

Sensitivity for Change Analyses of the Patient-Reported Outcomes in Obesity (PROS) Questionnaire: A Prospective Cohort Study

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Purpose: Many patients seeking bariatric surgery experience reduced health-related quality of life (HRQOL). A simple clinical tool, the Patient-Reported Outcomes in Obesity (PROS), was developed to address patients' HRQOL concerns during clinical consultations and facilitate meaningful dialogue. The present study aims to explore its sensitivity to change.

Patients and Methods: A prospective study of patients undergoing bariatric surgery was conducted. The patients responded to items on the PROS and the Obesity-related Problems Scale (OP) before surgery and three, 12 and 24 months after surgery. Longitudinal mixed-effects models were applied to estimate the change in PROS and OP scores over time.

Results: Thirty-eight patients were included. A significant change over time was detected for the PROS with the largest effect size at 24 months (effect size -1.34 , $p < 0.001$), while the corresponding effect size for the OP was -1.32 ($p < 0.001$). In all items of the PROS, the majority of patients responded not bothered at 24 months. The items physical activity, pain, sleep and self-esteem showed the largest change in the percentage of patients reporting not bothered from baseline to 24 months after surgery.

Conclusion: The PROS is sensitive to change over time and may be used as a brief, easy to administer tool to facilitate a conversation about obesity-specific quality of life in clinical consultations.

Keywords: health-related quality of life, Patient-Reported Outcomes in Obesity, PROS, patient-centered follow-up, bariatric surgery

Introduction

Bariatric surgery can significantly improve obesity-specific health-related quality of life (HRQOL).¹ However, the initial improvement in HRQOL is often shown to decline over time, especially the mental component.² This highlights the importance of assessing HRQOL over time in clinical consultations.

Several multidimensional questionnaires have been used to assess obesity-specific HRQOL in patients with obesity, including bariatric surgery patients.³ Examples of well-known questionnaires are the Impact of Weight on Quality of Life-Lite questionnaire (IWQOL-Lite),⁴ the Bariatric Quality of Life Index (BQL)⁵ and the Bariatric and obesity-specific survey (BOSS).⁶ Many obesity-related HRQOL questionnaires are lengthy or focus on limited domains of HRQOL. Thus, questionnaires that permit a broad but simple and rapid assessment of HRQOL in patients who undergo bariatric surgery are warranted. In response, the Patient-Reported Outcomes in Obesity (PROS) was developed.⁷ It is worth mentioning that disease specific measures tend to be highly sensitive to the condition being measured.

The PROS is a brief questionnaire developed to facilitate the clinical conversation in patient-centered follow-up. The questionnaire has been implemented as the principal HRQOL measure in the quality registry for patients undergoing bariatric surgery in Norway, SOReg-N.⁸ The PROS showed good psychometric properties in cross-sectional studies in Norway, Brazil and Turkey.^{4,9,10}

However, the PROS has not been assessed for sensitivity to change (also often referred to as responsiveness), a crucial feature of an HRQOL instrument. This study aimed to investigate its sensitivity to change over time in patients with severe obesity who underwent bariatric surgery.

Materials and Methods

This prospective cohort study included patients who had undergone bariatric surgery at Førde Hospital Trust, Norway. All patients underwent laparoscopic sleeve gastrectomy (LSG) from February 2018 to January 2022. Our power analyses showed that a minimum of 22 patients would be required to detect a statistical difference equaling one standard deviation for the PROS over time (based on paired *t*-test, power = 0.9, *P* = 0.05, and a correlation between scores of 0.4).

The Norwegian Centre for Research Data, Department of Data Protection Services (reference number 282738) approved the study. All patients signed informed consent to participate in research. The study complies with the Declaration of Helsinki.

The patients responded to a clinical feedback system (CFS) before the consultations with a nurse in the bariatric outpatient clinic.¹¹ PROS was one of the questionnaires included in the CFS. Inclusion criteria was patients which had responded to the CFS before surgery, 12 and 24 months after bariatric surgery.

Variables

We collected data on age, biological sex, BMI (kg/m²), and body weight (kg) at baseline, 12 months, and 24 months post-surgery.

The PROS is a obesity-specific multidimensional questionnaire containing eight items assessing physical activity, pain, discrimination, sleep, sex life, social life, work/school, and self-esteem. The patients are asked whether their body weight or shape bothers them in any of these domains. There are four response categories: not bothered (0), mildly bothered (1), moderately bothered (2), and considerably bothered (3). The questionnaire is intended to be used in clinical consultations to facilitate a patient-centered consultation. However, the PROS may also be used for research and can be analyzed through sub-scores and a sum score. The sum score is calculated by summing all items and multiplying by eight; scores < 0.5 indicate no discomfort, 0.5–1.49 mild discomfort, 1.5–2.49 moderate discomfort, and ≥ 2.5 extreme discomfort.⁷ Figure 1 displays the questionnaire.

We also used the Obesity-related problems scale (OP), a well-known questionnaire measuring the impact of obesity on psychosocial functioning, which has demonstrated excellent sensitivity to change after bariatric surgery.^{12,13} The OP questionnaire contains eight items, which asks the patients how bothered they are by obesity in specific social situations. The responses are on a four-point scale. The responses are aggregated on a scale of 0–100, where lower scores indicate less psychosocial bother. OP has been demonstrated to be highly sensitive to change.

Analyses

We performed descriptive analyses on the patients' characteristics with percentages (%) and number (n) for categorical measures; and mean and standard deviations (SD) for continuous measures. Longitudinal mixed-effects models were used to estimate the change in PROS and OP scores over time. To estimate the effect size for PROS and OP sum score changes over time, we extracted the mean difference at each time point and divided each by the baseline standard deviation. We used the standard criteria proposed by Cohen to judge effect sizes: trivial (< 0.2), small (0.2 to < 0.5), moderate (0.5 to < 0.8), and large (≥ 0.8). To analyze the single items of the PROS, we performed descriptive analyses on the number (%) of patients responding to each of the four response categories at each assessment point. A 1000-repetition bootstrap analysis was added to the mixed effect models for estimating 95% confidence intervals and p-values for change in the PRO-items, as these are on an ordinal scale. P-values are two-sided and are judged as continuous indicators of probability. A p-value < 0.05 were considered statistically significant. The analyses were conducted with IBM SPSS Statistics version 27.¹⁴

Does your *weight or body shape* bother you in the areas listed below?
(Mark the alternative that best describes your current situation)|

Areas	Considerably bothered	Moderately bothered	Mildly bothered	Not bothered
1. Common physical activities (walking, climbing stairs and similar)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Bodily pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Discrimination or discourteous behaviour	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Sleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Sexual life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Normal social interaction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Work, school or other daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Self-esteem	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 1 The Patient-Reported Outcomes in Obesity (PROS).

Results

For demographic information on the included patients, see [Table 1](#). All 38 patients underwent LSG, and almost all patients were female. The mean preoperative BMI was 42.6 (range 35.7–52.2); at 12 months mean BMI was 29.5 (range 23.6–37.9) and at 24 months it was 30.1 (range 23.6–40.0). Six patients were not included due to missing data.

Table 1 Characteristics of the Included Patients (n=38)

Variables	Values
Age (years), mean (SD)	40.1 (11.4)
Biological sex (female), % (n)	89.5 (34)
BMI (kg/m ²)	
Baseline, mean (SD)	42.6 (4.1)
12 months, mean (SD)	29.5 (4.1)
24 months, mean (SD)	30.1 (4.7)
Body weight(kg) baseline mean (SD)	123.6 (18.2)
Type of surgery, Laparoscopic SLEEVE gastrectomy % (n)	100 (38)

Abbreviations: n, number of patients; SD, standard deviation; BMI, body mass index.

The mean sum score of the PROS at baseline indicated that the patients had mild discomfort, and the mean sum score at 12 and 24 months indicated no discomfort. The effect size showed significant changes at three months, 12 months, and 24 months, with the largest effect size at 24 months. As a reference, the OP showed scores compatible with mild discomfort at baseline and no discomfort at 12 and 24 months after surgery. The effect sizes of the OP also showed significant change over time, however the maximum effect size was at 12 months (Table 2).

In Table 3 we present the percentage of patients responding to each of the four categories of each item for each time point. All items show an improvement in that more patients report being not bothered at 12 and 24 months compared to baseline. The items physical activity, pain, sleep and self esteem show the largest difference in patients reporting not bothered from baseline to 24 months after surgery. The item discrimination appears to be experienced less bothersome in this specific population.

In Table 4 we present the sub-item scores over time, and the change scores with 95% CI for final versus first observation.

Discussion

Previous research showed the PROS to be a reliable and valid of measure obesity-specific quality of life, and the results of the current study indicate that it is also sensitive to change over time. The PROS showed maximum effect at the last measurement point (24 months), suggesting that improvements in obesity-specific HRQOL after bariatric surgery endured. The effect sizes for PROS are comparable with the effect sizes for OP in this study. Unlike the PROS, the effect size for change in the OP was highest at 12 months. Karlsson, Taft¹⁵ conducted a controlled study where HRQOL was explored using the OP. During the 10-year follow-up, the peak improvements in the OP occurred after one year. Based on the results from the present study it seems that the PROS measures domains of obesity-specific quality of life that are more sustainable. One possible explanation may be that the OP scale measures only psychosocial functioning, whereas the PROS measures several aspects of HRQOL. However, data beyond two years are needed to establish when the maximum change in effect size is, as many patients experience maximum weight loss around this time.

The effects and consequences of bariatric surgery are more complex than weight loss and nutritional challenges. Both patients and clinicians acknowledge the importance of discussing HRQOL.¹⁶ There is therefore a need for brief, easily administered patient-reported measures that facilitate such a discussion. The PROS is a measure that can be used for such purposes because it measures different aspects of HRQOL that are important to patients, and at the same time the measure is brief. A lengthy measure may cause responder fatigue and as a consequence the patient may start responding carelessly to items.¹⁷ A recent study conducted in Australia and Aotearoa New Zealand explored the use of patient-reported outcome measures (PROMS) and patient-reported experience measures (PREMS) in bariatric clinics.¹⁸ While the majority of the clinics reported having not collected PROMS or PREMS, the respondents thought that PROMS would be useful to enhance patient-clinician communication, to monitor important changes and to get a deeper understanding of the patient's life in relation to HRQOL.

Table 2 Mean Score, and Effect Size for Changes Over Time for the PROS and the OP Total Scores

	Preoperative	3 Months	12 Months	24 Months
PROS				
Mean (SD)	1.29 (0.61)	0.63 (0.68)	0.49 (0.49)	0.47 (0.38) *
Effect size	Ref.	-1.07	-1.31	-1.34
OP-scale				
Mean (SD)	38.49 (18.57)	18.62 (15.71)	12.80 (10.91)	13.88 (10.75) *
Effect size	Ref.	-1.07	-1.38	-1.32

Note: *Overall effect for change over time was <0.001 for both PROS and OP.

Abbreviations: PROS, Patient-reported Outcomes in Obesity; OP, Obesity-related Problems Scale; SD, standard deviation; Effect size, mean difference divided by baseline SD.

Table 3 Percentage of Patients Reporting the Sub-Items of PROS at the Four Measuring Times Presented by Response Category

Item and Response Category	Preoperative	3 Months	12 Months	24 Months
Q1 Physical activity				
Not bothered (%)	23.3	55.9	87.5	73.9
Mildly bothered (%)	30.0	20.6	9.4	17.4
Moderately bothered (%)	26.7	20.6	3.1	8.7
Considerably bothered (%)	20.0	2.9	0	0
Q2 Pain				
Not bothered (%)	13.3	38.2	43.8	56.5
Mildly bothered (%)	26.7	35.3	28.1	17.4
Moderately bothered (%)	26.7	11.8	15.6	21.7
Considerably bothered (%)	33.3	14.7	12.5	4.3
Q3 Discrimination				
Not bothered (%)	63.3	76.5	84.4	95.7
Mildly bothered (%)	20.0	17.6	9.4	4.3
Moderately bothered (%)	16.7	2.9	6.3	0
Considerably bothered (%)	0	2.9	0	0
Q4 Sleep				
Not bothered (%)	20.0	52.9	53.1	60.9
Mildly bothered (%)	30.0	26.5	25.0	30.4
Moderately bothered (%)	40.0	14.7	21.9	8.7
Considerably bothered (%)	10.0	5.9	0	0
Q5 Sexual life				
Not bothered (%)	37.9	73.5	65.6	63.6
Mildly bothered (%)	20.7	8.8	25.0	22.7
Moderately bothered (%)	27.6	8.8	6.3	13.6
Considerably bothered (%)	13.8	8.8	3.1	0
Q6 Social life				
Not bothered (%)	40.0	67.6	90.6	82.6
Mildly bothered (%)	30.0	23.5	3.1	17.4
Moderately bothered (%)	26.7	5.9	3.1	0
Considerably bothered (%)	3.3	2.9	3.1	0
Q7 Work/ School				
Not bothered (%)	23.3	67.6	81.3	91.3
Mildly bothered (%)	33.3	14.7	9.4	4.3
Moderately bothered (%)	33.3	14.7	6.3	4.3
Considerably bothered (%)	10.0	2.9	3.1	0
Q8 Self-esteem				
Not bothered (%)	6.7	35.3	50.0	45.5
Mildly bothered (%)	13.3	47.1	34.4	30.4
Moderately bothered (%)	43.3	11.8	12.5	21.7
Considerably bothered (%)	36.7	5.9	3.1	4.3

Since the PROS was included as a measure in the national registry for bariatric surgery in Norway (SOREg-N) in March 2022,⁸ it was important to determine if it was sensitive to change over time – the aim of this study. A result of incorporating the PROS in the registry is that it may be used both for research purposes (such as examining long-term outcomes across and between bariatric surgery centers throughout Norway) and for clinical purposes (as a tool for

Table 4 Mean (SD) PROS Sub-Item Scores Over Time and Change Scores (95% CI) for Final versus First Observation

PROS Items Mean (SD)	Preoperative	3 Months	12 Months	24 Months	Change (95% CI), P-value
Q1 Physical activity	1.43 (1.07)	0.70 (0.90)	0.18 (0.45)	0.35 (0.65)	-1.07 (-1.53, -0.61), P<0.001
Q2 Pain	1.74 (1.06)	1.00 (1.06)	0.97 (1.06)	0.85 (0.96)	-0.89 (-1.39, -0.33), P=0.006
Q3 Discrimination	0.53 (0.78)	0.32 (0.68)	0.21 (0.55)	0.07 (0.21)	-0.46 (-0.77, -0.15), P=0.004
Q4 Sleep	1.32 (0.93)	0.72 (0.93)	0.73 (0.82)	0.59 (0.67)	-0.73 (-1.06, -0.33), P=0.002
Q5 Sexual life	1.06 (1.10)	0.52 (0.99)	0.57 (0.76)	0.56 (0.74)	-0.50 (-0.90, -0.08), P=0.037
Q6 Social life	0.90 (0.91)	0.43 (0.75)	0.21 (0.64)	0.25 (0.39)	-0.65 (-0.94, -0.29), P=0.004
Q7 Work/ School	1.28 (0.95)	0.52 (0.86)	0.36 (0.74)	0.16 (0.46)	-1.11 (-1.47, -0.62), P<0.001
Q8 Self-esteem	2.09 (0.89)	0.89 (0.84)	0.69 (0.82)	0.90 (0.92)	-1.18 (-0.159, -0.71), P<0.001

Note: The 95% CIs and P-values are adjusted using bootstrap analysis.

facilitating meaningful dialogue in the clinical consultation). When completing the PROS, patients have the option to share the data with their healthcare professional.

Limitations

Some limitations of this study must be noted. Although the power analyses showed that an appropriate number of patients were included to detect a meaningful change over time, the sample size is small. If these analyses were performed in larger populations and in several locations, the effect-sizes would possibly have differed. However, a meaningful effect size was detected even with this limited population.

Another important limitation is that almost 90% of the population was female. This means that our findings for change over time may not be generalizable to the male gender. This is an empirical question for further study.

The patients reported only mild discomfort at baseline. In a population of patients experiencing higher distress with obesity-related HRQOL at baseline, one would expect an even larger change over time.

In this study, only patients who had undergone LSG were included as this is the only procedure currently performed at this hospital trust. We therefore have no data on whether these findings are transferable to patient who have undergone other surgical procedures.

Implications

Through this study, a brief, easy to administer questionnaire assessing obesity-related HRQOL has been shown to be sensitive to change over 24 months. The advantage of the questionnaire is that it may be used as both a clinical and a research tool. The fact that the measure is multidimensional and at the same time has few items is an advantage for clinical use. The questionnaire is available for use at no cost.

There is still a need to explore how best to help patients after bariatric surgery, not only to lose weight but also to experience improvement in other aspects such as pain, mental health and HRQOL. Also, research on how to tailor the follow up to the patient's need are welcomed.

Conclusion

The PROS demonstrated satisfactory sensitivity to change over 24 months following bariatric surgery. This suggests that the PROS can be used for longitudinal studies in patients with obesity.

Disclosure

Professor Ronette L Kolotkin reports her company, Quality of Life Consulting, PLLC, receives royalties for weight-related quality of life questionnaires for IWQOL-Lite, IWQOL-Lite-CT, IWQOL-Kids. The authors report no other conflicts of interest in this work.

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