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Psychosocial functioning before and after surgical treatment for morbid obesity: reliability and validation of the Norwegian version of obesity-related problem scale

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Background: The aims of this study were to translate the Obesity-Related Problem scale (OP scale) into the Norwegian language and test its reliability, validity and responsiveness in a Norwegian sample.

Method: The questionnaire (OP scale) was translated from the original language (Swedish) into Norwegian. Patients completed the questionnaire prior to and one year after sleeve gastrectomy. Internal consistency was evaluated using Cronbach`s α. Floor and ceiling effect were calculated as percentages. Construct validity was tested by correlating the OP-scale with the SF-36 and the Cantril Ladder using the Pearson correlation coefficient. Exploratory factor analysis, using principal component analysis with varimax rotation, was used to test the unidimensionality of the OP scale. Responsiveness was tested by assessing changes in the OP scale from baseline to one year post-surgery using the paired sample t-test.

Result: A total of 181 patients (123 women) accepted for bariatric surgery was included in the study. The mean age was 43.1 ± 12.5 years, and mean body mass index (BMI) before surgery was 45 ± 6.9. The mean value of the OP scale at baseline was 63.30 ± 24.43 (severe impairment) and 21.01 ± 20.98 at one year follow-up (mild impairment). Cronbach`s α was high at baseline (0. 91), as well as one year after surgery (0.88). The floor effect was small at baseline and moderate at one year. The ceiling effect was small at baseline and at one year**.** Exploratory factor analysis showed one factor with a high percent of explained variance (baseline and post-surgery). Correlations between OP scale at baseline, SF-36, Cantril Ladder and BMI were statistically significant and in the predicted direction to support validity of the Norwegian OP scale . After one year correlations between the change in OP scale and the change in SF-36 scores, Cantril Ladder and BMI were also statistically significant, except for the change in the Role Physical-scale. The OP scale showed greater responsiveness than either the SF-36 or Cantril Ladder.

Conclusion: These results confirm that the Norwegian version of the OP scale is a valid and reliable instrument for measuring psychosocial functioning in patients with clinically severe obesity.

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Introduction

Individuals with obesity often report reduced health-related quality of life (HRQL) compared to individuals with normal weight (Fontaine & Barofsky 2001; Kolotkin et al. 2001b; Kushner & Foster 2000; Larsson et al. 2002) , and improvement in HRQL is one of the commonly stated objectives of surgical treatment of morbid obesity(Munoz et al. 2007). Several studies have shown a great improvement in HRQL after bariatric surgery (Aasprang et al. 2013; Helmio et al. 2011; Karlsson et al. 2007; Kolotkin et al. 2012; Schouten et al. 2011; Zijlstra H 2013) and the importance of evaluating HRQL and change in HRQL is underlined.

There are three basic approaches to measuring quality of life: disease-specific measures, generic measures and overall quality of life/life satisfaction. Both generic and disease-specific instruments are utilized to assess the burden of obesity (Fontaine & Barofsky 2001; Kolotkin et al. 2001b; Kushner & Foster 2000). Generic instruments focus on broad dimensions of health and do not cover all of the domains that are relevant for specific diseases, such as obesity. On the other hand disease-specific instruments are used to capture information that is most pertinent to particular patient groups (Karlsson et al. 2003). In the past decade several obesity-specific HRQL instruments have been introduced. (Duval et al. 2006; Kolotkin et al. 2001a; Le Pen et al. 1998; Sullivan et al. 1993).

Psychosocial functioning is important in the assessment of HRQL in obesity (Sullivan et al. 1993), and weight related psychosocial distress is not assessed in generic instruments. The Obesity-Related Psychosocial Problems scale (OP scale) was developed in the Swedish Obese

Subject Study (SOS) specifically to assess psychosocial problems related to obesity (Karlsson et al. 1998; Sullivan et al. 1993). The OP scale is scored so that lower scores represent higher psychosocial functioning. The OP scale has been used in several studies in different countries (Karlsson et al. 2007; Kaukua et al. 2003; Larusdottir et al. 2014; Oh et al. 2013; Sovik et al. 2013) , but to our knowledge the OP scale has only been validated in the Swedish, Spanish and Korean languages. Results of these validation studies show that the OP scale has satisfactory reliability and validity. (Bilbao et al. 2009; Karlsson et al. 2003; Lee et al. 2013). The OP scale has not been evaluated in surgical patients undergoing sleeve gastrectomy, nor has it been used prospectively, to our knowledge, with the exception of the SOS study.

The aims of this study were to translate the OP scale into the Norwegian language and test its reliability, validity and responsiveness in a Norwegian sample. The specific hypotheses were as follows: a) the Norwegian OP scale has satisfactory internal consistency; b) the variability of scores reflect one factor; c) the OP scale is negatively correlated with both the SF-36 and Cantril Ladder;) d) the OP scale is positively correlated with Body Mass Index (BMI); and e) changes in the OP scale are negatively correlated with changes in both the SF-36 and Cantril Ladder, as well as positively correlated with weight loss as assessed by changes in BMI.

Materials and Methods

Study design and patients

Before the study began we obtained permission from the author of the original Swedish OP scale to develop and validate a Norwegian version of the OP-scale.

The cohort study was performed from 2011-2013 in the western region of Norway. A total of 209 patients accepted for bariatric surgery (sleeve gastrectomy) were invited to join the study. The inclusion criteria were age 18-60 years, BMI $\geq$ 40.0 or 35.0-39.9 with obesity-related comorbidities, no active psychosis, no drug or alcohol problems, and previous failure to lose weight through other methods. Written informed consent was obtained from participants to complete self-report questionnaires prior to and one year after sleeve gastrectomy. The investigation conforms to the principles outlined in the Declaration of Helsinki. The study was approved by the Regional Committee of Ethics in Medicine, West-Norway (reference number: 2009/2174).

Demographic characteristics and clinical data

Data were collected using a standardized form. Body weight, height, age, gender, educational level, marital status and employment status of the patients were noted. 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 0.01 m. Body mass index (BMI) was calculated as weight divided by height squared (kg/m^2).

Questionnaires administered

The OP scale is an 8-item questionnaire developed for the SOS study to measure the impact of obesity on psychosocial functioning (Karlsson et al. 2003; Sullivan et al. 1993). The OP scales asks respondents to rate on a 4-point scale ("definitely not bothered", "not so bothered", "mostly bothered" and "definitely bothered.") if their obesity bothers them in activities such as private gatherings, community activities, and intimate relations. The scale

is coded so that lower scores represent higher psychosocial functioning. Scores on individual items are summed to create a raw total score, which can vary between 8 and 32. This score is standardized on a scale from 0 – 100, where 100 indicates the worst possible state and 0 the best possible state. Scores below 40 indicate mild impairment in psychosocial functioning and mental well-being. Scores between 40 and 60 indicate moderate impairment and scores above 60 indicate severe impairment. We used version 2 of the OP scale.

The Short Form -36 (SF-36) (Norwegian version *1.2)* is a well-established generic measure of the health burden of chronic diseases(Ware 2000). The questionnaire has demonstrated good validity and reliability(Loge & Kaasa 1998). SF-36 assesses eight dimensions of physical and mental functioning, each ranging from 100 (optimal) to zero (poorest). The subscales physical functioning, physical role function and bodily pain reflect physical functioning, and emotional role function and mental health reflect mental functioning. The subscales general health, vitality and social functioning reflect both physical and mental functioning. The SF-36 can also be divided into two summary scores, Physical Component Summary (PCS) and Mental Component Summary (MCS)(Ware 2000), where a higher score represents better physical or mental health. PCS and MCS scores are standardized so that a difference in 2- 4.9 points, respectively, can be interpreted as a small effect size, 5-7.9 points, respectively, a medium effect size and 8+ points a large effect size(Cohen 1988; Saris-Baglama 2004) .

Cantril Ladder is used to assess life satisfaction. The term life satisfaction is often used to describe quality of life, well-being and happiness. Respondents rate their current life satisfaction on a ladder ranging from 10 to 0, where 10 reflect the best life satisfaction and 0

reflects worst life satisfaction. A score below 6 is considered to be low life satisfaction, and a score of 6 or more is considered to be high life satisfaction (Levin 2014).

Translation process

The OP scale was translated from the original language (Swedish) into Norwegian, according to the standards established by the International Quality of Life Assessment Project group (Aaronson et al. 1992; Guillemin et al. 1993). Translation from Swedish to Norwegian was conducted by two individuals whose native language was Norwegian and who have a clear understanding of conceptual meanings in both Norwegian and Swedish languages. The translators were health professionals and were professionally familiar with the concept of morbid obesity. The back translation from Norwegian to Swedish was conducted by two other individuals with an academic background from the social sciences who had Swedish as their native language, as well as a clear understanding of conceptual meanings in both Swedish and Norwegian. The translators worked separately during this phase. A consensus panel of three people compared the original version with the two translated versions and reconciled the forward translations into one common version.

The Norwegian version of the questionnaire was tested on a small sample of patients (n=8) who had been accepted for bariatric surgery. The aim of the pilot study was to identify and solve any potential problems in the translations, such as confusing words. The patients gave feedback in focus groups composed of four individuals (4 + 4). The questionnaire was found to be easily understood, and no changes to the questionnaire were required.

Statistical Analysis

Clinical and sociodemographic data were described as percentages or means ± standard deviation (SD).

Internal consistency for each item in the OP scale was calculated using Cronbach`s α. Item-total OP score correlations were computed. Floor and ceiling effects were calculated as percentages. Construct validity was tested by correlating the OP scale with the SF-36, Cantril Ladder, and BMI, using the Pearson correlation coefficient. Given a significance level of 0.05 and a power of 80% we would be able to detect a significant correlation of 0.24 or more when N = 130. Exploratory factor analysis, using principal component analysis with varimax rotation, was used to test the unidimensionality of the OP scale.

Responsiveness was tested by assessing changes in OP scale from baseline to one year post-surgery using the paired sample t-test. The size of these differences was further studied by calculating effect sizes (i.e. mean change between assessments, divided by the standard deviation of change(Cohen 1988)).

Results

Figure 1 describes the flow of patients through the study. A total of 209 patients were invited to participate in the study. Baseline analyses were based on 181 patients, and follow-up analyses were based on 130 patients (Figure 1 flowchart).

Among the 181 included patients 123 (68 %) were female. Patient characteristics are presented in Table 1. The mean age was 43.1 ± 12.5 years, and mean body mass index before surgery was 45 ± 6.9.

The mean value of the OP-scale was 63.30 ± 24.43 (severe impairment) at baseline and 21.01 ± 20.98 (mild impairment) at 1 year (Table 2). Mean scores for the SF-36 and Cantril Ladder are also presented in Table 2, as well as results of the paired samples t-test to evaluate the responsiveness of changes in the OP scale following surgery. As expected, the OP scale had a higher responsiveness (ES 1.7) than the SF-36 (PCS 1.5, MCS 1.0) and Cantril Ladder (ES 1.4).

In Table 3 statistics are presented for OP scale item-total correlations, Cronbach's α, and exploratory factor analysis factor loadings at baseline and one-year follow-up. Item-total correlations ranged from 0.53 to 0.80 at baseline and from 0.52-0.80at post-surgery follow-up. Cronbach's α for the OP-scale total score at baseline was 0.91 and after one year 0.88. Cronbach's α ranged from 0.89 to0.91 for OP scale items at baseline and from 0.85 to 0.88 at one-year follow-up. The exploratory factor analysis of the eight items in the questionnaire showed high homogeneity with factor loadings ranging from 0.62 to 0.86 at baseline and from 0.57 to 0.89 post-surgery.

The percentage of patients scoring at the lowest possible level (floor effect) was low at baseline (1.1%) and moderate at 1 year (20 %). The percentage score at the highest possible level (ceiling effect) was also low both in baseline (3.9 %) and at 1 year (0%).

At baseline the correlation coefficients between the OP scale and all the self-reported measures and BMI were statistically significant and in the predicted direction (Table 4).We also tested the correlation between OP scale and age and gender and found no significant findings (data not shown).

After one year the correlation coefficients between the change in OP scale and the change in self-reported measures and change in BMI were also statistically significant, except for the change in the RP-scale (Table 4).

Discussion

Our aim was to translate the OP scale into the Norwegian language and to tests its psychometric properties and responsiveness in a group of severely obese Norwegians prior to and one year after bariatric surgery. The study shows that the Norwegian version of the OP scale is a reliable and valid instrument. The SOS study showed that the OP scale's psychometric properties were strongly supported, and our results reproduced the same good performance in terms of validity and reliability (Karlsson et al. 2003).

It has also been shown that the OP scale is valid and reliable for use in Spain and Korea (Bilbao et al. 2009; Lee et al. 2013). Our study population is similar to the study population in other validation studies of the OP scale (i.e. bariatric surgery patients) (Bilbao et al. 2009; Karlsson et al. 2003). The mean OP score in our sample prior to surgery was similar to the Korean validation study (Lee et al. 2013) but a little higher than in the original Swedish study and in the Spanish validation study (Bilbao et al. 2009; Karlsson et al. 2003) .

The item internal consistency was high in our study. A Cronbach's value above 0.70 is regarded as acceptable, above 0.80 as good and above 0.90 as excellent (DeSalvo et al. 2006). In our study the internal consistency was excellent at baseline and good at one year which confirms the hypothesis that the Norwegian version of the OP scale has satisfactory

internal consistency. This is a similar result as in other validation studies of the OP scale (Bilbao et al. 2009; Karlsson et al. 2003; Lee et al. 2013). The factor analysis results confirm the unidimensionality of the OP scale. The majority of the total variance is explained by one factor with a high percentage of the variance explained by this factor, similar to that found by the authors of the original questionnaire (Karlsson et al. 2003) and in the Spanish version (Bilbao et al. 2009). One year after surgery the total variance was still high which indicates that there is one strong underlying factor that explained the variability both at baseline and at one-year follow-up.

Baseline floor and ceiling effects of the OP scale were small, similar to the original version. It is desired that ceiling and floor effect should be minimal (Karlsson et al. 2003). That we found moderate floor effects at the one-year follow-up (20% of participants scored at the best possible state) suggests that the OP scale might lack the ability to capture changes occurring over time for given individuals. However the rather large responsiveness for change suggests that this likely is not a problem in this sample as a whole.

The construct validity of the OP scale was assessed by examining the relationship between the OP scale and SF-36 and Cantril Ladder. High levels of concurrent validity were found. The OP scale had significant negative correlation with all eight domains and the two summary measures of SF-36 and also for Cantril Ladder at baseline. The OP scale had a lower correlation coefficient with role physical and higher correlation coefficient with the social function domain. This is not surprising given that OP scale measures one aspect of psychosocial functioning. BMI showed a significant positive correlation with the OP scale, as was found in other studies (Bilbao et al. 2009; Karlsson et al. 2003).

We found significant negative correlations between changes in OP scale and changes in the SF-36 (all the domains and the two summary scores), except for physical role function. This is likely explained by the response categories for physical role which have a low degree of precision (yes versus no). As far as we know, there have not been any previously published studies describing correlations of change scores for the OP scale. Change in life satisfaction was also significant negative correlated with the OP scale, which means that there is a strong relationship between life satisfaction and psychosocial functioning.

Responsiveness in OP scale and other self-report measures was analysed by comparing changes in OP scale, SF-36 and Cantril ladder at baseline and one year after surgery. We found responsiveness to change after one year. The OP scale was more responsive to change compared than the SF-36 and Cantril Ladder. These findings are similar to the OP scale in Sweden, where the questionnaire was developed (Karlsson et al. 2003). Other validation studies have not tested the responsiveness before and after surgery (Bilbao et al. 2009; Lee et al. 2013).

The OP scale measures the impact of obesity psychosocial functioning. A limitation of the present study is that the OP scale was only validated in a group of patients that had been accepted for bariatric surgery (BMI ≥ 35), and it is therefore unknown if the Norwegian OP scale is equally valid, reliable, and responsive in other groups of individuals with obesity, for example patients with a BMI between 30 and 35. A strength of the study is, however, that we studied responsiveness from baseline to one year after surgery, and it also strengthens the study that we compared the OP scale with well validated HRQL instruments. Finally, as far as we know, this is the first study that has used correlation of change scores in the validation of OP scale.

In conclusion this Norwegian version of the OP scale is a valid and reliable instrument for measuring psychosocial functioning in a sample with clinically severe obesity in Norway.

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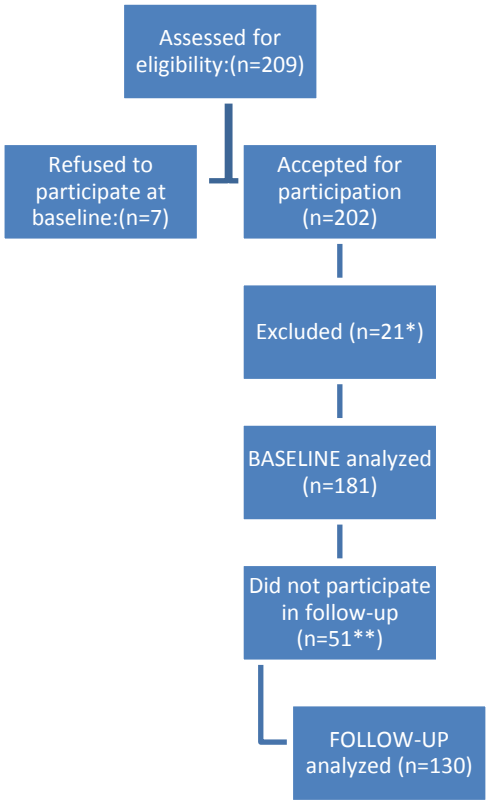
Table 1(on next page)

Figures and tables

Figure 1: Flow of patients



*Excluded due to problems with the data-gathering routines. ** For 26 of the patients we had no post-surgery data because there was less than a year since surgery. Three patients did not meet for follow-op appointment, 21 were excluded due to problems with the data-gathering routines and one had the control with his GP and did not send the questionnaire to the hospital.

Table 1. Characteristics of the patients (n=181)

Variables	Value
Age (yr), mean ± sd	43.1 ± 12,5
Gender, Woman, n (%)	123 (68)
Mean body mass index (kg/m^2) baseline, mean ± sd	45 ± 6.9
Current marital status, n (%)	
Married/cohabitants	114 (63)
Live alone	66 (37)
Education, n (%)	
Primary school	42(23)
High school	96(54)
University ≤ 4 y	28 (16)
University ≥ 4 y	13 (7)

Note: Numbers of patients ranging from 179-181.

Table 2. Mean score on OP scale, SF-36 and Cantril Ladder at baseline and at one year post-surgery

Scores	Baseline Mean (SD)	1 year post-surgery Mean (SD)	p-value	ES
OP scale	63.30 (24.43)	21.08 (20.98)	< 0.001	1.7
Cantril Ladder	5.01 (1.81)	7.49 (1.51)	< 0.001	1.4
PCS	37.41 (9.56)	51.90 (8.93)	< 0.001	1.5
MCS	42.82 (10.40)	53.35 (9.44)	< 0.001	1.0
Physical function	58.19 (21.99)	88.51 (16.68)	< 0.001	1.4
Physical role function	41.03 (38.03)	80.96 (31.56)	< 0.001	1.1
Bodily pain	49.44)24.63)	69.92 (26.16	< 0.001	0.8
General Health	46.99 (20.01)	78.36 (19.51)	< 0.001	1.6
Vitality	35.69 (18.32)	61.23 (22.02)	<0.001	1.4
Social function	64.60 (28.38)	88.65 (19.02)	< 0.001	0.8
Emotional role function	64.06 (39.60)	89.58 (27.35)	< 0.001	0.6
Mental health	69.84 (14.72)	82.12 (15.43)	< 0.001	0.7

Table 3. OP scale statistics at Baseline and 1 year post surgery

Item	Item description	Baseline Item-total correlation	Baseline α if one item deleted	Baseline Exploratory factor analysis loading	Post-surgery Item-total correlation	Post-surgery α if one item deleted	Post-surgery Exploratory factor analysis loading
1	Private gatherings in my own home	0.693	0.902	0.772	0.715	0.854	0.830
2	Private gatherings in a friend`s home	0.803	0.892	0.861	0.795	0.845	0.888
3	Going to a restaurant	0.799	0.893	0.860	0.593	0.864	0.729
4	Going to community activities	0.722	0.895	0.839	0.670	0.857	0.774
5	Holidays away from home	0.778	0.894	0.843	0.683	0.857	0.776
6	Trying and buying clothes	0.657	0.905	0.736	0.739	0.847	0.830
7	Bathing in public places	0.534	0.914	0.620	0.551	0.877	0.610
8	Intimate relations with partner	0.667	0.904	0.745	0.518	0.875	0.567

Standarized Cronbach`s α of OP scale baseline 0.91 and post-surgery 0.88

Table 4. Correlations between OP scale, SF-36 and Cantril Ladder at baseline and between changes in these scores after one year

	OP Baseline	Δ OP
PCS Baseline	- .410 (p < 0,001)	
MCS Baseline	- .624 (p < 0.001)	
Life satisfaction Baseline	- .561 (p < 0.001)	
BMI Baseline	.186 (p < 0.012)	
Physical function	-.321 (p < 0.001)	
Physical role function	-.268 (p < 0.001)	
Bodily pain	-.299 (p < 0.001)	
General Health	-.367 (p < 0.001)	
Vitality	-.460 (p < 0.001)	
Social function	-.582 (p < 0.001)	
Emotional role function	-.373 (p < 0.001)	
Mental health	-.570 (P < 0.001)	
Δ PCS		- .248 (p = 0.006)
Δ MCS		- .339 (p < 0.001)
Δ Life satisfaction		- .394 (p < 0.001)
Δ BMI		-.280 (p < 0.001)
Δ Physical function		-.266 (p = 0.002)
Δ Physical role function		-.091 (p = 0.306)
Δ Bodily pain		-.193 (p = 0.028)
Δ General Health		-.229 (p = 0.009)
Δ Vitality		-.255 (p = 0.004)
Δ Social function		-.328 (p < 0.001)
Δ Emotional role function		-.221 (p = 0.013)
Δ Mental health		-.250 (p =0.004)

Note : Δ = change. Since a higher score on the OP scale indicates poorer psychosocial functioning, the correlation between change in OP scale and change in SF-36 and Cantril Ladder is negative.