Long-term outcomes after vertical sleeve gastrectomy for severe obesity

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Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway

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"Nothing would be more tiresome than eating and drinking if God had not made them a pleasure as well as a necessity"

(Voltaire, 1694-1778)

Scientific environment

The doctoral education was carried out at Department of Global Public Health and Primary Care, Faculty of Medicine, University of Bergen, with affiliation to the Research Group for Lifestyle Epidemiology, the Research School in Global Public Health and Primary Care and The National Research School of Population based Epidemiology (EPINOR). From January 2019 I have acted as a local representative of EPINOR's steering committee.

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Abbreviations

ASMBS	American Society for Metabolic and Bariatric Surgery
BMI	Body mass index
BPDDS	Biliopancreatic diversion with duodenal switch
CI	Confidence interval
CVD	Cardiovascular disease
ΔBMI	Delta BMI
ES	Effect Size
FBG	Fasting blood glucose
GERD	Gastroesophageal reflux disease
HbA1c	Glycated hemoglobin
HRQOL	Health-related quality of life
ICD	International classification of diseases
IWQOL-Lite	Impact of weight on quality of life-Lite questionnaire
MCS	Mental component summary
NCD	Non-communicable Disease
OP	Obesity-related problems
OAGB	One-anastomosis Gastric Bypass
PCS	Physical component summary
%EBMIL	Percent excess body mass index loss
%EWL	Percent excess weight loss
PRO	Patient-reported outcome

PROM	Patient-reported outcome measure
QOL	Quality of life
RCT	Randomized controlled trial
RYGBP	Roux-en-Y gastric bypass
SD	Standard deviation
SF-36	Medical outcomes study short-form 36 health survey
SOS	Swedish Obese Subjects
VSG	Vertical sleeve gastrectomy
WEL-SF	Weight efficacy lifestyle questionnaire short-form

Abstract

Background: Severe obesity is a chronic disease entailed by increased risk of obesity-related comorbidities, impaired quality of life (QOL) and early death. Causes and consequences are multifactorial and reflect an interplay between biological, psychosocial and environmental factors. Bariatric surgery has evolved as a treatment option, providing weight loss and improvements in health. Vertical sleeve gastrectomy (VSG) is the latest and most frequently performed bariatric procedure worldwide, but data on long-term efficacy is scarcely reported. Little is known about factors that can explain the variability in long-term outcome after bariatric surgery. It is necessary to identify predictors of sustained weight loss and QOL improvements for a tailored patient-centric support.

Objectives: The main objective of studies I-III was to report long-term outcomes in terms of weight, obesity-related comorbidities and QOL after VSG. Firstly, we report five-year complication and revision rates, weight loss and changes in comorbidities (primarily type 2 diabetes, hypertension and gastroesophageal reflux disease (GERD)). Secondly, previous studies found that self-efficacy may be a predictor of behavioral change and long-term health outcome. We therefor assessed the association between self-efficacy related to eating, weight loss and obesity-specific QOL five years after VSG. Thirdly, long-term reports on QOL after VSG are particularly limited. We assessed QOL broadly, covering obesity-specific and generic health-related QOL, as well as overall life satisfaction, and examined the association between weight loss and all levels of QOL five years after VSG.

Methods: Demographic, clinical and patient-reported data from three separate patient cohorts was collected prospectively up to five years after VSG. In studies I and III, the data was extracted from the local obesity surgery registry in Førde Central Hospital, while the data in study II was collected at Voss Hospital. Eating self-efficacy was measured by the Weight Efficacy Lifestyle Questionnaire Short-Form. Health-related QOL and overall life satisfaction were measured by the Impact of Weight on Quality of Life-Lite, the Obesity-Related Problem Scale, Short-Form-36 and Cantril's ladder. All outcomes on QOL at five years were compared to population norms.

Results: In studies I-III, 168, 114 and 127 VSG patients were included with five-year participation rates of 82, 74 and 64%, respectively. Mean weight loss was profound and significant in all cohorts from baseline to five years, but modest, significant weight regain was seen between one/two and five years after VSG. In study I, complication and revision rates were low, and most obesity-related comorbidities significantly improved from baseline to five years, with a notable exception of GERD. The prevalence of preoperative GERD increased from 12 to 35% at five years after surgery. Remission rates of type 2 diabetes and hypertension were 63 and 60% at five years, respectively. In study II, changes in eating self-efficacy from baseline to one year predicted weight loss at five years, as opposed to preoperative eating self-efficacy. Improvement in eating self-efficacy from baseline to five years was associated with greater weight loss and better obesity-specific QOL at five years after surgery. In study III, clinically and statistically significant improvements from baseline to five years occurred in all three levels of QOL, with significant yet modest deteriorations seen between one and five years after surgery. Greater weight loss five years after surgery was significantly associated with improvements in obesity-specific QOL and physical health-related QOL, but not with mental health-related QOL and overall life satisfaction. All mean scores on QOL at five years after VSG were below population norms.

Conclusions: VSG is a safe and effective treatment of severe obesity. A majority of patients studied obtained enduring weight loss and improvements in health and QOL. Particular attention needs to be paid to symptoms of GERD after VSG. Still, over one third of patients experienced subsequent weight regain of 10 kg or more, and average QOL deteriorated between one or two and five years after VSG. Hence, an important minority of patients report less beneficial long-term outcomes after VSG, and some patients exhibit further deterioration in QOL compared to preoperative reports. The

observed associations between eating self-efficacy, long-term weight loss and QOL, may inform tailored patient support following bariatric surgery.

List of Publications

Paper I:

Flølo T.N., Andersen J.R., Kolotkin R.L., Aasprang A., Natvig G.K., Hufthammer K.O., Våge V. *Five-year outcomes after vertical sleeve gastrectomy for severe obesity: A prospective cohort study.* Obes Surg 2017; 27:1944-51. DOI: 10.1007/s11695-017-2605-x

Paper II:

Fløl0 T.N., Tell G.S., Kolotkin R.L., Aasprang A., Norekvål T.M., Våge, V., Andersen J.R. *Eating self-efficacy as predictor of long-term weight loss and obesity-specific quality of life after sleeve gastrectomy: A prospective cohort study.* Surg Obes Relat Dis 2018. DOI: 10.1016/j.soard.2018.12.011

Paper III:

Fløl0 T.N., Tell G.S., Kolotkin R.L., Aasprang A., Norekvål T.M., Våge, V., Hufthammer K.O., Andersen J.R. *Changes in quality of life five years after sleeve gastrectomy. A prospective cohort study.* BMJ Open 2019. DOI: 10.1136/bmjopen-2019-031170

Preface

Daniel Lambert was reportedly the heaviest man in England back in 1770 [1]. By his death at 39 years old, his anthropometrics were a height of 180 cm, weight 335 kg, waist 284 cm and calf circumference 94 cm. Literary sources portray Mr. Lambert with words like “portly”, archaically defined as “stately” or “imposing”, thus representing a prosperous gentleman. Modern dictionaries, however, provide several pejoratively charged synonyms, such as “corpulent”, “stout” or “fleshy”. Although Lambert seems to have been a popular man, well liked and considered a human wonder by his contemporaries, sentiments have been expressed in modern times by the word “fatty” appearing spray-painted on his tombstone. This example of linguistic disparity might well be said to represent a time-driven transformation of attitudes towards obesity – from greatness to indulgence, from seldom and rare and thus valuable, to common and increasingly a manifestation of character flaw.

In 2008, Voss Hospital’s department of surgery, my formative workplace for nearly two decades, was commissioned to perform surgery on individuals suffering from severe obesity. In this setting, working as a nurse, I first observed severe obesity as a medical condition, and my attitudes and judgements were probably biased: patients’ lack of self-control, proof of pure hedonism, ignorance and sloppiness. Fortunately, these preconceived attitudes were transformed as a result of day-to-day care of patients with obesity during my tenure as a ward- and outpatient nurse. Their experiences of prejudiced neglect, commonly performed by health professionals, have been ubiquitous. This tendency to interpret and judge other people simply by appearance or behavior is well known; we see what people look like, to a limited extent how they behave, and draw our premature conclusions. Though unconscious, these internalized verbal and non-verbal expressions of weight bias are offensive in form and ignorant in content. Treatment-seeking patients with severe obesity are all too often aware of their unhealthy life choices. In my experience, patients commonly express the following sentiment: “I know – the problem is in between my ears”. Such a belief reflects universal attitudes, and contributes to the already prevalent guilt of people with this disorder. If the brain, which governs and interacts with more of our body than the space between the ears, does not respond adequately to simplistic application of the laws of physics, one might consider other strategies to hold up in front of individuals with obesity than the energy balance equation.

A bigger picture

The evidence of human obesity goes back over 20 000 years, based on the archaeological findings of Venus von Willendorf in Germany [1]. Meticulous details in sculptures unearthed that the artist made a true representation of a woman with extreme obesity. Thus some people suffering from severe obesity appear to have existed from prehistory, probably with a strong genetic or pathological component. For decades, researchers developed increased understanding of the genetic component that together with environmental influence underpin weight-related behavior. The underlying genetic factors that are contributing to today's growing proportion of people becoming obese, have likely existed in our species for a long time. We have not suddenly become more genetically prone to obesity. Scientists maintain that obesity was once adaptive as so-called thrifty genes enabled efficient storage of energy between famines. In modern prosperous societies, famines do not occur. What we experience is thus a mismatch between our evolved biology and our modern lifestyle which will, for many of us, result in sustained weight gain. So why do many people remain lean in modern prosperity? One suggestion is that the predisposing obesity genes are neutral and have been drifting over time, which leads some individuals to be obesity-prone, and others obesity-resistant.

In most scientific explanations, obesity is an evolutionary maladaptive consequence. The simplistic notion that obesity is caused by lack of willpower, can thus safely be retired - and rest in peace.

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1. Introduction

Globally, there has been a fourfold increase in overweight and obesity over the last four decades, and the Norwegian population has followed this trend [2, 3]. The epidemic dimension has become a major public health concern. Besides being defined as a chronic, progressive disease in its own [4, 5], obesity is a risk factor for a range of diseases, increased mortality and reduced quality of life (QOL) [6-8]. Given the predicted increase in overweight and obesity [9], we can expect a concurrent increase in individuals with severe obesity, entailing individual suffering and socioeconomic load [10]. Prevention is better than cure, but effective treatment options for those already affected are needed.

Different surgical procedures may result in long-lasting weight loss and improvements in health and QOL in a substantial proportion of patients with severe obesity [11-14]. When compared to non-surgical lifestyle interventions, bariatric surgery has shown better results [15]. The technical procedures have been changed continuously and refined to improve outcomes and reduce adverse effects. Accordingly, it is important to survey the safety and efficacy of new surgical methods. To this end, long-term results and adequate controlled trials are needed for a full evaluation.

The conception of this thesis was a response to the Norwegian Research Centre for Health Services' call for scientific updates on long-term efficacy of bariatric surgery [16]. Their systematic review in 2014 compared obesity surgery to non-surgical interventions, or no treatment. A general knowledge gap concerning adverse events and long-term results was identified [17].

In three studies, we investigated five-year results on surgical complications, weight loss, obesity-related comorbidities and QOL after the most recent and now most commonly performed bariatric procedure: Vertical sleeve gastrectomy (VSG). Furthermore, possible predictors of weight loss and postoperative QOL after five years were examined.

1.1. Obesity

1.1.1. Classification and measures

Classifying levels of obesity in medicine and health care is mainly motivated by assessments of health risks (see section 1.1.3.) and treatment for the different risk categories. Currently, the most widely used classification in adults is based on the body mass index (BMI); body weight in kilograms (kg), divided by height in meters (m) squared (Table 1). The World Health Organization defines overweight and obesity as abnormal or excessive fat accumulation that may impair health [3]. The normal range is defined as BMI from 18.5 to < 25, associated with the least risk of health complications. This is not a statistical definition; in a population with increasing body weight, the average and thus normal range may well be above this interval. BMI values above 25, but below 30 kg/m^2 characterize a pre-obese state. Obesity class I is defined as BMI ≥ 30 to < 35 kg/m^2, class II as BMI ≥ 35 to < 40 kg/m^2 and class III as BMI ≥ 40 kg/m^2. In this thesis classification of obesity is based on BMI. We use the term severe obesity, defined as BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 with one or more obesity-related comorbidities [3, 6].

Table 1

Classification of adult underweight, overweight and obesity according to BMI [6]

Classification	BMI kg/m^2	Risk of comorbidities
Underweight	< 18.5	Low (but risk of other clinical problems increased)
Normal range	18.5 to < 25	Average
Overweight:	≥ 25	
Pre-obese	25 to < 30	Increased
Obese class I	30 to < 35	Moderate
Obese class II	35 to < 40	Severe
Obese class III	≥ 40	Very severe

A classification based on BMI, a measure of relative body size, may belie the real extent and distribution of excess adiposity or body fatness, the metabolic phenotype of interest [18]. Other measures of adiposity have been introduced, such as increased waist circumference that provides information of abdominal fat or central adiposity. Together with high blood sugar, abnormal lipid levels or high blood pressure, an increased waist circumference is a hallmark of the metabolic syndrome, and has been proposed as a risk estimator for complications of obesity [6, 19, 20]. Other more refined laboratory measures of fat distribution, such as bioelectrical impedance, underwater weighing, dual-energy X-ray absorptiometry scanning, computed tomography and magnetic resonance imaging, may estimate the details of fat tissue content and distribution more accurately [21, 22]. However, these methods are technically demanding and their ability to assess risk associated with obesity is not yet validated [23]. In practice, BMI is still used due to its high correlation with more sophisticated methods, high predictive capacity for important outcomes such as mortality due to cardiovascular disease (CVD), along with its practicality [6, 10]. Nonetheless, biomarkers beyond anthropometric measurements may provide a more personalized and precise identification of individuals at risk of disease development [23].

1.1.2. Epidemiology – global and national trends

The global epidemic of obesity has been named “a rising tide”, visualizing the uncontrolled and rapid growth in obesity [3, 24]. A 2016 update estimated above 1.9 billion adults being overweight, of these 650 million are classified as having obesity [3]. All countries are affected, with differences in prevalence over time related to geographic, demographic and ethnic distribution [25-28]. Sociocultural, economic, political or physical inequalities between countries may to some extent account for these differences in prevalence of obesity [29].

A threefold increase in the prevalence of obesity from 1975 to 2016 was observed both in the US and Norway [26]. For Norway, the proportion of individuals with obesity was estimated to be 7.7% in 1975 rising to 24% in 2016. Similarly, in the same period there was a six-fold increase in the prevalence of severe obesity from 1.2% (1.9% in women and 0.4% in men) to 7.8% (8.6% in women and 6.9% in men). In 2016, the average BMI in the Norwegian population was estimated to 26.9 kg/m^2, i.e. being overweight according to classifications based on health risk, is the statistical norm [26].

Socio-cultural and economic factors, such as family income, level of education, ethnicity, and geographic urbanity, are associated with the prevalence of obesity [27, 30, 31]. It is difficult to conclude how these socio-economic factors relate causally to obesity as they may not only be risk factors for later development of obesity. Social inequalities may also be consequences of comorbidities, reduced QOL, or a result of how individuals with obesity are met by their environment (weight stigma). Hence, obesity may have a negative impact on labor market outcomes which, in turn, reinforce existing social inequalities in a self-sustaining manner [32, 33].

1.1.3. Etiology

Energy homeostasis is an important characteristic of life. Obesity results from a positive energy balance in that energy consumed over time exceeds energy expended. This excess energy is stored as fat and consequently results in increased body weight. Hunger and satiety are complex responses to energy demands of the body and perceptions involving integration of stimuli between many neural sites, as well as peripheral organs and the brain [34, 35]. Physiology and behavior act in a coordinated, regulated manner [1]. The question to be answered, both to explain the epidemic rise in obesity on a population level and the difficulties for many individuals to maintain body weight within desired levels, is thus why some individuals fail to keep this balance. Multiple personal (genetic, physiological or psychological) and environmental factors associated with the risk of obesity have been described, but still there is a gap in knowledge on how these factors interact [36].

Genes and the environment

Genetic factors may be important determinants of obesity. The thrifty gene hypothesis suggests that the underlying genetic profile predisposes individuals to adverse or beneficial effects of environmental exposures, such as diet and exercise [36]. Findings in ethnic groups, such as the Pima people and Pacific Islanders, as well as family and twin studies show a genetic predisposition for obesity in humans [37]. Advances in molecular biology have allowed the detailed genetic and epigenetic profiling of individuals, looking specifically at the genetic basis of body weight regulation [38]. Nevertheless, as of today, the ability to predict or explain weight development in an individual, or to explain population variability based on the genetic profile, is limited. In a 2010 study, common genetic variants associated with susceptibility to obesity account for less than 1.5% of the overall inter-individual variation in BMI [39]. Accordingly, individuals with the highest genetic risk were observed to have only 2.7 kg/m^2 higher BMI on average than those at low genetic risk. A recent Norwegian population study revealed that individuals with the lowest genetic risk also gained weight throughout the last decades, although to a lesser degree than the high-risk individuals [40]. Accordingly, there is evidence that even a low-risk genetic profile does not fully protect against obesity.

In recent years, animal and human studies of gene-expression have shed light on weight regulation in mammals [38]. Maternal eating behavior and weight seem to have sustained effects on fetal life and later weight development, apparently by fetal programming via epigenetic mechanisms [41, 42]. In animal models, increased perinatal nutritional exposure exacerbates the sensitivity to an obesogenic food environment later in life [43]. Such findings have implications for the obesity epidemic of future generations.

Homo sapiens evolved genetically in environments with lower and less predictable food availability than we are facing in most parts of the world today. We are genetically selected for survival in environments where starvation is a larger threat than obesity. A genetic constitution very similar to our ancestors, ready access to processed, highly palatable food along with historically low demands for physical activity may be regarded major contributors to the obesity epidemic. Thus, the interaction between ancient genes and a modern obesogenic environment can lead to weight gain, and in turn, sabotage efforts of obesity management [44]. Corrections of these environmental factors represent an as yet unmet challenge to political authorities and society as a whole.

Eating behavior

"I'm a food addict. I've tried everything - Weight Watchers, The South Beach, raw food, Atkins, low-fat diets. Nothing works for me." I looked at him and said, "Have you tried suffering?" He laughed out loud, as if I was joking. I wasn't joking."

(Dr. Frederick Woolverton)

Eating behavior is a major contributor to overweight and obesity. Despite a genetic and biological basis, eating behavior is, to some extent, modifiable. Though feeling of hunger may be a powerful biological motivation to eat, people can consciously or unconsciously choose whether, when and what to eat. A growing body of evidence suggests a close relationship between obesity and psychological components comprising mood disturbances, altered reward perception, motivation or addictive behavior [37]. Identifying personal traits or skills that impact our eating behavior, may therefore be important to understand the development of obesity and the success of any therapeutic intervention [45].

To illustrate, two recent studies shed light on the personal efforts that may be needed to cope with increased appetite and reduced energy expenditure associated with conservative weight loss interventions [46, 47]. In a yearlong placebo-controlled weight loss trial of cangliflozine (an anti-diabetic drug that inhibits renal re-uptake of glucose) in patients with obesity and type 2 diabetes, average body weight decreased significantly more than in the placebo group [46]. Modelling the physiological response to weight loss, the authors found that appetite increased and energy expenditure was reduced due to weight loss, the latter phenomenon called metabolic adaptation. The few participants who successfully maintained long-term weight loss did so by "heroic efforts" to resist increased appetite in face of reduced energy expenditure. Similar findings are reported for individuals with obesity six years after participation in the US "Biggest Loser" competition [47]. Overall, the participants experienced a substantial weight regain, but the metabolic adaptation persisted. Paradoxically, those with greater long-term weight loss also had greater ongoing metabolic slowing. Thus, the authors suggested that overriding the persistent metabolic adaptation of weight loss requires a "vigilant combat".

Different patterns of pathological eating have been implicated in the development of obesity [48, 49]. Among different forms, binge eating disorder and loss-of-control eating are commonly associated with increased risk of overweight and obesity. Both are further related to high prevalence of psychiatric and physical comorbidities. Treatment-seeking individuals with obesity seem to report pathological eating more frequently than those who do not seek treatment, and binge eating disorder is observed in up to 49% of patients undergoing bariatric surgery [50, 51].

1.1.4. Consequences

Society's perception of obesity, as described above, has varied over time and being overweight is now normal in our population. From a medical perspective, overweight and obesity attract attention mainly because of their association with a number of other diseases, reduced QOL and shortened life expectancy. For society, increased obesity results in increased health expenditure. Correction of obesity by treatment may lower the burden of such comorbidities, improve QOL and prolong life. Neither societal attitudes nor population average weight should distract from this important medical perspective toward obesity.

Morbidity

Obesity is significantly associated with the risk of a series of comorbidities and conditions, such as hypertension, high blood levels of cholesterol and/or triglycerides (commonly called dyslipidemia), type 2 diabetes, CVD, osteoarthritis, sleep apnea and breathing problems, cancer and mental illness [52-54]. In a recent Norwegian study, the most prevalent comorbidities in men with obesity were non-alcoholic fatty liver disease, dyslipidemia and hypertension [55]. In women, dyslipidemia, fatty liver disease and joint pain were most common.

For the scope of this thesis, the most relevant obesity-related comorbidities are type 2 diabetes, hypertension and gastroesophageal reflux disease (GERD). An estimated 85% of all patients with type 2 diabetes, defined as glycated hemoglobin (HbA1c) ≥ 6.5% and fasting blood glucose (FBG) ≥ 7 mmol/L, either have overweight or obesity. Approximately 25% of people with obesity have type 2 diabetes [56, 57]. Similarly, obesity is believed to account for an estimated 77% of hypertension, defined as blood pressure ≥ 140/90 mmHg, in men and 65% in women, and the prevalence of hypertension in people with severe obesity is three times the prevalence in people with a normal body weight [58]. The risk of hypertension increases continuously with BMI, with a suggested relative risk of about 1.5 for a five unit increment in BMI [59, 60]. GERD, characterized by reflux of stomach content causing heart-burn and acid regurgitation, is commonly diagnosed in patients with obesity, presumable due to high intra-abdominal pressure [61, 62]. Available estimates suggest a weight gain greater than 3.5 kg/m^2 is associated with approximately two- to three-fold increased risk of developing reflux symptoms [63]. Most studies on psychiatric disease in obesity have focused on depression, but among others, anxiety disorders, eating disorders and alcohol abuse have been evaluated [54, 64]. The association between depression and obesity appears to be bidirectional. Psychiatric symptoms and mental disease are important comorbidities to evaluate before and after weight loss interventions, and have also been explored as predictors of weight loss (section 1.4.)

Quality of life

By considering QOL in medicine, the patient's own perception of well-being is set alongside biomedical readings as an important perspective on disease. The World Health Organization has defined health as *"the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"* [65]. QOL is a broader term than health with no universally accepted definition, but commonly includes well-being, happiness, life satisfaction, attainments of goals, meaning in life and functioning [66]. Improvement in health is the main goal of medical treatment, and consequently QOL represents an important outcome measure. For this purpose a more specific definition of health-related QOL has been provided: *"A term referring to the health aspects of QOL, generally considered to reflect the impact of disease and treatment on disability and daily functioning; it has also been considered to reflect the impact of perceived health on an individual's ability to live a fulfilling life"* [67].

QOL is an example of a patient-reported outcome (PRO) relevant in bariatric surgery research and clinical practice. The intention of utilizing PRO is to capture patients' perspectives on their own health. Thus, *"a patient-reported outcome (PRO) is directly reported by the patient without interpretation of the patient's response by a clinician or anyone else and pertains to the patient's health, QOL, or functional status associated with health care or treatment"* [68, 69]

Obesity has been shown to negatively impact physical, psychological and social functioning, comprised by health-related QOL [70-72]. An inverse relationship between obesity and overall life satisfaction has also been found in several studies [73, 74]. Furthermore, individuals with obesity who seek treatment report poorer health-related QOL than those who do not [75, 76], and the poorest health-related QOL has been found in individuals with severe obesity who choose to undergo bariatric surgery [71, 75, 77]. In 1993, QOL assessments were included in standards for evaluating obesity interventions [78].

Obesity has been found to negatively impact different aspects of life. In general, these effects have been described on three levels of QOL; 1) overall QOL, covering satisfaction with life as a whole 2) generic physical and mental health and 3) obesity-specific QOL. The latter two represent examples of health-related QOL [79, 80].

Mortality

Obesity is an important risk factor for reduced life expectancy in Western populations. Recently the risk was estimated to loss of three to four disease-free years in individuals with obesity class I, and seven to eight disease-free years in case of severe obesity [81]. Above a BMI of 25 kg/m^2, each additional 5 kg/m^2 is associated with 30% higher overall mortality, 40% higher vascular mortality and 60-120% higher diabetic, renal and hepatic mortality. Median survival at BMI 40-45 kg/m^2 was estimated as reduced by 8-10 years, comparable with the effects of smoking [82]. Similar findings pertain to the Norwegian population [83, 84]. Furthermore, it has been calculated that the number of disability-adjusted life years lost due to overweight accounted for 6.5% of all life years lost in the Norwegian population in 2016 [85]. High BMI is one of the most important risk factors for loss of health and longevity in Norway.

Weight stigma

Research has consistently documented discrimination against individuals with obesity [86-90]. Weight stigma can be defined as the social rejection and devaluation that affect people who do not adhere to prevailing social norms of body weight and shape [86]. Stigmatization itself has negative implications for weight-related health [90, 91]. In addition to psychosocial and economic consequences, discrimination tends to reinforce adverse health behaviors that in turn exacerbate obesity and poor health. As examples, Norwegian studies of weight stigma have emphasized patients' experiences of prejudice from health professionals as barriers for adequate medical treatment and desired weight loss [88, 92]. Overall, stigmatization poses a threat to preventive and therapeutic efforts [86, 91].

Social costs

The economic burden on society also motivates prevention and treatment of obesity. It has been estimated that health problems related to overweight and obesity account for 2-7% of total health care costs in industrialized countries and 3% of total global health costs [93]. For Norway, 70 billion Norwegian kroner are estimated to be spent directly or indirectly on management of obesity, equivalent to 3.3% of total health care costs [85].

1.2. Management of obesity

Both treatment and prevention, be it primary or secondary, are needed to address the increase in obesity, and to improve the health, functioning and QOL of individuals with obesity [94]. In Norway, a diagnosis of severe obesity grants access to treatment within the public health services [95]. Currently, three treatment modalities are available: Lifestyle intervention, pharmacotherapy and bariatric surgery.

1.2.1. Conservative interventions

Different lifestyle interventions for obesity, focusing on diet, physical exercise and/or behavioral therapy, reveal modest outcome in terms of weight loss [96-98]. After intensive lifestyle interventions, average weight loss of approximately 10% at one year is observed, with 5% of weight loss maintained over longer periods. Nonetheless, patients may experience clinically meaningful health benefits, such as improved glycemic control, reduced blood pressure and lower cholesterol levels, even when body weight is reduced by only 10% or less [99, 100]. Low costs and minimal risk of complications suggest that such lifestyle interventions should be the first options considered for patients with obesity [101, 102]. However, even when losing weight during or shortly after an intervention, the majority of patients seem to regain most, all or more weight than they initially lost [47, 103, 104].

The improved understanding of biological mechanisms regulating appetite, food uptake and metabolism, has allowed for pharmacological interventions to treat obesity. So called anti-obesity drugs have been introduced primarily as adjuncts to other conservative forms of therapy [105, 106]. Three types of weight-reducing drugs are approved and currently available in Norway: Xenical® (orlistat), Mysimba® (A combination of naltrexone and bupropion), and recently Saxenda® (liraglutide) [107]. In short-term clinical trials, an increased average weight loss of 4-8% of body weight compared to placebo while on drug therapy is typically reported [105, 106]. A concern with pharmacological treatment is that weight tends to rise when treatment is discontinued [108, 109]. Long-term use of anti-obesity medication may be necessary for sustained weight control. Disappointing results in terms of weight loss, adverse effects and substantial costs, may explain why these drugs are not used extensively [101, 110]. Of interst, liraglutide has been studied as short-term treatment in patients with poor weight loss or weight regain after bariatric surgery [111].

1.2.2. Bariatric surgery

Bariatric surgery, also termed metabolic surgery, includes a number of procedures that work primarily by restricting food intake and/or absorption of nutrients. It has been proposed that bariatric surgery may also alter gut hormones and thereby contribute to weight loss and metabolic benefits [112].

Weight-reducing and metabolic effects of small bowel bypass surgery in animals and humans were first published in the 1950s and 60s, respectively [113, 114]. During the ensuing decades, refinements and new surgical techniques were introduced, motivated to a large extent by the recognition of long-term complications associated with earlier procedures [115-117]. The same concern about adverse effects led to an overall skepticism to bariatric surgery in the global medical community during the 1980's, also in Norway [116]. Still, evidence suggested that the procedures in use were safe and effective for patients with severe obesity [118]. Hence, to help legitimize bariatric surgery as a treatment option, previously missing standards for practice were established in 1991 [118, 119]. Since then, the use of bariatric surgery markedly and continuously increased.

The Swedish Obese Subjects (SOS) Study started in 1987 as a non-randomized, matched intervention trial [11, 120]. This is so far the longest running trial of bariatric surgery worldwide. With the limitations of a non-randomized comparison, it has shown what can be achieved by surgery, including decreased overall mortality, remission of type 2 diabetes, fewer CVD events, decreased risk of certain cancers and lowered medication costs compared to conservative treatment [11, 119]. The most frequently performed surgical procedures in SOS are, however, rarely performed today.

At present, an estimated 3000 bariatric operations are performed in Norway annually, and about 2/3 of these are publicly funded [121]. No data exist concerning Norwegian patients who choose to have bariatric surgery performed abroad [122].

Bariatric procedures in current use

Today, a variety of improved bariatric procedures are in use. Knowledge of their relative efficacy and risks, and whether different procedures may be appropriate for different categories of patients is needed [123, 124].

According to global estimates, more than 600 000 primary bariatric operations were performed in 2016 [125]. This number encompasses 54% VSG, 30% Roux-en-Y Gastric Bypass (RYGBP), 5% one-anastomosis gastric bypass, 3% adjustable gastric banding and 0.5% biliopancreatic diversion with duodenal switch (BPDDS) [125]. With incomplete coverage, this trend is mirrored by the national obesity surgery registry in Norway (SOReg-Norway) where VSG accounted for 58% and RYGBP for 42% of the primary operations performed in 2017 [121, 126].

The procedures in scope for this thesis are presented below, with focus on VSG, the intervention studied, and RYGBP and BPDDS (in reverse, but historical order) for comparison and discussion purposes. Despite some use in recent years, other procedures are not discussed.

Biliopancreatic diversion with duodenal switch

The biliopancreatic diversion procedure was first developed by Nicola Scopinaro, and included a distal gastrectomy with a long limb and a short common channel [127]. The modification with a duodenal switch was introduced later to reduce the incidence of anemia and protein malnutrition. BPDDS involves a substitution of the distal gastrectomy by a VSG to preserve vagal innervation and pyloric function [128]. Although BPDDS results in greater weight loss and higher remission rates of type 2 diabetes, it is associated with higher rates of complications and risk of mortality than other surgical procedures in current use, and is rarely performed today [125, 129].

Roux-en-Y gastric bypass

The first gastric bypass was performed by Edward E. Mason after recognizing that patients with sub-total gastrectomy for cancer experienced considerable weight loss [130]. To prevent bile reflux, a reconstruction with a "Roux-en-Y" loop was developed [131]. This procedure has until recently been considered the gold standard among bariatric operations. RYGBP is suggested to work by restricting food intake, rerouting the food stream and changing gut hormones [129].

Vertical sleeve gastrectomy

VSG was initially proposed as a first, restrictive step of the full BPDDS procedure for patients with a very high BMI (Figure 1). Later, the efficacy of VSG as a stand-alone bariatric procedure was recognized by Michel Gagner and colleagues [132]. In brief, the procedure involves removal of 80-90% of the stomach, in particular the fundus, leaving a narrow «sleeve» between the esophagus and the duodenum. Otherwise, the gastrointestinal tract is undisrupted. Weight loss and metabolic benefits after VSG are believed to result from restricted energy intake, accelerated gastric emptying and altered gut hormones [129].

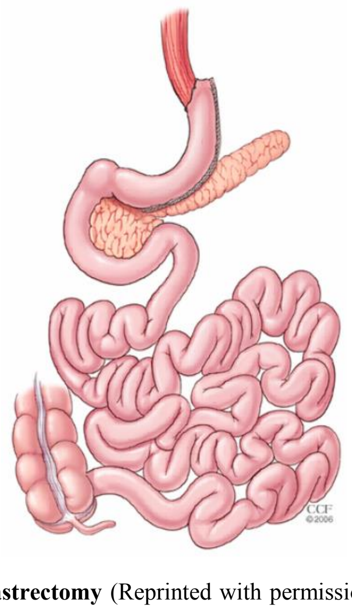

Figure 1. **Vertical Sleeve Gastrectomy** (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2019 All Rights Reserved)

VSG has recently become the most common bariatric procedure worldwide and in Norway, slightly above RYGBP [125, 133]. As of 2016, only two small randomized trials from China were available with five years follow-up, but none of them allow a full comparison of the two procedures [134, 135]. Still, there are some conceptions why VSG may be preferable to RYGBP. VSG does not require anastomoses, and may represent a versatile first step of most other procedures [136]. In addition, patients' preferences may contribute to the choice. However, until a few years ago, few long-term studies on VSG had been published and no randomized comparisons to RYGBP with adequate numbers of patients and follow-up had been reported.

Recommendations for pre- and postoperative care

Pre- and postoperative follow-up, recommended to be carried out by a multidisciplinary team, are mandatory in bariatric surgery [137-139]. Minimal requirements for follow-up are: 1) Check-up after one month, minimal follow-up every three months for the first year, every six months for the second year and annually thereafter. 2) Prescription of vitamin and micronutrient supplements and annual laboratory tests to evaluate metabolic and nutritional status. 3) Regular contact with and lifelong follow-up at an obesity management center [137, 139].

1.3. Outcomes after vertical sleeve gastrectomy

As VSG is a relatively new bariatric procedure, long-term data from prospective studies has been lacking [140-143]. By 2015, data beyond two years after VSG was not available for the Nordic countries or Norway [144, 145]. This section provides a basic summary of outcomes close to or above five years after VSG, as published by the time the research work of this thesis started, focusing on endpoints addressed in studies I-III. The results of studies I-III will be discussed further in section 4.3., with reference to research on long-term outcome evolving after 2016.

1.3.1. Weight loss

Reporting weight and weight loss data in bariatric surgery research is recommended to include initial BMI, change in BMI, percent of total weight loss (%TWL), percent excess BMI loss (%EBMIL) and/or percent excess weight loss (%EWL) [62]. Nevertheless, reported weight loss measures vary among studies, commonly using either %EWL or %EBMIL [140, 146, 147]. By using ideal weight corresponding to 25 kg/m^2 in the %EWL formula, % EBMIL provides identical information. Although not universally accepted, a threshold of < or ≥ 50% EWL is most commonly reported as weight loss "failure" or "success" after bariatric surgery [147].

In a 2014 systematic review, Puzziferri and colleagues assessed 29 studies in which 22 reported weight loss as a primary outcome two to five years after bariatric surgery [148]. Neither of the two retrospective cohort studies of VSG included reported five-year weight loss data. A concurrent literature review focusing on VSG only, reported on 377 patients from 12 studies, with a follow-up of five years or more, and revealed an overall mean EWL of 59.3% [149]. Based on a review of 20, mainly cohort studies with more than five years of follow-up, Juodeikis et al. identified 17 studies with weight loss data from 1501 patients [140]. Only five studies included more than 100 patients, and the range of mean %EWL across studies was 40 - 86%. The calculated mean for all studies combined was 58.4% five years after VSG. As for other surgical procedures, after an initial steep weight loss a varying proportion of patients seemed to gain weight also after VSG [146, 150, 151].

1.3.2. Obesity-related comorbidities and mortality

Common comorbid conditions related to obesity are discussed in section 1.1.4. Data on changes in type 2 diabetes, hypertension and GERD after VSG, as they were available in 2016, are presented below.

Type 2 diabetes

There is ample evidence that bariatric procedures may lead to improvement of type 2 diabetes [62, 152]. The definition of remission of type 2 diabetes varies between studies and hampers comparative analysis. According to current standards for outcome reporting, a complete remission is defined as HbA1c < 6% and FBS < 5.6 mmol/L, partial as HbA1c ≤ 6.4% and FBS ≤ 7.0 mmol/L [62], both in the absence of medication.

In their 2017 review, Juodeikis and colleagues identified 11 out of 20 studies that report on type 2 diabetes five years after VSG. They estimated remission or improvement rates, as referred to normal clinical parameters without medication or reduction in medical therapy, to a mean of 77.8% across all studies (range 61.5 to 100%) [140]. Only nine out of 11 reviewed studies reported remission criteria, and four used criteria as recommended [62]. Another partially overlapping review, focusing especially on the resolution of type 2 diabetes, found an overall remission rate of 60.8 % after VSG [153].

Hypertension

After bariatric surgery, improvement in hypertension is commonly defined as a decrease in use of antihypertensive medication, a reduction in blood pressure or both. According to standard criteria, complete remission is defined as blood pressure < 120/80 mmHg, and partial remission <140/90 mmHg, both in the absence of medication [62]. Depending on the definition, early reports reveal varying rates of improvement five years and more after VSG [148, 154]. In their systematic review, Juodeikis et al., reported a mean improvement or resolution rate of 68% at five years after VSG, although with highly variable rates (range 28.6 to 95%) among nine relevant studies [140]. Heterogeneous definitions of improvement or resolution may account for some of the variability between studies.

Gastroesophageal reflux disease

Symptoms related to GERD are reported as improved after different bariatric procedures [155]. Monitoring of GERD is recommended to include symptom reports from patients, preferably by validated questionnaires, use of antacid medication, or both. Complete resolution can be subjectively assessed by absence of symptoms and medication use, and objectively by physiological tests and/or endoscopy [62]. It has been suggested that GERD may worsen after VSG when present preoperatively, or that VSG may be followed by the development of de novo GERD [156, 157]. The rates of improvement, resolution or deterioration of GERD and the incidence of de novo GERD after VSG vary in early studies. A 2011 review of 15 early studies acknowledges the diverging results and difficulties in providing numeric data regarding the effect of VSG on GERD [158]. In the review by Juodeikis et al. two studies reported improvement of GERD symptoms, while eight studies reported new-onset GERD in 0-23% of patients at five years after VSG [140].

Mortality

The analysis of mortality after bariatric surgery, be it all-cause or due to specific complications of obesity, is mostly based on cohort or case-control studies. While smaller studies may have lacked statistical power to detect relevant differences in survival, larger studies with adequate follow-up point to benefits in terms of overall survival [159, 160]. Significant improvements in cause-specific survival from comorbidities, such as diabetes or cardiovascular disease are also detected [159]. There is no clear indication whether specific procedures, let alone VSG lead to better survival than other bariatric methods. In the present thesis, mortality after VSG has not been analyzed.

1.3.3. Complications and reoperations

Benefits of bariatric surgery must be balanced against the risk of surgical complications. Postoperative complications after bariatric surgery may be classified as major or minor, occurring either early (≤ 30 days postoperatively) or late (> 30 days postoperatively) [62]. Major early complications may involve prolonged hospitalization beyond seven days, administration of an anticoagulant, reintervention or reoperation.

Overall, the mortality rate within 30 days after bariatric surgery has been estimated between 0.07 and 0.35% [161, 162]. In early studies the most common major complications reported after VSG were bleeding, staple line leak, stricture and venous thrombosis [163]. While postoperative bleeding has been reported in up to15% of patients, staple line leak occurred more rarely – varying between 0 and 5.5% [163, 164]. Stricture and thrombosis after VSG was seen in up to four and one percent of patients, respectively, but reoperation is rarely required [163]. Based on non-randomized comparisons to RYGBP, VSG was estimated to have a somewhat lower rate of early complications [165, 166]. The most frequent reasons for reoperation described after VSG were GERD or insufficient weight loss [156, 167-169]. To the best of our knowledge, only limited Norwegian data on complications and reoperations after VSG was available as of 2016 [145].

1.3.4. Quality of life

As outlined in section 1.1.4., impairments in QOL are reported by patients with obesity. There are significant improvements in QOL after bariatric surgery demonstrated also in previous research from our group [14, 170-172]. In general, trajectories of QOL seem to coincide with postoperative changes in weight [172].

At the time of commencement of this thesis, limited data on QOL five years after VSG was available. As reviewed by Juodeikis et al, only one of 20 studies (including 32 patients) assessed pre- and postoperative QOL and reported a significant improvement at five years after surgery [135, 140]. Four other studies were cross-sectional and reported QOL at different points in time after VSG. One of these compared QOL of three smaller cohorts at one, three and five years postoperatively, showing a decline in some aspects of QOL at five years compared to one year [173]. A range of different questionnaires was used across studies, making comparison of results difficult. Thus comprehensive and prospective studies on QOL, using well established tools, were warranted.

Methodological and conceptual considerations related to the evaluation of QOL are addressed further in section 4.2.4.

1.4. Predictors of weight loss and quality of life in bariatric surgery

Identifying patients who are most likely to benefit from surgery is important to optimize resource allocation, avoid exposing patients unlikely to benefit, manage patients' expectations and tailor follow-up. Several studies have evaluated factors that may predict weight loss and other outcomes following bariatric surgery [124, 174-177]. Conceptually, characteristics assessed before or after treatment, and time dependent changes of such factors after surgery could be used to predict outcome. Weight reduction has been evaluated as the outcome of interest in most studies, but it may be argued that resolution of comorbidities, functional or psychological improvement, QOL and increased life expectancy, are additional or more appropriate goals to aim for in this regard.

Predictors of weight loss

No commonly accepted predictors for weight loss after bariatric surgery seem to exist [124, 178-180]. Preoperative BMI, type 2 diabetes, education, marital status, sex, age, ethnicity and socioeconomic factors have been evaluated as predictors of weight loss after different procedures, but results vary. With considerable heterogeneity between studies, recommended preoperative weight loss may be positively associated with postoperative weight loss, whereas higher preoperative BMI, superobesity (defined as BMI ≥ 50 kg/m^2) and certain psychosocial factors may be negatively associated with weight loss after surgery. Among such psychosocial factors, eating disorders, mostly binge-eating disorder, other maladaptive eating behaviors, such as snacking, symptoms of depression or anxiety and alcohol abuse have been studied, but no uniform results are seen [124, 175, 178, 181]. Norwegian guidelines recommend excluding patients with active psychosis or drug/alcohol abuse from surgery, which is enforced in all studies in the present thesis [95].

Predictors of QOL

Other studies have addressed predictors of QOL following bariatric surgery [177]. In one study, higher preoperative BMI and self-reported symptoms of depression were suggested as predictors for a lower level of health-related QOL determined 12 months after RYGBP [182]. Moreover, the association between postoperative improvements in depression and health-related QOL were found to be stronger than the association between weight loss and health-related QOL. Actual weight loss was mainly associated with the physical aspects of health-related QOL at 12 months. Others have also suggested that the predictors of physical health-related QOL and weight loss are similar, while the association between postoperative weight loss and mental health-related QOL is not convincingly demonstrated [176]. Further studies also demonstrate the predictive capacity of preoperative age, BMI and depression severity [183, 184], and psychiatric disorders that persists postoperatively on health-related QOL both short- [177, 183, 185] and long-term after bariatric surgery [186]. It seems unclear whether pre- or postoperative eating behavior, e.g. maladaptive eating or binge eating, may predict health-related QOL [176, 177, 187]. Studies on early post-operative changes in psychosocial factors with potential relevance to long-term outcome, e.g. weight loss, QOL or others, are limited [188].

1.4.1. Eating self-efficacy

Eating behavior is introduced briefly in section 1.1.3. It has been suggested that bariatric surgery may affect key factors involved in regulation of eating behavior and hedonic taste perception [189]. These include food-craving, the influence of emotions and external food cues and the palatability of sucrose. Both restrictive effects of surgery and changes in gut hormones may be mediators of these effects. Still, some patients struggle to change old eating habits even after bariatric surgery [190]. Physiological adaptation may be part of the problem [191, 192], but cognitive control of eating behavior seems crucial for weight management also after surgery [193].

Self-efficacy is a key concept in social cognitive theory and refers to perceived capabilities of performing behaviors at designated levels [194, 195]. It may influence the choice of activities, effort, persistence and achievement. Information on ones self-efficacy for a specific activity may be acquired from previous performance, vicarious experiences, forms of persuasion and physiological symptoms. Perceptions of progress and success, specifically mastery experiences, may reinforce self-efficacy, and thus promote the capacity to manage obstacles [195]. As such, individuals with high perceived self-efficacy seem to attempt more, accomplish more and persist longer at a specific task than those with low perceived self-efficacy. Levels of self-efficacy appear positively correlated with health-related self-management, for instance in adjustment to CVD and smoking cessation [196, 197]. Self-efficacy may therefore be a useful measure of patients' self-management following weight loss interventions [198-200].

While general self-efficacy may be defined as a universal measure of an individual's ability to manage several different tasks and settings [201], Bandura argued that self-efficacy is context-dependent [194]. Thus, self-efficacy could be considered a modifiable, situation-specific attitude that seems to be a stronger predictor of behavior than more stable personality traits [202]. Eating self-efficacy refers to the confidence to control eating in specific challenging situations [203]. A validated questionnaire of eating self-efficacy, the Weight Efficacy Lifestyle Questionnaire short-form (WEL-SF) has been applied for research purposes [198, 203].

Studies on the association between self-efficacy, whether general or related to eating or physical activity, and weight, have mainly focused on conservative weight loss interventions. The existing research does not fully support the conclusion that self-efficacy is a valuable concept for predicting or improving health behavior and outcome in patients with obesity [204, 205]. However, important lessons can be learned from a number of these studies. It appears important to distinguish between studies of self-efficacy prior to an intervention and its ability to predict future weight loss, and self-efficacy after treatment changing concurrently with weight loss. At the outset of this thesis work, no studies were available on the value of self-efficacy assessments prior to bariatric surgery. In a cross-sectional study, Batsis et al. compared eating self-efficacy four years after either RYGBP or non-surgical treatment. They found that greater weight loss was associated with higher eating self-efficacy, and that the values were higher in the surgical group than in the conservatively treated patients [206]. In a cross-sectional study on Norwegian patients one year after VSG, we observed a similar correlation between weight loss and eating self-efficacy assessed postoperatively [198]. Prospective studies are, however, needed to investigate pre-surgical levels and changes in eating self-efficacy after surgery, and to explore their possible association with weight loss over time.

Interestingly, there seems to be an association between QOL and both general self-efficacy and health literacy [207-209]. Prospective assessments of the association between self-efficacy and long-term health-related QOL after bariatric surgery seem to be lacking.

1.5. Aims

To summarize, patients seeking surgical treatment for severe obesity often suffer from obesity-related comorbidities and report poor QOL. VSG has recently become the most frequently performed bariatric surgical procedure worldwide and in Norway, but knowledge on long-term outcomes is still limited. Particularly, predictors of weight loss and QOL are scarcely examined after VSG. In this context, the aims of this doctoral research were:

1. To report five-year outcome after VSG, specifically complication and revision rates, weight loss measures and changes in obesity-related comorbidities (Paper I)
2. To investigate the predictive value of eating self-efficacy on long-term weight loss and obesity-specific QOL after VSG (Paper II)
3. To investigate 1) long-term trajectories in QOL at different levels (obesity-specific and generic health-related QOL, and overall QOL) following VSG, compared to general population norms and 2) the predictive value of weight loss on QOL five years after VSG (Paper III)

2. Materials and methods

2.1. Settings and study design

We studied three separate patient cohorts. For studies I and III, data was derived from the bariatric surgery registry at Førde Central Hospital. After a longer halt in bariatric surgery from about 1980, Førde Central Hospital was the first hospital in Norway to resume bariatric surgery for severe obesity in 2001. By establishing a local registry, research and quality control were emphasized from the outset. Since 2007, VSG has been the preferred procedure, with approximately 40 patients operated on annually. For study II, data was collected at Voss Hospital where bariatric surgery has been performed since 2008. Approximately 200 patients undergo bariatric surgery annually since 2012, with VSG being used in 90% of cases. From a national perspective, both hospitals have pioneered VSG as a bariatric surgical procedure.

At Førde Central Hospital, all patients accepted for surgery are invited to contribute to the registry. Following informed consent, data from hospital charts and registry-specific forms, including PROs, are entered prospectively. Studies I and III are covered by ethical approval of the registry (REK no: 2009/2174).

Study II is a prospective study recruiting patients accepted for surgery at Voss Hospital (REK no: 2012/1481). Following informed consent, study-specific data from PROMs were collected and aligned with clinical data from hospital charts. The follow-up period of the study was later extended from two to five years (REK no: 2017/948).

All three studies in this thesis have a prospective design based on five-year observational follow-up.

2.2. Participants

Adult (18 to 70 years) patients with severe obesity (BMI ≥ 40 kg/m^2, or ≥ 35 with obesity-related comorbidities) accepted for VSG based on standard criteria, i.e. absence of alcohol or drug abuse and active psychosis, as assessed by the multidisciplinary team and the treating surgeons, were invited to participate in the studies. In study I and III, patients operated from December 2005 to November 2010, and from January 2010 to December 2013, respectively, were included. In study II, included patients were operated on from December 2012 to May 2013.

2.2.1. Preoperative information and evaluation

Before surgery, patients were invited to a multidisciplinary meeting with information about obesity, bariatric surgery and its risks, required changes in habits of eating and physical activity and likely life changes after surgery. This was followed by an individual and structured out-patient consultation (Appendix I) two to three months before the operation, with the surgeon and other health-personnel. Blood samples were taken after over-night fasting and routine clinical evaluation and relevant study questionnaires were completed (Appendix II). Preoperative advice centered on smoking cessation, increased physical activity, weight reduction and a diet restricted to 1000 kilocalories/day.

2.3. The vertical sleeve gastrectomy

VSG was performed according to identical technical standards in both institutions, as described [145]. In brief, the stomach was vertically resected along a 32 French (≈ 11 mm) tube from 1-2 cm proximal to the pylorus ending at the cardia. Prophylactic staple line reinforcement and gastropexia (suturing the rest-stomach to the omentum) was not part of the standard procedure. Preoperative upper gastrointestinal endoscopy was only performed in selected cases, and perioperative hiatal repair was not performed.

2.3.1. Postoperative evaluation

After surgery, patients were followed with out-patient visits at three, 12, 24 and 60 months. Consultations included blood samples after over-night fasting, weighing, blood pressure measurement and relevant study questionnaires. The operating surgeon participated regularly at the three-month visit, while later visits were done mainly by a nurse and nutritionist. All study visits followed a standardized checklist (Appendix I) and covered complications, physical and mental health, medication, physical activity, nutritional intake, the need for supplementation and study questionnaires. Individual health challenges were addressed and, if needed, referral to other specialists was initiated.

2.4. Variables and measures

2.4.1. Demographic, anthropometric and clinical variables

Demographic, anthropometric and clinical data was registered from hospital charts and standardized checklists (Appendix I). Data on patients' age, sex, marital/cohabitation-status, medically treated anxiety and depression, BMI and QOL are included in all three studies. Study I contained additional data on employment, medically treated comorbidities, early major complications and re-operations. Study II contained additional data on education level and eating self-efficacy. Body weight was measured in light clothing without shoes to the nearest 0.1 kg. Height was measured in a standing position without shoes to the nearest centimeter. BMI was calculated as weight divided by height squared (kg/m^2).

The American Society for Metabolic and Bariatric Surgery (ASMBS) standards guided the outcome definitions and assessments [62].

Weight loss

Weight loss was presented as change in BMI (ΔBMI = initial BMI − postoperative BMI) or percentage total weight loss (TWL = (initial weight – postoperative weight/initial weight) x 100). In addition, loss of excess body weight above the ideal or upper normal reference for the individual was calculated as percent excess BMI loss (%EBMIL = ΔBMI/(initial BMI − 25) × 100), or percent excess weight loss (%EWL = (initial weight – postoperative weight)/(initial weight – ideal weight) x 100). For the calculation of %EWL in study I ideal weight was defined by the Metropolitan height and weight table [210] while in studies II and III, ideal weight was defined by a BMI of 25 kg/m^2. In all three studies, the percentages of patients with weight loss below 50% in terms of %EWL and/or %EBMIL are stated.

Postoperative complications and revision surgery

In study I, we report major complications occurring early (≤ 30 days) or late (> 30 days) in the postoperative time-span. Reoperation was reported if patients had a second operation due to insufficient weight loss or adverse events at any time.

Obesity-related comorbidities

In study I, we report prevalence of type 2 diabetes, hypertension, dyslipidemia, sleep apnea, obstructive lung disease, musculoskeletal pain, anxiety, depression and GERD. These conditions were considered present if patients reported relevant medical treatment on a regular basis. In addition, all patients were screened for type 2 diabetes, hypertension and dyslipidemia. Absence or remission of type 2 diabetes, hypertension and dyslipidemia were registered if the patient used no medication for the condition, and if FBS was < 7 mmol/L and HbA1c ≤ 6.4%, blood pressure was < 140/90 mmHg, and lipids were within normal values, respectively. For type 2 diabetes and hypertension, these cut-off values correspond to the definition of a partial remission by the ASMBS [62]. Snoring, urinary leakage, amenorrhea and infertility (in premenopausal women) were recorded based on self-reported symptoms, treated or not. Infertility was recorded if a premenopausal woman had attempted pregnancy for more than one year without succeeding [211].

2.4.2. Patient reported outcome measures

Quality of life

QOL, assessed in different dimensions, is reported in all three studies. Study I includes a cross-sectional assessment of generic health-related QOL at five years. Study II reports prospectively weight-specific QOL. Study III includes three different levels of QOL encompassing multiple life domains. Results are compared to population norms.

The Short-Form 36

In study I and III Short-Form 36 (SF-36) was used to measure generic health-related QOL. The questionnaire is a valid and reliable measure of the perceived health burden related to chronic diseases [212]. It has been recommended for obesity research and is validated for Norwegian patients with obesity [213]. The SF-36 encompasses 8 dimensions of health, each ranging from 0 (poorest) to 100 (optimal), reflecting 1) physical functioning, 2) physical role functioning, 3) bodily pain, 4) general health, 5) vitality, 6) social functioning, 7) emotional role functioning, and 8) mental health. We report results from the two SF-36 summary scores based on factor analysis with oblique rotation; i.e. physical component summary (PCS) and mental component summary (MCS). The PCS and MCS cluster the eight subscales according to common physical and mental attributions [214]. Each of the two summary components is assessed on a transformed scale where higher scores represent better perceived physical and mental health. For comparison, we used population scores derived from a randomly selected Norwegian sample including all BMI categories [215].

The Impact of Weight on Quality of Life-Lite questionnaire

In study II the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire was used to measure obesity-specific QOL. This is a 31-item questionnaire comprising 1 total score and scores on 5 subdomains. These include 1) physical function, 2) self-esteem, 3) sexual life, 4) public distress and 5) work. Scores are transformed into a scale from 0 to 100 where high scores indicate high obesity-specific QOL [216]. The IWQOL-Lite has been validated for Norwegian patients [171]. We report outcomes solely based on the total score. For comparison, we used data from the US general population, including individuals in all BMI categories [217].

The Obesity-related Problem Scale

In study III we used the Obesity-related Problem (OP) scale to measure obesity-specific psychosocial functioning in different daily life situations. This questionnaire comprises 8 items covering situations like 1) parties/social gatherings at home, 2) parties/social gatherings at a friend's or relative's place, 3) going to restaurants, 4) participating in organizations, attending courses, etc., 5) going on vacations, 6) trying on and buying clothes, 7) bathing in public areas (swimming pools, beaches), and 8) sexual intercourse/intimate relations with partner. Patient scores range from 0 to 3; "definitely not bothered" (0), "not so bothered" (1), "mostly bothered" (2) and "definitely bothered" (3). A summary score is transformed to a standardized scale from 0 to 100 where lower scores refer to higher degrees of psychosocial functioning. Scores below 20 indicate no or mild psychosocial impairment, from 20 to < 40; mild impairment, from 40 to < 60; moderate impairment, from 60 to 80; severe impairment and ≥ 80; extreme impairment [71]. We report both total score and responses to the eight individual items. The OP has been psychometrically validated for Norwegian bariatric patients [218]. For comparison, we used population data derived from a Swedish sample with a BMI < 30 kg/m^2 [219].

Cantril's Ladder

In study III we applied Cantril's ladder to measure overall QOL [220]. This widely used measure contains one item. Patients were asked to think of a ladder with 10 rungs from 0 (bottom) to 10 (top) where the top of the ladder represents the best possible life and the bottom represents the worst. Thereafter they were asked to "place" their own current life to one of the rungs – resulting in a score from 0 to 10. A score of 6 or more is labelled "high life satisfaction" and less than 6 "low life satisfaction". For comparison, we used population data from a Norwegian sample including all BMI categories [220].

Eating self-efficacy

The Weight efficacy lifestyle questionnaire Short-Form

In study II, the WEL-SF was used to measure eating self-efficacy. WEL-SF was originally developed for US patients undergoing bariatric [203] and later validated for Norwegian patients [198]. The questionnaire consists of 8 questions representing "confidence in ability to resist eating" related to emotional situations (3 items), availability of food (2 items), social pressure (1 item), positive activities (1 item) and physical discomfort (1 item). The Likert scale ranges from 0 (not at all confident) to 10 (very confident), with total scores ranging from 0 to 80. Higher scores indicate higher eating self-efficacy. WEL-SF data from a general population was not available for comparison.

2.5. Statistical analyses

Continuous variables are presented as arithmetic means ± standard deviation (SD) or 95% confidence intervals (CI). Categorical variables are presented as counts and percentages (%).

To examine longitudinal changes in binary variables, i.e. obesity-related comorbidities, we used the McNemar test with mid-P correction. Changes in continuous variables (with time as a categorical explanatory variable) were tested using mixed effects models with random intercept or longitudinal regression models with a heteroscedastic error structure (different variances at each time point) and an unstructured correlation matrix. These models use data from all patients, even patients with partially missing data. For other analyses, we used complete-case analysis, but reported the number of measurements on which each result was based.

In study III, we adjusted the OP, SF-36 and Cantril's ladder population norms for age and sex to reflect the same distribution as in our patient cohort. Such an adjustment was not done for population norms in studies I and II. The one-sample t-test was used to compare with the population norms [71].

In study II and III, associations between %EBMIL and QOL as the dependent variables, and other explanatory variables were investigated using multiple regression analyses. We performed initial tests for normal distribution of residuals, homoscedasticity, linearity and collinearity to ensure that underlying assumptions for the regression analysis were not violated. Predictors of long-term %EBMIL and disparate levels of QOL were assessed. In study II we chose to use ordinary least square regression based on available data for the predictor analysis [221]. For handling missing data in study III, we performed multiple imputation based on predictive mean matching and used imputed data in the regression models.

To assess the clinical relevance of observed changes in PROMs, we calculated effect-sizes as proposed by Cohen [222]. In study III, we also assessed effect-sizes of differences in QOL scores between the study cohort at five years and the population norm. Effect sizes less than 0.2 were considered trivial, from 0.2 to 0.5 small, from 0.5 to less than 0.8 moderate and estimates above 0.8 were considered large [222].

Statistical analysis were performed using R 3.5.1 (R Foundation for statistical computing, Vienna, Austria) and Statistical Package for Social Sciences for Windows, version 23.0 (SPSS, Chicago, IL). Two-sided P-values $\leq$ 0.05 were considered statistically significant. No corrections for multiple tests were performed.

Power calculations

Initial power analyses were performed for each study cohort to estimate the risk of type II errors.

Study I: Based on BMI changes from baseline to five years after surgery, N = 137, power = 90% and P = 0.05, we could discover a statistically significant change equal to 0.27 SD (paired t-test). Expected change was > 2 SD [170].

Study II: Based on correlations between changes in eating self-efficacy, BMI and HRQOL, N = 114, power = 90% and P = 0.05, we could discover a statistically significant correlation equal to 0.29. Cross-sectional correlations with these variables have been reported as Pearson's r > 0.33 [198].

Study III: Based on changes in HRQOL from baseline to 5 years after surgery, N = 120, power = 90% and P = 0.05 we could discover a statistically significant change equal to 0.30 SD (paired t-test). Expected change was > 0.76 SD [170].

Calculations assumed a correlation between the time points of 0.5.

2.6. Ethics

Written, informed consent was obtained from the participants prior to study entry. The Regional Committee for Medical and Health Research Ethics – Western Norway, approved the studies (Reference numbers study I and III: 2009/2174, study II: 2012/1481 and 2017/948).

3. Results and summary of the papers

3.1. Study I

Sample characteristics

During the recruitment period a total of 168 patients accepted for VSG where included in the Førde registry. Complete follow-up data was available for 137 (82%) at 60 months after surgery, with no apparent attrition bias at that point.

Weight

Weight loss was profound and significant from baseline to two and five years for the whole group. Mean change in BMI was 15.7 kg/m² at two years and 13.6 kg/m² at five years. Mean %EBMIL was 77.6% and 66.1% at two and five years, respectively. The weight loss varied across the cohort with a failure rate at five years of 39% (i.e., six patients had revision surgery for inadequate weight loss and 49 had EWL ≤50%). The proportion of patients with ≥ 10 kg weight regain from two to five years was 44%.

Major complications and re-operations

Major early complications occurred in 10 (6%) of the patients, including two patients with bleeding and two with leakage. Reoperation was performed on seven patients (4.2%), one due to GERD and six due to inadequate weight loss between one and three years after the initial operation. Four of the seven patients had a surgical conversion to BPDDS, one to RYGBP and two underwent a second VSG.

Comorbidities

For most obesity-related comorbidities the prevalence decreased two years after surgery. Exceptions were the prevalence of anxiety and depression, which remained unchanged, and the proportion receiving treatment for GERD, which increased. From two to five years, findings remained largely unchanged except for an increase in the proportion of patients receiving treatment for musculoskeletal pain, and a further increase in the number of patients taking antacids.

Generic health-related quality of life

Mean PCS and MCS were 46.5 and 48.2 in the study cohort at five years, with no associations between %EWL and either PCS or MCS. Mean PCS and MCS at five years after VSG were significantly higher than preoperative scores found in a separate cohort of severely obese patients planned for VSG. Mean scores at five years were significantly lower than population norms.

3.2. Study II

Sample characteristics

A total of 114 patients accepted for VSG agreed to participate in the study. Complete follow-up information was available for 84 (74%) patients at 55 months after surgery, with no apparent attrition bias.

Weight

Weight loss was profound with significant improvements from baseline to 16 and 55 months for the whole group: mean change in BMI was 13.1 kg/m² from baseline to 16 months, and 11.4 kg/m² from baseline to 55 months. The mean %EBMIL was 76% and 67% at 16 and 55 months, respectively. Some showed less prominent weight loss with %EBMIL < 50% seen in 30.1% of patients at 55 months. Thirty-two percent of patients regained ≥ 10 kg from 16 to 55 months.

Obesity-specific quality of life

Preoperative IWQOL-Lite score increased significantly from baseline to both 16 and 55 months, with a non-significant decline between 16 and 55 months. The effect-size was 1.5 at five years, indicating a large clinical relevance. At 55 months, the mean IWQOL-Lite score was significantly below the general population level.

Eating self-efficacy

Eating self-efficacy (WEL-SF) increased significantly from baseline to both 16 and 55 months after VSG, with a non-significant change from 16 to 55 months. Mean change from baseline to 55 months was 6.8 corresponding to a small effect size of 0.4.

Predictors of long-term weight loss and obesity-specific quality of life

Preoperative WEL-SF scores did not predict postoperative weight loss at 55 months. However, the change in WEL-SF scores from baseline to 16 months significantly predicted weight loss at 55 months, as did the change in eating self-efficacy from baseline to 55 months.

Neither preoperative WEL-SF scores predicted obesity-specific QOL 55 months after VSG, nor did changes in WEL-SF scores from baseline to 16 months. However, change in WEL-SF scores from baseline to 55 months revealed a significant association to obesity-specific QOL at 55 months after VSG.

3.3. Study III

Sample characteristics

During the recruitment period, a total of 150 patients accepted for VSG were identified in the registry, but 23 patients were later excluded from study III due to missing PRO data for all time-points (22 patients due to administrative errors and one patient due to early death not related to surgery). For the 127 patients, included PRO data was available in 81 (64%) patients and anthropometric data in 103 (81%) patients at 60 months after surgery, with no apparent attrition bias.

Weight

For the group as a whole, mean %EBMIL was 76 and 64 after one and five years, respectively. A proportion of patients had less pronounced weight loss with %EBMIL < 50 seen in 30 out of 103 (29%) patients at five years after VSG. Thirty-eight out of 102 (37%) patients gained ≥ 10 kg from one to five years postoperatively.

Health-related QOL/QOL

All dimensions of QOL (i.e. OP, PCS, MCS and Cantril's ladder) improved significantly from baseline to one year, with a modest, but significant decline in the group as a whole from one to five years. The improvement in OP total score from baseline to five years had a large clinical relevance with an ES of 1.3. Ten out of 81

(8%) patients reported poorer psychosocial functioning five years after VSG than before.

Significant improvements in mean PCS and MCS scores occurred from baseline to one year, followed by a subsequent modest, yet significant decline from one to five years after surgery. Improvements from baseline to five years showed an ES of 0.9 for PCS (large relevance) and 0.44 for MCS (small relevance), respectively. Twenty-one out of 76 (17%) and 16 out of 76 (13%) patients reported poorer MCS and PCS at five years postoperatively than before VSG, respectively.

A significant improvement from baseline to one year, followed by a modest but significant decline thereafter was found for Cantril's ladder. The ES was 0.8 (large relevance) for the change from baseline to five years. Twenty-two out of 72 (17%) patients reported lower overall life satisfaction five years postoperatively than before VSG.

Mean OP total score at five years after VSG was significantly higher than in the general population, indicating poorer psychosocial functioning. Furthermore, mean PCS, MCS and Cantril's ladder scores at five years were significantly lower than in the reference population, again showing lower health-related QOL and overall QOL. These differences correspond to ES values of 0.7 (modest relevance) for OP, 0.4 (small) for PCS, 0.3 (small) for MCS and 0.8 (large) for Cantril's ladder scores.

Predictors of health-related QOL/QOL

The three QOL domains, OP, PCS and MCS as measured at baseline significantly predicted their corresponding QOL outcomes at five years. A similar association was not seen for Cantril's ladder. Also, baseline BMI significantly predicted the OP score at five years, but none of the other QOL outcome measures. Percent EBMIL at five years was significantly associated with OP and PCS scores, but not with MCS and Cantril's ladder scores after five years.

4. Discussion

4.1. Methodological considerations

4.1.1. Study design and samples

Studies I-III represent examples of prospective cohort studies. In these studies, we assess the effect of VSG (the exposure) on various outcomes; weight loss, comorbidities, complications, eating self-efficacy and QOL, within predefined groups of patients.

In our studies, no control groups were used for comparison, and unknown external factors may have contributed to the outcomes. We therefore cannot draw firm conclusions about causes from our findings alone. The prospective design allows for a temporal comparison before and after the intervention on an individual level. Undoubtedly, VSG contributes to weight loss, resolution of comorbidities and improvement in QOL in the years following surgery. It is more difficult to assess whether these changes are the direct consequence of surgery alone, to what extent other components of the treatment, follow-up, or external factors can explain the variability in these outcomes. Similarly, direct comparison to outcomes seen after other surgical procedures is hampered. To this end, appropriately designed and conducted randomized controlled trials (RCTs) are required (see section 4.3.).

In the absence of an adequate control group, multivariable analyses identify factors that themselves predict outcomes beyond surgery itself. In studies II and III multivariable regression analyses were performed to study whether available baseline characteristics, and their changes over time, were associated with long-term weight loss and improvements in QOL after VSG.

The sample size in all three studies was relatively small, limited first and foremost by the number of annual VSG operations performed in the two hospitals recruiting patients. The number of patients could only be increased by extending the inclusion period, or involving other hospitals.

A main concern with a small sample size is the inherent risk of type II errors. Therefore, in all three studies *a priori* power calculations confirmed that the predicted lower bounds of differences in the main endpoints of interest would be detectable with adequate statistical confidence. An example of a possible type II error in study II is the absence of any association between baseline eating self-efficacy and weight loss or QOL after five years. In this study we lacked data to estimate the magnitude of association between the baseline WEL-SF scores and the two outcomes after five years for adequate power calculations. The study could only provide an initial exploration of this topic.

For several of the other outcomes studied, we reported post-surgical variations below the threshold of statistical significance that could turn out to represent truly significant differences if our sample size were bigger, i.e. more patients included. This may hold true for instance for some of the more subtle changes in comorbidities, e.g. type 2 diabetes, during the weight-gaining period two to five years after surgery (study I). Another example is the lack of association of weight loss and five year MCS, where the trend towards significance does not rule out a contribution detectable if larger cohorts were investigated (study III).

Also, with our lower number of patients, the number of independent variables allowed in multivariable analyses, such as the linear regression models, is limited by standard statistical cautioning [223].

4.1.2. Generalizability

All three studies benefit from the inclusion of patients referred to surgery under routine conditions in the western health region of Norway.

We can assume, with some reservations, that our cohorts mirror Norwegian patients with severe obesity that undergo bariatric surgery, i.e. the external validity seems adequate. We have no information about patients from the capture regions of Førde and Voss hospitals operated on in other public or private hospitals during the recruitment periods of studies I-III. About two thirds of patients in Norway are operated on in public hospitals, and mostly, these patients are referred to their regional hospital. At the same time, we cannot control for the inherent bias that results from surgeons' and patients' choice of procedure. No uniform criteria for treatment allocation exist [224]. However, operations under routine conditions and study consultations as part of routine post-operative follow-up let the results reflect the effect of current practice. By virtue of mirroring "real world experience", observational studies of the kind reported herein, supplement results from RCTs. Due to the stringent design, strict inclusion criteria and selected endpoints, RCTs may not be fully representative of every day practice [225].

For several reasons the internal validity of the results seems to be high. The number of VSG procedures performed during the recruitment periods can be extracted from hospital records and we can assess the extent to which eligible patients are included in the Førde registry (studies I and III) and recruited to study II at Voss hospital. At inclusion, this coverage is close to complete, reflecting the high willingness of patients and hospital staff to contribute to bariatric surgery research.

Internal validity of longitudinal studies may be reduced by attrition, that is, loss of subjects during the study period. Retention rates at five years varied from 82% in study I, to 74% in study II and 64% in study III. For study III this was lower than expected, mainly due to administrative difficulties on the part of the registry. For prospective cohort studies, retention rates of 80% or greater are considered a standard target [226], but this is rarely achieved after bariatric surgery [140]. High attrition rates can ultimately compromise interpretation of results and violate internal validity [227]. In our studies, we compared baseline characteristics of patients available at five years with those lost during follow-up, which revealed no statistical differences in the three cohorts. Thus there seems to be no non-random loss of patients during follow-up and the internal validity does not seem to be violated by attrition.

Data loss during follow-up was handled differently in the three studies. In studies I and II all analyses were carried out with original data and the results based on the number of actual data points. In study III missing data was substituted by results of multiple imputations, which reduces the bias introduced by non-random loss of data. Strikingly, the analyses in study III yield identical results when repeated with the original data set – which corroborates the claim that the loss of patient data was random.

4.1.3. Data quality and validity

Compared to larger multi-institutional or registry studies, the inclusion of patients from only two hospitals with direct access to clinical and study-related data, allows for registration of a higher number of variables and a higher frequency of assessment. Furthermore, ambiguities in registered data may be corrected by source verification in medical records. Some specific aspects related to the validity of registered data are considered below.

Comorbidities

In most cases, registration of comorbidities was based solely on patient-reported use of medication. The exceptions were type 2 diabetes, hypertension and dyslipidemia for which biomarkers and blood-pressure measurements, represented complementary and objective metrics. Self-reporting of diagnoses is a common approach to collect data on health status [228]. However, recall bias may lead to over- or underestimating the presence of comorbidities. No external sources, such as prescription registries, were used for verification, and the duration of treatment was not recorded. Furthermore, the use of medication may not be a reliable indicator of disease or disease severity. For example, our findings for depression and anxiety in study I may be error-prone, as impaired mental health cannot be represented by patients' use of medication alone. Study I did not include supplemental patient-reported mental health, i.e. symptoms of depression or psychiatric evaluations based on clinical interviews. Therefore, the prevalence of depression and anxiety, and its apparent relative stability must be interpreted with caution.

Patient reported outcomes

In all three studies PROs were captured by questionnaires that are well established in previous obesity research or QOL studies in other medical fields. However, some noteworthy points regarding the choice of questionnaires can be emphasized.

Quality of life

In study III, overall QOL was measured by Cantril's ladder consisting of one question aiming to capture the patient's satisfaction with life as a whole. Although widely tested and validated [229], it has rarely been used in obesity research and is not validated for this purpose [218]. Thus, its sensitivity for changes in the lives of bariatric patients may be questioned. However, the large effect-size of change detected in study III suggests a good capture of how patients perceive their life situation as a whole before and after VSG. Cantril's ladder is similar to the visual analog scale used by Charalampakis et al, one of the few other studies on QOL with five years follow-up after VSG [230].

Generic health-related QOL was measured by the SF-36, chosen due to its widespread use in obesity research and therefore useful for wider comparison of outcomes. Results of the two sum scores, PCS and MCS, were used as they have shown stronger stability in patients with obesity than the eight constituent scores on which they are based [213]. PCS and MCS were calculated by an oblique method allowing free correlation between physical and mental health as these are not independent phenomena, but inherently strongly linked.

Obesity-specific QOL was measured with two different questionnaires, the OP scale and the IWQOL-Lite, both validated in Norwegian bariatric patients. While OP solely measures psychosocial functioning, IWQOL-Lite approaches several areas of daily life functioning (physical, self-esteem, sexual, public distress and work) [231]. The OP scale has been employed by the Førde registry to allow comparison of results with the SOS study [232]. Study II was planned separately and the IWQOL-Lite was chosen due to its broader coverage of functional areas.

Eating self-efficacy

The WEL-SF is a convenient questionnaire of eating self-efficacy in bariatric patients due to its sensitivity for change and clinically feasible short-form properties. The selected situations included are obtained through exploratory factor-analyses, all strongly correlated with the component "confidence to resist eating" [203]. The utility of the questionnaire is still limited by the absence of general population data for comparison.

In hindsight, all studies in this thesis are hampered by the lack of patient-reported symptoms of mental health and distress [233]. Such measures have shown to be highly correlated with MCS in the SF-36, still it has been suggested that symptoms of anxiety and depression should be measured separately and in addition to SF-36 for QOL assessment [234].

4.2. Interpretation of outcomes in light of current data

Knowledge on long-term outcomes after VSG has grown since the conception of the studies included in this thesis. The major results of studies I-III will be discussed with reference to new data evolved after 2016.

4.2.1. Weight loss

"Honeymoon - with the weight just dropping off…feeling ten foot tall and bullet proof" [235]

Studies I-III all include patients with severe obesity selected with uniform criteria, and the VSG procedure and follow-up are performed according to the same standards. Outcomes in terms of weight loss are remarkably similar in the three studies. For easier comparison and discussion, we have combined the three cohorts, using standard outcome measures for changes in BMI and body weight.

In total, we have baseline anthropometric data for 409 patients. Between one and two years, data was available for 378 patients (92%) and at five years for 323 patients (79%). The mean change in BMI was 15.1 kg/m^2 (± 4.9) and 12.8 kg/m^2 (± 5.9) at one-two years and five years respectively, while corresponding figures for mean %EBMIL at one-two and five years was 77.0% (± 20.0) and 65.5% (± 24.5), respectively. Mean TWL was 32.7% (± 8.4) at one-two years after VSG, and 27.7% (± 11.0) at five years. A regain ≥ 10 kg from one-two to five years was observed in 121 out of 323 patients (37.5%). At five years, 93 out of 323 (29%) had an EBMIL < 50% whereas 120 out of 323 (37%) obtained a BMI < 30 kg/m^2.

The combined data on five-year weight loss underscores the benefit of VSG as a stand-alone bariatric procedure. Weight changes follow a biphasic pattern with a rapid weight loss during the first one-two years and a slow increase in body weight up to five years in a fraction of patients.

Since the start of this PhD-work, data on long-term weight loss after VSG has accumulated from both observational studies [236-238] and from RCTs [239-242]. The efficacy of VSG in terms of weight loss for patients with severe obesity can best be assessed by comparison with two of the recent RCTs that report on five-year weight loss [240, 241]. In the SLEEVEPASS and SM-BOSS studies, patients with severe obesity were randomized to VSG or RYGBP and weight loss at five years was the primary endpoint. In the SLEEVEPASS study, including 240 patients, %EWL was 49 at five years after VSG and 57 after RYGBP (corresponding to %EBMIL at five years 65.5 in studies I-III). Although RYGBP was associated with greater %EWL, the difference was not statistically significant based on pre-specified equivalence margins. The SLEEVEPASS study reports %EWL by using ideal weight as the weight corresponding to a BMI of 25 kg/m^2, that is, identical to %EBMIL. The SM-BOSS study randomized 217 patients and reported %EBMIL at five years of 61.1 for VSG and 68.3 for RYGDP, with a non-significant difference of 7.2 after correction for multiple testing.

The outcomes in terms of weight loss in studies I-III compare favorably with both the SLEEVEPASS and SM-BOSS studies. It is reassuring that real-world routine patient care can achieve similar results as seen in two recent academic trials. Although both the SLEEVEPASS and SM-BOSS studies show modest and non-significant differences in weight loss in favor of RYGBP over VSG, the clinical significance of this difference is not clear. Larger randomized trials with power to detect small, but possibly meaningful differences in efficacy are needed to address this question. To this end, a Swedish multicenter RCT is currently taking place to examine whether VSG is associated with non-inferior results in terms of weight loss compared to RYGBP. With the power calculations of the protocol, 2100 patients will be randomized to one out of two bariatric procedures - VSG or RYGBP [243].

The two other RCTs of VSG versus RYGBP in patients with obesity are both smaller and not fully comparable to the cohorts in studies I-III. In the STAMPEDE trial 150 patients with a BMI between 27 and 33kg/m^2 and type 2 diabetes were randomized to either intensive medical treatment alone or to intensive medical treatment combined with either VSG or RYGBP [239]. TWL, a secondary endpoint, was 18.6% five years after VSG, with a small, but significant difference compared to the 23.2% TWL after RYGBP favoring the latter. This corresponds to TWL at five years being 27.7% in studies I-III. In a French single center study involving 100 patients with a BMI of 40-60 kg/m^2, %EWL at 5 years after VSG was 65.1 [242].

There is no clear understanding of how much weight loss is needed to reverse the different consequences of obesity, such as comorbidities, reduced QOL or increased mortality. No consensus exists for what defines inadequate weight loss after bariatric surgery. In the combined analysis of cohorts I-III we report 29% of patients with EBMIL < 50% at five years, representing a group of patients with lower weight loss. This compares to the percentage of patients with EBMIL < 50% in VSG arm of the SM-BOSS trial of 31.7% [240]. In the SLEEVEPASS trial, mean EWL at 5 years after VSG was 49%, i.e. more than half of the patients did not reach the level of 50% EWL [241]. Semantically, potentially “misleading” or prejudiced terminology (success or failure) should be avoided [244].

4.2.2. Regain of weight

"Coming down to reality…everything went to custard" [235].

Maintaining reduced body weight over time is a challenge to most individuals after any weight-loss intervention [46, 47, 245]. Weight regain, reported to start at approximately 18-24 months [146, 150, 151], is common after all bariatric procedures [151, 246], and appears to be significant after VSG [141, 246, 247].

In studies I-III we demonstrate the same biphasic weight curves after VSG, where a significant minority of patients steadily regain weight up until five years. Based on combined data from all three cohorts, 37% of the patients gained more than 10 kg compared to the lowest weight recorded after surgery. Interestingly, within the rigor of an academic trial, the SM-BOSS and SLEEVEPASS trials referred to above show similar weight curves characterized by a steep decline in weight until one-two years followed by a subsequent modest rise. From other sources with longer follow-up, likely inference is that this increase may continue beyond five years [248]. Bearing in mind the expected lifespan of most patients operated for obesity, this increase may result in future problems, both in terms of the weight regain itself, ensuing comorbidities and loss of QOL.

The biphasic weight curve after surgery underscores the chronic nature of obesity that may be ameliorated, but probably not "cured" by surgery alone. Weight regain is also an example of where long-term results of surgery vary from one individual to another. In study II we found that patients regaining weight had lower eating self-efficacy 16 months after surgery than those maintaining stable weight, and in study III we show that patients with lower weight loss at five years after surgery also had poorer QOL. A better characterization of patients at risk of regaining weight and development of tailored secondary prevention strategies, such as enforced follow-up, are important future research issues.

4.2.3. Comorbidities

Improvements in obesity-related comorbidities reported in study I can be appraised in light of recently published results on long-term outcome after VSG. Among the range of comorbidities presented in study I, the discussion here is restricted to changes in type 2 diabetes, hypertension and GERD, highly relevant and commonly reported comorbidities in the literature on bariatric surgery. Data on dyslipidemia is presented in paper I and published elsewhere [145]. The stable prevalence of psychiatric comorbidities is presented in paper I and alluded to in different contexts of this discussion. However, with self-reported use of medication for anxiety and depression as the sole basis of this classification, the aspect of psychiatric comorbidity does not seem to be adequately covered in any of our studies. Due to shortage of space, other comorbidities are not discussed herein.

Type 2 diabetes

Preoperatively, type 2 diabetes was present in 20% of the patients included in Study I. Significant improvement was seen at two years after VSG, with a non-significant increase in the prevalence of diabetes between two and five years.

In the STAMPEDE trial, control of type 2 diabetes as the primary endpoint was compared between three arms, intensive medical treatment on its own, or combined with either VSG or RYGBP [239]. The study used a level of HbA1c ≤ 6% as the definition of diabetes control, with or without medication. With 47 patients randomized to VSG and medical treatment, 11 patients (23%) achieved levels of HbA1c below this cut-off. The use of glucose-lowering medication, including insulin, was significantly reduced from baseline. In the SM-BOSS trial, 26 of the 101 patients (26%) randomized to VSG had type 2 diabetes, and at five years, remission (defined as HbA1c ≤ 6%, FBS <5.6 mmol/L and no glucose-lowering medication) was achieved in 16 of these 26 patients (61.5%) [240]. The VSG arm of the SLEEVEPASS study included 52 out of 121 patients (43.0%) with diabetes, and reported complete or partial remission (defined as HbA1c ≤ 6.4% and FBS < 7 mmol/L and no relevant medication) in 36.6% of available patients at five years [241]. In study I, with similar inclusion criteria as these two randomized studies, 63% achieved at least a partial remission defined by the criteria used in the SLEEVEPASS study. The effect of VSG on resolution of type 2 diabetes across studies is difficult to assess due to different patient cohorts, with the duration of type 2 diabetes prior to surgery being a possible explanation for the variation in outcome [241]. However, VSG is an efficient metabolic surgical procedure for patients with obesity in the presence of diabetes.

The complex biological pathways involved in diabetes remission after obesity surgery, are not clearly understood. An Italian study revealed that hormonal changes (e.g. decreased ghrelin-, and increased GLP-1 plasma concentrations) influence glucose homeostasis in the early postoperative stage after VSG, but in the longer term, weight control determined the metabolic results [249]. The STAMPEDE trial revealed a significant association between initial weight loss and the rate of diabetic control at one year after randomization. In an analysis performed for study I, no such association was seen between weight loss and type 2 diabetes at any time point, but with 33 out of 168 patients having type 2 diabetes at baseline, changing to 7 out of 152 and 13 out of 136 at two and five years respectively, our study does not have the power to assert such associations.

Relapse of diabetes has been reported after VSG in earlier trials [140]. In study I the prevalence of type 2 diabetes doubles from two to five years after VSG, but the difference does not reach the statistical significance threshold. This appears to be due to the low number of patients. The metabolic consequences of weight regain as a possible explanation for relapse of comorbidities, appear important also in the context of VSG.

The STAMPEDE trial found significantly better diabetes control after medical treatment and surgery compared to medical therapy alone. Bariatric surgery is now recommended as a standard treatment option for type 2 diabetes in patients with BMI levels ≥ 30 kg/m^2 [250].

The relative efficacy of VSG in terms of glycemic control compared to other surgical procedures is still not fully established. The STAMPEDE trial has diabetes control as the primary endpoint, but with too few patients included it does not demonstrate any difference between VSG and RYGBP. In the SLEEVEPASS and SM-BOSS studies, no significant difference in outcome for patients with type 2 diabetes was detected during five years either.

Hypertension

Preoperatively, hypertension was present in 61% of the patients included in study I. This prevalence decreased significantly up to two years after VSG, and the improvements remained stable until the five-year point.

The recent RCTs encompassing VSG show improvements in blood-pressure and resolution of medically treated hypertension five years after randomization [239-241]. The SM-BOSS study reported 64 out of 101 patients in the VSG arm with hypertension at baseline, which resolved to blood pressure <140/90 mm Hg and absence of medication in 40 patients. This corresponded to a remission rate of 62.5% [240]. In SLEEVEPASS, 170 of the 216 VSG patients had hypertension at baseline and 29% of these had discontinued anti-hypertensive medication at five years after surgery. The study did not report actual blood pressure measurements during follow-up [241]. In the STAMPEDE trial, 65% of the 134 randomized patients had hypertension at baseline and the authors reported improvement in both systolic and diastolic blood pressure and reduced use of cardiovascular medication after VSG [239]. Again due to difficulties in comparing the studies, the remission rate of 60 % at five years reported in study I is within the range of recent academic trials.

The RCTs together allow no clear conclusion on whether VSG is as effective as RYGBP in controlling hypertension. The SLEEVEPASS study shows significantly better remission rates of hypertension after RYGBP than VSG, but such a difference is not seen in the other RCTs referred to above. In the STAMPEDE study, the reliance on cardiovascular medication was significantly lower in the patient groups who had surgery than in the group only given medical therapy, but with no difference between the VSG and RYGBP groups.

Gastroesophageal reflux disease

In study I, 12 % of patients reported taking medication for GERD at baseline. The prevalence of patients with GERD more than doubled from baseline to five years after VSG and one out of seven patients needed a reoperation due to GERD.

Based on early studies (section 1.3.1.), both improvement and de novo occurrence of GERD have been reported in patients after VSG [156, 157]. More recently, new-onset GERD has been related to weight regain and the development of hiatal hernia [238]. Furthermore, an Italian study with long-term follow-up after VSG found a high incidence of erosive esophagitis and Barrett's esophagus irrespective of GERD symptoms, suggesting a need for systematic endoscopic surveillance after VSG [251]. GERD represents a major indication for reoperation after VSG, and Bohdjalian et al. found that 3.8% of patients had a second operation due to GERD [168, 238].

The SM-BOSS and SLEEVEPASS studies allow to some extent comparison of resolution or development of de-novo GERD after surgery. In SLEEVEPASS, the baseline occurrence of GERD was not reported, but symptoms of GERD were present in 18 out of 121 patients during the first five years after VSG, and seven of these underwent reoperation [241]. No reoperation for GERD was indicated after RYGBP. In SM-BOSS, GERD was reported at baseline for 92 out of 205 (45%) randomized patients [240]. At five years after VSG, remission or worsening of GERD was reported for 25% and 32% of patients, compared to 60% and 6% after RYGBP, all respectively. New-onset GERD was reported for 32 % of patients after VSG and 11 % after RYGBP. Reoperations for GERD were carried out in nine out of 121 patients after VSG, and none after RYGBP.

The results concerning GERD as reported in study I are in agreement with the recent trials, showing worsening or de novo occurrence of GERD to be a problem of particular relevance to VSG.

Surgical techniques to prevent deterioration or new-onset GERD, are now a part of the VSG procedure in many hospitals. In a 2017 guideline, preoperative counselling specific to GERD-related outcomes is recommended for all patients undergoing VSG [252].

Complications and reoperations

Study I shows incidence of early major complications in 6% and the need for reoperations in 4.2% of patients. Complications included two cases of bleeding, two of leakage, three of deep wound infections and one of dislocated drainage. Two patients experienced vomiting (one due to stricture and one without pathological findings even after gastroscopic exploration). Reoperation was indicated in one patient due to GERD and in six patients due to inadequate weight loss.

Despite a small sample size, the rate of early major complications in study I exceeds the 0.9% reported in the SM-BOSS trial, but compares favorably to the 5.8% complication rate after VSG in the SLEEVEPASS study. The cohort in study I overlaps partially with patients from Førde Central Hospital for whom early results after VSG were published in 2014 [145]. For completeness, it is worth underscoring that both studies covers the early period where VSG was first introduced as an option for patients with severe obesity. Together with data in study I, these two reports from Førde Central Hospital, where VSG was pioneered within Norway, demonstrate the procedure as feasible and safe in line with other bariatric procedures.

The rate of late major complications, all requiring reoperations, was 10% in SM-BOSS and 8.3% in SLEEVEPASS. In both studies, a frequent reason for reoperations after VSG appears to be deterioration or de novo development of GERD. A second major problem necessitating reoperations appears to be inadequate weight loss, but in the

ASMBS recommendations this is formally not considered a complication of surgery [62]. Reoperations due GERD or inadequate weight loss in study I were performed between one and three years after the primary operation. According to a literature review by Felsenreich et al., the rate of conversion to other surgical operations after VSG increases with the length of follow-up period [238]. Adequate follow-up is therefore needed to estimate the rate of reoperations correctly.

The recent RCTs contribute to the empirical evidence base about the relative frequency of post-operative complication and re-operations after VSG and RYGDP. None of the studies were designed specifically to measure differences in the incidence of complications. As mentioned before, with low patient numbers, clinically important differences may pass undetected. In both the SM-BOSS and SLEEVEPASS studies no significant differences in the rate of early complications and frequency of reoperation were found when comparing VSG and RYGBP, although the reasons for reoperation varied between the procedures. In a recent registry study summarizing real-world experience from more than 65000 US patients, the thirty-day rates of major adverse events after VSG and RYGBP were 2.6 % and 5 %, respectively, with a significant odds ratio of 1.57 in favor of VSG [253]. No rates of reoperations were reported, however. The ongoing national RCT from Sweden to compare RYGBP with VSG with the rate of complications as a co-primary endpoint, and will probably add important knowledge on the safety of the different procedures [243].

4.2.4. Quality of life

"*The truth is in the patient*" [254].

With differences in design and instruments used, all studies in scope of this thesis assess changes in QOL after VSG. In study I, generic health-related QOL (SF-36) was assessed at five years and reported to be significantly better than in an independent cohort of severely obese patients prior to surgery. In study II, obesity-related QOL (IWQOL-Lite) was improved from baseline to both 16 months and five years after VSG. In study III, clinically meaningful improvements were seen for three different levels of QOL (OP, SF-36 and Cantril's ladder) after VSG. Similar to the biphasic weight loss pattern after VSG, serial measurements of QOL in study III show marked improvements at one year and modest subsequent deteriorations thereafter. A minority of patients reported poorer QOL five years after treatment compared to baseline.

As outlined in section 1.1.4. and 1.3.4., deterioration in QOL is reported by patients seeking bariatric surgery, and assessment of QOL is important for evaluating the efficacy of surgical treatment [70, 255]. Patient self-assessments have practical utility, are highly relevant to patients and should therefore be included in intervention studies. However, patient-reports are subjective and presumably influenced by factors outside the control of health-care providers [255]. As endpoints in medical research, biomedical outcomes have traditionally been ranked higher than QOL. This trend has changed over the past decades, giving QOL as a patient perspective on disease an important complementary position. Implementing QOL assessment has contributed to improved understanding of symptom relief, care and rehabilitation of patients in multiple medical disciplines [256]. Challenges in measuring patients' health status have led to development of advanced methods to evaluate the reliability and validity of different instruments for specific patient populations and specific conditions or diseases [257].

A recent systematic review of QOL research addressed concerns of conceptual and methodological ambiguity in QOL studies, but did not focus on obesity [258]. The authors noted that QOL assessment is based on subjective self-reports, i.e. PROs, but a large variety of questionnaires were applied to similar conditions, hampering comparison between studies. As for conceptual clarity, a consistent definition of QOL should be applied. Furthermore, QOL should be defined broadly to capture the effect of interventions on different life domains. In this thesis, three defined levels of QOL were measured; 1) overall life satisfaction (study III), 2) general physical and mental health-related QOL (studies I and III) and 3) obesity-specific QOL (Studies II-III) [79, 80].

Prior to 2016, there were only a few reports on QOL outcomes after VSG [140]. Therefore, studies I-III add significant insights into five year outcomes in terms of different levels of QOL. All outcomes that we tracked improved significantly, but with varying magnitude in terms of effect size. In studies II-III the conclusion is based on a longitudinal and prospective comparison of patients before and after surgery. In study I, two separate cohorts are compared, one before and the other five years after surgery.

Since 2016, in addition to the RCTs referenced above, QOL after VSG has been evaluated in one prospective long-term study from Greece [230, 239-242]. Charalampakis et al. found a significant improvement from baseline to two years, both in terms of overall and obesity-specific QOL (assessed by a visual analogue scale and the Moorehead-Ardelt II questionnaire) [230]. This improvement was followed by a significant decline from two to five years in a biphasic pattern similar to findings for all levels of QOL in study III. In our study II, we observed a slight deterioration in IWQOL-Lite from 16 to 55 months, but this difference did not reach statistical significance. In their smaller single-center RCT, Ignat et al. report a similar biphasic curve for Moorehead-Ardelt II scores after VSG, but not for the scores in the Gastrointestinal Quality of Life Index [242]. The SLEEVEPASS, SM-BOSS and STAMPEDE trials all report significant improvements in QOL (as captured by different tools) from baseline to five years for patients who underwent VSG, but no further details are reported [239-241]. In the randomized trials there is no clear difference between VSG and RYGBP in terms of QOL. Neither Charalampakis et al. nor the RCTs report details of mental health or mental health-related QOL, and no effect sizes that would allow estimation of the clinical significance of QOL improvements are provided. Collectively, the data from recent studies show that VSG entails a similar biphasic trajectory of QOL as do other bariatric procedures, and that a majority of patients benefit from surgery.

In studies II and III, the magnitude of postoperative improvement in the different domains of QOL varies when looking at effect sizes from baseline to five years. The clinically most relevant improvements are found in obesity-specific and overall QOL. As suggested by others, patients seem to benefit least in terms of improved mental health-related QOL, as measured by the SF-36 [176, 182]. In study III, weight loss, the most direct effect of surgery, predicts some of the variation in long-term obesity-specific QOL and physical health-related QOL, but not mental health-related QOL or overall life satisfaction. Inclusion of mental health data in addition to QOL assessment may therefore be useful for better understanding of patients and improving patient-care before and after bariatric surgery [177, 259].

Similarly, there is variation in individual benefits of surgery obtained for different levels of QOL, and factors that predict QOL outcome are not well characterized. In study III, between eight and 17% of patients report poorer obesity-specific- or generic health-related QOL, or overall QOL at five years compared to baseline. Also, weight loss together with other covariates evaluated in study III does not seem to predict more than between 13% and 36% of the variation in QOL outcome. The highest prediction was achieved for obesity-specific QOL, where OP scores at five years were significantly associated with baseline OP-scores, baseline BMI and %EBMIL at five years (adjusted r^2 of 0.36). In study III, only sex and age were presented as covariates of the final models, but also marital status, level of education and medically treated anxiety and/or depression were explored initially without revealing significant associations. For reasons presented above, using medical treatment alone as a measure of mental disease has limitations.

Factors other than weight and weight loss may significantly impact QOL after surgery, and identification of such factors merit attention in future research. Associations between health-related QOL after bariatric surgery, psychiatric disorders and self-reported depressive symptoms have been suggested by others, but these aspects were not evaluated in depth in study III [176, 177, 185, 186].

With this background, study II explored the possible impact of eating self-efficacy on obesity-specific QOL after VSG. Baseline eating self-efficacy was not associated with obesity-specific QOL five years after surgery, but changes in eating self-efficacy from baseline to 55 months were significantly and positively associated with IWQOL-Lite at 55 months (model 3, table 3 in Paper II). The magnitude of explained variance in IWQOL-Lite at five years covered by improvement in eating-self-efficacy can be derived from a comparison of regression models of obesity-specific QOL in studies II and III presented in Table 2 below. The value for adjusted r^2, the explained variance of model 3 in paper II, is 0.47. This number is not included in Paper II, but included in Table 2 below (right columns). The regression model for IWQOL-Lite scores at 55 months, repeated without baseline eating self-efficacy or changes thereof, gives baseline IWQOL-Lite and %EBMIL as significant predictors with an adjusted r^2 of 0.34 (Table 2 below, mid columns). Thus 14% of the variation of long-term health-related QOL is explained by variables representing eating self-efficacy. An interpretation of these models could be that enhanced eating self-efficacy after surgery contributes to improved obesity-specific QOL together with, but independently of weight loss.

Interestingly, the linear regression with IWQOL-Lite at five years as the dependent variable when omitting eating self-efficacy (Table 2 below, mid columns), is identical to the model for obesity-specific QOL assessed by OP scores in paper III (Table 2 below, left columns). We also find similar significant predictors and the same level of explained variance (r^2 of 0.36). Reassuringly, such direct comparison of the two independent cohorts serves to validate the models derived in studies II and III to explain long-term outcome in obesity-specific QOL.

Logically, eating self-efficacy may contribute to obesity-specific QOL through improved eating behavior and ensuing weight loss as mediators. However, the independent contribution to obesity-specific QOL could have other mediators. It may be that consistent and enhanced cognitive control over one's eating, such as improved control in difficult eating situations, contributes to a better health-related QOL more than what is mediated by weight loss alone. Alternatively, the improved QOL may precede the improvements in eating self-efficacy. To this end, our study lack frequent assessments of both outcome measures (see section 4.3. on improvements in eating self-efficacy and weight loss).

Table 2. Regression models of obesity-specific QOL in studies II and III#

Psychosocial functioning (OP) Study III				Impact of Weight on Quality of life-Lite (IWQOL-Lite) Study II						
Table 4								Table 3; model 3		
	B Coeff	95 % CI	p		B Coeff	95 % CI	P	B Coeff	95 % CI	P
sex	2.07	-9.4, 13.5	0.723	sex	1.880	-4.927, 8.687	0.584	0.30	-5.96, 6.16	0.924
age	-0.17	-0.7, 0.3	0.480	age	-0.135	-0.417, 0.146	0.340	-0.09	-0.35, 0.17	0.477
Baseline BMI	1.65	0.6, 2.7	**0.003**	Baseline BMI	-0.177	-0.863, 0.509	0.610	-0.44	-1.07, 0.20	0.172
%EBMIL	**-33.90**	**-52.7, -17,1**	**<0.001**	**%EBMIL**	**37.30***	**23.60, 51.00**	**<0.001**	**25.00***	**11.00, 39.00**	**<0.001**
Baseline OP	**0.32**	**0.1, 0.5**	**0.004**	**Baseline IWQOL**	**-0.234**	**-0.411, -0.058**	**0.01**	**-0.24**	**-0.01, 0.43**	**0.008**
				Baseline WEL-SF				0.21	-0.41, 0.07	0.064
				Change WEL-SF				**0.43**	**0.24, 0.62**	**<0.001**
Adjusted r^2	**0.358**				**0.336**			**0.469**		

#The left four columns are derived from model predicting OP in Table 4 from paper IIII. The right three columns are derived from Model 3 in Table III in Paper II. The mid four columns present a regression model of IWQOL-Lite with the same baseline independent variables as for OP to the left. This model allows comparison of predictors and explained variance, r^2, between models. *For comparison, all models are presented with %EBMIL used as fractions between 0 and 1, not percentages between 0 and 100%. Significant associations ($P < 0.05$) in bold.

Better understanding of what factors influence different levels of QOL after bariatric surgery could improve follow-up of patients. With inter-individual variation, these factors may only be evident if the specific situation of each patient is captured, for example by implementing relevant PROs into clinically follow-up care. Structured surveys by questionnaires also allow for tailored patient-centered consultations and health management after surgery [256]. To this end, the implementation of PROMs into routine care of obese patients is now piloted at Førde Central Hospital [260].

4.3. Eating self-efficacy

"I think that emotional eating…type psychological stuff was missing and I think that's what needs to kick in from twelve months onwards" [235]

Bariatric surgery can induce profound and long-lasting weight loss in a large proportion of patients with severe obesity. The acting mechanisms appear to be mostly physiological, i.e. by restrictive, absorptive or possibly endocrine changes in the gastrointestinal tract. Still, the results show inter-individual variability and other factors may contribute to this variation. As cognitive control over eating behavior seems important for endured weight loss after bariatric surgery, we studied eating self-efficacy as a possible psychosocial predictor of weight loss.

In study II, eating self-efficacy improved significantly from prior until 16 months after surgery, and remained improved at 55 months. Baseline levels of eating self-efficacy was not associated with weight loss. However, improvements in eating self-efficacy from baseline to 16 and 55 months were both associated with improved weight loss at 55 months.

To our knowledge, at the time we started this doctoral research there were no prospective studies of eating self-efficacy as a predictor of long-term weight loss after bariatric surgery. Only two cross-sectional studies showed a correlation between eating self-efficacy assessed one or four years after surgery and the magnitude of weight loss [198, 206]. However, in study II there is no association between preoperative eating self-efficacy scores and the extent of weight loss five years after VSG. More recent studies on weight loss after surgery have also failed to detect clear associations with either general- or eating self-efficacy [181, 261], and we have as yet no results from the large Swedish study [262]. Despite variations in their results, the lack of such an association in these studies is notably different from a number of studies where patients' eating self-efficacy are assessed prior to conservative management [263-266]. This also contrasts to findings in other fields of health behavior, where higher self-efficacy generally predicts improved outcomes [196, 197, 267].

Various reasons may account for the lack of association of preoperative eating self-efficacy and weight loss after surgery. Weight loss can only occur when the energy balance is negative, and patients' net intake of calories, at least in the early postoperative phase up until one-two years, is therefore not closely linked to their preoperative level of eating self-efficacy. It is conceivable that changes in eating behavior in the early phase of rapid weight loss, are enforced by surgical changes in the gastrointestinal tract, more than by cognitive control. This is a striking difference to conservative weight loss interventions, where eating behavior during and after treatment probably remains under cognitive control to a greater extent. An alternative explanation may be a severe impairment in a patient's confidence in controlling eating after earlier weight loss attempts. Patients with obesity, seeking any kind of treatment, often look back on several and invariably failing attempts to maintain reduced weight. Previous "mastery experience" has been proposed as the most important source for high self-efficacy expectations, and in obesity, cognitive control over eating may be worn down by years of disappointing experiences [194]. Differences in the predictive power of eating self-efficacy between studies may also be explained by variations in baseline levels between patients opting for conservative or surgical interventions [261, 268].

Despite the absence of associations with baseline levels, study II points to a role of eating self-efficacy in the long-term weight management of patients after bariatric surgery. Eating self-efficacy improves significantly during the first one-two years after surgery and changes during the first 16 months predict weight loss at both 16 and 55 months. At five years, patients who regain weight have lower scores than those who maintain their weight loss. Thus, achieving a higher level of eating self-efficacy is associated with improved control of body weight in the long-term. It is impossible from an observational study alone to infer any causation. Even so, the profound weight loss brought about by surgery could constitute a "mastery experience" that improves the patient`s eating self-efficacy and subsequently alters eating behavior. The inverse relationship may also be true, that weight loss due to surgically enforced changes in eating behavior come first and subsequently enhances self-efficacy. Without frequent measurements of both self-efficacy, eating behavior and weight, study II allows no conclusion, but similar improvements in self-efficacy during conservative treatment of obesity have also been found [204]. In conclusion, it is possible that interventions during postoperative follow-up that enhance eating self-efficacy can improve long-term outcome.

Study II is limited to assessing only eating self-efficacy as the psychosocial predictor of weight loss after surgery. However, a range of other psychosocial factors have been evaluated by others with no uniform results [124, 178, 181, 269]. Only sex and age are presented as covariates of the final models in study II, but also marital status and level of education were explored initially without findings of significant contributions to the models. Self-reported mental health was not assessed in study II. At the request of one reviewer during the publication process of paper II, statistical analyses of medically treated depression and anxiety recorded at baseline related to both weight and obesity-specific QOL at five years postoperatively, were performed. This revealed no association with any of these dependent variables. However, with few patients reporting medically treated depression and anxiety, and with no other assessment of mental health, this result was omitted from the manuscript.

Physical activity, a key factor in the energy balance equation, is an important aspect in the care of patients with obesity. In study II patients reported self-efficacy for physical activity at three time points. Others have identified an association of general self-efficacy with the degree to which patients follow recommendations for physical activity after bariatric surgery [269]. In preparation of paper II, analyses of the associations between self-efficacy for physical activity, on one hand, and weight loss and obesity-specific QOL, on the other, were not reported on for a number of reasons: Firstly, there was collinearity with eating self-efficacy, prohibiting analyses in the same regression models. Secondly, there was no significant association with weight loss or obesity-specific QOL in a separate regression model, with neither baseline values nor changes in self-efficacy for physical activity compared from baseline to two or five years. Thus, to reduce the length of paper II, analyses of self-efficacy for physical activity were omitted from the manuscript.

5. Implications for practice and future perspectives

"It is like climbing Mount Everest…and being at war for the rest of my life" [270]

Results presented in studies I-III show that VSG is a safe and effective surgical treatment for patients with severe obesity. Relative to RYGBP, deteriorating or de novo occurrence of GERD is a particular concern after VSG, and therefore important considerations when planning for surgery in individual patients. Whether to choose VSG ahead of other bariatric procedures, and whether specific patient groups will benefit more from VSG, are still unresolved questions.

With core concepts such as body weight, co-morbidity, QOL and self-efficacy, the present thesis touches upon aspects of the complex nature of obesity: the wider issues revolve around the multi-faceted life of individuals with a body weight higher than recommended medically and accepted socially. The variation in outcome and complexity of problems faced by at least some patients, points to potential for improvement in their care - before and after surgery.

Several models have been developed to inform management of patients with obesity [37, 271-273]. These include socioecological models focusing on environmental and neuropsychological factors driving obesogenic behavior. Other models emphasize the chronic, relapsing and progressive nature of obesity and medical complications [272, 274]. Based on reductionist approaches, these models run the risk of over-simplifying and disregarding the diversity of humans with obesity and their unique experiences, problems and life situations. On the contrary, the effect of bariatric surgery should ideally be determined by effects on health and wellbeing of the entire person, acknowledging health as a relative and subjective phenomenon [275].

Direct patient involvement in health care strategies has contributed to improvements in clinical outcomes, patient satisfaction, and ultimately a reduction in costs and resource expenditure in other medical fields [276-278]. Fastenau and colleagues recently described an "obesity disease-illness model" with the intention to provide a patient-centered framework to treat and support adult patients with obesity [256].

Despite years of increasing body weight and numerous attempts to halt a vicious circle, surgery as a single intervention seems to deliver substantial weight loss with improvements in health status and QOL. For patients with the best outcomes, the combined effect of surgery and standard management including postoperative follow-up visits at three - six months intervals, alternating at a bariatric outpatient clinic and a general practitioner, may be considered adequate. Identifying these patients early in the postoperative phase and tailoring further follow-up could be valuable, also to save resources. The studies in this thesis, as well as others, suggest the importance of evaluating the patients' complete life situation, even in those with the best weight loss, since weight loss alone may not be fully representative of their general health perceptions. To this end, detailed patient-centered consultations are needed both before surgery and during follow-up for all patients. Also, educating even the best responding patients and their general practitioners about the requirement of follow-up seems important to enable further self-management [279].

From a research perspective it would be useful to identify more comprehensively the factors that characterize patients with a good or worse outcome at the earliest possible time before or after surgery. Learning from the properties and abilities of the best responders could lead to improvements also for the patients with suboptimal results. To this end, results of paper II point to further investigation of social cognitive self-efficacy.

Results from our and other researchers' studies clearly demonstrate that patients do not benefit equally from surgery in terms of weight loss, and that a significant subset of patients may experience weight regain and worsening of other problems in the intermediate to long-term. Despite remedying the symptoms of obesity, for these patients, surgery does not seem to alter sufficiently the chronic, progressive or relapsing nature of the disease. Lessons learned from other chronic conditions could be valuable and potentially incorporated into treatment of patients with clinically severe obesity. Thus, postoperative support may require more tailored resources, such as more comprehensive multidisciplinary support. Interventions to predict, prevent or correct weight regain are needed, possibly guided by experience in conservative intervention for obesity. After lifestyle intervention and adjuvant therapy with anti-obesity drugs have not delivered sufficiently [111, 280], our results suggest targeting self-efficacy to improve cognitive control of eating behavior in the weight regain phase.

From the patients' perspective, a range of problems are associated with obesity, and measures to capture this range more fully will be valuable. The most important problem for a particular patient need not be inadequate weight loss, adherence to diet or exercise recommendations, but rather poor sleep, low self-esteem, sexual problems, pain or trauma [254, 256]. To this end, broad, efficient, yet comprehensive assessment of patient perspectives are required. This could be supplemented by the incorporation of existing or future PROs into clinical consultations, enabling immediate feedback to both patient and clinician. This could ultimately prove valuable for the individual patient and more cost effective for health care funders [260].

Today's routine follow-up may put too little emphasis on the role of the obesogenic environment as a target for both preventing and treating obesity [273]. Some models consider traditions or expectations related to food or physical activity as social contagions that contribute to obesity, and suggest incorporating the personal environment of the patient, i.e. family and friends, into follow-up consultation. In such meetings, shared obesogenic behaviors may be discovered and possibly corrected. The utility of extended follow-up visits should be researched further.

"Yes, I feel scared… it just feels like the whole operation was a physical cure for a mental problem and of course it doesn't actually effect a cure. It gives you a handup but it, you know, doesn't stop …" [270]

6. Conclusions

Based on the purposes of studies I-III, this thesis has three main conclusions:

1. Our findings strengthen the evidence-based knowledge on long-term results after VSG. Overall, VSG is a safe option for the treatment of severe obesity, providing long-lasting weight loss and improvements in health and QOL. Both pre- and postoperatively, attention should be paid to symptoms of GERD.

2. Results in terms of weight loss vary and a significant minority of patients experienced suboptimal long-term weight loss. There are also great variations observed in different levels of QOL at five years postoperatively, with a small group of patients reporting less benefit or even worsening of QOL. For these patients, ways to improve postoperative follow-up, possibly in a tailored, patient-centric manner, should be considered.

3. The predictive value of early postoperative enhancement in eating self-efficacy on five-year postoperative weight loss, suggests to study further the relationship between eating self-efficacy, eating behavior and weight loss after bariatric surgery. Ultimately, interventions to strengthen eating self-efficacy during follow-up may be of interest.

7. References

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SURGERY FOR OBESITY AND RELATED DISEASES

ELSEVIER

Surgery for Obesity and Related Diseases xxx (xxxx) xxx

Original article

Eating self-efficacy as predictor of long-term weight loss and obesity-specific quality of life after sleeve gastrectomy: A prospective cohort study[☆]

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Abstract

Background: A person's confidence to control eating, eating self-efficacy (ESE), has been identified as a target for long-term weight management in nonsurgical weight loss interventions, but has to a limited extent been studied after bariatric surgery.
Objective: We investigated the association between ESE, weight loss, and obesity-specific quality of life (QOL) after sleeve gastrectomy (SG).
Setting: A single-center longitudinal study.
Methods: Data from adult patients were collected before SG, and at mean 16 months (±standard deviation 4 mo) and 55 (±4) months postoperatively. ESE was measured by the Weight Efficacy Lifestyle Questionnaire Short-Form. Multiple regression analyses were performed with excess body mass index loss (%EBMIL) and obesity-specific QOL as dependent variables. Age, sex, and other preoperative values were covariates in all models.
Results: Of 114 preoperative patients, 91 (80%) and 84 (74%) were available for follow-up 16 and 55 months after SG, respectively. Mean %EBMIL from baseline to 16 and 55 months was 76% (95% confidence interval: 71.9, 79.6) and 67% (95% confidence interval: 61.9, 72.2), respectively. Preoperative ESE scores improved significantly at both 16 and 55 months ($P = .002$) but did not predict postoperative %EBMIL or QOL at 55 months ($\beta = -.08$, $P = .485$). Greater change in ESE from 0 to 16 months predicted higher %EBMIL ($\beta = .34$, $P = .013$) at 55 months, and improvements in ESE from 0 to 55 months were significantly associated with higher %EBMIL ($\beta = .46$, $P = .001$) and obesity-specific QOL ($\beta = .50$, $P < .001$) 55 months after SG.

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Conclusion: Significant improvements in ESE were seen at 16 months, and remained high at 55 months after SG in this cohort. Patients who improved their ESE the most also experienced the highest weight loss and obesity-specific QOL 5 years postoperatively. Future research should address whether enhancement of ESE corresponds to sustained improvements in eating behavior after bariatric surgery. (Surg Obes Relat Dis 2019;00:1–7.)

Key words: Bariatric surgery; Sleeve gastrectomy; Eating self-efficacy; Obesity-specific quality of life

Sleeve gastrectomy has globally become a preferred bariatric surgery treatment option, in which persistent (≥5 yr) postoperative weight loss and remission of comorbidities are achieved in a majority of patients [1]. However, inadequate weight loss or weight regain is a concern after all bariatric procedures [2,3]. Obesogenic environments and compensatory neurobiologic mechanisms to hedonic eating are known barriers to weight loss maintenance [4,5]. On the other hand, specific self-regulating attitudes may potentially override weight driving forces, by providing a sense of control, and may be important factors in determining the outcome after bariatric surgery [6].

Self-efficacy is a key concept in social cognitive theory, referring to an individual's confidence in his or her ability to respond adequately to perceived obstacles [7]. Previous studies have demonstrated that self-efficacy is an important predictor of behavioral change in areas such as tobacco dependence, cardiac rehabilitation, and exercise [8,9]. Specific to weight loss, the self-efficacy concept has shown to be strongly associated with self-regulating skills for weight management, specifically eating behavior and physical activity [10–12]. Within this theoretic framework, personal factors, behavior, and environmental influence interact reciprocally. Environmental factors (e.g., availability of food, or personal factors, such as former weight loss experience) do not impact a person's eating behavior directly. Instead they influence individual confidence in reaching the desired weight loss. Individuals may understand that a particular behavior (restrictive eating) will lead to a certain outcome (weight loss), but such knowledge does not influence their (eating) behavior unless they believe in their ability to adhere to it consistently [7]. A person's self-efficacy typically varies from one coping area to another, and tends to change over time [6]. Previous mastery or failed behavioral experiences may enhance or inhibit self-efficacy, respectively, and can be modified by treatment [13–15].

Eating self-efficacy refers to a person's confidence to control eating in challenging situations [16]. A few cross-sectional studies found significant associations between eating self-efficacy, and weight loss after bariatric surgery [10,17]. Nonsurgical weight loss interventions performed to increase eating self-efficacy were followed by superior improvements in eating behavior [18,19]. By comparing eating self-efficacy 4 years after either bariatric surgery or nonsurgical treatment for obesity, Batsis et al. [17] found that weight loss was associated with improvements in current eating self-efficacy, and that these improvements were more pronounced in the surgical group. However, prospective data to examine fluctuations in eating self-efficacy before and after bariatric surgery are needed to explore eating self-efficacy as a possible predictive measure for weight loss after surgery.

Because restricted stomach volume and hormonal changes, induced by sleeve gastrectomy, dominate the regulation of food intake and appetite the first 12 to 18 months postoperatively, we further examined changes in eating self-efficacy during the critical weight regain phase, reported to start at approximately 18 months [20,21].

Self-efficacy is related to positive emotions, effective problem solving, and life satisfaction, and may provide individuals with a sense of control over their environment [6]. Hence, self-efficacious individuals tend to perceive high quality of life [22]. However, prospective long-term data on quality of life after sleeve gastrectomy are sparse although considered an important outcome after bariatric surgery [23]. In their cross-sectional study, Batsis et al. [17] found eating self-efficacy scores to be highly related to quality of life, as measured by a generic quality of life questionnaire [17]. Disease-specific quality of life questionnaires contain characteristics and complaints most relevant to a disease (e.g., obesity), and tend to be more sensitive to change than generic measures [24].

Collectively, there is a need to explore the predictive value of eating self-efficacy on long-term outcome after bariatric surgery, both in terms of weight loss and obesity-specific quality of life. Because eating self-efficacy may change over time and be subject to interventions, such investigations may assist health professionals in support of patients before and after surgery.

Objective

We investigated the predictive value of eating self-efficacy on weight loss and obesity-specific quality of life at 55 months after sleeve gastrectomy.

Methods

Eligible patients underwent sleeve gastrectomy during a 7-month period from 2012 to 2013 at Voss Hospital,

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Western Norway. Approximately 230 bariatric operations are performed annually with 90% being sleeve gastrectomy. Five dedicated surgeons performed the operations according to a standardized procedure, using a 32-Fr tube. Eligibility criteria have been described previously [10,25]. In brief, patients were accepted if they had a body mass index (BMI) $\geq$40 kg/m², or $\geq$35 kg/m² with at least one obesity-associated co-morbidity, age 18 to 65 years, no alcohol or drug abuse, and no active psychosis.

After informed consent, anthropometric, demographic, and self-reported data were collected 3 months before sleeve gastrectomy, that is before initiation of preoperative dietary restriction, and during the second year at mean 16 months ($\pm$ standard deviation 4 months) after surgery. For follow-up during the fifth year, mean 55 ($\pm$4) months after sleeve gastrectomy, questionnaires on eating self-efficacy and obesity-specific quality of life were sent to the patients by mail, requesting information about weight, medically treated co-morbidity, any late complications or revisional surgery. The Regional Committee for Medical and Health Research Ethics approved the study.

Outcomes

Definitions of weight outcome

Weight loss was presented as change in BMI (ΔBMI = initial BMI − postoperative BMI) and percent excess BMI loss (%EBMIL = ΔBMI / (initial BMI − 25) × 100). Inadequate weight loss was reported in patients with revisional surgery for low weight loss, or %EBMIL <50%. The number of patients gaining >10 kg of weight from 16 to 55 months postoperatively is reported [3].

Patient-reported outcome measures

Eating self-efficacy was measured by the Weight Efficacy Lifestyle Questionnaire Short-Form (WEL-SF) comprising 8 questions representing the patients' "confidence in ability to resist eating" related to emotional eating situations (3 items), availability of food (2 items), social pressure (1 item), positive activities (1 item), and physical discomfort (1 item). Summed scores range between 0 and 80, with higher scores indicating higher eating self-efficacy. WEL-SF is psychometrically validated for bariatric surgery patients and is available in English and Norwegian [10,16].

Obesity-specific quality of life was measured by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire, a 31-item questionnaire comprising a total score and scores on 5 subdomains, including physical function, self-esteem, sexual life, public distress, and work. Scores are transformed into a scale from 0 to 100, where high scores indicate high obesity-specific quality of life [24]. This measure holds strong psychometric properties, and has been validated for Norwegian bariatric surgery patients [26].

Statistics

Continuous variables are presented as means $\pm$ standard deviation or 95% confidence intervals (CI). Categoric variables are presented as counts and percentages. As appropriate, the independent *t* test and $\chi 2$ test were used.

Mixed-effect modelling was performed to study changes in variables over time. Effect sizes of change were calculated and assessed for clinical relevance, according to the following standard criteria: trivial (<.2), small (.2 to <.5), moderate (.5 to <.8), and large ($\geq$.8) [27].

Multiple regression analyses were performed with %EBMIL and IWQOL-Lite (both at 55 mo) as the dependent variables, and WEL-SF as the predictor. We studied whether preoperative WEL-SF predicted %EBMIL, adjusting for age, sex, and preoperative BMI. Next, we studied whether change in WEL-SF from baseline to 16 months or from baseline to 55 months after surgery predicted %EBMIL, adjusting for age, sex, preoperative BMI, and preoperative WEL-SF in both models.

In the analysis on whether preoperative WEL-SF predicted IWQOL-Lite at 55 months, we adjusted for age, sex, preoperative BMI, and preoperative IWQOL-Lite. Furthermore, we studied whether change in WEL-SF from baseline to either 16 or 55 months postoperatively predicted IWQOL-Lite, controlling for %EBMIL from baseline to 16 or 55 months, respectively, and adjusting for age, sex, preoperative BMI, preoperative IWQOL-Lite, and preoperative WEL-SF in both models.

Unstandardized and standardized beta-coefficients with CI are reported. As described, the clinical importance of regression analysis results was estimated by change in the dependent variables associated with a 2 standard deviation difference in the independent variables [28].

Two-sided P values $\leq$ .05 were considered statistically significant. Statistical Package for Social Sciences for Windows version 23.0 (SPSS, Chicago, IL, USA) was used.

Results

The study's inclusion, attrition, and follow-up flow are shown in Supplementary Fig. 1. Of 127 eligible patients undergoing sleeve gastrectomy, 114 (67% women) with a mean age of 41.9 $\pm$ 11.4 years and a mean initial BMI of 42.7 $\pm$ 4.6 kg/m² were included. Participation rates were 80% and 74% at 16 and 55 months, respectively. The preoperative characteristics were similar in patients participating at follow-up after 55 months and those who declined (Supplementary Table 1).

Preoperative BMI decreased significantly to 16 months postoperatively (P < .001). Furthermore, there was a small,

Table 1
Change in weight, Weight Efficacy Lifestyle Questionnaire Short Form, and Impact of Weight on Quality of Life Lite across time.

Measures	Preoperative (n = 114)		Within 16 mo (n = 91)		Within 55 mo (n = 84)		P value	P value
	Mean	CI 95%/SD	Mean	CI 95%	Mean	CI 95%	0–55 mo	16–55 mo
BMI, kg/m²	42.7	(41.9, 43.5)	29.6	(28.7, 30.4)	31.2	(30.3, 32.1)	<.001	<.001
Weight, kg	124.7	(121.5, 128.2)	86.1	(83.7, 88.4)	90.4	(87.7, 93.7)	<.001	<.001
%EBMIL	NA		75.6	(71.9, 79.6)	66.9	(61.9, 72.2)	<.001	<.001
IWQOL-Lite total	52.1	(48.8, 55.3)	84.8	(81.1, 88.5)	83.5	(79.7, 87.3)	<.001	.633
WEL-SF	53.6	(50.5, 56.7)	59.8	(56.2, 63.0)	60.1	(56.2, 63.3)	.002	.926

CI = confidence interval; SD = standard deviation; BMI = body mass index; EBMIL = excess BMI loss; IWQOL-Lite = Impact of Weight on Quality of Life – Lite; WEL-SF = Weight Efficacy Lifestyle Questionnaire Short Form.

Change over time was analyzed by mixed-effect modeling.

but statistically significant increase in BMI from 16 to 55 months postoperatively (P < .001) (Table 1, Supplementary Fig. 2a). This corresponds to 76% (CI: 71.9, 79.6, P < 0.001) and 67% (CI: 61.9, 72.2, P < 0.001) %EBMIL from baseline to 16 and 55 months, respectively. ΔBMI was 13.1 kg/m² (CI: 12.1, 13.7, P < 0.001) from baseline to 16 months, and 11.4 (CI: 10.5, 12.4, P < 0.001) kg/m² from baseline to 55 months. Inadequate weight loss (including 6 patients with revisional surgery due to low weight loss) was seen in 25 of 83 (30.1%) patients at 55 months. Twenty-five of 79 patients (32%) regained weight of ≥10 kg from 16 to 55 months.

Eating self-efficacy (WEL-SF) increased significantly from baseline to both 16 and 55 months after sleeve gastrectomy (P = .002), with a nonsignificant change from 16 to 55 months (P = .926) (Table 1, Supplementary Fig. 2c). Mean change from baseline to 55 months after sleeve gastrectomy was 6.8 (CI: 2.7, 10.9, P = .002). The effect size was .4, indicating a small, clinically relevant improvement in eating self-efficacy from baseline to 55 months postoperatively.

Preoperative IWQOL-Lite score increased significantly to both 16 and 55 months (P < .001), with a nonsignificant change between 16 and 55 months (P = .633) (Table 1, Supplementary Fig. 2b). The effect size was 1.5, indicating a large clinically relevant improvement in obesity-specific quality of life from baseline to 55 months.

We conducted 3 multiple regression analyses with %EBMIL at 55 months as the dependent variable (Table 2). Preoperative score on WEL-SF did not predict weigh loss at 55 months postoperatively (P = .485). However, change in WEL-SF scores from baseline to 16 months predicted weight loss at 55 months (P = .013), as did change in eating self-efficacy from baseline to 55 months (P < .001).

We conducted 3 multiple regression analyses with obesity-specific quality of life (IWQOL-Lite) after 55 months as the dependent variable (Table 3). Preoperative WEL-SF score did not predict obesity-specific quality of life 55 months after sleeve gastrectomy (P = .266), nor did change in WEL-SF scores from baseline to 16 months (P = .177). However, change in WEL-SF scores from baseline to 55 months, revealed a highly significant correlation

Table 2
Multiple regression analysis with % excess BMI loss after 55 months as the dependent variable.

Model 1*	b	(95% CI)	β	P value
Age	−.34	(−.79, .10)	−.17	.131
Sex	1.47	(−9.19, 12.15)	.03	.783
BMI baseline	−1.29	(−2.37, −.20)	.26	.021
WEL–SF baseline	−.11	(−.42, .20)	−.08	.485
Model 2†	**b**	**(95% CI)**	**β**	**P value**
Age	−.29	(−.74, .15)	−.15	.192
Sex	4.06	(−6.77, 14.90)	.08	.457
BMI baseline	−.93	(−2.01, .14)	−.20	.089
WEL –SF baseline	.08	(−.29, .46)	.06	.643
Change WEL-SF (0–16 mo)	.45	(.09, .79)	.34	.013
Model 3‡	**b**	**(95% CI)**	**β**	**P value**
Age	−.25	(−.67, .17)	−.12	.247
Sex	−.50	(−10.53, 9.52)	−.01	.920
BMI baseline	−1.33	(−2.34, .32)	−.27	.010
WEL–SF baseline	.25	(−.09, .60)	.18	.149
Change WEL-SF (0–55 mo)	.542	(.24, .84)	.46	.001

CI = confidence interval; BMI = body mass index (kg/m²); WEL-SF = Weight Efficacy Lifestyle Questionnaire Short Form.

* Prospective model with only baseline variables as predictors.

† Prospective model with change in WEL-SF (0–16 mo) as main predictor adjusted for baseline variables.

‡ Prospective association model with Change in WEL-SF (0–55 mo) as the main independent variable adjusted for baseline variables.

to obesity-specific quality of life at 55 months after sleeve gastrectomy (P < .001).

Compared with patients with successful weight loss, patients with inadequate weight loss reported significantly lower eating self-efficacy (mean difference 13.0, CI: 5.8, 20.1, P = .001) and obesity-specific quality of life (mean difference 15.1, CI: 8.2, 22.0, P < .001) at 55 months postoperatively.

Discussion

We prospectively determined the association between eating self-efficacy, weight loss, and obesity-specific quality of life after sleeve gastrectomy. Associations were

Table 3
Multiple regression analysis with Impact of Weight on Quality of Life Lite summary score after 55 months as the dependent variable.

Model 1*	b	(95% CI)	β	*P* value
Age	−.29	(−.60, .02)	−.20	.069
Sex	3.33	(−4.60, 11.25)	.09	.406
BMI baseline	−.67	(−1.45, .13)	−.19	.096
IWQOL baseline	−.31	(−.53, −.10)	.36	.005
WEL–SF baseline	−.13	(−.36, −.10)	−.13	.266
Model 2†	**b**	**(95% CI)**	**β**	***P* value**
Age	−.16	(−.46, .15)	−.11	.299
Sex	3.87	(−3.64, 11.41)	.11	.307
BMI baseline	−.26	(−1.04, .51)	−.08	.494
%EBMIL (0–16 mo)	.30	(.10, .49)	.35	.003
IWQOL baseline	−.27	(−.49, -0.05)	−.30	.016
WEL–SF baseline	.01	(−.27, .28)	.01	.963
Change WEL-SF (0–16 mo)	.16	(−.08, .40)	.17	.177
Model 3‡	**b**	**(95% CI)**	**β**	***P* value**
Age	−.09	(−.35, .17)	−.06	.477
Sex	.30	(−5.96, 6.16)	.01	.924
BMI baseline	−.44	(−1.07, .20)	−.12	.172
%EBMIL (0–55 mo)	.25	(.11, .39)	.34	<.001
WEL–SF baseline	.21	(−.01, .43)	.20	.064
IWQOL baseline	−.24	(−.41, .07)	−.27	.008
Change WEL-SF (0–55 mo)	.43	(.24, .62)	.50	<.001

CI = confidence interval; BMI = body mass index (kg/m²). IWQOL = Impact of Weight on Quality of Life – Lite; WEL-SF = Weight Efficacy Lifestyle Questionnaire Short Form; EBMIL = excess body mass index loss.

* Prospective model with only baseline variables as predictors.

† Prospective model with change in WEL-SF (0–16 mo) as the main predictor adjusted for baseline variables and EBMIL (16 mo).

‡ Prospective association model with change in WEL-SF (0–55 mo) as the main independent variable adjusted for baseline variables and EBMIL (55 mo).

investigated during the short-term postoperative phase (0–16 mo), where most of the surgically induced weight loss occurs, and the long-term postoperative period where weight regain may follow. The purpose was to identify (1) whether patients' self-efficacy toward eating is associated with weight loss after surgery, with a potential to override homeostatic weight regain mechanisms, and (2) whether improvements in eating self-efficacy would correspond to higher quality of life.

Overall, the majority of patients in this cohort achieved profound and persistent weight loss associated with clinically significant improvements in eating self-efficacy and obesity-specific quality of life. This supports former research on sleeve gastrectomy as an effective treatment option for severe obesity [3]. Still, similar to previous reports, close to one third of the patients did not achieve the predefined limit for a successful weight loss over time [3,25]. There is no international recognized definition for what constitutes a suboptimal weight loss outcome (failure) after bariatric surgery, though the most commonly reported measure is <50% excess weight loss [29]. Because the formula of percent excess weight loss is based on an ideal BMI = 25 kg/m^2, %EBMIL provides the same information. Defining inadequate weight loss as <50% EBMIL has obvious limitations on an individual level given that metabolic health benefits may occur even at lower levels. Nevertheless, as the intention was to assess associations between eating self-efficacy and weight change as continuous variables, defining a lower cut-off for successful weight loss would not affect the main results of this study.

We found no association between preoperative levels of eating self-efficacy and weight loss at 55 months after sleeve gastrectomy treatment, reflecting the observations in patients undergoing nonsurgical interventions [30]. In a recent review of a large number of pretreatment characteristics for weight control after nonsurgical interventions, including psychosocial factors, such as eating self-efficacy, only fewer prior weight loss attempts had a positive impact on weight loss outcome [30]. Social cognitive theory addresses previous “mastery experience” as the most important source for high self-efficacy expectations [7]. Thus, several prior failed weight loss attempts, as is typical for bariatric surgery patients, may impair their confidence in managing their weight, wherein eating is a key issue. Consequently, their efforts toward a restrictive food intake may decrease.

Instead, we found a significant increase in eating self-efficacy during the initial weight loss phase, and the improvement of eating self-efficacy remained stable 55 months after sleeve gastrectomy. This is in accordance with the above observations in nonsurgically treated patients where treatment itself significantly improved participants' eating self-efficacy [30]. In our cohort, greater improvement in eating self-efficacy from baseline to 16 and 55 months predicted greater weight loss at 55 months, and patients with inadequate weight loss reported significantly lower eating self-efficacy at 55 months than did patients with a successful weight loss. Thus, reported eating self-efficacy closely mirrored weight loss at the same follow-up time point. This indicates that, due to surgically induced initial weight loss, patients' confidence in their ability to control eating increases, and is subsequently maintained in correspondence with weight change. As such, bariatric surgery may result in a feeling of cognitive control through a profound mastery weight loss experience.

The question arises whether improvements in eating self-efficacy in patients with sufficient weight loss simply mirror changes in weight, or whether these changes in eating self-efficacy may themselves contribute to a successful outcome after bariatric surgery. In this regard, our study is limited by lack of data on the patients' eating behavior. On the other hand, evidence for the predictive impact of domain-specific self-efficacy on disparate forms of health enforcing behavior may support the latter assumption [6,19]. This assumtion is also in line with basic concepts of self-efficacy, suggesting that individuals will not make an effort to reduce weight unless they believe they have the necessary competence, eating self-efficacy, to change eating behavior. Because eating self-efficacy clearly is modifiable, our observations warrant further studies of eating self-efficacy as a contributing cognitive factor for sustained weight loss after bariatric surgery.

Overall, obesity-specific quality of life improved significantly in this cohort of patients treated with sleeve gastrectomy. At 55 months, the mean IWQOL-Lite score was 83.5 (CI: 79.7, 87.3), slightly below the level of 91.8 ± 12.0 reported for the U.S. general population [31]. To our knowledge, long-term quality of life outcome after sleeve gastrectomy has not been adressed in larger cohorts previously [23,32]. The association between change in eating self-efficacy and obesity-specific quality of life also suggests an important contribution of patients' perceived control over eating to other life areas. All domains of the IWQOL-Lite revealed strong correlations with improvement in eating self-efficacy (data not shown), with the most profound association occurring in the domain "self-esteem." These findings are in line with former results on the impact of general self-efficacy on generic quality of life after bariatric surgery [22].

Although we had a strong set of independent variables in this study, we cannot rule out residual and unmeasured confounding. For example, it could be interesting to investigate in future studies how patient-reported mood or distress relates to eating self-efficacy, weight loss and obesity-specific quality of life.

Strengths of the present single center study are the prospective design of follow-up from before sleeve gastrectomy up until the fifth year after treatment. High acceptance of the study among operated patients and prospective follow-up reduces bias introduced by attrition, loss to follow-up, and recall difficulties. Furthermore, we add novel insights by recording eating self-efficacy from baseline through short- and long-term postoperative phases believed to be influenced first by surgically induced restriction of food intake and later by possible homeostatic compensation and weight regain.

Conclusion

The majority of patients maintained significant weight loss and improvements in eating self-efficacy and obesity-specific quality of life at 55 months after sleeve gastrectomy. Preoperative eating self-efficacy did not predict either weight loss or quality of life at 55-months follow-up. Nevertheless, greater improvement in eating self-efficacy between baseline and 16 months after sleeve gastrectomy predicted better weight loss outcome at 55 months postoperatively. Improvement in eating self-efficacy at 55 months was significantly associated with both weight loss and obesity-specific quality of life. Further research should address whether interventions targeting enhancement of eating self-efficacy, during and after the initial phases of weight loss after bariatric surgery, can contribute to improvements in eating behavior.

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Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.soard.2018.12.011.

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PAPER III

BMJ Open

Changes in quality of life 5 years after sleeve gastrectomy: a prospective cohort study

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ABSTRACT

Objectives Sleeve gastrectomy (SG) is the most frequently performed bariatric surgery procedure worldwide, but reports on long-term quality of life (QOL) outcomes are scarce. We investigated 5-year trajectories in QOL and their associations with weight loss after SG.

Design A prospective cohort study.

Setting The study was conducted in a single Norwegian bariatric surgery centre.

Participants Out of 150 operated patients, 127 were included. Mean age was 41 years, 68% were women and the follow-up rate at 1 year was 85% and 64% at 1 and 5 years, respectively.

Outcome measures Data were collected preoperatively, and 1 and 5 years after surgery assessing three different levels of QOL. The main exposure was weight loss after SG, assessed as per cent excess body mass index (kg/m^2) loss (%EBMIL). The Obesity-Related Problem (OP) scale was used to measure obesity-specific health-related QOL (HRQOL). Physical (PCS) and mental (MCS) composite summary scores of the Short Form 36 Health Survey were used to capture generic HRQOL and Cantril Ladder was used to assess overall QOL.

Results All HRQOL/overall QOL measures significantly improved at 1 year, followed by modest decline from 1 to 5 years after surgery. Greater %EBMIL 5 years after surgery was significantly associated with improvements in OP and PCS scores, but not with MCS and Cantril Ladder scores. Although significant ($p<0.001$) and clinically relevant improvements in HRQOL/overall QOL outcomes were observed at 5 years, scores were still below the general population norms.

Conclusion Most patients undergoing SG experience substantial weight loss accompanied by statistically significant and clinically relevant long-term improvements in HRQOL/overall QOL. However, an important minority of patients still report low HRQOL/overall QOL 5 years after SG. Further research should aim to identify other factors that contribute to impaired QOL after bariatric surgery, even in the presence of successful weight control.

Strengths and limitations of this study

- This prospective 5-year study expands the limited knowledge of long-term quality of life outcomes and their association with weight loss after sleeve gastrectomy for severe obesity.
- By applying obesity-specific, generic and overall quality of life outcome measures, the impact of weight loss following sleeve gastrectomy on diverse life domains is assessed broadly.
- All long-term quality of life outcomes are compared with general population norms.
- The proportion of patients lost to follow-up at 5 years is a limitation.

INTRODUCTION

Impaired quality of life (QOL) is a strong incentive for individuals with severe obesity to seek help for their condition. Thus, QOL is considered a main measure of treatment efficacy after bariatric surgery.[1–4] The broad concept of QOL encompasses overall, generic and disease-specific QOL domains.

Sleeve gastrectomy (SG) is now the most frequently performed bariatric surgery procedure worldwide, and keeping the intestines intact is regarded as a main advantage compared with other surgical methods.[5] Although associated with substantial short (1 year) and medium-term (2–3 years) improvements in a range of patient-reported outcomes, long-term (≥5 years) reports on QOL after SG are scarce.[6–8]

To the best of our knowledge, only one publication reports prospective long-term QOL data after SG.[9] In a single-centre study, the obesity-specific Moorehead-Ardelt II (MAII) questionnaire and a visual analogue scale to represent overall QOL were used. The authors reported improvements in QOL until 2 years, followed by subsequent declines from 2 to 5 years after SG. Weight loss was not associated with either obesity-specific or overall QOL. The absence of a generic questionnaire precluded comparisons with QOL in the general population. Cross-sectional reports on generic QOL using the Short Form 36 Health Survey (SF-36) 5 years after

SG are published.[10–12] Comparing two similar cohorts of patients before and 5 years after surgery, we reported that mean SF-36 scores were significantly higher in the 5-year cohort than in the baseline cohort, although still below the general population norm.[12] However, firm conclusions on improvements in QOL cannot be drawn from cross-sectional studies alone and should rely on more than solely generic QOL measures.

Thus, the aim of this prospective study was to investigate long-term trajectories in QOL following SG, and to compare long-term QOL scores to those from the general population. To avoid conceptual ambiguity, the broad term QOL was divided into three levels: (1) overall QOL representing satisfaction with life as a whole, (2) generic health-related QOL (HRQOL) representing broad domains of physical and mental health, and (3) obesity-specific HRQOL representing patients' perception of QOL specifically related to their weight.[13] Furthermore, we aimed to investigate associations between long-term weight loss and QOL at all three levels.

METHODS

Patients

The eligibility criteria for SG were a body mass index (BMI) ≥40 kg/m^2, or ≥35 kg/m^2 with obesity-related comorbidities, age from 18 to 65 years and absence of active psychosis, alcohol or drug abuse. All eligible patients who underwent SG from January 2010 to December 2013 at a single bariatric centre were recruited. Written informed consent was obtained at the preoperative outpatient visit. Preoperative evaluation and follow-up were routinely performed by a multidisciplinary team including the surgeon, a dietitian and a nurse 3 months before surgery, and 3, 12, 24 and 60 months postoperatively. Other healthcare professionals, such as a physiotherapist or psychologist were consulted as needed. Data were collected preoperatively, and during follow-up consultations 1 and 5 years after surgery.

Patient and public involvement

In line with requirements from the public funder of this research, patient involvement was ensured by discussing the initial study protocol with the national support group for people with overweight and obesity. The results will be disseminated to the study participants via newsletters and social media platforms after the study results are published.

The treatment: Sleeve gastrectomy

Two surgeons performed the SG operations using a 32 French tube as template for the resection, starting 1–2 cm proximal to the pylorus and ending at the cardia. The standardised technical procedure has been previously described.[12 14]

Demographics and clinical variables

Information on patients' age, sex, marital/cohabitation status and educational level was recorded. Body weight was measured in light clothing without shoes to the nearest 0.1 kg, while height was measured in a standing position without shoes to the nearest 0.01 m. BMI was calculated as weight divided by height squared (kg/m^2). Weight loss is presented as change in BMI (ΔBMI=initial BMI−postoperative BMI) and per cent excess BMI loss (%EBMIL=ΔBMI/(initial BMI−25)×100).[15] We also report number of patients with more than 10 kg weight regain between 1 and 5 years[16] and number of patients whose %EBMIL was below 50 at 5 years.[17] Furthermore, we report number of patients whose BMI was below 30 kg/m^2 5 years after SG.[18]

Obesity-specific HRQOL

The Obesity-Related Problem (OP) scale, which captures obesity-specific psychosocial functioning in various daily life situations, was used to measure obesity-specific HRQOL. The questionnaire comprises eight items regarding (1) parties/social gatherings at home; (2) parties/social gatherings at a friend's place; (3) going to restaurants; (4) participating in organisations, attending courses, and so on; (5) going on vacations; (6) trying on and buying clothes; (7) bathing in public areas (swimming pools, beaches); and (8) sexual intercourse, intimate relations with partner. Patients' statements range from 0 to 3: 'definitely not bothered' (0), 'not so bothered' (1), 'mostly bothered' (2) and 'definitely bothered' (3). The summary raw total score is transformed to a standardised scale from 0 to 100, in which lower scores refer to higher degrees of psychosocial functioning. Scores below 20 indicate no or mild psychosocial impairment, from 20 to <40 mild impairment, from 40 to <60 moderate impairment, from 60 to <80 severe impairment and ≥80

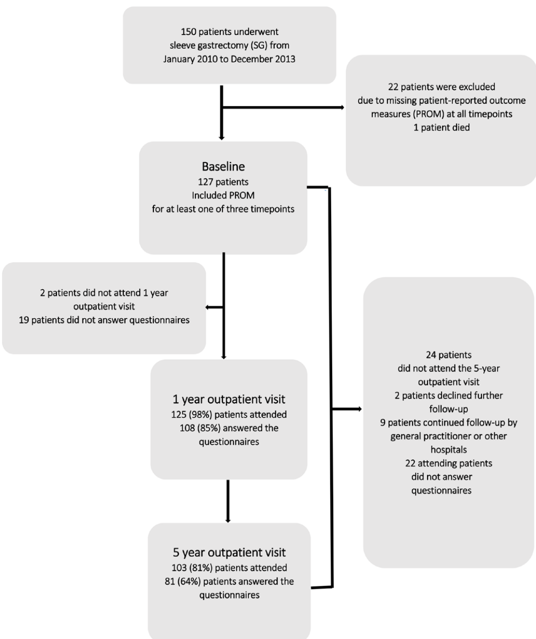

Figure 1 Patient flow chart from recruitment to 5-year follow-up.

Table 1 Preoperative characteristics in patients with follow-up data at 5 years compared with patients lost to follow-up

	All patients n=127	Available at follow-up (5 years) n=81 (64%)	Lost to follow-up (5 years) n=46 (36%)	Difference (P value)
Age (years)	41.4±12.6	41.0±12.5	42.2±12.9	0.589
Women, n (%)	86/127 (68%)	55/81 (67.9%)	31/46 (77.4%)	0.953
BMI (kg/m², mean±SD)	44.8±6.0	44.2±2.9	46.0±6.1	0.113
Superobese (BMI ≥50 kg/m²)	22/127 (17.3%)	12/81 (14.8%)	10/46 (21.7%)	0.322
Married/cohabitants, n (%)	74/127 (58.7%)	48/81 (59.3%)	26/45 (57.8%)	0.851
Higher education, n (%)*	32/125 (25.6%)	19/81 (23.4%)	13/44 (29.5%)	0.322
Anxiety (medically treated), n (%)	13/126 (10.3%)	7/80 (8.8%)	6/46 (13.0%)	0.446
Depression (medically treated), n (%)	24/127 (18.9%)	15/81 (18.5%)	9/46 (19.6%)	0.855
OP total (mean±SD)	63.2±24.6	62.7±25.3	64.0±23.6	0.421
MCS (mean±SD)	42.9±10.8	43.0±10.8	42.6±11.0	0.458
PCS (mean±SD)	38.4±8.8	39.0±8.7	37.3±9.0	0.458
Cantril's Ladder (mean±SD)	4.9±1.8	5.0±1.8	4.8±1.8	0.697

*Higher education = ≥3 years at university/college. χ^2 test was performed for comparing categorical variables. Independent t-test was performed for comparing continuous variables. Differences were considered statistically significant if p≤0.05.
BMI, body mass index;Cantril's Ladder, overall quality of life; MCS, mental composite summary score; OP total, Obesity-Related Problem scale total score; PCS, physical composite summary score.

extreme impairment.[19] In addition to the OP total score, we report responses to the eight individual items. The OP has been translated and validated for Norwegian bariatric patients.[20]

Generic HRQOL

The SF-36 was used to measure generic HRQOL. This is a widely used HRQOL instrument, also recommended as the generic measure of choice in obesity research.[21 22] It contains 36 items with eight subscales regarding (1) physical functioning, (2) physical role, (3) bodily pain, (4) general health, (5) vitality, (6) social functioning, (7) emotional role functioning, and (8) mental health.[23] Herein we use the two SF-36 summary scores based on factor analysis with oblique rotation; that is, physical composite summary (PCS) and mental composite summary (MCS). The PCS and MCS cluster the eight subscales according to common physical and mental attributions. Each of the two summary components is assessed on a transformed scale where higher scores represent better physical or mental HRQOL.[23] The SF-36 is psychometrically validated for use in Norwegian patients with severe obesity.[24]

Overall QOL

Cantril Ladder, containing one item, has been widely used in various populations and in different settings and is considered a valid and reliable measure of overall QOL.[20 25 26] Respondents were asked to think of a ladder numbered from 0 to 10, with the best possible life being 10, and the worst possible life being 0. They were then asked to rate the perception of their own current lives on one of the steps between 0 and 10. A score of 6 or more is labelled 'high life satisfaction' and less than 6 'low life satisfaction'.

General population scores on HRQOL and overall QOL

For comparison, HRQOL and overall QOL values representing the general population were obtained from three different data sets. Population scores on the OP scale were derived from a randomly selected Swedish sample (n=1.017) with a BMI <30.[27] Population scores on SF-36 (n=5.396)[28] and data representing Cantril Ladder (n=6.129)[29] were derived from two randomly selected Norwegian samples including all BMI categories.

Statistical analyses

Continuous variables are presented as means±SD or 95% CIs. Categorical variables are presented as counts and percentages (%). Available patients at 5-year follow-up and patients lost to follow-up were compared for baseline differences.

An a priori power calculation was performed based on previous changes observed in HRQOL from baseline to 5 years after biliopancreatic diversion with duodenal switch (BPDDS) surgery.[30] With an expected n=120, power=90% and p=0.05 we could discover a statistically significant change equal to 0.30 SD (two-sided paired t-test). Expected change was >0.76 SD.

The BMI values, OP scale, QOL, SF-36 MCS and SF-36 PCS scores were all modelled using longitudinal regression models with time as a (categorical) explanatory variable, a hetereoscedastic error structure (different variances at each time point) and an unstructured correlation matrix. These models use data from all patients, even patients with partially missing data, reducing potential bias introduced by non-random loss to follow-up. The models were fitted using generalised least squares by the 'nlme' R package.[31] For testing changes in single OP items, we used paired t-tests, not adjusted for multiple comparisons.

To assess whether the OP total score, SF-36 (MCS and PCS) and Cantril Ladder at 5 years were associated with %EBMIL from baseline to 5 years, or could be predicted by baseline variables, we fitted four unadjusted and adjusted linear regression models. The following covariates were included: age, sex, baseline BMI, the corresponding baseline HRQOL/overall QOL score of the dependent variable and %EBMIL from baseline to 5 years.

For handling missing data, we used multiple imputation (200 imputations), based on predictive mean matching. This was done with the 'aregImpute()' function in the 'rms' R package,[32] with default arguments. The variables used in the imputation models were the ones included in the regression models.

Population norms for SF-36 and Cantril Ladder were adjusted by age and gender to reflect the same distribution as in our study sample. The method for this adjustment has been described elsewhere.[33] For the OP score, the published average non-obese population score was used; 58% were women and age ranged from 37 to 61 years.[19] The one-sample t-test was used to compare the study sample with the population norms.

Clinical relevance of changes in patient-reported outcomes over time was defined by calculating the mean difference in HRQOL/overall QOL between two time points divided by the pooled SD, using Cohen's d for effect size (ES) ([M2–M1]/SD baseline). These ES were judged according to general criteria: trivial (<0.2), small (0.2 to <0.5), moderate (0.5 to <0.8) and large (≥0.8).[34] Cohen's cut-offs are in accordance with findings from a range of study populations suggesting that a difference of 0.5 SD in HRQOL outcomes, either at individual or at group level, most likely is clinically relevant. Smaller ES may also be important.[35] Hence, these criteria also guided the assessments of clinically relevant differences in HRQOL/overall QOL between the present cohort at 5 years and population norms.

Statistical significance was set to p≤0.05. Analyses were performed using R V.3.5.1[36] and Statistical Package for Social Sciences for Windows, V.23.0 (SPSS).

The Strengthening the Reporting of Observational Studies in Epidemiology cohort reporting checklist was used according to *BMJ* open's author guidelines.[37]

Table 2 Comparisons of mean QOL scores/BMI values at baseline, 1 year and 5 years after sleeve gastrectomy (n=127)*

	n	Mean	SD	95% CI	Baseline versus 5 years
BMI					
Baseline	127	45	6	44 to 46	
1 year†	125	30	5	29 to 31	
5 years‡	103	32	6	31 to 33	
OP					
Baseline	127	63	25	59 to 67	
1 year†	110	21	21	18 to 25	
5 years‡	81	31	28	25 to 36	
Effect size					1.3
SF-36 MCS					
Baseline	123	43	11	41 to 45	
1 year†	108	53	9	51 to 55	
5 years‡	78	48	12	45 to 50	
Effect size					0.3
SF-36 PCS					
Baseline	123	38	9	37 to 40	
1 year†	108	52	8	51 to 54	
5 years‡	78	46	12	44 to 49	
Effect size					0.4
Cantril's Ladder					
Baseline	121	4.9	1.8	4.6 to 5.2	
1 year†	109	7.4	1.6	7.1 to 7.7	
5 years‡	72	6.4	1.9	5.9 to 6.8	
Effect size					0.8

*All estimates, CIs and p values are based on longitudinal models, that is, on the joint distribution of measurements/responses from all three time points (stratified by questionnaire/method).
†All p values for differences in mean scores for 1 and 5 years compared with baseline were <0.001.
‡All p values for differences in mean scores for 5 years compared with 1 year were <0.001.
BMI, body mass index; MCS, mental composite summary score; OP, Obesity-Related Problem scale; PCS, physical composite summary score; QOL, quality of life; SF-36, Short Form 36 Health Survey.

RESULTS

Sample characteristics

During the recruitment period, 150 patients underwent SG. Twenty-three patients were later excluded as study participants; 22 because patient-reported data were missing at all time points due to administrative mistakes, and one patient died of reasons unrelated to the SG. Of the 127 included SG patients (mean age 41±13 years, 68% women), complete follow-up data were available for 85% and 64% of the patients at 1 and 5 years, respectively (figure 1). No statistically significant differences were seen in preoperative characteristics between patients available and lost to follow-up at 5 years postoperatively (table 1).

Change in BMI

On average, a significant decrease in BMI occurred from baseline to 1 year, followed by a subsequent modest, but statistically significant increase from 1 to 5 years after surgery (table 2). Mean %EBMIL was 76 (95% CI 72 to 80) and 64 (95% CI 59 to 70) after 1 and 5 years, respectively, and weight loss corresponding to %EBMIL ≥50 was seen in 73/103 (71%) patients at 5 years after SG. Highest observed %EBMIL at 5 years was 125 and the lowest was −18. Forty of 103 (39%) evaluable patients obtained a

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BMI <30 kg/m^2 after 5 years, and 38/103 (37%) patients gained ≥10 kg from 1 to 5 years postoperatively.

Changes in obesity-specific HRQOL

Significant improvement in mean OP scores occurred from baseline to 1 year, followed by a subsequent modest, but statistically significant, decline from 1 to 5 years after surgery (table 2). The improvement in the OP total score from baseline to 5 years was statistically significant with an ES of 1.3.

Preoperatively, 61% of the patients reported extreme or severe psychosocial impairment in all daily life activities (OP total score ≥60). One year after surgery, extreme or severe impairment was reported by 6% of the patients, and by 16% after 5 years. Four patients (5%) reported higher psychosocial impairment 5 years after SG compared with their preoperative status.

Scores on each of the eight daily life situations covered by the OP largely improved from baseline to 1 year ($p<0.001$) (figures 2 and 3, table 3). From 1 to 5 years, there were small, but significant declines ($p≤0.05$) for all situations, except for ‘bathing in public areas’ ($p=0.58$) and ‘sexual intercourse/intimate situations’ ($p=0.22$). The greatest improvement was seen for ‘trying on and buying clothes’, with 67% of patients reporting this activity to be ‘definitely bothersome’ preoperatively, compared with 9% at 5 years postoperatively. Patients who obtained a BMI <30 kg/m^2 at 5 years after SG reported significantly higher psychosocial functioning (ie, mean OP total) than did patients with a BMI ≥30 kg/m^2 (20 vs 35, mean difference 15, 95% CI 3.8 to 26.1, $p=0.01$), yet still significantly below the population norm (mean difference 11.5, 95% CI 3.7 to 19.4, $p=0.005$). Mean OP total score at 5 years was 20.6 (95% CI 14.7 to 26.6; $p<0.001$) points higher (ie, poorer psychosocial functioning) in the present cohort than in the population norm.[19] This difference corresponds to an ES of 0.7.

Changes in generic HRQOL

Significant improvements on mean PCS and MCS scores occurred from baseline to 1 year, followed by a subsequent modest, but significant decline from 1 to 5 years after surgery (table 2, figure 4). Nevertheless, improvements from baseline to 5 years were statistically significant for both domains with an ES of 0.9 and 0.44 for PCS and MCS, respectively. Mean PCS and MCS scores at 5 years in the present cohort were 4.9 (95% CI 2.3 to 7.6; $p<0.001$) and 4.2 (95% CI 1.5 to 6.9; $p=0.003$) points lower (ie, poorer), respectively, than in the population norm.[28] These differences correspond to ES of 0.4 and 0.3, respectively. Patients who obtained a BMI <30 kg/m^2 at 5 years after SG reported significantly higher PCS scores than did patients with a BMI ≥30 kg/m^2 (50.9 vs 44.1, mean difference 6.8, 95% CI 1.7 to 12.1, $p=0.01$). There was no significant difference in MCS scores in the two groups of patients.

Changes in overall QOL

Significant improvement in the Cantril Ladder mean score occurred from baseline to 1 year, followed by a subsequent modest, but significant decline from 1 to 5 years after surgery (table 2). The improvement from baseline to 5 years was still statistically significant ($p<0.001$) with an ES of 0.8. Low overall QOL (Cantril Ladder score <6) was reported by 67% of the patients preoperatively, compared with 13% and 32% of the patients at 1 and 5 years after SG, respectively. The mean Cantril Ladder score at 5 years was 1.5 (95% CI 1.1 to 2.0; $p<0.001$) points poorer in the present cohort than the population norm,[29] equivalent to an ES of 0.8. There was no significant difference in overall QOL at 5 years in patients who obtained a BMI

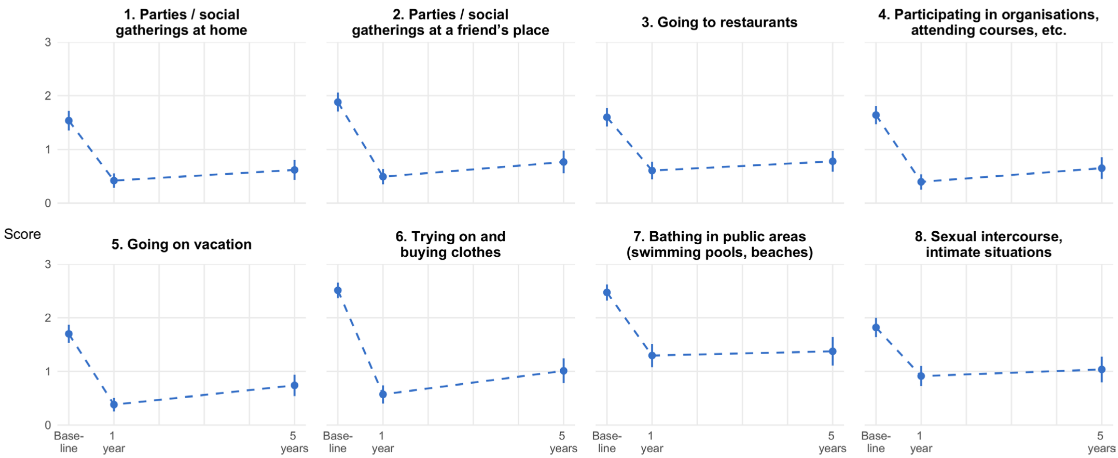

Figure 2 Mean scores with 95% CIs for the eight Obesity-Related Problem (OP) scale items at baseline, 1 year and 5 years (n=127*). *The number of responses differed by time point and questions: 122–127 at baseline, 105–110 at 1 year and 79–81 at 5 years.

<30 kg/m² at 5 years after SG compared with patients with a BMI ≥30 kg/m².

Associations between weight loss and HRQOL/overall QOL

In the adjusted regression models with OP, MCS, PCS and Cantril Ladder scores at 5 years as dependent variables, the baseline HRQOL/overall QOL variables predicted OP, MCS and PCS, but not Cantril Ladder at 5 years. In addition, baseline BMI predicted OP score, but none of the other HRQOL/overall QOL outcome measures at 5 years. According to the adjusted model, the OP score increases by on average 1.7 points (95% CI 0.6 to 2.7) for each baseline additional BMI point. The OP total score decreased by on average 29.2 points (95% CI 8.7 to 49.8) for each additional %EBMIL between baseline and 5 years (table 4). Moreover, %EBMIL at 5 years was significantly associated with OP and PCS scores, but not with MCS and Cantril Ladder after 5 years. The adjusted values for R^2, contributed by all variables together, on OP total score and PCS were 0.36 and 0.29, respectively.

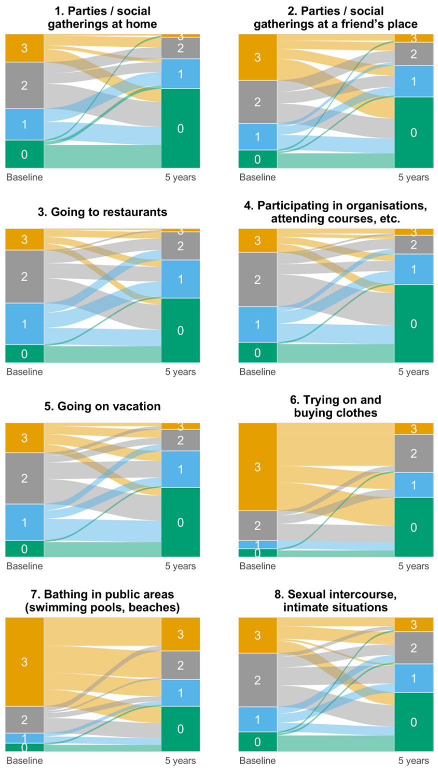

Figure 3 Individual changes in Obesity-Related Problem (OP) items from baseline to 5 years (n=81*). The response options were 0 ('definitely not bothered'), 1 ('not so bothered'), 2 ('mostly bothered') and 3 ('definitely bothered'). The height of each bar is proportional to the number of patients with the corresponding response, and the width of the ends of each flow line is proportional to the number of patients with the given response pattern. *Only patients who answered the questionnaire at both time points are included, and the number of patients varied between 75 and 81 (depending on the question).

DISCUSSION

Principal findings and comparisons with other studies

In this prospective 5-year study of patients undergoing SG, we observed statistically significant and clinically meaningful improvements in all levels of QOL (ie, obesity-specific and generic HRQOL, and overall QOL) from before SG to 5 years after the procedure. In terms of weight loss, the average BMI dropped significantly and markedly during the first year with a subsequent modest regain in BMI occurring at 5 years. A corresponding pattern was seen for all QOL measures demonstrating significant mean improvements at 1 year, followed by a slight decline from 1 to 5 years postoperatively. Adjusted regression analyses showed that preoperative BMI significantly predicted OP score at 5 years, and that %EBMIL from baseline to 5 years was significantly associated with both OP and PCS scores 5 years after SG. Although significantly improved, mean total scores on both obesity-specific, generic HRQOL and overall QOL outcomes in the current study were below the general population norms 5 years after SG.

The purpose of our study was to expand the limited knowledge on long-term changes in disease-specific and generic HRQOL, as well as overall QOL after SG. To our knowledge, only one study on long-term obesity-specific HRQOL and overall QOL after SG has been published, but the use of different questionnaires hampers direct comparison of HRQOL/overall QOL outcomes.[9] In the study of Charalampakis *et al*, the time-dependent changes in weight and obesity-specific HRQOL/overall QOL were mainly consistent with findings in the current paper. Furthermore, our results on changes in HRQOL are in accordance with previous reports on long-term trajectories following BPDDS and Roux-en-Y gastric bypass (RYGBP) as measured by the OP scale and/or SF-36.[22 38–41] Specifically, Karlsson *et al* reported changes in OP total score from before to 10 years after RYGBP corresponding to an ES of 1.0, compared with 1.3 in the current study, that is, large clinically relevant improvements.[38] Aasprang *et al* reported mean MCS and PCS, as measured by the SF-36, at 5 years after BPDDS nearly identical to the current study, also with small to moderate ES for improvements.[40] Long-term HRQOL scores were significantly below the population norm in both studies. Furthermore, Kolotkin *et al* compared HRQOL changes between RYGBP and non-surgery patients at 6 years using the obesity-specific Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire and SF-36.[39] For the RYGBP group, large and significant improvements in both obesity-specific and generic HRQOL (PCS only) were seen from baseline to 6 years; nonetheless, PCS scores at 6 years were below US norms and IWQOL-Lite total score was below a non-obese community reference group. Overall, there seem to be

Table 3 Comparison of mean scores on individual items in the OP scale, at baseline, 1 year and 5 years after sleeve gastrectomy (n=127)

	Respondents	Mean	SD	95% CI	P value*
OP 1: Parties/social gatherings at home					
Baseline	127	1.5	1.0	1.4 to 1.7	–
1 year	110	0.4	0.7	0.3 to 0.6	<0.001
5 years	81	0.6	0.8	0.4 to 0.8	0.01
OP 2: Parties/social gatherings at a friend's place					
Baseline	127	1.9	1.0	1.7 to 2.1	–
1 year	110	0.5	0.8	0.3 to 0.6	<0.001
5 years	81	0.8	1.0	0.6 to 1.0	0.002
OP 3: Going to restaurants					
Baseline	127	1.6	1.0	1.4 to 1.8	–
1 year	109	0.6	0.9	0.4 to 0.8	<0.001
5 years	81	0.8	0.9	0.6 to 1.0	0.05
OP 4: Participating in organisations, attending courses, and so on					
Baseline	125	1.6	1.0	1.5 to 1.8	–
1 year	109	0.4	0.7	0.3 to 0.5	<0.001
5 years	80	0.6	0.9	0.4 to 0.9	0.002
OP 5: Going on vacation					
Baseline	127	1.7	1.0	1.5 to 1.9	–
1 year	110	0.4	0.7	0.3 to 0.5	<0.001
5 years	81	0.7	0.9	0.5 to 0.9	<0.001
OP 6: Trying on and buying clothes					
Baseline	127	2.5	0.8	2.4 to 2.7	–
1 year	110	0.6	0.9	0.4 to 0.7	<0.001
5 years	81	1.0	1.0	0.8 to 1.2	<0.001
OP 7: Bathing in public areas (swimming pools, beaches)					
Baseline	127	2.5	0.9	2.3 to 2.6	–
1 year	108	1.3	1.1	1.1 to 1.5	<0.001
5 years	80	1.4	1.2	1.1 to 1.6	0.58
OP 8: Sexual intercourse, intimate situations					
Baseline	122	1.8	1.0	1.6 to 2.0	–
1 year	105	0.9	1.0	0.7 to 1.1	<0.001
5 years	79	1.0	1.1	0.8 to 1.3	0.22

*P value for change in mean score from *previous* time point (only based on respondents with data from both time points). The p values for change from baseline to 5 years are not listed, but are all <0.001.
OP, Obesity-Related Problem scale.

remarkable similarities in the pattern of long-term changes in HRQOL across different bariatric surgery procedures (gastric banding, BPDDS, RYGBP and SG), outcome measures and countries.[22]

Several researchers have suggested a dose–response correlation between change in weight and HRQOL.[38 39 42] In the present cohort, weight loss at 5 years after surgery was significantly associated with perceived obesity-specific HRQOL at 5 years. Although most patients reported severe to extreme psychosocial impairment before the operation, their reports after 1 year improved significantly. As weight regain occurred, the proportion of patients reporting severe impairment again increased. The clear association between %EBMIL and OP indicates that the patients' perception of obesity-specific HRQOL is particularly sensitive to changes in BMI. Similar results were also reported by Karlsson *et al* for patients with 10-year follow-up after RYGBP.[38] In addition, Kolotkin *et al* reported that percentage excess weight loss at 6 years for RYGBP patients correlated significantly with changes in the IWQOL-Lite total score and PCS, but not MCS.[39] This close association may, however, not hold true for

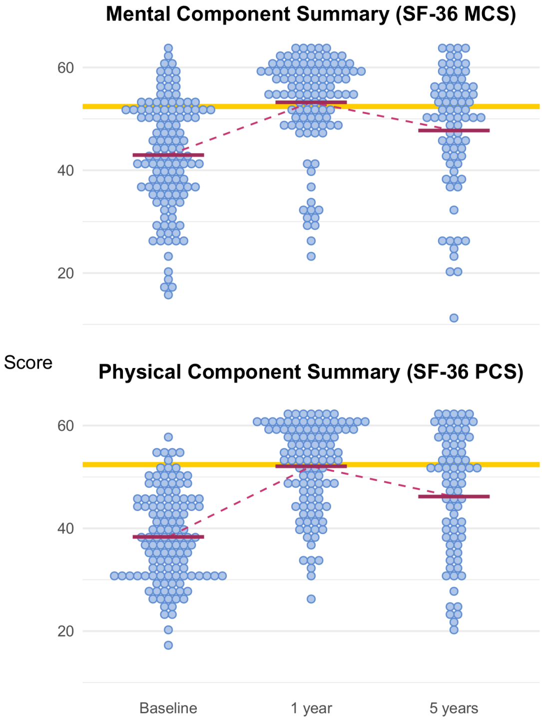

Figure 4 Individual scores for the Short Form 36 Health Survey (SF-36) mental (MCS) and physical (PCS) composite summary scores (n=123*). Each point corresponds to a single patient. The mean score is marked with horizontal lines. The Norwegian general population norm is marked with a yellow horizontal line. *The number of patients was 123 at baseline, 108 at 1 year and 78 at 5 years, for both PCS and MCS.

all levels of HRQOL, as weight loss at 5 years was significantly associated only with PCS at 5 years and not MCS in our study. Of note, in their study on 5-year outcomes after SG, Charalampakis *et al* found no such correlations of weight loss and obesity-specific HRQOL, as measured by the MAII questionnaire.[9] Furthermore, Aasprang *et al* found no significant correlations between weight loss and MCS and PCS using the SF-36 in their 10-year study after BPDDS.[40]

As the terms HRQOL/overall QOL encompass diverse life domains, one could expect a disparity in the influential power of weight loss on different aspects of life. Along these lines, we report no statistically significant associations between weight loss and broader QOL domains, such as overall QOL. In fact, a recent cross-sectional study on generic and obesity-specific HRQOL 4 years after bariatric surgery, controlling for a number of other variables that may affect QOL, questions the importance of weight loss as the main determinant of improvements in all levels of QOL after surgery.[43] For a more accurate assessment of the relationship between surgically induced weight loss and QOL it appears important to differentiate between narrow QOL concepts, related specifically to constraints and concerns associated with changes of weight, and the broader aspects of QOL. The latter may to a larger degree be influenced by other weight-independent factors. Furthermore, despite profound weight loss in a majority of patients we report a noteworthy difference in all aspects of QOL compared with the population norm, suggesting that weight loss alone may be overemphasised in terms of improving patients' lives. In clinical practice, this calls for patient care that centres on other important determinants of QOL than weight loss alone.

Strengths and limitations

Along with the prospective design and long-term follow-up, the present study reports broad measures of QOL covering overall, generic and disease-specific domains relative to general population scores. To our knowledge this has not been presented after SG before. We cannot rule out other factors that could possibly modify the observed relationships of preoperative weight, weight loss and HRQOL/overall QOL, such as comorbidities, stressful life events and eating disorders. For example, redundant skin has been reported as an important determinant of poorer psychosocial functioning and generic HRQOL after RYGBP.[44] No systematic assessment of excessive skin and the degree to which this was a concern for the patients was done in the present cohort.

The proportion of patients lost to follow-up at 5 years represents a limitation. High attrition rates are common in longitudinal bariatric surgery research, comparable to the follow-up rate of 64% in the present study.[8 45] However, there were no significant baseline differences in registered traits comparing patients attending the 5-year follow-up after SG and those missing. By using multiple imputation, any bias caused by missing data is reduced.

Implications and suggestions for future research

Significant and meaningful long-term improvements in HRQOL/overall QOL after bariatric surgery appear to be consistently reported. Particularly, improved psychosocial functioning as measured by the OP scale may considerably enhance patients' performance in daily life situations. Still, the trend towards weight regain and concurrent decline in HRQOL/overall QOL after initial postoperative improvements remains a concern. This underscores obesity as a refractory chronic condition. Though limited, some knowledge exists about factors that may promote or hinder maintenance of weight loss.[46 47] Hence, postoperative support may be of crucial importance to maintain successful short or medium-term outcomes after bariatric surgery. Several studies have emphasised associations between thorough long-term follow-up programmes and endured weight management.[48–51] As weight control appears particularly important for patients' perceived psychosocial functioning in daily life situations, as reported herein, deciphering

Table 4 Associations between baseline variables and long-term (5 years) %EBMIL and quality of life outcomes at 5 years after sleeve gastrectomy

Independent variables	Psychosocial functioning (OP) (n=127)*			Mental health (MCS) (n=127)*			Physical health (PCS) (n=127)*			Overall QOL (n=127)*		
	B coeff	(95% CI)	P value	B coeff	(95% CI)	P value	B coeff	(95% CI)	P value	B coeff	(95% CI)	P value
Sex												
Unadjusted	7.51	(–5.2 to 20.3)	0.247	–5.91	(–11.6 to –0.2)	**0.042**	–3.37	(–8.7 to 2.0)	0.216	–0.73	(–1.8 to 0.2)	0.114
Adjusted	2.07	(–9.4 to 13.5)	0.723	–3.31	(–8.8 to 2.2)	0.235	–0.92	(–5.8 to 4.0)	0.713	–0.69	(–1.7 to 0.3)	0.158
Age												
Unadjusted	–0.47	(–0.9 to 0.0)	0.056	0.07	(–0.1 to 0.3)	0.521	–0.05	(–0.3 to 0.2)	0.676	0.03	(–0.0 to 0.1)	0.203
Adjusted	–0.17	(–0.7 to 0.3)	0.48	0.02	(–0.2 to 0.2)	0.884	0.02	(–0.2 to 0.2)	0.852	0.02	(–0.0 to 0.1)	0.408
Baseline BMI												
Unadjusted	1.96	(0.9 to 3.0)	**<0.001**	–0.24	(–0.7 to 0.2)	0.309	–0.31	(–0.8 to 0.1)	0.181	–0.07	(–0.2 to 0.0)	0.131
Adjusted	1.65	(0.6 to 2.7)	**0.003**	–0.21	(–0.7 to 0.3)	0.385	–0.24	(–0.7 to 0.2)	0.303	–0.04	(–0.1 to 0.06)	0.477
Baseline OP												
Unadjusted	0.41	(0.2 to 0.6)	**<0.001**									
Adjusted	0.32	(0.1 to 0.5)	**0.004**									
Baseline MCS												
Unadjusted				0.55	(0.3 to 0.8)	**<0.001**						
Adjusted				0.5	(0.3 to 0.8)	**<0.001**						
Baseline PCS												
Unadjusted							0.62	(0.3 to 0.9)	**<0.001**			
Adjusted							0.56	(0.3 to 0.9)	**<0.001**			
Baseline overall QOL												
Unadjusted										0.26	(–0.1 to 0.5)	0.061
Adjusted										0.2	(–0.1 to 0.5)	0.184
%EBMIL (0–5 years)												
Unadjusted	–29.21	(–49.8 to –8.7)	**0.005**	8.93	(–1.0 to 18.9)	0.078	13.56	(5.1 to 22.0)	**0.002**	1.19	(–0.5 to 2.9)	0.163
Adjusted	–33.9	(–52.7 to –15.1)	**<0.001**	7.7	(–1.4 to 16.8)	0.097	12.44	(4.5 to 20.4)	**0.002**	1.2	(–0.4 to 2.8)	0.151
Adjusted R^2			**0.358**		**0.262**				**0.293**		**0.128**	

Significant p values (p<0.05) in bold. OP: Continuous scale. Lower scores represent higher psychosocial functioning. MCS: Continuous scale. Higher scores represent higher mental QOL. PCS: Continuous scale. Higher scores represent higher physical QOL. Overall QOL (measured by Cantril Ladder): Continuous scale. Higher scores represent higher life satisfaction. %EBMIL: Percent excess body mass index loss. CI: Confidence interval. B coeff: Unstandardized coefficient

*81, 78 and 72 patients had respectively OP, MCS, PCS and overall QOL scores at 5 years, but the results are based on a multiple imputation model, which uses information on all 127 patients.

B coeff, Unstandardized coefficient; B coeff, unstandardised coefficient; BMI, body mass index; CI, confidence interval; %EBMIL, percent excess body mass index loss; %EBMIL, per cent excess body mass index loss; MCS, mental composite summary score; OP, Obesity-Related Problem scale; PCS, physical composite summary score; QOL, quality of life.

components of successful weight maintenance programmes after surgery seems mandatory. Also, our results emphasise that the magnitude of weight loss does not equally influence all aspects of HRQOL and overall QOL. Properly distributed, this knowledge should help bariatric surgery patients to form realistic expectations for their well-being as a result of weight loss alone. Further research should aim to identify coexisting factors that may contribute to impaired QOL before and after bariatric surgery and address the effect of novel interventions to support both long-term weight loss maintenance and HRQOL/overall QOL after surgery.

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Contributors TNF, VV and JRA are responsible for the study concept and design. VV, JRA and AA are responsible for data collection. TNF, JRA and KOH are responsible for analysis of data. TNF, JRA, RLK, VV, GST, AA, TMN and KOH are responsible for interpretation of data. TNF, JRA, GST and RLK are responsible for initial draft of manuscript. All authors revised the paper critically for important intellectual content and approved the final version of the manuscript. TNF, JRA and KOH had full access to all of the data (including statistical reports and tables) in the study, and take responsibility for the integrity of the data and the accuracy of the data analysis.

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SUPPLEMENTARY PAPER II

Table 1 **Preoperative characteristics in patients available at follow-up compared to patients lost to follow-up 55 months after sleeve gastrectomy for severe obesity.**

	All patients **N=114**	Available for follow-up (at 55months) **N=84 (74%)**	Lost to follow-up (at 55 months) **N=30 (26%)**
Age	41.9 ± 11.4	42.9 ± 11.4	39 ± 11.3
Women	76/114 (67%)	59/84 (70%)	17/30 (57%)
BMI (kg/m², mean ± SD)	42.7 ± 4.6	42.4 ± 4.7	43 ± 4.5
Superobese (BMI ≥ 50)	12/114 (11%)	11/84 (13%)	1/30 (3%)
Married/Cohabitants	71/114 (62%)	51/84 (61%)	20/30 (67%)
Higher Education*	26/114 (23%)	21/84 (25%)	5/30 (17%)
Employed	75/114 (66%)	57/84 (68%)	18/30 (60%)
Anxiety/depr	27/114 (24%)	23/84 (27%)	5/30 (17%)
T2DM	27/114 (24%)	20/84 (24%)	7/30 (23%)
Hypertension	37/114 (32.5%)	27/84 (32%)	10/30 (33%)
WEL-SF (mean ± SD)	53.6 ± 16.3	53.8 ± 15.8	53 ± 17.6
IWQOL-Lite (mean ± SD)	52.1 ± 20.2	51.6 ± 19.1	54 ± 23.3

BMI = Body mass index. SD = Standard deviation. T2DM = Type 2 diabetes mellitus. WEL-SF = Score on weight efficacy lifestyle questionnaire short form.
*Higher Education = Bachelor, Master or PhD. Chi-square test was performed for comparing categorical variables. Independent t-test was performed for comparing continuous variables. None of the differences were statistically significant with $P \leq 0.05$.

Fig 2a. WEL-SF

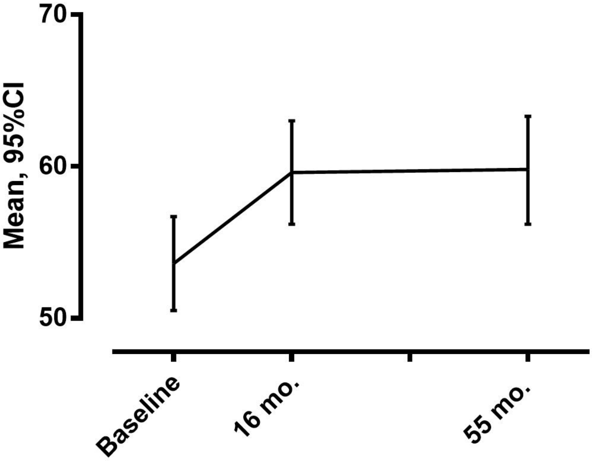


Fig 2b. BMI

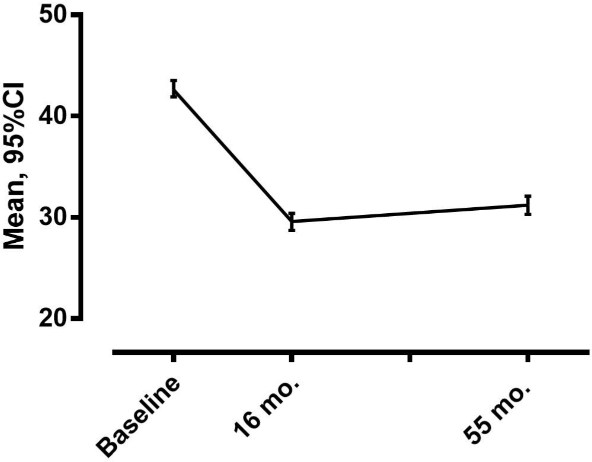
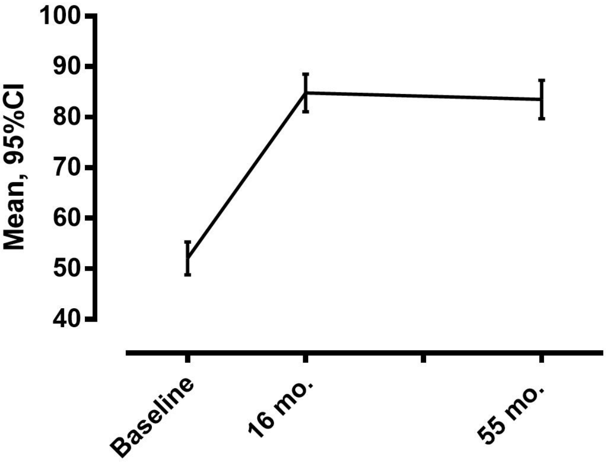


Fig 2c. IWQOL-total



APPENDIX I

Preoperativt kontrollskjema ved sjukleg overvekt

Namnelapp: **Kjønn:** 1 = Kvinne 2 = Mann

Høgde: **Vekt:** **KMI (kg/m^2):** **Vektendring (kg, 6 mnd):** **Blodtrykk:**

Sjukdommar (sett ring rundt):
Hypertensjon: 1 = Nei 2 = Ja, ubehandla (Def: BT ≥ 140/90): 3 = Behandla med eit medikament 4 = Behandla med to eller fleire med.
Angina pectoris: 1 = Nei 2 = Ja Hjartesvikt ? 1 = Nei 2 = Ja
Diabetes mellitus (type II): 1 = Ikkje kjent DM 2 = Kostregulert 3 = Tablettregulert 4 = Insulin 5 = Diabetes mellitus type I Dersom diabetes (I eller II); Kjent sidan:………….. Insulin sidan:…………….
Lipidsenkande medisin? 1 = Nei 2 = Ja Thyroxin? 1 = Nei 2 = Ja, i så fall sidan:………..
Astma? 1=Nei 2 = Med v/behov 3 = Fast medisin Snorker du?: 1 = Nei 2 = Ja 3 = Veit ikkje
Bruker CPAP? 1=Nei 2=Ja BiPAP? 1=Nei 2=Ja Pickwickian syndrom? 1 = Nei 2 = Ja
Hatt gallesteinsplager ? : 1 = Nei 2 = Ja Nyrestein ? : 1 = Nei 2 = Ja
Antall oppkast pr. veke (tall): Antall avføringar pr. døgn (tall):
Fast medisin mot diare ? 1=Nei 2 = Ja Plagsomt illeluktande avføring ? 1 = Nei 2 = Ja
Urinlekkasje ? 1 = Nei 2 = Ja ubehandla 3 = behandla
Belastningssmerter i hofte /kne/ ankler: 1 = Nei 2 = Smertestillande v/behov 3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Låge ryggsmerter: 1 = Nei 2 = Smertestillande v/behov 3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Hatt blodpropp? 1 = Nei 2 = Ja Hatt lungeemboli:? 1 = Nei 2 = Ja
Depresjon: 1 = Ubehandla 2 = Under behandling, i så fall plager sidan:….. . Behandla sidan:……..
Angst: 1 = Ubehandla 2 = Under behandling, i så fall plager sidan:…… Behandla sidan:……..
Kvinner: Infertilitet (Def: Ubeskytta samleie gjennom to år utan å bli gravid) 1 = Nei 2 = Ja
: Amenorhe: 1 = Nei 2 = Ja 3 = Menopause
Einingar insulin pr. dag: Røyk ? 1 = Nei 2 = Ja Om ja, tal sig/dag:
Allmenntilstand: 1 = God 2 = Mindre god 3 = Dårleg Dersom 2 eller 3 spesifiser:
Mat du ikkje toler ? 1 = Nei 2 = Ja Dersom ja , spesifiser (bruk evt. baksida).
Har / har hatt sårinfeksjon ? 1 = Nei 2 = Ja Ventralhernie ? 1 = Nei 2 = Ja

Blodprøver:
Na, K, Ca, Fosfat, Mg, Alb, Kreat, Bili, Urat, ASAT, ALAT, ALP, GGT, Ferritin
Kobalamin (B12), Folat, CRP, LPK, Hb, Tpk, INR, Cephotest, Blodgruppe, Forlik.
Sink, PTH, Vitamin D, Vitamin D metabolitter, Vitamin E, Karoten.
Bestille til neste dag ***(fastande)***; Blodsukker, HbA1c, Kol, Trigl, HDL, Insulin, Insulin C-peptid
og (forutsatt signert samtykke): Serum for nedfrysing merka: "Adipositas

Urinstix (albumin, sett ring rundt):
0 = Ikkje albumin 1 = +1 Albumin 2 = + 2 Albumin 3 = + 3 Albumin

ALLE PASIENTANE SKAL TA:
EKG
RØNTGEN THORAX

EVENTUELT:
BLODGASS
SPIROMETRI

DATO: Sign(lege):

Kontrollskjema etter overvektsoperasjon. **Tid postop (mnd):**

Namnelapp: **Kjønn:** 1 = Kvinne 2 = Mann

Høgde: **Vekt:** **KMI (kg/m²):** **Blodtrykk:**

Sjukdommar (sett ring rundt):
Hypertensjon: 1 = Nei 2 = Ja, ubehandla (Def: BT ≥ 140/90): 3 = Behandla med eit medikament 4 = Behandla med to eller fleire med.
Angina pectoris: 1 = Nei 2 = Ja Hjartesvikt ? 1 = Nei 2 = Ja
Diabetes mellitus (type II): 1 = Ikkje kjent DM 2 = Kostregulert 3 = Tablettregulert 4 = Insulin 5 = Diabetes mellitus type I
Lipidsenkande medisin? 1 = Nei 2 = Ja Thyroxin? 1 = Nei 2 = Ja
Astma? 1=Nei 2 = Med v/behov 3 = Fast medisin Snorker du?: 1 = Nei 2 = Ja 3 = Veit ikkje
Bruker CPAP? 1=Nei 2=Ja BiPAP? 1=Nei 2=Ja Pickwickian syndrom? 1 = Nei 2 = Ja
Hatt gallesteinsplager ? : 1 = Nei 2 = Ja Nyrestein ? 1 = Nei 2 = Ja
Antall oppkast pr. veke (tall): Antall avføringar pr. døgn (tall):
Fast medisin mot diare ? 1=Nei 2 = Ja Plagsomt illeluktande avføring ? 1 = Nei 2 = Ja
Urinlekkasje ? : 1 = Nei 2 = Ja ubehandla 3 = behandla
Belastningssmerter i hofte /kne/ ankler: 1 = Nei 2 = Smertestillande v/behov 3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Låge ryggsmerter: 1 = Nei 2 = Smertestillande v/behov 3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Hatt blodpropp? 1 = Nei 2 = Ja Hatt lungeemboli:? 1 = Nei 2 = Ja
Depresjon: 1 = Ubehandla 2 = Under behandling Angst: 1 = Ubehandla 2 = Under behandling
Kvinner: Infertilitet (Def: Ubeskytta samleie gjennom to år utan å bli gravid) 1 = Nei 2 = Ja
: Amenorhe: 1 = Nei 2 = Ja 3 = Menopause
: Født barn etter overvektsop? 1 = Nei 2 = Ja Dersom ja, antall månader etter op:
Einingar insulin pr. dag (tall): Røyk ? 1 = Nei 2 = Ja Om ja, tal sig/dag:
Allmenntilstand: 1 = God 2 = Mindre god 3 = Dårleg Dersom 2 eller 3, spesifiser:
Mat du ikkje toler ? 1 = Nei 2 = Ja Dersom ja , spesifiser (bruk evt. baksida).
Har / har hatt sårinfeksjon ? 1 = Nei 2 = Ja Ventralhernie ? 1 = Nei 2 = Ja
Sidan forrige kontroll: Hatt tilsyn av lege eller vore innlagt på sjukehus pga. overvektsoperasjonen? ……

Blodprøver (antall månader postoperativt):
1, 3, 9 mnd: Hb, Lpk, Na, K, Ca, Fosfat, Mg, Alb, Kreat, Bili, ASAT, ALAT, ALP, GGT, INR, CRP, HbA1c
I tillegg ved 6, 12, 18, 24 mnd og årleg: Cephotest, Tpk, Urat, Kobalamin (B12), Folat, PTH
Vitamin D, Vit D metabolitter, Vit E, Karoten. (*Fastande*): Glucose, Kolesterol, Trigl, HDL, HbA1c
12 mnd, 24 mnd, 5 år, 10 år: (*Fastande*): S-Insulin, S-Insulin C-Peptid.

Urinstix (albumin, sett ring rundt):
0 = Ikkje albumin 1 = +1 Albumin 2 = + 2 Albumin 3 = + 3 Albumin

Dato: **Signatur (lege):**

Utfylt skjema med blodprøvesvar sendast til :
Dr. Våge, kirurgisk avdeling,
Førde Sentralsjukehus, 6807 FØRDE

Kontrollar:

Etter operasjonen skal pasienten kontrollerast klinisk, med blodprøver og urinprøve. Nokre av desse kontrollane skal vere ved kir. pol Førde Sentralsjukehus, men mange kontrollar kan også utførast av pasienten sin eigen lege / ved med. pol. på eige sjukehus. Dette vert avtalt individuelt med den einskilde pasient. **Pasienten har sjølv eit ansvar for å passe på at kontrollane vert utført til rett tid.** Tidspunkt for kontrollar: **1 mnd, 3 mnd, 6 mnd, 9 mnd, 12 mnd, 18 mnd og 24 mnd etter operasjonen, deretter årleg livet ut.**

Ved kvar kontroll skal skjemaene "**Pasientopplysingar**" og "**Kontrollskjema etter overvektsoperasjon**" fyllast ut. Prøver som skal takast går fram av "**Kontrollskjema etter overvektsoperasjon**".

Skjemaet "**Pasientopplysingar**" fyller pasienten sjølv ut så nøyaktig som råd og sender underteikna. Skjemaet "**Kontrollskjema etter overvekstoperasjon**" skal fyllast ut av legen som kontrollerer pasienten og sendast saman med blodprøvesvar til underteikna.

(Blodprøver for Vitamin D og Karoten - analyser sendast til Forskningslaboratoriet, Barneklinikken, Haukeland Sykehus).

Dr Villy Våge
Kirurgisk avdeling
Førde Sentralsjukehus
6807 FØRDE

APPENDIX II

SF-36 SPØRRESKJEMA OM HELSE

INSTRUKSJON: Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å krysse av det svaralternativet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. Stor sett vil du si din helse er

Utmerket...	1 ☐
Meget god.......................................	2 ☐
God..	3 ☐
Nokså god......................................	4 ☐
Dårlig..	5 ☐

2. <u>Sammenlignet med for ett år siden</u>, hvordan vil du si at din helse stort sett er <u>nå</u>?

Mye bedre enn for ett år siden...........	1 ☐
Litt bedre enn for ett år siden...........	2 ☐
Omtrent den samme som for ett år siden	3 ☐
Litt dårligere nå enn for ett år siden......	4 ☐
Mye dårligere nå enn for ett år siden....	5 ☐

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

AKTIVITETER	Ja, begrenser meg mye	Ja. Begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	1☐	2☐	3☐
b. Moderate aktiviteter som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid	1☐	2☐	3☐
c. Løfte eller bære en handlekurv	1☐	2☐	3☐
d. Gå opp trappen flere etasjer	1☐	2☐	3☐
e. Gå opp trappen en etasje	1☐	2☐	3☐
f. Bøye deg eller sitte på huk	1☐	2☐	3☐
g. Gå mer enn to kilometer	1☐	2☐	3☐
h. Gå noen hundre meter	1☐	2☐	3☐
i. Gå hundre meter	1☐	2☐	3☐
j. Vaske deg eller kle på deg	1☐	2☐	3☐

4. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	JA	NEI
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1☐	2☐
b. Du har **utrettet mindre** enn du hadde ønsket	1☐	2☐
c. Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål	1☐	2☐
d. Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (f.eks. fordi det krevde ekstra anstrengelser).	1☐	2☐

5. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som for eksempel å være deprimert eller engstelig).

	JA	NEI
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1☐	2☐
b. Du har **utrettet mindre** enn du hadde ønsket	1☐	2☐
c. Du har utført arbeidet eller andre gjøremål **mindre grundig** enn vanlig?	1☐	2☐

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

Ikke i det hele tatt.................................. 1☐

Litt .... 2☐

En del... 3☐

Mye.. 4☐

Svært mye.. 5☐

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene

Ingen.. 1☐

Meget svake .... 2☐

Svake.. 3☐

Moderate... 4☐

Sterke... 5☐

Meget sterke....................................... 6☐

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt daglige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt.............................. 1☐

Litt .... 2☐

En del.. 3☐

Mye... 4☐

Svært mye.. 5☐

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

	Hele tiden	Nesten hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Følt deg full av tiltakslyst?	1☐	2☐	3☐	4☐	5☐	6☐
b. Følt deg veldig nervøs?	1☐	2☐	3☐	4☐	5☐	6☐
c. Vert så langt nede at ingenting har kunnet muntre deg opp?	1☐	2☐	3☐	4☐	5☐	6☐
d. Følt deg rolig og harmonisk	1☐	2☐	3☐	4☐	5☐	6☐
e. Hatt mye overskudd?	1☐	2☐	3☐	4☐	5☐	6☐
f. Følt deg nedfor og trist?	1☐	2☐	3☐	4☐	5☐	6☐
g. Følt deg sliten?	1☐	2☐	3☐	4☐	5☐	6☐
h. Følt deg glad?	1☐	2☐	3☐	4☐	5☐	6☐
i. Følt deg trett?	1☐	2☐	3☐	4☐	5☐	6☐

(SF-36 Norwegian version 1.2).

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsesmessige problemer påvirket din sosiale omgang (som å besøke venner, slektninger osv)?

Hele tiden..	1 ☐
Mye av tiden...	2 ☐
En del av tiden....................................	3 ☐
Litt av tiden..	4 ☐
Ikke i det hele tatt..............................	5 ☐

11. Hvor RIKTIG eller GAL er hver av følgende påstander for deg?

	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a. Det virker som jeg blir syk litt lettere enn andre	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b. Jeg er like frisk som de fleste jeg kjenner	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
c. Jeg tror helsen min vil forverres	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
d. Jeg har utmerket helse	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Vennligst kontroller at du har besvart alle spørsmålene

Ames, G.E., et al., Eating self-efficacy: Development of a short-form WEL, Eating Behaviors (2012), doi: 10.1016/j.eatbeh.2012.03.013.

Norsk versjon av "Weight Efficacy Lifestyle Questionnaire Short-Form" (WEL-SF)

(Flølo T.N., et al., 2012)

Les igjennom situasjonene som er beskrevet nedenfor. Velg ETT tall på skalaen, fra 0 (ikke sikker i det hele tatt) til 10 (veldig sikker), som beskriver hvor sikker du er på å lykkes med å motstå å spise for mye. Skriv dette tallet etter hvert spørsmål.

0	1	2	3	4	5	6	7	8	9	10
Ikke sikker i det hele tatt										**Veldig** sikker

JEG ER SIKKER PÅ AT:	Tall for hvor sikker du er
1. Jeg kan motstå å spise for mye når jeg er engstelig eller nervøs	________
2. Jeg kan motstå å spise for mye i helgene	________
3. Jeg kan motstå å spise for mye når jeg er trøtt	________
4. Jeg kan motstå å spise for mye når jeg ser på TV	________
5. Jeg kan motstå å spise for mye når jeg er deprimert eller nedstemt	________
6. Jeg kan motstå å spise for mye når jeg er i sosiale sammenkomster eller på fest	________
7. Jeg kan motstå å spise for mye når jeg er sint eller irritabel	________
8. Jeg kan motstå å spise for mye når andre presser meg til å spise	________

The Obesity-related problem scale (OP)

Kjenner du deg plaget på grunn av din vekt eller kroppsform når det gjelder nedenforstående aktiviteter og situasjoner

Sett kryss i ruten for det svaralternativ som passer best for deg i dag.

	Mye plaget	*Noe plaget*	*Ikke særlig plaget*	*Ikke plaget i det hele*
1. Ha fest, tilstelning hjemme	1☐	2☐	3☐	4☐
2. Gå ut på fest, tilstelning hos andre	1☐	2☐	3☐	4☐
3. Spise ute på restaurant	1☐	2☐	3☐	4☐
4. Delta i foreningsliv, kurs eller lignende	1☐	2☐	3☐	4☐
5. Reise på ferie	1☐	2☐	3☐	4☐
6. Prøve og kjøpe klær	1☐	2☐	3☐	4☐
7. Bade offentlig (svømmehall, offentlig badeplass)	1☐	2☐	3☐	4☐
8. Seksuelt samvær, intime situasjoner	1☐	2☐	3☐	4☐

Sprørreskjema om betydningen av vekt for livskvalitet – versjon Lite (IWQoL – Lite)

Vær vennlig å ta stilling til følgende utsagn ved å sette ring rundt tallet som best beskriver din situasjon i løpet av den siste uken. Vær så ærlig som mulig. Det finnes verken riktige eller gale svar.

	Fysisk funksjonsevne	**Stemmer alltid**	**Stemmer vanligvis**	**Stemmer av og til**	**Stemmer sjelden**	**Stemmer aldri**
1	På grunn av vekten min har jeg problemer med å plukke opp ting.	5	4	3	2	1
2	På grunn av vekten min har jeg problemer med å knyte skolissene mine	5	4	3	2	1
3	På grunn av vekten min har jeg problemer med å komme opp av stoler	5	4	3	2	1
4	På grunn av vekten min har jeg problemer med å gå i trapper	5	4	3	2	1
5	På grunn av vekten min har jeg problemer med å kle av og på meg.	5	4	3	2	1
6	På grunn av vekten min har jeg problemer med å bevege meg	5	4	3	2	1
7	På grunn av vekten min har jeg problemer med å sitte med beina i kross	5	4	3	2	1
8	Jeg blir tungpustet selv etter lette anstrengelser	5	4	3	2	1
9	Jeg er plaget av smertefulle eller stive ledd	5	4	3	2	1
10	Anklene og nedre del av leggene mine er hovne på slutten av dagen.	5	4	3	2	1
11	Jeg er bekymret for helsen min	5	4	3	2	1
	Selvfølelse					
1	På grunn av vekten min er jeg opptatt av hva andre tenker om meg.	5	4	3	2	1
2	På grunn av vekten min er ikke selvfølelsen min hva den kunne vært	5	4	3	2	1
3	På grunn av vekten min er jeg usikker på meg selv.	5	4	3	2	1
4	På grunn av vekten min liker jeg ikke meg selv	5	4	3	2	1
5	På grunn av vekten min er jeg redd for å bli avvist	5	4	3	2	1
6	På grunn av vekten min unngår jeg å se i speil eller se på bilder av meg selv.	5	4	3	2	1
7	På grunn av vekten min er jeg flau over å vise meg på offentlige steder	5	4	3	2	1

9925 (email address: rkolotkin@yahoo.com)

	Seksualliv	**Stemmer alltid**	**Stemmer vanligvis**	**Stemmer av og til**	**Stemmer sjelden**	**Stemmer aldri**
1	På grunn av vekten min har jeg ingen glede av seksuell aktivitet	5	4	3	2	1
2	På grunn av vekten min har jeg ingen seksuell lyst	5	4	3	2	1
3	På grunn av vekten min har jeg problemer med seksuell yteevne	5	4	3	2	1
4	På grunn av vekten min unngår jeg nærkontakt av seksuell karakter	5	4	3	2	1
	Offentlig belastning					
1	På grunn av vekten min opplever jeg latterliggjøring, erting eller uønsket oppmerksomhet.	5	4	3	2	1
2	På grunn av vekten min bekymrer jeg meg for om jeg får plass i seter på offentlige steder (f.eks. teatre, kinoer, restauranter, biler eller fly).	5	4	3	2	1
3	På grunn av vekten min bekymrer jeg meg for om jeg kommer gjennom midtganger eller dreiekors/telleapparater.	5	4	3	2	1
4	På grunn av vekten min bekymrer jeg meg for om jeg finner stoler som er sterke nok til å holde vekten min.	5	4	3	2	1
5	På grunn av vekten min opplever jeg diskriminering	5	4	3	2	1
	Arbeid (Merk: De som ikke har lønnet arbeid svarer ut fra sine daglige aktiviteter)					
1	På grunn av vekten min har jeg problemer med å få gjort ting eller oppfylle mine forpliktelser	5	4	3	2	1
2	På grunn av vekten min er jeg mindre produktiv enn jeg kunne ha vært	5	4	3	2	1
3	På grunn av vekten min får jeg ikke forventede lønnsøkninger, forfremmelser eller anerkjennelse på jobben.	5	4	3	2	1
4	På grunn av vekten min er jeg redd for å gå på jobbintervjuer	5	4	3	2	1

Errata for
“Long-term outcomes after vertical sleeve gastrectomy for severe obesity”

Tone Nygaard Flølo

Thesis for the degree philosophiae doctor (PhD)
at the University of Bergen

2/1-2020 2/1-2020

(date and sign. of candidate) (date and sign. of faculty)

Errata

Paper I:

- Figure 4 is referred to as Figure 3 in the text

Paper II:

- Table 1, 3rd column, “/SD” in the headline, and “SD = standard deviation” in the legend is misprinted. Should have been deleted.

uib.no

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