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A preliminary report on the development of a validated tool for measuring psychosocial outcomes for massive weight loss patients

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Summary *Aim:* To validate the newly developed patient report outcome measure (PROM): the Post Bariatric Outcome Tool (PBOT). The tool is designed and developed for massive weight loss patients seeking body contouring procedures.
Method: The PBOT was piloted with three cohorts: massive weight loss patients seeking body contouring; massive weight loss patients who have had body contouring; and healthy, non-obese subjects as controls matched for age and gender. Each cohort completed two PROMS at week one, and then for a second time at week three. The PROMS used were the new Post Bariatric Outcome Tool (PBOT) and the Derriford Appearance Scale 24 (DAS24).
Conclusion: The PBOT was shown to be reliable both in terms of its internal consistency and test-retest reliability. Comparison to the DAS24 demonstrated the PBOT to be valid. However, the cohorts were small and responsiveness was not tested. This needs to be tested in further larger validation studies, ideally, with comparison to functional scales such as the SF-36 or other validated massive weight loss body contouring PROMs; such as the Body Q.
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Introduction

Following bariatric surgery, morbidity and mortality decreases,[1] however ptotic redundant skin folds do not contract with the volume loss[2] resulting in intertriginous rash, hygiene issues and functional and psychological impairment.[3] Identifying outcomes in these patients requires an understanding of the complex adjustment they are making to their new body

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habitus, the redundant skin, removal of the coping mechanism of food, identity and the functional and psychosocial fall out. Evidence-based health policy emphasizes the importance of using scientifically rigorous patient-based outcome measures to evaluate the impact of disease and treatment.[4]

Ensuring valid, robust data is generated from patient reported outcome measures (PROMs) depends on an appropriate assessment tool,[5] reflecting the population, disease and specific domains relevant to the cohort. Although PROMs have been used widely in chronic illness and cancer, they are still a relatively new concept in the field of surgery.[6] The aim of PROMs is to assess the patient's perspective of health, illness, and the effects of health care interventions in a reliable, valid, acceptable, and feasible way.[7] Darzi's "NHS Next Stage Review"[8] indicates that PROMs will be increasingly used in the evaluation and policy making[9] of healthcare technologies and services. The drive to improve quality of care has led to the recognition of the importance of patient perspective and consequently the development of robust PROMs.[10] Currently there is no measure for the massive weight loss body contouring (MWLBC) patient that is psychometrically sound; derived from patient and user experiences; has face validity; and is easy to administer and score.

We have developed a patient report outcome measure for massive weight loss (MWL) patients wishing to undergo body contouring called the Post Bariatric Outcome Tool (PBOT) (Appendix A). This PROM has been designed to fit in with the national guidelines of massive weight loss body contouring published by BAPRAS in 2014.[11]

Utilising this PROM as part of the referral pathway will help identify which patients meet the national criteria and will heighten awareness of psychological disturbance that may warrant early psychological intervention. We anticipate users of the PBOT will come from a range a professional backgrounds including GPs, bariatric surgeons, plastic and reconstructive surgeons, clinical health psychologists and specialist nurses, as well as academics. The PBOT is five pages long. The referrer completes pages 1—2. The patient completes pages 3—5.

The length of time taken to complete the PBOT varies, but is usually between 10 and 15 min for pages 3—5. The completed form (pages 1—5), along with a clinical photograph of the patient is then sent to the MWLBC MDT for analysis and scoring. Figure 1.

In order to measure psychological and functional adjustment to MWLBC it is recommended that the patient completes pages 3—5 of the PBOT for a second time at the final plastic surgery outpatient clinic.

To develop a conceptual model and generate items for the PBOT we followed an established method of: literature review; semi structured patient interviews and expert opinions. This has been described elsewhere[12] and is beyond the remit of this paper. This paper highlights the outcomes of assessment of validity of the PBOT in a prospective study, as per the guidance developed by the Scientific Advisory Committee of the Medical Outcomes Trust.[13]

Methods

Field test and psychometric analysis

The following 3 groups were posted and completed the PBOT and Derriford 24 (DAS24) at week one and week three.

- 10 non-obese, healthy population
- 10 patients following massive weight loss (MWL)
- 10 patients post massive weight loss and body contouring (MWLBC)

Psychometric analysis was then performed on results for conceptual and measurement model, acceptability, responsiveness, reliability and validity.

Conceptual and measurement model

"A PROM should have documentation defining and describing the concept(s) included and the intended population(s) for use."[14,15] The PROM is supported by appropriate documentation. Appendices B & C.

Administrative burden/acceptability

The burden of acceptability was assessed by completion percentage of the PBOT. We were willing to accept <10% frequency of missing data from completed scores. Response distributions were examined, focussing on maximum endorsement frequencies, i.e. highest proportion of respondents who endorsed a single category for an item (should be <80%). Reading ease should be assessed. The Flesch/Flesch—Kincaid readability tests are designed to indicate comprehension difficulty when reading a passage of contemporary academic English.[16] There are two tests, the Flesch Reading Ease, and the Flesch—Kincaid Grade Level.[17]

Responsiveness

This is the ability of a PROM to detect change over time or following intervention/surgery.[18]

Reliability

Reliability is a measure of the extent to which a PROM is free from random error.[6] For PROMs, the two most common types of reliability assessed are internal consistency and test-retest reliability. Internal consistency can be measured with Cronbach's Coefficient Alpha.[19] We judged $r > 0.70$ acceptable.[20] Test-retest reliability is a measure of the reproducibility of the PROM to provide consistent scores over time in a stable population. Test-retest reliability was assessed by estimated Bland and Altman's method for agreement of repeated scores, where >95% of the mean of the re-test against the difference of the re-test within 2 standard deviations of the bias was considered acceptable.

Validity

Construct validity is the extent to which scores on the PROM relate to other validated measures (for the PBOT we have compared it to the DAS24[21]) in a manner that is consistent with theoretically derived hypotheses concerning the constructs that are being measured.[7,22] It is calculated using Spearman rank correlation co-efficient for mean scores. Content validity was determined in our previous paper.

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