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ORIGINAL CONTRIBUTIONS

Five-Year Outcomes After Vertical Sleeve Gastrectomy for Severe Obesity: A Prospective Cohort Study

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Abstract
Background We present 5-year outcomes after vertical sleeve gastrectomy (VSG), including complications and revisions, weight change, obesity-related diseases and health-related quality of life (HRQOL).
Methods Patients operated from December 2005 to November 2010 were included. All variables except HRQOL (obtained using Short Form-36) were assessed prospectively. HRQOL data was assessed cross-sectionally, comparing 5-year results to both a baseline cohort of severely obese patients prior to bariatric surgery and to Norwegian norms.
Results Of 168 operated patients (mean age, 40.3 ± 10.5 years; 71% females), 92% completed 2-year and 82% 5-year follow-up. Re-intervention for complications occurred in four patients, whereas revision surgery was performed in six patients for weight regain and in one patient for gastroesophageal reflux disease (GERD). Mean body mass index (BMI) decreased from 46.2 ± 6.4 kg/m^2 at baseline to 30.5 ± 5.8 kg/m^2 at 2 years and 32.9 ± 6.1 kg/m^2 at 5 years. Remission of type 2 diabetes mellitus (T2DM) and hypertension occurred in 79 and 62% at 2 years, and 63 and 60% at 5 years, respectively. The percentage of patients treated for GERD increased from 12% preoperatively to 29% at 2 years and 35% at 5 years. The physical and mental SF-36 summary scores showed significantly better HRQOL at 5 years compared with the baseline cohort, but did not reach population norms.
Conclusion The majority of VSG patients maintained successful weight loss and improvement of T2DM, hypertension and HRQOL at 5 years. Preventing weight regain and GERD are important considerations with this procedure.

Keywords Vertical sleeve gastrectomy · Weight loss · Comorbidities · Health-related quality of life

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Introduction

During the last four decades, the age-standardized global prevalence of obesity increased from 3.2 to 10.8% in men, and from 6.4 to 14.9% in women. Norway has followed this pattern: A large population study spanning over two decades revealed increased body weight in all weight categories [1]. Obesity and severe obesity are associated with elevated risks of adverse health outcomes and premature mortality [2, 3], and there has been an increased demand for the surgical treatment of severe obesity [4].

Vertical sleeve gastrectomy (VSG) is gaining acceptance as a stand-alone bariatric procedure. From 2008 to 2014, the use of VSG in the USA increased from 3 to 54%, while gastric bypass (GBP) decreased from 52 to 32% [5]. Advantages of VSG include an undisrupted gastrointestinal tract, an absence of dumping syndrome, and a lower risk of vitamin deficiencies [5, 6] compared with other bariatric surgeries. However, studies of VSG that include follow-up data from five or more years after surgery report heterogeneous results for weight change and comorbidity remission, making it difficult to draw firm conclusions regarding long-term efficacy [7–9]. In addition, according to a recent systematic review, studies on long-term health-related quality of life (HRQOL) after VSG are warranted [10, 11].

We report 5-year outcome data for VSG, specifically complication and revision rates, weight loss measures, changes in the incidence of weight-related diseases (primarily type 2 diabetes [T2DM] and hypertension) and HRQOL scores.

Methods

Clinical and demographic data from consenting patients who underwent VSG between December 2005 and November 2010 was collected preoperatively and at 3, 12, 24 and 60 months postoperatively. During the study period, 168 patients were operated (16 with open surgery and 152 laparoscopically) and were eligible for follow-up evaluation.

Eligibility requirements for VSG were body mass index (BMI) ≥ 40 or ≥35.0–39.9 kg/m^2 with obesity-related diseases, no active psychosis, no alcohol or drug abuse and age between 18 and 65 years. Pre- and postoperative patient care was provided, and the surgical procedure was performed as previously described [12]. In brief, gastric resection was performed using a 32 Fr tube, starting 1–2 cm proximal to the pylorus and ending at the cardia. Staple line reinforcement, gastropexia, and hiatal repair were not performed.

Outcome Definitions

The American Society for Metabolic and Bariatric Surgery (ASMBS) reporting standards guided outcome assessments [13]. Surgical complications were identified as early (≤30 days) or late (>30 days), major (associated with a hospital stay >7 days) or minor (everything not included under major). Weight loss is presented as the change in BMI (ΔBMI = initial BMI − postoperative BMI), percent excess BMI loss (%EBMIL = [ΔBMI/(initial BMI − 25)] × 100%) and percent total weight loss (%TWL = [initial weight – postoperative weight]/[initial weight] × 100%). Weight loss failure was reported if the patient required revision surgery due to inadequate weight loss, or if the percent excess weight loss (%EWL) was ≤50% using the following original formula, %EWL = [initial weight – postoperative weight]/[initial weight – ideal weight], where "ideal weight" was defined using the Metropolitan height and weight table [14]. This calculation was used to allow comparisons with previously published data on weight loss failure [15]. Additionally, the number of patients with a weight regain of more than 10 kg was determined [16].

The obesity-related conditions evaluated were type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia, sleep apnea, obstructive lung disease, musculoskeletal pain, anxiety, depression and gastroesophageal reflux disease (GERD). A condition was recorded as present if the patient reported receiving medical treatment for it. Remission of T2DM, hypertension and hyperlipidemia were defined as fasting glucose <7 mmol/L and HbA1c ≤6.4%, blood pressure <140/90 and a normal lipid panel, respectively, all in the absence of medication.

We also included patient reports of snoring, urinary leakage, and, for premenopausal women, amenorrhea and infertility, independently of whether the patient received treatment. Infertility was defined as attempting to get pregnant for more than 1 year without success. Biochemical variables for lipid and nutritional status are not presented in this paper but have been recently reported for this cohort [6, 12].

Measures of HRQOL

The Short Form-36 (SF-36) was used to measure HRQOL for this study. HRQOL 5 years after VSG in the study cohort was cross-sectionally compared with both a baseline cohort of obese patients eligible for VSG and a cohort representative of the Norwegian general population [17]. The psychometric properties of the SF-36 are validated for use in a morbidly obese Norwegian population [18]. Results for HRQOL are presented as mean physical (PCS) and mental component summary (MCS) scores, and indicate perceived health status, with 50 being the average PCS and MCS score in the US population.

Statistical Analysis

Continuous and categorical variables are described using means, standard deviations, 95% confidence intervals, counts and/or percentages, as appropriate. To examine longitudinal changes in binary variables (i.e. for obesity-related conditions), we used the McNemar test with mid-*P* correction. We also report

confidence intervals for each time point, calculated using the Wilson score method. Longitudinal BMI and weight are modelled as linear models with dummy variables for time and an unstructured covariance matrix, fitted using generalized least squares. By explicitly modelling the correlation between the continuous measurements at different time points, we reduced potential bias introduced by non-random loss to follow-up. For the other analyses, we used complete-case analysis, but reported the number of measurements on which each result was based. Two-sided P values ≤0.05 were considered statistically significant. Statistical Package for Social Sciences, for Windows, version 23.0 (SPSS, Chicago, IL, USA) and R 3.3.0 [19] were used for statistical analyses.

Results

A total of 168 patients (119 [71%] women) with a mean age of 40.3 ± 10.5 years were included with complete data available at baseline. At the 2- and 5-year follow-up points, complete data was available for 155 (92%) and 137 (82%) patients, respectively. There were no statistically significant differences in any of the evaluated baseline characteristics between patients participating in the 5-year follow-up and those lost to follow-up (Table 1).

Complications and Revisions

The mean operating time was 131 ± 43.3 min, and the mean postoperative hospital stay was 4.3 ± 2.1 days. Major complications occurred in 10 (6%) of the patients, including two patients (1.2%) with bleeding and two (1.2%) with leakage. Except for one patient who developed serious malnutrition and extreme weight loss, these patients did not differ significantly in terms of weight measures at 2 and 5 years compared with patients without major complications.

Revision surgery was performed in seven patients (4.2%), one due to GERD and six due to inadequate weight loss between 1 and 3 years after the initial operation (Fig. 1). Four of the seven patients had revisions consisting of biliopancreatic diversion with duodenal switch (BPDDS), two underwent re-sleeve surgery, and one had GBP. Two of the seven patients were lost to follow-up at 5 years. Weight loss data for the remaining five did not significantly influence the results.

Weight Change

Mean initial weight was 134.8 ± 24.9 kg, and mean initial BMI was 46.2 ± 6.4 kg/m^2. Mean ΔBMI was 15.7 ± 5.7 kg/m^2 at 2 years and 13.6 ± 6.1 kg/m^2 at 5 years (Fig. 2). The mean %EBMIL was 77.6 ± 22.9% and 66.1 ± 23.3% at 2 and 5 years, respectively; mean TWL was 33.7 ± 9.9% at 2 years and 28.4 ± 10.7% at 5 years. The weight loss failure rate at 5 years (i.e. patients either having been revised for low weight loss [n = 6] or having EWL ≤50% [n = 49]) was 39%. The proportion of patients with excessive (>10 kg) weight regain at 5 years was 44% (60 out of 137).

Obesity-Related Conditions

There were significant reductions after surgery in the proportions of patients who received treatment for all the obesity-related conditions except for anxiety, depression and GERD (Table 2). Overall, between the 2- and 5-year follow-up, findings remained largely unchanged except an increase in the proportion of patients receiving treatment for

Table 1 Preoperative status in patients at 5-year follow-up compared to patients lost to follow-up

	All patients 5 years n = 168	Available for follow-up (at 5 years) n = 137 (82%)	Lost to follow-up (at 5 years) n = 31 (18%)	P values
Age	40 ± 10.5	41 ± 10.5	38 ± 10.5	0.14
Women	119/168 (71%)	97/136 (71%)	22/32 (69%)	0.59
Weight (kg, mean ± SD)	135 ± 24.9	135 ± 24.0	137 ± 29.3	0.69
BMI (kg/m^2, mean ± SD)	46 ± 6.3	46 ± 6.2	46 ± 6.9	0.72
Superobese (BMI ≥ 50)	34/168 (20%)	26/134 (19%)	8/32 (25%)	0.46
Open sleeve	16/168 (10%)	14/136 (10%)	2/16 (13%)	0.74
Smoking	35/163 (21%)	28/133 (21%)	7/30 (23%)	0.42
Unemployed	59/160 (37%)	44/131 (34%)	15/29 (52%)	0.58
Anxiety	25/168 (15%)	18/136 (13%)	7/24 (29%)	0.26
Depression	34/168 (20%)	24/136 (18%)	10/32 (31%)	0.08
T2DM	33/168 (20%)	28/136 (21%)	5/32 (16%)	0.31
Hypertension	98/161 (61%)	81/132 (61%)	17/29 (59%)	0.93

BMI body mass index, *SD* standard deviation, *No* number, *T2DM* type 2 diabetes mellitus

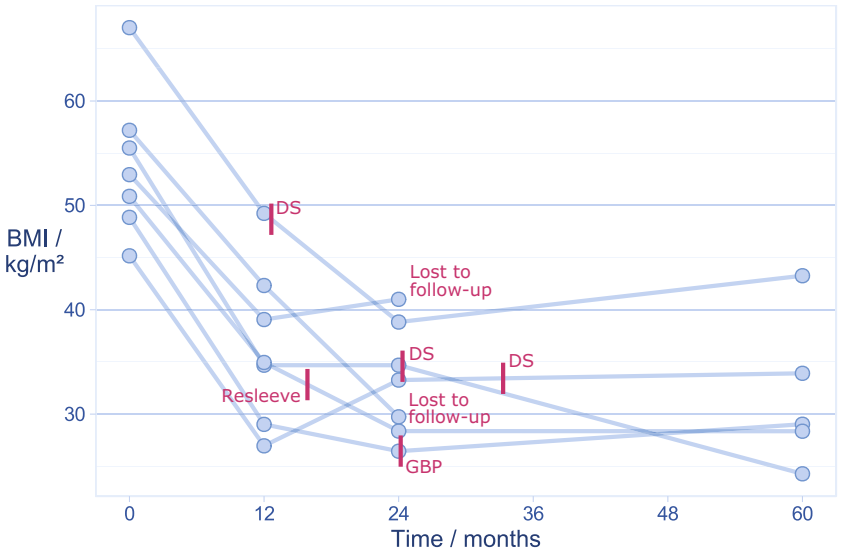

Fig. 1 Longitudinal trajectory for the seven patients revised for low weight loss failure

musculoskeletal pain, and a further significant increase in the number of patients taking antacids (Fig. 3).

The remission rate for T2DM was 19/24 (79%) at 2 years and 15/24 (63%) at 5 years; the 5-year remission rate was 29% for patients using insulin preoperatively and 77% for non-insulin users. There was a significant drop in serum glucose from 6.1 ± 1.9 mmol/L to 5.2 ± 1.8 mmol/L ($P < 0.001$), and in HbA1c from 5.8 ± 1.2 mmol/L to 5.2 ± 0.9 mmol/L ($P < 0.001$) from baseline to 5-year follow-up. Remission of hypertension was found in 55/89 (62%) at 2 years and in 47/78 (60%) at 5 years. Hyperlipidemia remission was seen in 15/21 (71%) at 2 years and 9/19 (47%) at 5 years.

The number of patients suffering from snoring and urinary leakage decreased significantly, and nearly all premenopausal female patients regained menstruation, several becoming pregnant.

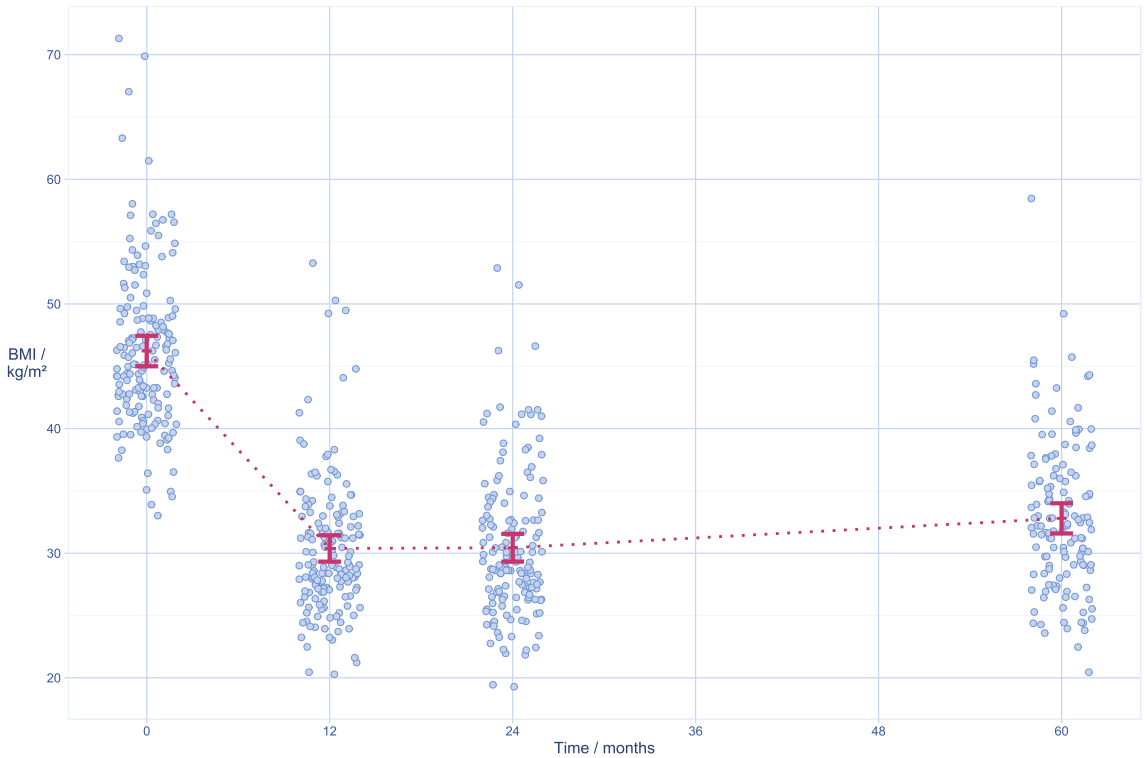

Fig. 2 Body mass index (BMI) at baseline and 12, 24 and 60 months after vertical sleeve gastrectomy. Mean BMI values with 95% confidence intervals are shown as error bars

Table 2 Mean body weight and BMI and proportion of patients (%) with obesity-related diseases prior to and at 24 and 60 months after vertical sleeve gastrectomy

	Preoperative		24 months		60 months		*P* value		
	Mean/ count	SD/ (prop.)	Mean/ count	SD/ (prop.)	Mean/ count	SD/ (prop.)	24 vs. 00 months	60 vs. 00 months	60 vs. 24 months
Continuous variables									
Number of observations	168	(100%)	155	(92%)	137	(82%)	–	–	–
Weight (kg)	135.1	25.0	89.1	18.5	95.7	19.3	<0.001	<0.001	<0.001
BMI (kg/m^2)	46.2	6.3	30.5	5.7	32.9	6.0	<0.001	<0.001	<0.001
Treated for									
Hypertension	98/161	(61%)	36/150	(24%)	36/134	(27%)	<0.001	<0.001	0.84
Joint pain	51/167	(31%)	35/153	(23%)	41/136	(30%)	0.05	0.88	0.03
Musculoskeletal pain	51/167	(31%)	35/153	(23%)	41/136	(30%)	0.05	0.88	0.03
Low back pain	48/166	(29%)	31/153	(20%)	36/136	(26%)	0.05	0.27	0.12
Depression	34/168	(20%)	27/151	(18%)	25/134	(19%)	0.27	0.79	0.75
T2DM	33/168	(20%)	7/152	(5%)	13/136	(10%)	<0.001	0.002	0.18
Obstructive lung disease	28/168	(17%)	18/152	(12%)	13/137	(9%)	0.006	0.003	0.18
Sleep apnoea (OSAS)	28/168	(17%)	9/153	(6%)	7/136	(5%)	<0.001	<0.001	0.69
Anxiety	25/168	(15%)	18/151	(12%)	17/134	(13%)	0.15	0.80	0.73
Hyperlipidaemia	25/168	(15%)	10/151	(7%)	16/135	(12%)	0.01	0.45	0.15
GERD	20/168	(12%)	44/152	(29%)	48/136	(35%)	<0.001	<0.001	0.03
Suffering from (treated or not)									
Snoring	124/165	(75%)	22/149	(15%)	33/136	(24%)	<0.001	<0.001	0.09
Urinary leakage	46/168	(27%)	15/150	(10%)	21/135	(16%)	<0.001	<0.001	0.14
Amenorrhea*	19/97	(20%)	0/76	(0%)	2/63	(3%)	<0.001	0.002	0.50
Infertility*	15/95	(16%)	7/75	(9%)	3/62	(5%)	0.12	0.06	0.81

* Only reported for non-menopausal women

SD standard deviation, *Prop.* proportion, *BMI* body mass index, *T2DM* type 2 diabetes mellitus, *GERD* gastroesophageal reflux disease

HRQOL

The PCS score was 39.1 ± 10.3 in the baseline cohort and 46.5 ± 10.3 in the study cohort at 5 years ($P < 0.001$), while the MCS score was 43.5 ± 11.5 in the baseline cohort and 48.2 ± 11.3 in the study cohort 5 years after VSG ($P < 0.001$; Fig. 3). The mean PCS and MCS scores for the general population cohort were 52.5 ± 9.3 and 52.5 ± 9.1, respectively, significantly higher than the study cohort's 5-year mean scores on both dimensions ($P < 0.001$ for both). We identified no association between %EWL and either PCS ($r = 0.03$, $P = 0.76$) or MCS ($r = -0.07$, $P = 0.51$) at the 5-year follow-up.

Discussion

In this study, which focused on 5-year follow-up results for VSG, we found that a majority of patients had a profound, sustained weight loss as well as a significant improvement in (or remission of) obesity-related conditions. The HRQOL scores were significantly better than the corresponding scores for patients waiting for bariatric surgery, but somewhat lower than those representing the general population. However, weight regain and the occurrence of GERD need to be further addressed.

Severe obesity is a chronic, progressive disease highly refractory to treatment, and weight recidivism is, therefore, a concern after all bariatric procedures. In our experience, weight regain after VSG may occur beginning at approximately 2 years following surgery. Inadequate weight loss or weight regain after VSG may be due to technical errors (such as leaving too much stomach behind), psychiatric comorbidity, or physiological factors including hormones such as ghrelin [20, 21]. Although the weight loss seen in this series is higher than that reported by others [7, 8], we did see cases of inadequate weight loss and weight regain between 2 and 5 years. The size and form of the gastric remnant might influence both the leak rate and the reflux rate. There is some evidence, though, that creating a smaller stomach volume gives better

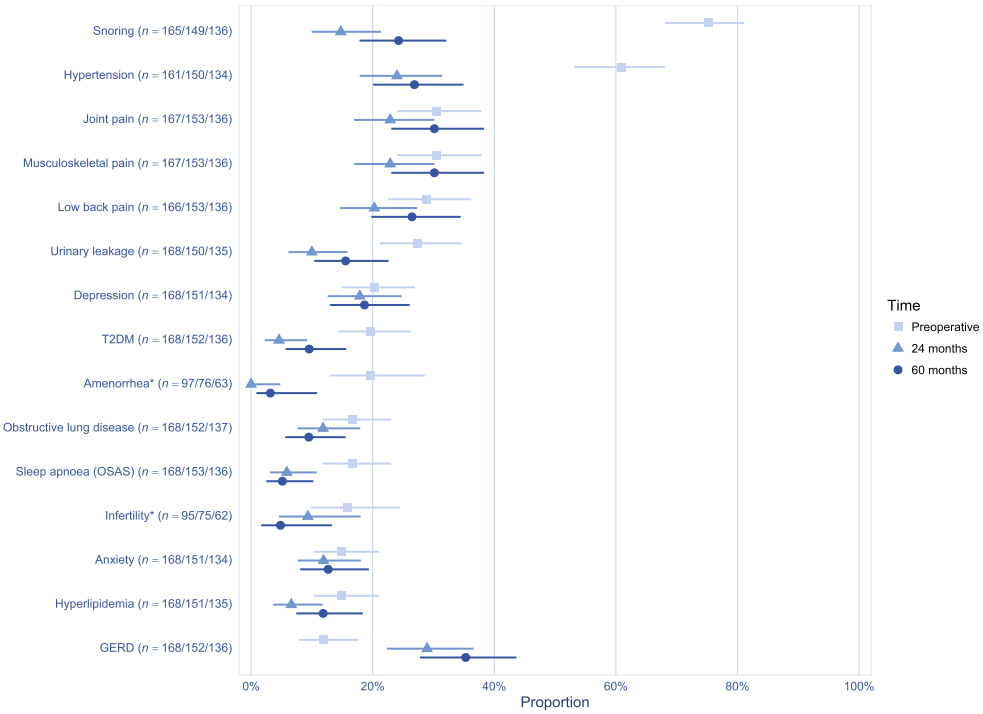

Fig. 3 Proportion of patients treated for/suffering from obesity-related diseases at baseline at after 24 and 60 months after vertical sleeve gastrectomy, with 95% confidence intervals. The diseases are ordered by proportion at baseline

weight loss [16, 22]. The study by Rawlins et al. [9] who found excellent, continuous weight loss between 2 and 5 years after having resected closely along a 26.4 Fr endoscope may indicate that stapling along a 32 Fr tube leaves too much stomach behind to prevent weight regain between 2 and 5 years.

Improvement or remission was seen in all the obesity-related conditions studied except for anxiety, depression and GERD in

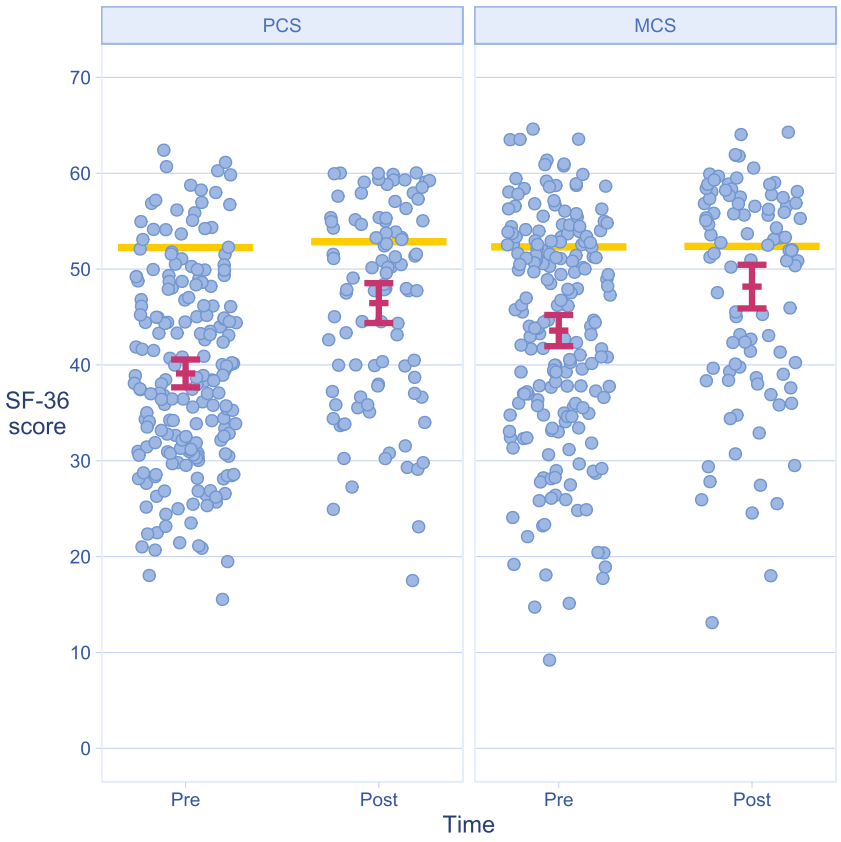

Fig. 4 Short Form 36 (SF-36) scores before and 60 months after vertical sleeve gastrectomy (two separate cohorts). Mean scores with 95% confidence intervals are shown as error bars. The mean scores of a general Norwegian population matched by age and sex are shown as horizontal lines

our study. Although there is a clear connection between obesity and T2DM, the underlying mechanisms are not clearly understood. Predictors for non-remission of T2DM after bariatric surgery include insulin usage and less postoperative weight loss [23]. In this cohort, in which eight of 33 type 2 diabetic patients used insulin prior to the operation, we found remission rates of 79% at 2 years and 63% at 5 years. This is consistent with recent reviews describing remission rates of 60.8% 5 years after VSG and 66.7% 5 years after Roux-en-Y gastric bypass [24, 25]. However, differences in preoperative diabetic status and varied definitions for remission may limit the validity of comparisons with these reviews.

For hypertension, we see remission rates of 62% at 2 years and 60% at 5 years, which are somewhat higher than the 54.4% reported by Golomb et al. [7] for 5 years, but similar to the resolution rate of 61% for 5 years published by Lemanu et al. [8]. Most of the published data on blood pressure control after bariatric surgery comes from trials on metabolic surgery for T2DM [26]. It has been suggested that the significant effect of VSG on hypertension entails the same mechanisms involved in remission of T2DM, and that these mechanisms go beyond weight loss. Furthermore, the link between sleep apnea and blood pressure has been addressed in previous studies [27], and the rate of sleep apnea dropped dramatically among our patients.

The incidence of GERD (based on symptoms and medication use) more than doubled from baseline to 2 years, and increased further to a rate of 35% at 5 years. This exceeds the reported GERD incidence rates of 0–30% from the Gagner et al. [28] VSG survey. Although generally manageable with proton-pump inhibitors, GERD is a concern after VSG, and surgical techniques to avoid GERD should be sought. Accordingly, two preventative techniques, gastropexia (suturing of the omentum to the staple line to prevent transhiatal migration of the remaining stomach) and selective crural repair became part of our standard technique in 2013.

Health-related quality of life represents an important outcome measure after surgical obesity treatment, and our results suggest a significant improvement in self-reported physical and mental health status. Even though our baseline data were collected from a different patient cohort, the SF-36 data seem to reflect the life changes that VSG patients experience (Fig. 4). The 5-year HRQOL scores for this cohort are generally consistent with other long-term HRQOL data after VSG and other surgical procedures [10, 11, 29]. Nevertheless, due to our cross-sectional study design and the lack of obesity-specific HRQOL questionnaires, firm conclusions cannot be drawn about changes in HRQOL over time.

Conclusion

VSG performed by resecting the stomach along a 32 Fr tube from the pylorus to the cardia results in 5-year weight loss, remission of obesity-related conditions and increased HRQOL scores similar to those seen after Roux-en-Y gastric bypass. Future investigation on and development of VSG, however, should focus on prevention of weight regain and GERD.

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Compliance with Ethical Standards

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Disclosure Statement The authors declare that they have no conflicts of interest.

Informed Consent Informed consent was obtained from all the study participants. Data were prospectively collected and stored in a database that is part of a continuous surveillance program.

Ethical Approval This investigation conforms to the principles outlined in the Declaration of Helsinki.

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