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Translation and validation of a Swedish version of the BODY-Q: a patient-reported outcome instrument for weight loss and body contouring surgery

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ABSTRACT

BODY-Q is self-administered questionnaire that evaluates appearance, function and symptoms related to bariatric- and body contouring surgery. The purpose of this article was to describe the translation process of a Swedish version of BODY-Q and to evaluate its criterion validity to the Swedish questionnaire Sahlgrenska Excess Skin Ouestionnaire, SESO.

Materials and methods: BODY-Q was translated according to International Society for Pharmacoeconomics and Outcome Research's guidelines. The test of validity was made between parts which were comparable to SESQ. Both questionnaires were responded by 30 subjects who were suffering from excess skin after massive weight loss following bariatric surgery or dieting.

Results: The correlation between the two questionnaires varied. The parts of BODY-Q evaluating excess skin on the whole body and parts of the body had higher correlations (r_s 0.328-0.766) than the parts evaluating side effects of excess skin and body-image (r_s 0.103–0.574).

Conclusion: The Swedish version of BODY-Q has a good criterion validity and can be recommended in the healthcare for patients with excess skin after massive weight loss and for evaluation of the outcomes from reconstructive surgical procedures.

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Introduction

Excess skin is a well-known side effect of massive weight loss [1,2]. It affects both younger and older people as well as both genders, and it is commonly located on the abdomen, upper arms, inside of the thighs and on the back [1–3]. There is limited knowledge about which patients who will develop excess skin, but preoperative BMI, ptosis and circumference play important roles in degree of excess skin on the abdomen, breasts, upper arms and thighs after weight loss [4]. Preoperative factors such as BMI, ptosis and circumference explain between 40% and 61%, of the excess skin on these body parts is related to. Furthermore, it has been shown that for every centimetre of ptosis on the abdomen preoperatively, there is a twofold higher probability of having a postoperative ptosis on the abdomen of > 3 cm [4].

It is important to develop and evaluate questionnaires that assess patients' symptoms and experiences i.e. patient reported outcomes (PROs). BODY-Q is a questionnaire that evaluates different functional, and obesity-specific symptoms related to bariatric- and body contouring surgery [5,6]. It has been developed following guidelines for item generation, item reduction and psychometric evaluation [5,6]. BODY-Q has already been translated to several other languages as Danish, Finnish, German, Italian and French [7–11]. However, there is a need for translations into other Swedish as well as other languages to be used in countries performing bariatric surgery, since BODY-Q measure the patients reported negative effects related to post-bariatric excess skin. This perspective, including functional, psychosocial and psychological impairments, must be taken into account when treating obesity, not only the positive effects on metabolism.

There are different scales to assess the degree of excess skin after massive weight loss [1,12] but only a few of them focus on the patients' perspective. The Sahlgrenska Excess Skin Questionnaire (SESQ) was developed in the 2008-2011 and has been used in trials evaluating excess skin among different patient groups as well as in normal population [4,13-15]. SESQ has earlier been tested for reliability [16] and a validity process to test its internal and known group validity is ongoing. Since there has been a lack of similar questionnaires, the validation process has been challenging. However, there are now two different PROMs in the same area, which opens the opportunity for evaluating their validity and comparing them.

The aims of this article were to describe the translation process of a Swedish version of BODY-Q and to evaluate its criterion validity compared to SESQ.

Materials and methods

Questionnaires

BODY-Q is a patient reported outcome instrument to assess appearance, function and symptoms related to bariatric- and

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body contouring surgery. The original version, evaluated in this article [5], contains 18 scales covering different aspects of appearance and function, experience of care and an obesity-specific symptom checklist. For all but one subscale 'Physical symptoms', the raw summed scale score are to be converted into scores from 0 (worst) to 100 (best).

SESQ [16] consists of three different parts, including demographic data, statements about activity and daily life and guestions about experience and discomfort from excess skin on specific body parts. Statements about activity and daily life are rated on a five-grade scale from 'always' to 'never' and the amount of excess skin for each body part is rated on a five-grade scale from 'none' to 'very much'. The degree of discomfort is rated on an 11-grade scale from 'no problems' to 'worst possible problems'. SESQ has been tested concerning reliability and found to have an Intra Class Correlation of 0.72-0.92 [16].

Translation process

Prior to translation, we obtained the necessary agreement from the developers of the questionnaire. The process of the translation of BODY-Q was done according to the International Society for Pharmacoeconomics and Outcome Research (ISPOR) guidelines [17]. Two independent professional translators, both born in Sweden and specialised in medicine or medical terminology, made the forward translation into Swedish. A pooled version, reconciliation, was set together. The goal was to create a translation with clear and simple formulations, understandable for all Swedish speaking patients. Back translation into English was performed by two other professional translators, one born in England and the other born in Australia both specialised in medicine or medical terminology, and another pooled version was set together. The Swedish version was compared with the original English version, and minor adjustments were made. A cognitive debriefing, testing the instrument, was performed on a group of health care professionals to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation. The preliminary version was sent to six researchers with clinical and scientific expertise in the field of bariatric and body contouring surgery. They were asked to give comments on the questions and the interpretation of these. All researchers had Swedish as their mother tongue, and they were fluent in English. A comparison of the researcher's interpretation of the translation

with the original version was thereafter performed as well as proofreading.

Criterion validity

To evaluate the criterion validity, questionnaires from 30 subjects were required for applicable analyses. Subjects with known excess skin after massive weight loss were, therefore, identified from the waiting list after referral to the department of Plastic Surgery for abdominoplasty because of excess skin. A convenience sample of forty-nine were invited by mail and sent the two questionnaires, BODY-Q and SESQ. If there was no response, one reminder was posted. Thirty patients (61%) of them returned the questionnaires. They were an average age of 48.6 years (min 26 and max 67 years), had a current body mass index (BMI) of 33.6 kg/m² (min 22.9 and max 44.3) and maximal BMI of 49.6 kg/m² (min 38.2 and max 81.5). All but one had undergone bariatric surgery, the last one had lost weight through diet. The average time since bariatric surgery was 6.9 years (1-17 years).

Furthermore, to enrich the cognitive debriefing, the patients were asked to write feed-back on the content of the two questionnaires concerning if the instructions, questions, and response options were understandable and relevant.

A validation of the questionnaires was performed between the sub-scales which were comparable in the two questionnaires. Scores in BODY-Q were analysed to experience and discomfort of excess skin on the same body parts in SESQ regarding abdomen, upper arm, back, buttocks, inner thigh, and hips/outer thighs as well as score in total. In addition, body image, sexual function, physical function and physical symptoms were analysed to similar items in SESQ. As the patients included in the validation had not undergone any body-contouring surgery, the subscales, containing questions about scars and experiences of the healthcare, were not included. A flow-chart of the procedure of the trial is presented in Figure 1.

Statistics and ethics

Correlation between BODY-Q (raw scale or score from 0 to 100) and SESQ was analysed with Spearman's correlation coefficient. Correlation was defined as poor (r > 0.20), fair (r = 0.21 - 0.40), moderate (r = 0.41-0.60), good (r = 0.61-0.80) and very good (r = 0.81-1.00) [18].

The translation and validation processes were conducted in accordance with the ethical standards of the World Medical

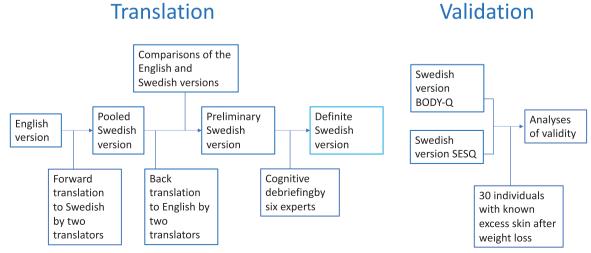


Figure 1. Flow chart of the study.

Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. The participants gave their consent by returning the questionnaire.

Results

Translation

In the translation process, some words needed further discussions before a consensus could be made.

- As there are two Swedish words for 'abdomen' both were used.
- The word 'buttock' was translated to a non-formal but adequate Swedish wording.
- 'Bumpy' and 'crooked scars' were translated to words describing irregularities of height and a bent shape.
- 'Take part in life instead of sitting back' gave rise to discussions about its interpretation to be active instead of passive. In the Swedish version, 'active' was added to make the statement clearer.

Criterion validity

The respondents' results of the both questionnaires are presented in Tables 1 and 2. The patients rated very low scores in BODY-Q concerning appearance of three body parts: abdomen (median 0),

Table 1. Results of BODY-Q in the 30 patients with known excess skin.

Category	Raw sum score	Scale (0–100)
Appearance		
Abdomen (0–21)	7 (7–14)	0 (0-35)
Upper arms (0-21)	11 (5–22)	22 (0-74
Back (0–12)	8 (4–16)	33 (0-100)
Appearance of body (0-30)	14 (10–24)	23 (0-46)
Buttocks (0–15)	11.5 (5–20)	40.5 (0-100)
Hips and outer thighs (0-12)	9.5 (5–20)	30 (0-100)
Inner thighs (0–15)	4.5 (4–12)	4.5 (0-66)
Excess skin (0–21)	8 (6–17)	12 (0-47)
Function		
Psychological (030)	17 (0–30)	50 (0-100)
Social (0–30)	19 (3–30)	57 (22-100)
Sexual (0–15)	50 (0–15)	35 (0-100)
Physical function (0-21)	16.5 (2–21)	68.5 (22-100)
Other		
Body image (0–21)	5 (0-12)	31 (0-54)
Physical symptoms (0–33)	21.5 (0-29)	_

Higher scores indicate better outcome.

inner thighs (median 4.5) and upper arms (median 20). Moreover, ratings concerning excess skin (median 12), sexual function (median 35) and body image (median 31) were also low. Low scores in SESQ were seen concerning abdomen and thighs (median 4 and 3) and unattractive body (median 4).

The correlation analyses revealed that there were good correlations ($r_s>0.6$) between the scores in BODY-Q and SESQ (Table 3), for both assessment of experience of the excess skin and discomfort from it with one exception. The value for excess skin in total was fair for SESQ experience (r_s =0.328). The sexual and physical function had moderate correlation between the questionnaires $(r_s>0.5)$ compared to body image and physical symptoms which had a poor correlation ($r_s < 0.2$).

Six of the patients wrote comments about BODY-Q. Two gave positive response concerning the content, three wrote that some questions were hard to answer as they had not undergone any reconstructive surgery and one commented about it being difficult to answer questions about their sex-life because they were single. Three commented on SESQ where one had no comments, one awaited reconstructive surgery and thought some questions were difficult to answer before surgery and the last one missed some questions about social function.

Discussion

It is of great importance that questionnaires addressing patient reported outcomes are constructed to measure the actual

Table 3. Correlations between the BODY-Q and SESQ.

SESQ		
Experience	Discomfort	
0.328	0.609**	
0.702**	0.766**	
0.702**	0.766**	
0.656**	0.715**	
0.659**	0.664**	
0.709**	0.712**	
0.653**	0.577**	
SESQ, symptoms		
•	•	
0.103		
0.574**		
0.555**		
0.190		
	0.328 0.702** 0.702** 0.702** 0.656** 0.659** 0.709** 0.653** SESQ, sy	

^{**}p<0.01.

Table 2. Results of SESQ in 30 patients with known excess skin after massive weight-loss.

	Experience (0–4)	Degree of discomfort (0–10)
Assessment of excess skin at various body parts		
Excess skin in general (0–10)	1 (0–1)	9 (0–10)
Arms (0–10)	2 (0-4)	7 (0–10)
Breast (0-10)	2.5 (0-4)	7 (0–10)
Abdomen (0–10)	4 (2–4)	9 (7–10)
Back (0–10)	1 (0-4)	4 (0–9)
Buttock (0–10)	1 (0-4)	4 (0-10)
Thighs (0–10)	3 (0-4)	7 (1–1)
Symptoms from excess skin		
Itching and rash (0–4)	3 (0-4)	
Difficulties to run/walk fast (0-4)	3 (0-4)	
Difficulties to find clothes that fit (0-4)	3 (1–4)	
Hinders me in everyday life (0–4)	3 (0–4)	
Hinders me in intimate situations (0-4)	3 (0-4)	
Difficulties with personal hygiene (0–4)	2 (0-4)	
The body is unattractive (0–4)	4 (1–4)	
SESQ, score (0–28)	21 (6–28)	

Median (min-max). Higher scores correspond to higher experience and discomfort of the excess skin.

symptoms associated with the disease in focus. The BODY-Q was developed with that in mind. After extensive work to develop and evaluate this questionnaire, the work to translate it to different languages remains, to make it a universal questionnaire (PROM) for evaluating the problems experienced by post-bariatric patients. BODY-Q has already been translated into several languages [7-11] and now has also been translated in Swedish. The work to translate a questionnaire is comprehensive and we used the guidelines according to ISPOR by Wild et al. [17]. In these guidelines, four different translators, a group of researchers and two groups of patients must be included. In the Danish translation [9], they used a combination of guidelines from ISPOR and the one from the World Health Organization.

When translating questionnaires, there is a challenge to create a version which is understandable, but also adapted to the culture where it is used. In the process used in this translation, we used translators with linguistically knowledge as well as knowledge within the medical field. The expert panel consisted of health care professionals (doctors, nurses, and physical therapists) with long experience of working with patients undergoing bariatric and/or body contouring surgery. The group was determined to cover a broad perspective of the medical care. Thereafter, the patients evaluated the questionnaire by both completing it and by giving their opinion whether the questionnaire was understandable and relevant regarding the instructions, the questions and the response options. Only a few of the participants gave their opinion of the questionnaire and had no constructive suggestions for improvements.

The next step was to test the criterion validity of the questionnaires. As there is no gold standard for assessing function and body image for patients undergoing bariatric or body contouring surgery, we decided to validate the sections which focus on different body parts and excess skin to the parts in SESQ. The two questionnaires have some similarities but are different in focus, structure, and response options. SESQ is shorter and subsequently, less time to answer than BODY-Q. The results from evaluation of the validity indicates that the correlations in questions concerning specific body parts are good, but not for the guestions assessing the body in total. Concerning body image and symptoms, the correlations were moderate in sexual and physical function but poor in body image and physical symptoms. SESQ is not as extensive as BODY-Q. Though, based on the results of our trial, the two questions of experience of excess skin and discomfort from it on different body-parts are comparable to the sets of questions in BODY-Q. Body image and functions are more complex and this may explain the lower level of correlations between the guestionnaires. It seems like the two guestionnaires complement each other. SESQ has limited questions for each body part, which gives an overall knowledge about the patient's experience of the excess skin and discomfort from it. BODY-Q contains several questions for each part of the body which gives a broader and deeper perspective. BODY-Q also includes other perspectives as experiences of scars and healthcare experiences. It is and would, therefore, be use of both questionnaires in parallel and parts of them when appropriate.

There are some limitations of the trial. The Swedish version of BODY-Q is based on the original English version from 2014 [5]. Since then, it has been further developed. Already during the translation process subscales concerning stretch marks, breast area of the chest (for men) and nipples (for men) were fieldtested. Even if the current version of BODY-Q is different to the version which was translated to Swedish, the parts which were translated and validated are the same. The original version of BODY-Q was developed according to Rasch measurement theory and it would have been a strength to have included such an analysis also in the translated version.

It is also a limitation that the patients who participated in the validation were on the waiting list for body contouring surgery. It was, therefore, not relevant to include the questions about scars and healthcare experiences. In future trials, it is of importance to include a larger variety of patients to cover all parts of the questionnaire.

Excess skin is common after massive weight loss. There is a lack of knowledge regarding who develops excess skin and how much it will affect the individual. However, we do know that excess skin is a major problem for many patients after obesity surgery. In previous studies, patients have described that they feel that their body is more deviant after the weight loss as the skin hangs, causing itching and rashes and makes it hard to find clothes that fit [2]. In addition, the skin prevents them from being as active as they want as they are ashamed over the 'new' body [4]. Therefore, it is of great importance to have valid PROM:s to evaluate the patient's situation regarding symptoms related to excess skin to have as a basis for decision regarding financing of post-bariatric plastic surgery. Both BODY-Q and SESQ are suitable in evaluating the patients' experiences of their body and excess skin.

Conclusion

The Swedish version of BODY-Q has a good criterion validity and can be recommended in the healthcare for patients with excess skin after massive weight loss and for evaluation of the outcomes from reconstructive surgical procedures.

Disclosure statement

The authors have no conflict of interest.

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