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ORIGINAL CONTRIBUTIONS

Body Image and Weight Loss Outcome After Bariatric Metabolic Surgery: a Mixed Model Analysis

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Abstract

Purpose As in nonsurgical weight loss populations, body image may partly explain differences in weight loss outcomes after surgery. The aim of this study was to determine the prospective association between body image and weight loss in a longitudinal cohort of patients up to 3 years after bariatric metabolic surgery.

Materials and Methods The BODY-Q self-report questionnaire was used to assess body image. Linear mixed models evaluated associations of baseline body image with weight loss in the first year as well as associations of body image at 12 months and first-year change in body image with weight loss 12 to 36 months after surgery.

Results Available body image data included 400 (100%), 371 (93%), 306 (77%), 289 (72%), and 218 (55%) patients at baseline and 4, 12, 24, and 36 months, respectively. Body image scores improved significantly until 12 months, followed by a gradual decline. Scores remained improved in comparison to baseline ($\beta = 31.49$, 95% CI [27.8, 35.2], $p < .001$). Higher baseline body image was associated with less weight loss during the first year, and the effect size was trivial ($\beta = -0.05$, 95% CI [−0.09, −0.01], $p = .009$). Body image and change in body image were not associated with weight loss 12 to 36 months after surgery.

Conclusion Body image improved after bariatric metabolic surgery. Although no clinically relevant associations of body image with weight loss were demonstrated, the gradual decline in body image scores underlines the importance of long-term follow-up with regular assessment of this aspect of quality of life.

Keywords Bariatric surgery · Body image · Body image concerns · BODY-Q · Weight loss

Abbreviations

α	alpha
ß	beta
BMI	Body-mass index
LMM	linear mixed models
MBSRQ-AS	Multidimensional Body-Self Relations Questionnaire-Appearance Scales
MCID	minimum clinically important difference

Key Points
- The association between baseline body image and first-year weight loss is very small
- Body image at 12 months and weight loss at 12 to 36 months were not associated
- A sustained improvement in body image was observed after bariatric metabolic surgery

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Introduction

Bariatric metabolic surgery is the most effective weight loss treatment for people with obesity [1–3]. Demonstrated effects include weight loss, remission of associated medical problems, and improvements in health-related quality of life (HRQL). Despite overall positive results, there is heterogeneity in weight loss outcome and weight loss maintenance [4, 5]. The identification of factors associated with weight loss may facilitate optimizing these outcomes. Similar to nonsurgical weight loss populations [6, 7], a more positive body image may be associated with increased weight loss after bariatric metabolic surgery. Body image is a complex multidimensional construct that describes one's body-related self-perceptions and self-attitudes, including feelings, beliefs, thoughts, and behaviors [8, 9]. Concerns with body image are assumed to play a role in the origin of obesity [10], and obesity is associated with body image concerns [11–13]. Particularly, patients undergoing bariatric

metabolic surgery experience more body image concerns than people with normal weight [14–21].

Body image concerns are believed to be a motivational catalyst for weight-changing behavior [22]. Indeed, patients undergoing bariatric metabolic surgery reported enhancing body image as a motivator to pursue surgery [23] and showed a greater dissatisfaction with body image in comparison to matched controls from the general population [16]. Generally, after bariatric metabolic surgery, an improvement in body image is observed [14, 15, 18–21, 24–36]. Some studies suggest that a more negative body image before surgery may represent increased motivation to behavioral change and may give rise to increased weight loss [29, 37], while others do not observe this relationship [24, 31] or even report the opposite [38]. These apparently contradictory outcomes may be the result of small sample sizes [24, 29, 31], short follow-up periods [24, 29, 31], confounding bias [37], and the use of distinct questionnaires. In addition to body image before surgery, postoperative body image may be associated with prospective longer-term weight loss (maintenance), a hypothesis that has not been investigated.

While improvement of body image after bariatric metabolic surgery has been frequently observed, knowing whether body image and changes in body image are associated with more favorable weight loss may help to identify patients who would benefit from tailored guidance before and after bariatric metabolic surgery. Therefore, the objective of this study was to examine the association between body image and prospective weight loss in a large longitudinal sample up to 3 years after bariatric metabolic surgery.

Materials and Methods

Participants

The data were collected in an ongoing prospective, multicenter study conducted in two bariatric metabolic surgery hospitals: the OLVG West, Amsterdam and St. Antonius Hospital, Nieuwegein, the Netherlands. Eligible patients were 18 years or older and had undergone either laparoscopic sleeve gastrectomy (SG) or laparoscopic Roux-en-Y gastric bypass (RYGB). An exclusion criterion was insufficient proficiency of the Dutch language. All participants were recruited prior to surgery between December 2017 and November 2018 at outpatient clinics. Before enrollment, an informed consent form was signed. Ethical approval was obtained from each site's ethics committee (registration number NL60699.100.17). All patients were previously screened according to the IFSO criteria at one of the largest outpatient clinics for bariatric metabolic surgery in the Netherlands: the Dutch Obesity Clinic (Nederlandse Obesitas Kliniek, NOK). The NOK provides a specialized multidisciplinary approach to assist patients in adopting and sustaining a healthy lifestyle during a 5-year follow-up program [39].

Data Collection

Participants completed the BODY-Q questionnaire before surgery and 4, 12, 24, and 36 months after surgery. Non-responders received two reminders spaced a week apart. A secure web-based application (CASTOR) was used to send the online questionnaires and store data [40]. All participants completed the questionnaire at baseline and at least once during follow-up.

Questionnaire Data: BODY-Q

The BODY-Q—a patient-reported outcome measure (PROM) for people with obesity and people who underwent surgical or nonsurgical weight loss interventions—was developed according to international standards [41, 42]. It is composed of input from patients and experts in the field of obesity treatment and has been psychometrically validated in multiple studies [43, 44]. The BODY-Q measures the domains of appearance, HRQL and health care experiences using scales that can be applied separately. BODY-Q scale scores were converted into a Rasch score that ranges from 0 (worst) to 100 (best) [45]. For this study, we used data from the "body image" and "excess skin" scales, both response formats contained a 4-point Likert scale:

- Body image: this scale includes seven items that ask respondents to indicate how much they disagree/agree that they are happy with their body, proud of their body and feel positive toward their body (e.g., "My body is not perfect, but I like it" or "I am happy with my body" [45]). A higher score indicates more positive feelings. Cronbach's α was .96 [43].
- Excess skin: this scale contains seven items that measure how much an individual is bothered by their excess skin (extremely bothered/not at all) (e.g., "The amount of excess skin you have" or "Having to dress a certain way to hide your excess skin"). A higher score indicates fewer complaints of excess skin. Cronbach's α was .95 [43].

Patient Demographics

Demographic characteristics, including age, sex, height and weight measurements, medical history, and % total weight loss (%TWL), were derived from the electronic patient file of the NOK. Weight data were available preoperatively and at 6, 12, 24, and 36 months after surgery. If data regarding weight (loss) were not available, they were supplemented with self-reported data provided by the additional

questionnaire that was sent to the patients. This questionnaire also included questions concerning level of education, migration background, work, marital status, and smoking status.

Statistical Analysis

All analyses were conducted using SPSS software version 26. A two-tailed $p < .05$ was considered to indicate statistical significance. Variables were checked for normality. Normally distributed variables are presented as the mean (standard deviation), and nonnormally distributed variables are presented as the median (interquartile range, IQR). To investigate multivariate outliers, residuals of regression models were examined, and Cook's distances were calculated; a value exceeding one was considered divergent. The level of education was transformed into two categories: elementary or secondary school and intermediate, higher vocational education, or university. Employment status was divided into parttime, fulltime, or self-employed and no paid work, looking for work, or student. Marital status was dichotomized into married, living together, or in a relationship and divorced, widowed, or single. Smoking status was divided into never smoked and active smoker or quit smoking. Migration background was transformed into Dutch or non-Dutch. Bariatric metabolic surgery type was split into RYGB or SG; patients with secondary procedures were not included.

Patient characteristics were presented with descriptive statistics. Baseline associations of body image with baseline variables were examined using univariable linear regression analyses for each variable. Descriptive statistics were used to present %TWL at 6, 12, 24, and 36 months postoperatively. Linear mixed-model analysis (LMM) was used to assess the association between surgery type and change in %TWL from 6 to 12, 24, and 36 months after surgery.

Linear mixed-model analysis is suitable for the analysis of longitudinal datasets because an adjustment is made for the correlation between repeated observations within the subject [46]. Additionally, all available data points are used without the need for imputation methods [47]. LMM compared %TWL between all timepoints (Bonferroni correction, six comparisons, $p < .008$). Body image scores were presented preoperatively and at 4, 12, 24, and 36 months after surgery, and differences were evaluated by LMM (Bonferroni correction, 10 comparisons, $p < .005$). LMM was used to assess the association between surgery type and change in body image from preoperatively to 4, 12, 24, and 36 months after surgery.

To examine the association of body image with weight loss, two follow-up periods were analyzed: first, the period of massive weight loss and second, the weight stabilization phase. After evaluation of %TWL, the transition between these phases was set at 12 months. The association of body image with weight loss was analyzed under three conditions: (1) the association between baseline body image and the massive weight loss phase (change in %TWL between 6 and 12 months postoperatively), (2) the association between body image at 12 months and the weight stabilization phase (change in %TWL from 12 to 24 and 36 months postoperatively), and (3) the association of the improvement in body image from baseline to 12 months with the weight stabilization phase (change in %TWL from 12 to 24 and 36 months postoperatively). All models contained a crude variant and one with predetermined confounders, which were based on previously investigated factors that were associated with weight loss (baseline BMI, type of bariatric-metabolic surgery and any obesity-associated medical problem). The change in body image (baseline to 12 months after surgery) was calculated by subtracting the baseline score from the 12-month score. To correct for regression to the mean, baseline body image was added to the model.

In all models, an interaction of the dependent variable (body image) with time was added to assess whether the association of body image with %TWL differed between specific follow-up moments. In analyses of the change in %TWL scores after the first postsurgical year (12, 24, and 36 months), the excess skin score at 12 months, which indicated to what extent patients were bothered by their excess skin, was included as a confounder.

Results

Patient Characteristics

Patient characteristics are presented in Table 1. The study sample consisted of 400 patients with a mean age of 45.2 ± 11.0 years, mostly women (85.8%) with a mean preoperative BMI of 42.9 ± 4.6 kg/m^2. Most patients had a primary RYGB (63.5%).

Weight Change After Surgery

Data regarding %TWL were available from 400 (100%), 376 (94%), 367 (92%), 329 (82%), and 266 (67%) patients at baseline and 6, 12, 24, and 36 months, respectively (Fig. 1). The lowest weight was achieved 24 months postoperatively with a mean %TWL of 33.6 ± 9.0; however, the mean %TWL varied from 32.7% and 33.6% to 31.7% in the follow-up interval from 12 to 36 months after surgery. In this period, LMM showed only a significant difference from 24 to 36 months ($\beta = -1.88$, 95% CI [−3.18, −0.57], $p = .005$). There was a significant difference in the change in %TWL from 6 to 12, 24, and 36 months between RYGB ($\beta = 4.25$, 95% CI [3.29, 5.21], $p < .001$] and SG.

Table 1 Baseline characteristics of the included population ($n = 400$)

Gender, *n* (%)	
Female	342 (85.8)
Male	57 (14.2)
Age (years), mean (SD)	45.2 (11.0)
Baseline BMI (kg/m^2), mean (SD)	42.9 (4.6)
Level of education, *n* (%)	
Elementary or secondary school	62 (15.5)
Intermediate vocational education	212 (53.0)
Higher vocational education or university	125 (31.3)
Employment status, *n* (%)	
Parttime, fulltime, or self-employed	302 (75.5)
No paid work, looking for work, or student	97 (24.3)
Marital status, *n* (%)	
Married, living together, or in a relationship	281 (70.3)
Divorced, widowed, or single	118 (29.5)
Any obesity-associated medical problem, *n* (%)	346 (86.5)
History of eating disorder, *n* (%)	7 (1.8)
History of depression, *n* (%)	38 (9.5)
Smoking status, *n* (%)	
Never	193 (48.3)
Active smoker or quitted	207 (51.7)
Migration background ($n = 257$), *n* (%)	217 (84.4)
Dutch	205 (79.8)
Non-Dutch	52 (20.2)
Bariatric surgery type, *n* (%)	
Roux-en-Y gastric bypass[1]	265 (66.2)
Sleeve gastrectomy[2]	135 (33.8)

[1]Includes ten procedures secondary to gastric banding and one procedure secondary to Mason vertical gastroplasty

[2]Includes one procedure secondary to gastric banding

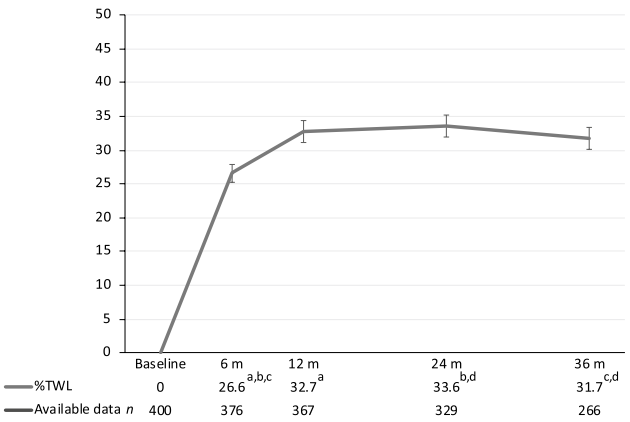

Fig. 1 Mean percentage total weight loss (%TWL) [95% confidence interval bars] at baseline and during follow-up in months. Significant differences (Bonferroni correction, six comparisons, $p < .008$) between timepoints are indicated by similar superscripts.

Body Image

Body image data were available from 400 (100%), 371 (93%), 306 (77%), 289 (72%), and 218 (55%) patients at baseline and 4, 12, 24, and 36 months, respectively (Fig. 2). Body image scores were highest 12 months after surgery, with a mean score of 55.7 ± 23.5, followed by a gradual decline in the following years. LMM showed only a significant difference from 12 to 36 months ($\beta = -7.40$, 95% CI [−11.29, −3.51], $p < .001$). Scores at the 36-month follow-up were substantially higher than baseline scores ($\beta = 31.49$, 95% CI [27.8, 35.2], $p < .001$). Body image scores were not significantly different between surgery types.

Associations with Body Image Before Surgery

No significant associations were demonstrated between baseline variables and body image at baseline (Supplementary Table S1). There was no significant relationship between BMI and body image before surgery (β −0.05, 95% CI [−0.43, 0.33], $p = .81$), which is exemplified in the scatterplot (Supplementary Figure S1). Approximately 40% of the participants, who were evenly distributed across the BMI range, had the lowest possible body image score (0).

Relationship Between Baseline Body Image and Weight Loss

The results on the association between baseline body image and change in %TWL between 6 and 12 months after surgery are presented in Table 2. Higher baseline body image was related to significantly less change in %TWL up to 12 months postoperatively ($\beta = -0.05$, 95% CI [−0.09, −0.01], $p = .009$). A one-point increase in baseline body image was associated with a 0.05-point lower %TWL up to 12 months after surgery. The association between baseline body image and change in %TWL was not different when comparing 12 to 6 months (Model 2). When adjusting for other confounders, the association between baseline body image and %TWL was not significant (Model 3, $\beta = -0.03$, 95% CI [−0.07, 0.009], $p =. 14$).

Relationship Between Body Image and Weight Loss

There was no association of body image 12 months after surgery with change in %TWL from 12 to 24 and 36 months postoperatively ($\beta = 0.009$, 95% CI [−0.03, 0.05], $p = .69$) (Table 3). Additionally, the interaction with time did not yield a significant association, nor did the addition of confounders.

Similarly, the analyses evaluating the relationship between change in body image from baseline to 12 months and change in %TWL from 12 to 24 and 36 months did

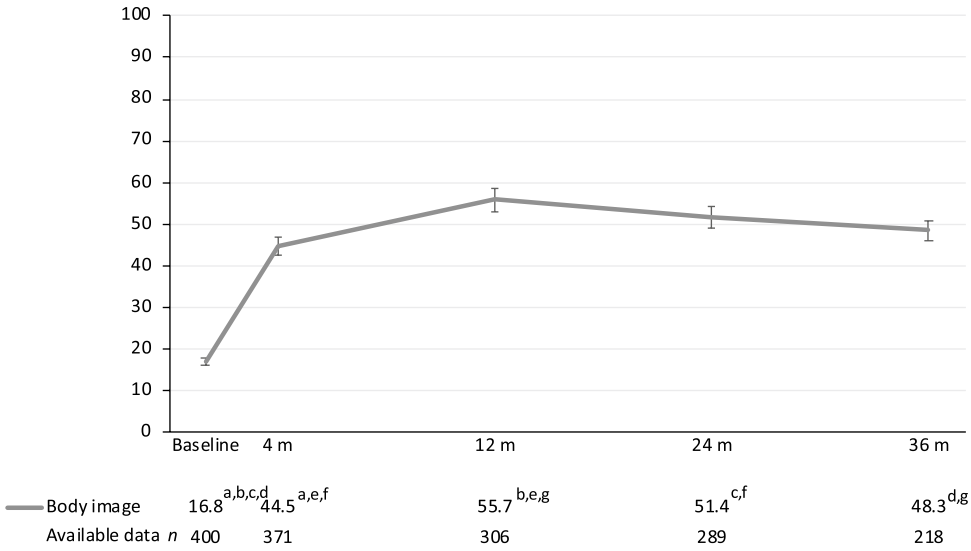

Fig. 2 Mean body image scores [95% confidence interval bars] at baseline and during follow-up in months. Significant differences (Bonferroni correction, 10 comparisons, $p < .005$) between timepoints are indicated by similar superscripts

Table 2 Multivariable linear mixed model analyses of associations between baseline body image and change in percentage total weight loss (%TWL) from 6 to 12 months after surgery (crude and with confounders)

Model	Variable	*Beta*	*p*	95% confidence interval	
				Lower	Higher
1	Baseline body image	−0.05	.009	−0.09	−0.01
2	Baseline body image	−0.04	.03	−0.08	−0.003
	*Baseline body image * Time 6 months*[1]				
	Baseline body image * Time 12 months	−0.02	.10	−0.04	0.003
3	Baseline body image	−0.03	.14	−0.07	0.009
	*Baseline body image * Time 6 months*				
	Baseline body image * Time 12 months	−0.02	.11	−0.04	0.004
	Baseline body-mass index	0.11	.16	−0.04	0.25
	Bariatric surgery type[2]	−3.47	< .001	−4.91	−2.03
	Any associated medical problem[3]	−2.76	.005	−4.71	−0.82

[1]The interaction term body image * time evaluates whether the association between baseline body image and change in %TWL 6 to 12 months after surgery is significantly different between follow-up moments

[2]Bariatric surgery type was categorized into Roux-en-Y gastric bypass (reference 0) and sleeve gastrectomy (1)

[3]Any associated medical problem was categorized into absent (reference 0) and present (1)

not show significant associations ($\beta = 0.02$, 95% CI [−0.02, 0.07], $p = .22$) (Table 4).

Discussion

The objective of this study was to determine the association of body image with weight loss in patients undergoing bariatric metabolic surgery. Preoperative body image and BMI were not related. There was a statistically significant, but not clinically relevant, association between preoperative body image and weight loss in the first year after surgery, suggesting that people who felt better about their body image before surgery lost less weight 1 year after surgery. Neither the level of body image at 12 months nor the change in body image from baseline to 12 months was associated with changes in weight loss 12 to 24 and 36 months postoperatively.

Our results showed that body image scores significantly improved after surgery. The highest body image scores were found 12 months postoperatively, with a gradual, but statistically significant, decline from 12 to 36 months. It is unclear if this decline of 7.4 points is also clinically relevant for individual patients, since the minimum clinically important difference (MCID) of all BODY-Q scales has not yet been determined. Previous longitudinal studies with measurements at baseline, 12 and 24 months indicated relatively stable body image scores after 1 year [20, 25] or a gradual decline [17, 18]. Thus, while durable improvements in body

Table 3 Multivariable linear mixed model analyses of associations between body image one year postoperatively and change in percentage total weight loss (%TWL) 12 to 24 and 36 months after surgery (crude and with confounders)

Model	Variable	*Beta*	*p*	95% confidence interval	
				Lower	Higher
1	Body image	0.009	.69	−0.03	0.05
2	Body image	0.02	.49	−0.03	0.06
	*Body image * Time 12 months*[1]				
	Body image * Time 24 months	−0.01	.47	−0.04	0.02
	Body image * Time 36 months	−0.01	.38	−0.04	0.02
3	Body image	0.03	.35	−0.04	0.10
	*Body image * Time 12 months*				
	Body image * Time 24 months	−0.01	.41	−0.04	0.02
	Body image * Time 36 months	−0.02	.18	−0.05	0.01
	Bariatric surgery type[2]	−5.48	< .001	−7.60	−3.37
	Any associated medical problem[3]	−3.98	.009	−6.95	−1.01
	Baseline body-mass index	0.20	.07	−0.2	0.42
	Excess skin 12 months postoperatively	−0.03	.28	−0.09	0.03

[1]The interaction term body image * time evaluates whether the association between body image one year postoperatively and change in %TWL 12 to 36 months after surgery is significantly different between follow-up moments

[2]Bariatric surgery type was categorized into Roux-en-Y gastric bypass (reference 0) and sleeve gastrectomy (1)

[3]Any associated medical problem was categorized into absent (reference 0) and present (1)

Table 4 Multivariable linear mixed model analyses of associations between first year change in body image[1] and change in percentage total weight loss (%TWL) from 12 to 24 and 36 months after surgery (crude and with confounders)

Model	Variable	*Beta*	*p*	95% confidence interval	
				Lower	Higher
1	Change in body image	0.023	.22	−0.02	0.07
	Baseline body image	−0.05	.10	−0.11	0.009
2	Change in body image	0.03	.28	−0.02	0.07
	Baseline body image	−0.05	.10	−0.11	0.01
	*Change in body image * Time 12 months*[2]				
	Change in body image * Time 24 months	0.003	.82	−0.02	0.03
	Change in body image * Time 36 months	0.004	.74	−0.02	0.03
3	Change in body image	0.04	.21	−0.02	0.11
	Baseline body image	−0.03	.49	−0.11	0.05
	*Change in body image * Time 12 months*				
	Change in body image * Time 24 months	0.001	.92	−0.03	0.03
	Change in body image * Time 36 months	−0.006	.69	−0.04	0.02
	Bariatric surgery type[3]	−2.66	< .001	−4.08	−1.25
	Any obesity associated medical problem[4]	−3.43	.02	−6.38	−0.49
	Baseline body-mass index	0.29	.008	0.08	0.50
	Excess skin 12 months postoperatively	−0.03	.37	−0.08	0.03

[1]The first-year change in body image was calculated by subtracting the raw scores of baseline body image and one year body image

[2]The interaction term change in body image * time evaluates whether the association between change in body image and change in %TWL 12 to 36 months after surgery is significantly different between follow-up moments

[3]Bariatric surgery type was categorized into Roux-en-Y gastric bypass (reference 0) and sleeve gastrectomy (1)

[4]Any associated medical problem was categorized into absent (reference 0) and present (1)

image are demonstrated, the deterioration that follows after the first postbariatric year warrants further investigation. Determining how many individuals experience a clinically meaningful improvement or deterioration of body image will be possible after establishing the MCID for the BODY-Q, which will be established in future studies.

At baseline, no association of body image with BMI was demonstrated. Many participants (41%) who were evenly distributed across the range of BMI had the lowest possible body image score (0). Although there seems to be a relation of higher weight with more body image concerns [48], it could be that this is not the case for people with obesity and a very low body image [18, 24, 31, 49]. Weight may be related to specific body image dimensions, whereas the items of the BODY-Q reflect mostly cognitive and affective aspects. Additionally, the BODY-Q might not be sensitive enough to detect interindividual differences in the lower range of the scale due to the items included. Although its items overlap with the appearance evaluation scale of the Multidimensional Body-Self Relations Questionnaire-Appearance Scales (MBSRQ-AS), which reflects satisfaction with one's appearance, the MBSRQ-AS also addresses satisfaction with appearance when dressed, opinions of other people and reversed (negative) items [50]. The body image items of the BODY-Q are all verbalized positively with words such as happy, proud and positive and lack reversed (negative) items, which makes the scale prone to acquiescence bias [51].

In this study, we found an association between baseline body image and weight loss in the first year postsurgery: people with a more positive body image at baseline lost less weight. However, the beta coefficient was very small (β −0.05) and therefore considered not clinically relevant. The two prospective studies that evaluated associations of baseline body image with first-year weight loss postsurgery found none [31, 37]. Hence, the combination of results indicates that there is probably a nonexistent or trivial association between higher baseline body image and less weight loss the first year after surgery. Regarding the change in weight loss 12 to 24 and 36 months postsurgery, our results did not show an association with body image at 12 months or with the first year change in body image. These associations have not been previously evaluated in a bariatric metabolic surgery population. The findings in our study cannot be generalized beyond emotional appreciation of the body (cognitive and affective components of body image), which is emphasized by the body image scale of the BODY-Q.

The results in this study support previous observations of lasting improvement of body image after bariatric metabolic surgery but could not confirm any association between body image and weight loss suggested by previous studies. While the courses of mean body image and weight loss show a more or less similar slope and direction, our results suggest that changes in body image and changes in weight loss are accounted for by distinct processes. Although the BODY-Q was designed for patients undergoing bariatric metabolic surgery, the assessment of body image emphasizes positive emotional feelings toward one's body, while in this group, negative feelings and other features of body image are also important (e.g., body (dys)functionality and body shape or size perception). Moreover, comparison of body image outcomes with other literature is hampered by the wide variety of questionnaires used, as well as the limited number of BODY-Q validation studies and comparison materials. Thus, there is a need to standardize body image questionnaires used in bariatric metabolic surgery. To achieve this goal, a broad group of clinicians, scientists, and people living with obesity have started an initiative to reach consensus about standard instruments to measure HRQL, including relevant domains such as body image, in bariatric metabolic surgery [52].

The strengths of this study included the prospective nature, the large number of participants and the use of a questionnaire validated for people undergoing bariatric metabolic surgery. Some limitations must also be considered. The percentage of missing data increased after a longer period of follow-up. Therefore, LMM was used, which is most suitable for handling longitudinal databases with missing data. Missing data regarding weight measurements were corrected by adding self-reported weight data, which may be less accurate [53]. Moreover, almost half of our sample had the lowest possible body image score on the BODY-Q before surgery; therefore, there was no means to further differentiate between the people who were dissatisfied with their body.

Conclusion

This prospective study evaluated the course of body image and its associations with weight loss in the first 3 years after bariatric metabolic surgery. A higher baseline body image was associated with weight loss the first year after surgery, but this effect was too small to be considered clinically relevant. Body image was not associated with longer-term weight loss. Our results suggest that changes in body image and changes in weight loss are accounted for by distinct processes. Although the mean body image remained very much improved during the postbariatric interval, the gradual decline in body image between 1 and 3 years after surgery underlines the importance of long-term follow-ups with regular assessment of this aspect of quality of life.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11695-023-06690-4.

Declarations

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Conflict of Interests The authors declare no competing interests.

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