight and weight-related problems on self-perceived well-being and, therefore, more sensitive to detecting the changes in HRQOL after weight loss [20,21]. These limitations in diagnostic accuracy and method should be taken into account in evaluating the results of our study, but these should be partly compensated for by the rather high number of participants and the multicenter design.

Conclusion

Our results have confirmed that HRQOL was severely impaired in morbid obese candidates to LAGB but substantially improved in the first year after surgery, particularly in patients with lower baseline HRQOL levels. A high self-perceived efficacy of the LAGB in eating control was at least equally important as a good weight loss in determining HRQOL changes. The sustainability of these effects over time remains debated, and it will be specifically investigated in the continuation of the ongoing GILBPLUS 3-year observational study on the changes in HRQOL in patients undergoing LAGB.

Disclosures

The activities of the Italian Group for Lap-Band (Gruppo Italiano Lap-Band [GILBPLUS]) are partly supported by Allergan Medical (Irvine, CA), manufacturer of the LAP-BAND AP Adjustable Gastric Banding System. None of the participating investigators or institutions received direct financial incentives for the enrollment of the patients in the study and the sponsor did not have any role in the analysis of the data collected in the database, their interpretation, or in the preparation of the report.

Appendix

The following investigators and institutions participated in the Italian Group of Lap-Band (Gruppo Italiano Lap-band [GILBPLUS]) prospective 3-year observational study on the changes of HRQOL in patients treated with LAGB. The number of cases enrolled at each center is provided in parentheses: A. M. Schettino, C. Pari, V. Pasini, U. O. di Chirurgia, Casa di Cura Malatesta Novello, Cesena (52); V. Pilone, P. Forestieri, S. Tramontano, Dipartimento di Chirurgia Generale, Oncologica, Bariatrica e Videoassistita, Università degli Studi Federico II, Napoli (45); F. Furbetta, S. Gennai, N. Furbetta, U. O. di Chirurgia, Casa di Cura Leonardo, Empoli (43); E. Mozzi, E. Lattuada, M. Zappa, Cattedra di Chirurgia Generale, Università degli Studi di Milano–Fondazione IRCCS Ca'Granda Ospedale Maggiore Policlinico, Milano (41); A. Di Maro, S. Civitelli, Istituto Ninetta Rosano, Clinica Tricarico, Belvedere Marittimo (32); C. Giardiello, V. Antognozzi, U. O. C. Chirurgia Generale, d'Urgenza e Metabolica, Centro per il trattamento Obesità, Presidio Ospedaliero Pineta, Grande, Castelvolturno (30); M. Battistoni, M. Genna II Chirurgia Generale, Servizio di Chirurgia dell'Obesità, Azienda Ospedaliera Universitaria Integrata, Verona (26); A. Gardinazzi, M. Bazzana, Ospedale Generale Classificato di Zona S. Orsola, Fondazione Poliambulanza, Brescia (24); N. Perrotta, A. Cappiello, UOC di Chirurgia Generale, Ospedale di Villa d'Agri, Azienda Sanitaria di Potenza (22); G. Micheletto, E. Moroni, Cattedra di Chirurgia Generale Università degli Studi di Milano–UOC di Chirurgia Generale, Istituto Clinico Sant'Ambrogio, Milano (20).

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