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Patient-reported quality of life with obesity – development of a new measurement scale

BACKGROUND

Many questionnaires for measuring the quality of life for patients with obesity require comprehensive calculation before they are used. There is a need for questionnaires that permit simple assessment of the responses during a patient consultation. We have developed the questionnaire Patient-Reported Outcomes in Obesity (PROS). The objective of the study was to test the reliability and validity of the questionnaire.

MATERIAL AND METHOD

The questionnaire was used to ask patients about the extent to which they perceived their weight or body shape as bothersome. A group of patients with an average body mass index (BMI) of 42 ($n = 109$) completed the PROS questionnaire and The Impact of Weight Quality of Life questionnaire (IWQOL-Lite) before undergoing obesity surgery. Another group with an average body mass index of 29 ($n = 95$) completed the PROS questionnaire 1–5 years after having undergone obesity surgery. 67.7% of the patients were > 40 years and 79% were women. For the statistical analysis we used Cronbach's alpha, factor analysis, Spearman's rank test and independent t-test.

RESULTS

Cronbach's alpha for the total PROS score was 0.90, and the factor analysis showed a significant factor (eigenvalue = 4.7) that explained 58.4% of the variance. The test-retest correlation was 0.93 ($p < 0.001$). The correlation coefficients between the PROS score, the total IWQOL-Lite score ($r_s = -0.91$) and body mass index ($r_s = 0.60$) were all significant ($p < 0.001$). The t-test showed an effect size (difference in standard deviation) between the non-surgery and the surgery groups of 1.9 (95% CI 1.6–2.5) for the PROS questionnaire and 2.1 (95% CI 1.7–2.5) for the total IWQOL-Lite score.

INTERPRETATION

The PROS questionnaire is a reliable and valid questionnaire for measurement of obesity-specific quality of life.

MAIN FINDINGS

There is a need for questionnaires to measure quality of life, where the responses can be easily assessed during a patient consultation

The PROS questionnaire (Patient-Reported Outcomes in Obesity) has been shown to be a reliable and valid questionnaire suitable for use in both clinical practice and for research purposes

Patients with severe obesity often have low health-related quality of life (1), and improving it is therefore a main goal for treatment (2). Although most patients improve their quality of life after obesity surgery, some patients who have lost little weight and/or suffer from many adverse effects experience a deterioration (3, 4). Some patients have symptoms of anxiety and depression, irrespective of weight change (5). The follow-up of the patients' mental health after obesity surgery is not standardised (6). There is no universal definition of quality of life, but this concept is often understood as an expression of subjective perception of well-being (7). The concept is used in many different ways, and in a Norwegian context it is commonly used to denote how individuals experience life. In measurements of quality of life, reference is frequently made to physical health and functioning, mental health, social interaction and economic status (8).

Both generic and disease-specific questionnaires are used to assess the burden of obesity (9, 10), and a number of disease-specific quality-of-life questionnaires for obesity have been developed in recent decades (11). Many of the questionnaires have been developed for research purposes and often require comprehensive calculations. We have seen a need for questionnaires with few questions that can be used for patient consultations, and have developed an obesity-specific quality-of-life questionnaire, Patient-Reported Outcomes in Obesity (PROS) in collaboration with clinicians and patients. It is intended for use in both research and clinical practice. The objective of this study was to test the reliability and validity of this questionnaire.

Material and method

We conducted a cross-sectional study among patients who had undergone obesity surgery (vertical ventricular resection) one to five years previously ($n = 95$) or were on a waiting list for obesity surgery ($n = 109$). This sample size permitted detection of a statistically significant, but small correlation ($r = 0.22$) and a statistically significant, but small standardised difference in scores between groups measured with an independent t -test (0.41; given p -value = 0.05 and strength = 0.90). All those who fulfilled the inclusion criteria were asked to participate in the study when attending an information meeting or a follow-up visit at the outpatient obesity clinic at Førde Central Hospital or Voss Hospital. Data were collected in the period from August 2015 to March 2016. Inclusion criteria for the study were completed obesity surgery or fulfilment of the criteria for surgical treatment of obesity.

There was no contact between the researchers and the patients during the data collection. Questionnaires, accompanied by a written invitation to participate and information about the study, were handed out in the outpatient clinic. A returned, completed question-

naire was considered to imply consent to participation. We used the checklist prepared by the Norwegian Centre for Research Data to assess whether the study was subject to duty of notification. All questions in the checklist came out with a negative answer. Ethical guidelines were complied with, and since the study was anonymous, we deemed it not to be subject to notification to the data protection officer or the research ethics committee.

Measurement instruments

In the PROS questionnaire, patients are asked to report the extent to which they perceive their weight or body shape as bothersome in the following areas: physical activity, pain, discrimination, sleep, sexual life, social life, work/school and self-esteem. The questionnaire has four response categories: not bothered (0), mildly bothered (1), moderately bothered (2) and considerably bothered (3). Patients are asked to tick the alternative that best describes their current situation (appendix 1 at tidsskriftet.no).

The questionnaire was developed in collaboration between patients, clinicians and researchers, and can be defined as an indicator of quality of life, or more specifically: obesity-

Table 1 Characteristics of the included patients ($n = 204$) who had undergone obesity surgery ($n = 95$) or were on a waiting list for obesity surgery ($n = 109$) at the hospitals in Førde and Voss in August 2015 – March 2016. Number (%) unless otherwise specified.

Characteristics ¹	All	Non-surgery	Surgery
Age			
< 30 years	23 (11.3)	12 (11.0)	11 (11.6)
30–39 years	43 (21.1)	26 (23.9)	17 (17.9)
40–49 years	63 (30.9)	39 (35.8)	24 (25.3)
50–59 years	55 (27.0)	24 (22.0)	31 (32.6)
> 50 years	20 (9.8)	8 (7.3)	12 (12.6)
Gender, women	157 (77.0)	82 (75.2)	75 (78.9)
BMI (kg/m ²), baseline value, average \pm SD		41.7 \pm 5.2	29.4 \pm 4.9
Marital status			
Married/co-habiting	143 (70.4)	76 (70.4)	67 (70.5)
Single	60 (29.6)	32 (29.6)	28 (29.5)
Education			
Primary/lower secondary	34 (16.8)	25 (22.9)	9 (9.7)
Upper secondary	117 (57.9)	56 (51.4)	61 (65.6)
University \leq 4 years	43 (21.3)	23 (21.1)	20 (21.5)
University \geq 4 years	8 (4.0)	5 (4.6)	3 (3.2)

¹ Patient numbers varied from 200 to 204 for the different variables.

related quality of life. The questionnaire targets the degree of discomfort or absence of discomfort, rather than 'positive health aspects'. Total scores and sub-scores can both be used. The total score should be used as an indicator of the patient's degree of discomfort and calculated as an average value by totalling the response scores and dividing by the number of responses. A minimum of five questions must be answered. Tentatively defined threshold values indicate < 0.5 as no discomfort, 0.5–1.49 as mild discomfort, 1.5–2.49 as moderate discomfort and ≥ 2.5 as extreme discomfort. In clinical work, total scores should not be used in isolation, since a patient may have a low total score, but still experience considerable discomfort in specific areas.

The Impact of Weight on Quality of Life Questionnaire short-form (IWQOL-Lite) is a validated, self-reported quality-of-life questionnaire for assessment of obesity-specific quality of life (12). It is considered the gold standard for measuring quality of life in this patient group. Here, the impact of body weight is assessed in the areas of physical functioning, self-esteem, sexual life, public distress and work. The questionnaire can be summed up in a total score or with a sum score for each of the five areas that have been transformed into a scale from 0 to 100. A high score indicates high obesity-related quality of life (12).

The questionnaire has been validated for Norwegian conditions (13)

Pilot study

We tested the questionnaire in a pilot study involving 17 persons who attended an infor-

Table 2 Reliability analysis and exploratory factor analysis for the Patient Reported Outcomes in Obesity (PROS) questionnaire (n = 204)

PROS question	Item-total correlation ¹	Cronbach's alpha if one question is excluded	Factor load	Communality
Normal physical activities	0.73	0.88	0.80	0.64
Bodily pain	0.67	0.88	0.74	0.55
Discrimination/discourteous behaviour	0.60	0.89	0.70	0.49
Sleep	0.57	0.89	0.66	0.43
Sexual life	0.65	0.89	0.74	0.54
Normal social interaction	0.72	0.88	0.81	0.65
Work, school, daily activities	0.75	0.88	0.83	0.69
Self-esteem	0.75	0.88	0.83	0.68

¹ Total correlation with the separate PROS scale corrected for overlap. Cronbach's alpha for the total PROS score was 0.90. Principal component analysis showed that one individual factor (eigenvalue = 4.7) explained 58.4 % of the variance in the questionnaire. Kaiser-Meyer-Olkin value = 0.89 and Bartlett's sphere test < 0.001.

mation meeting prior to surgery. We asked about 'the extent to which they had problems with their weight or body shape'. In response to feedback from the patients, the question was rephrased as 'to what extent your weight or body shape are perceived as bothersome'. The questionnaire was subsequently tested in another pilot study in three groups comprising a total of 54 persons: two groups that were attending an information meeting prior to surgery (39 patients) and one group that was attending an update training course two years after surgery (15 patients). The questionnaire was subsequently retested at the end of

the training course session. Altogether 26 persons completed the questionnaire. The patients evaluated the questionnaire in writing and through participation in a group interview chaired by the project director. The patients (n = 54) reported that all questions and response categories used in the final pilot study were easily understandable.

Statistical analysis

Descriptive statistics were used to describe clinical and sociodemographic characteristics, and are presented as percentages or averages with standard deviations (SD). Because

Table 3 Correlation between the Patient Reported Outcomes in Obesity (PROS) questionnaire, the Impact of Weight on Quality of Life questionnaire short-form (IWQOL-Lite) and body mass index (BMI)

PROS ¹	IWQOL-Lite and BMI						
	Sum score	Physical functioning	Self-esteem	Sexual life	Public distress	Work	BMI
Sum score	-0.91	-0.88	-0.84	-0.76	-0.77	-0.87	0.60
Physical activity	-0.75	-0.80	-0.64	-0.63	-0.62	-0.72	0.55
Pain	-0.70	-0.71	-0.52	-0.51	-0.52	-0.65	0.39
Discrimination	-0.69	-0.62	-0.66	-0.45	-0.70	-0.63	0.46
Sleep	-0.54	-0.57	-0.49	-0.43	-0.44	-0.54	0.32
Sexual life	-0.67	-0.61	-0.59	-0.74	-0.54	-0.62	0.42
Social interaction	-0.76	-0.70	-0.76	-0.65	-0.68	-0.72	0.56
Work, school	-0.76	-0.74	-0.68	-0.57	-0.64	-0.79	0.53
Self-esteem	-0.81	-0.68	-0.87	-0.71	-0.69	-0.73	0.50

¹ Patient number for PROS was 204, IWQOL-Lite 158–195 and 200 for body mass index. P-values for all correlations are < 0.001.

Table 4 Overview of the distribution (%) of responses to the Patient Reported Outcomes in Obesity (PROS) questionnaire in the non-surgical (n = 109) and surgical groups (n = 95)

PROS sub-scores	Non-surgical group		Surgical group	
	Not/mildly bothered	Moderately/considerably bothered	Not/mildly bothered	Moderately/considerably bothered
Physical activity	29.4	70.6	87.4	12.6
Pain	27.5	72.5	68.4	31.6
Discrimination	66.1	33.9	97.9	2.4
Sleep	41.3	58.7	77.9	22.1
Sexual life	46.8	53.2	86.3	13.7
Social interaction	59.6	40.4	93.7	6.3
Work, school	40.4	59.6	93.7	6.3
Self-esteem	24.8	75.2	78.9	21.1

this is a validation study, we used only scores from fully completed PROS and IWQOL-Lite questionnaires.

Internal consistency was measured by estimating Cronbach's alpha, and a value above 0.7 was deemed satisfactory (14). Cronbach's alpha was also estimated when a question was excluded. In addition, we correlated each individual question with the total score on the PROS questionnaire and corrected for overlap. To investigate whether the total score remained stable when the questionnaire was completed by the same patient at five-hour intervals, a test-retest analysis with the aid of Spearman's rank test was used. A correlation coefficient > 0.7 is recommended, while values > 0.85 are ideal (15).

Principal component analysis was used to investigate construction validity, i.e. whether the questions in the PROS questionnaire constituted a single total score or multiple scores. A component with an eigenvalue ≥ 1 was considered indicative of an independent score. The explained variance for a component with an eigenvalue ≥ 1 will be reported, and factor loads on individual questions in a score > 0.40 are acceptable (16). We tested criterion validity, i.e. a new score compared to a gold standard that intends to measure the same phenomenon, by correlating the total score in the PROS questionnaire with the total score in the IWQOL-Lite questionnaire with the aid of Spearman's rank test. A correlation coefficient > 0.7 is recommended, while values > 0.85 are ideal (15). We investigated converging validity, i.e. whether the total score and questions scores in the PROS questionnaire were correlated with variables that are not

identical with, but theoretically considered to be related to the PROS questionnaire.

Correlation coefficients for converging validity were interpreted as follows: > 0.5 was a large, 0.3–0.49 a moderate, 0.1–0.29 a small and < 0.1 an insignificant effect size (14). Floor and ceiling effects, i.e. those who score as low or as high as possible, are presented and should amount to less than 15 % (17).

All analyses so far are based on non-surgical and surgical patients having been merged into a single group. Stratified analyses can be found in Appendix 2 (NB! The tables in Appendix 2 have not been peer reviewed. Editor's note). An independent t-test was used to compare the groups (surgical vs. non-surgical). The effect size was estimated by calculating the difference between the average PROS scores for the surgical and non-surgical groups divided, with the total standard deviation

$$\sqrt{\frac{SD_1^2 + SD_2^2}{2}}$$

As thresholds for effect size we used 0.2 (small), 0.5 (moderate) and 0.8 and above (large) (14).

The statistical analyses were undertaken in GPower 3.1.9.3 and Statistical Package for Social Sciences for Windows (SPSS), version 24.0 (Chicago, IL). A two-tailed $p < 0.05$ was set as the level of statistical significance.

Results

A total of 204 out of 210 (97 %) patients agreed to participate in the study. Patient characteristics are shown in Table 1. All patients retur-

ned a fully completed PROS questionnaire, while for the IWQOL-Lite questionnaire, the degree of completion varied between the five areas (78–96 %).

Cronbach's alpha for the total PROS score was 0.90. If one question was excluded, Cronbach's alpha was 0.88–0.89. The item-total correlation, corrected for overlap, was 0.57–0.75. The test-retest value for the PROS questionnaire was 0.93 ($p < 0.001$). Principal component analysis showed that a single factor explained 58.4 % of the variance in the questionnaire. The factor load showed a high degree of homogeneity and varied from 0.66 to 0.83. Community was 0.43–0.69 (Table 2). In the PROS questionnaire, 2 % of the patients in the non-surgery group scored at the lowest possible level (floor effect), compared to 28 % in the surgery group. Altogether 4 % of the non-surgical group scored at the highest possible level (ceiling effect), compared to 1 % in the surgical group. The correlation coefficients between the total PROS and IWQOL-Lite scores and BMI were statistically significant ($p < 0.001$) and had the expected direction and size (Table 3). When conducting stratified analyses for the non-surgical and surgical groups, we found generally similar, but somewhat weaker associations than in the sample as a whole, as well as a possible two-factor model for the PROS questionnaire (Appendix 2). The t-test shows a high sensitivity to group differences, and the effect size between the non-surgical and surgical groups was 1.9 (95 % CI 1.6–2.5) for the total PROS score and 2.1 for the total IWQOL-Lite score (95 % CI 1.7–2.5). Other effect sizes for the different questions in the PROS questionnaire between the non-surgical and surgical groups are given as percentages (Table 4).

Discussion

One may ask why we have chosen to develop a new questionnaire instead of using existing obesity-specific ones, such as the Obesity-Related Problem Scale (OP) (18), the Moorehead-Ardelt Quality of Life Questionnaire II (19) or IWQOL-Lite (12). The latter is considered to be the gold standard, but it contains a large number of statements (20) and the scores are difficult to calculate during a consultation with the patient. The Moorehead-Ardelt Quality of Life Questionnaire II is a brief, commercial questionnaire. This restricts its use for clinical purposes. Experience indicates a need for a questionnaire that can be completed

quickly, is easy to sum up and can be used free of charge in the clinic. We were inspired by the Obesity-Related Problem Scale, which we have also translated into Norwegian and validated (18). This is an obesity-specific questionnaire that measures psychosocial functioning (18). In addition to psychosocial functioning we also wanted to collect data on physical activity, pain, sleep, discrimination and self-esteem, since these areas also have a bearing on health-related quality of life (20–24).

The main purpose of the PROS questionnaire is to facilitate dialogue between the patient and the clinician, and thus help produce more targeted consultations. The total PROS score is based on giving equal weight to all sub-items, although this may not always be relevant at the individual level. The extent to which a patient experiences discomfort may thus differ from the total score. We therefore recommend that patients be asked about their general perception of discomfort, ranging from 'not bothered' to 'considerably bothered'. This permits a check of whether

the total score provides a meaningful reflection of the situation as seen by the patient.

The PROS questionnaire measures the extent to which the respondent perceives his or her weight or body shape as bothersome. This study has the limitation that the questionnaire has been validated only in a group of patients who qualify for obesity surgery. Therefore, we cannot be certain that the PROS questionnaire is equally reliable and valid for use with other patients that do not qualify for or do not want to undergo obesity surgery. Another limitation is that we did not follow patients up over time, but used a cross-sectional design. As a result, the sensitivity of the PROS questionnaire to change may be a little uncertain. It also relies on self-reported height and weight, which may give rise to inaccuracy. Further studies with larger samples will be undertaken to examine the factor structure of the PROS questionnaire.

One of the study's strengths lies in its high number of included patients and the high response rate among representative patients.

In addition, the PROS questionnaire has been compared to the gold standard for this patient group, the IWQOL-Lite questionnaire (24). The questionnaire is freely available for use in clinical practice and research (Appendix 1).

Conclusion

The PROS questionnaire is a reliable and valid questionnaire for measurement of obesity-specific quality of life. It can be suitable for use in both clinical practice and research. The questionnaire shows a high degree of validity when compared to the IWQOL-Lite questionnaire, and should be easy for the clinician to interpret. There is a need for studies that use the questionnaire to follow patients over time, including groups of patients with obesity who do not seek surgical treatment.

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