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SESQ, a patient-reported outcome instrument addressing excess skin; report on the updated version and the validation process

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ABSTRACT

Excess skin after weight loss is perceived as a major problem for the majority of the bariatric patients, between 68 and 90% desire additional reconstructive surgery. However, only about 20% of the patients actually have the possibility to undergo these procedures. Reliable and valid patient-reported outcome instruments, PROM, are required in order to consider the patients' perspective of excess skin when discussing reconstructive surgery. The aim of this study was to present the updated version of Sahlgrenska Excess Skin Questionnaire, SESQ and to report on the validation process. The material for the process to evaluate internal consistency and known group validity was based on four different studies conducted at the Department of Plastic Surgery at Sahlgrenska University Hospital, Sweden. Internal consistency was high in all four groups examined; the normal population, the obese patients, the post-bariatric patients and the post-abdominoplasty patients. Values for Cronbach's alpha were >0.86 in all groups, and the highest value was seen in the obese patients (0.92). Furthermore, regarding known group validity, there were strong significant differences between the answers from the normal population in comparison with most of the other studies. In conclusion, patients thought that the questions in SESQ were easy to understand, that they covered all appropriate aspects of excess skin and the patients did not think that SESQ overlooked any questions or aspects concerning excess skin. SESQ is a valid questionnaire addressing excess skin in post-bariatric patients. The updated version of the SESQ is both accurate and user-friendly.

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Obesity; post-bariatric patients; reconstructive surgery; excess skin; Sahlgrenska Excess Skin Questionnaire; validity

Introduction

In a historical perspective, abdominal lipectomy was first described and performed more than 100 years ago and it was initially used for functional repairs. In 1910, Kelly [1] reported several benefits of abdominoplasty, such as improved wellbeing, reduction of back pain, increased level of physical activity and better personal hygiene. Later, in 1967, Pitanguy began to use abdominoplasty for cosmetic purposes [2]. When the number of bariatric procedures increased in the 1960s and 1970s, post-bariatric procedures also became more common. Today, consistent studies have reported that patients experience that excess skin is most commonly located on the abdomen, upper arms, inner thighs and breasts [3–6] and that excess skin causes problems with fungal infections, eczema and lesions below the abdomen, the breasts or chest and/or in the groins, causing bad odor, itching, perspiration and problems with personal hygiene [3,7].

Excess skin after massive weight loss is perceived as a major problem for the majority of the post-bariatric patients. Various studies report that between 68 and 90% of the patients desired additional reconstructive surgery [5,7–10]. However, only about 11–20% of the patients actually have the possibility to undergo these procedures [6,10]. This lack of coherence needs to be further investigated. For instance, our research group presented that objective measurements of excess skin correlate fairly with the

patients' perceived discomfort from it [11]. This might be a part of this low consistency. Another explanation is that many post-bariatric patients do not meet the criteria for a reconstructive operation, for example they do not have a BMI $< 30 \text{ kg/m}^2$.

It is important to evaluate quality of life (QoL), and reliable and valid patient-reported outcome instruments, PROM, are required in order to consider the patients' perspective of excess skin when discussing reconstructive surgery. Sahlgrenska Excess Skin Questionnaire, SESQ, is a questionnaire which has been developed by our research group and which aims to evaluate excess skin, symptoms and discomfort from the patients' perspective. It has earlier been used in different studies, for example in normal population [12], in a general survey of excess skin in post-bariatric patients [4], before and after bariatric surgery [11], in super obese patients [13], in adolescents undergoing bariatric surgery [14] and to evaluate the results of abdominoplasty [15]. In addition, we have recently published a comprehensive article with our collective experience of SESQ and research on post-bariatric patients' experiences of excess skin [16]. Furthermore, SESQ is previously tested concerning reliability and found to have an Intra Class Correlation of 0.72–0.92 [17].

The aim of this study was to present the updated version of SESQ and to report on the validation process.

Materials and methods

SESQ [17] is developed to address post-bariatric patients' different aspects of excess skin. It consists of three parts:

1. Questions regarding demographic data as well as general information.
2. Assessment of symptoms caused by excess skin. It contains questions regarding the impact of excess skins on activity and daily life and it is assessed by eleven statements. Each statement has been rated from 1 'never' to 5 'all the time'.
3. Combined questions about the experience of excess skin on different body parts. Amount of excess skin is rated on a 5-grade scale from 'no' to 'very much'. Degree of discomfort is rated on an 11-grade scale from 'no problems' to 'worst possible problems'. One summary question regarding the degree of discomfort from excess skin on the whole body was rated on an 11-grade scale from 'no problems' to 'worst possible problems'.

Update of the questionnaire

Following changes have been made to the different parts of the questionnaire:

1. Demographic data
 - a. Age has been replaced by year of birth.
 - b. A question about smoking has been added.
 - c. The questions about sick leave because of excess skin has been removed.
 - d. The question about profession has been removed.
2. Assessment of symptoms
 - a. Three of the statements have been removed or adjusted in the updated version.
 - i. Two items containing evaluation of pain in the upper or lower back were removed, as the patients have reported difficulties in discriminate between pain because of excess skin and other causes.
 - ii. Participate in sports was removed as it was described like the one 'run/walk fast'.
 - b. Quantification of the responses has been adjusted from 1 to 0 regarding the answer 'never' and from 5 to 4 regarding answer 'all the time'.
 - c. A score, SESQ score, has been developed in order to receive a more comprehensive understanding of patients' symptoms:
 - 'My excess skin is causing itching and rash'
 - d. 'My excess skin makes it difficult to run/walk fast'
 - e. 'My excess skin makes it difficult to find clothes that fit'
 - f. 'My excess skin hindrances me in everyday life'
 - g. 'My excess skin hindrances me in intimate situations'
 - h. 'My excess skin makes it difficult with personal hygiene'
 - i. 'My body is unattractive because of my excess skin'

Summarizing the answers from every statement gives a score from 0 to 28, the SESQ score. To be able to correspond the score to values between 0 and 100 (%) the sum is multiplied by 3.57, where a higher score indicates a higher degree of problem.

Questions about the experience and discomfort of excess skin on different body parts.

- a. The last question in the initial version, about assessing excess skin on the body in total, has been moved. This question is now placed earlier in the questionnaire, before patients are asked to assess excess skin on every separate body part.

- b. The questions regarding excess skin on the chin and knees have been removed.

Validation

The material for the process to evaluate internal consistency and known group validity was based on four different studies conducted at the Department of Plastic Surgery at Sahlgrenska University Hospital, Sweden. The studies are briefly presented below. For details, see references.

- Evaluation of excess skin in Swedish adults 18–59 years of age by Ockell et al. [12]. The SESQ was sent to 1408 residents (response rate 37.6%) between 18 and 59 years of age in Västra Götaland County, Sweden. These individuals were randomly selected from the population registry of the Swedish Tax Agency, and the sexes were equally distributed. From now on, this study will be referred to as 'normal population'.
- Understanding excess skin in postbariatric patients: objective measurements and subjective experiences by Björserud et al. [11]. From 2009 to 2012, 200 patients were included and assessed with respect to excess skin before and 18 months after bariatric surgery. Patients were measured according to a standardized protocol and they completed SESQ. From now on, this study will be referred to as 'obese patients' (before bariatric surgery) and 'post bariatric patients' (after bariatric surgery).
- Development of excess skin and request for body-contouring surgery in postbariatric adolescents by Staalesen et al. [14]. Forty-seven of 86 adolescents that had undergone gastric bypass surgery answered SESQ and study-specific questions regarding requests for and performed body-contouring surgery. From now on, this study will be referred to as 'adolescent patients'.
- The effect of abdominoplasty and outcome of rectus fascia plication on health-related QoL in post-bariatric surgery patients by Staalesen et al. [15]. Ninety-four post-bariatric surgery patients answered SESQ and questionnaires regarding health-related QoL before and one year after abdominoplasty. All study participants were assigned randomly to either undergo or not to undergo rectus fascia plication. From now on, this study will be referred to as 'pre abdominoplasty' and 'post abdominoplasty' (one year after abdominoplasty).

Demographics of the patients included in the different studies are presented in Table 1.

Results from the different samples were used for test of internal consistency. Known group comparison was performed with the results from the normal population as comparison group.

Face validity was performed with 30 patients and demographics are presented in Table 1.

Statistics and ethics

Data is presented as mean and standard deviation or median with min and max. For internal consistency, Cronbach's alpha was used. For comparison between groups, the Mantel–Haenszel Chi Square test was used for ordered categorical variables and the Mann–Whitney U-test was used for continuous variables.

The ethical approvals are specified in the separate articles.

Table 1. Demographics of the patients included in the different studies.

	Normal population	Obese patients	Post-bariatric patients	Adolescent patients	Pre- and post-abdomino-plasty patients	Face validity
Patients included (n)	528	200	149	47	94	30
Gender						
Female/male	294/234	143/57	109/40	29/18	80/14	29/1
Age (years)	37.8 (11.9)	44.7 (11.5)	44.6 (11.5)	19.8 (1.9)	43.4 (9.7)	48.6 (8.9)
BMI (kg/m ²)	24.8 (4.2)	44.6 (6.0)	30.8 (5.3)	31.1 (5.3)	26.4 (2.3)	33.6 (5.3)

For continuous variables mean (SD) is presented.

Table 2. Internal consistency; the normal population, the obese patients, the post-bariatric patients and the post-abdominoplasty patients.

	Normal population	Obese patients	Post-bariatric patients	Post-abdomino-plasty patients
Cronbach's alpha	0.87	0.92	0.91	0.89

Table 3. Known group comparison: SESQ score (0–100), experience (0; no – 4; very much) and discomfort (0; no problems – 10; worst possible problems) from excess skin on abdomen, upper arms and thighs.

	Normal population	Obese patients	Post-bariatric patients	Adolescent patients	Pre-abdomino-plasty patients	Post-abdomino-plasty patients
SESQ score	18.4 (21.1) 10.7 (0– 85.7)	37.1 (30.2) 35.7 (0–100)***	40.6 (28.4) 39.3 (0–100)***	51.5 (27.4) 54.2 (0–100)***	61.5 (17.7) 64.3 (17.9– 92.9)***	10.3 (18.4) 0.0 (0–85.7) ***
Experience abdomen	0 (0–4)	2 (0–4)***	2 (0–4)***	2 (0–4)***	3 (1–4)***	0 (0–3)*
Discomfort abdomen	2 (0–10)	6 (0–10)***	6 (0–10)***	7 (0–10)***	8 (4–10)***	2 (0–9)
Experience upper arms	0 (0–2)	1 (0–4)***	2 (0–4)***	2 (0–4)***	2 (0–4)***	2 (0–4)***
Discomfort upper arms	2 (0–9)	3 (0–10)*	3 (0–10)***	7 (0–10)***	5 (0–10)***	4 (0–10)***
Experience thighs	0 (0–4)	1 (0–4)***	2 (0–4)***	2 (0–4)***	2 (0–4)***	2 (0–4)***
Discomfort thighs	3 (0–10)	4 (0–10)***	3 (0–10)***	7 (0–10)***	6 (0–10)***	6 (0–10)***

Data is presented as mean (SD) and/or median (min–max).

*indicates a significant difference compared to normal (comparison) population * $p < 0.05$, *** $p < 0.001$.

Result

Internal consistency was high in all four groups; the normal population, the obese patients, the post-bariatric patients, and the post abdominoplasty patients. Values for Cronbach's alpha were > 0.86 in all groups, and the highest value was seen in the obese patients (0.92) (Table 2).

Known group comparison was used to compare how patients in the different studies reported symptoms caused by excess skin. There are strong significant differences between the answers from the normal population in comparison with most of the other studies. This applies all seven statement about symptoms, as well as the SESQ score. Values for SESQ score are presented in Table 3. However, there are exceptions when comparing normal population and post-abdominoplasty patients. Between these groups there are only significant differences for the statements regarding 'difficulties finding clothes that fit' ($p = 0.0015$), 'hindrances in everyday life' ($p = 0.012$) and 'feeling unattractive' ($p = 0.0014$). Furthermore, there is a significant difference between these groups regarding SESQ score ($p = 0.0003$).

Known group comparison regarding experience of excess skin on the abdomen, upper arms and thighs, and the patients' discomfort from excess skin on these body parts revealed that there are significant differences between the normal population and all of the other patients (Table 3). However, there are one exception, there were no significant difference between normal population and post-abdominoplasty patients experience of discomfort from excess skin on the abdomen.

According to face validity with post-bariatric patients, the SESQ consists of relevant questions. Patients thought that the questions were easy to understand, that they covered all appropriate aspects of excess skin and furthermore, they did not think that SESQ overlooked any questions or aspects concerning excess skin.

Discussion

The SESQ was developed at Sahlgrenska University Hospital during 2009 – 2010. Since then, it has been used in all studies in our research group, from assessing excess skin in normal population to patients with superobesity and after reconstructive surgery [12,13,15]. After several years of use and with so much overall experience of the questionnaire, it was appropriate to update the SESQ and at the same time evaluate the questionnaires validity.

Some minor changes were made regarding the questions concerning demographics; age was replaced by year of birth since it facilitates various calculations. Furthermore, we added a question about smoking habits since smoking is a well-documented cause of complications in patients undergoing reconstructive surgery. Smoking gives an increased risk of both wound infection and wound dehiscence [18] and it is therefore important to have this information when addressing the patients. However, we removed the questions about 'sick leave because of excess skin' and 'profession' since these data have not been shown to be appropriate in our previous studies.

As the questionnaire has been used in diverse and larger contexts, we have queried some of its content. A few of the questions have been found to be irrelevant and others have more often been misunderstood by the patients. Therefore, these questions have been removed or adjusted in this updated version. Patients found it difficult to assess the impact of excess skin on back pain and their answers were therefore not reliable and the question irrelevant. Two of the questions were too similar (difficulties to participate in sport activities vs. difficulties to run/walk fast) and they were therefore merged into one question. Furthermore, to facilitate statistics, the response options were quantified. To further facilitate quantification and comparisons, we developed the SESQ score. A score can provide a merged and comprehensive understanding of the patients' symptoms and a score can

easily be used to evaluate the effect of interventions, such as patients experience of excess skin before and after reconstructive procedures. The score has already been used in a comparison of different patient groups and normal population [16].

One question that was often misunderstood was the summarizing question about the experience and discomfort of excess skin on the body in total. This question was initially in the end of the questionnaire, after the patients had answered questions about excess skin for each specific body part. When patients came to this question many thought this question was strange to answer because they had just answered specifically for each body part. However, it is valuable to receive the patient's overall experience of excess skin and this specific question is therefore relocated and it is now in the start of the questionnaire, before patients are asked to assess excess skin on every separate body part. Furthermore, the questions regarding excess skin on the chin and knees have been removed since patients rarely reported any considerable excess skin or discomfort on these body parts.

Values for Cronbach's alpha were found to be high. That is, the internal consistency and coherence in the SESQ is good. Furthermore, the significant differences in known group comparison indicate that excess skin is a major problem for our 'target' population, the post-bariatric patients, while it is not a very troublesome question for the normal population. However, there are exceptions, as when comparing normal population and post-abdominoplasty patients. Between these groups, there are only significant differences for three of the seven statements. Though these patients have had a reconstructive procedure and they are now, hopefully, not that affected by excess skin anymore.

A recent systematic review recommended the BODY-Q for use in post-bariatric patients [19]. In addition, Baillot et al. [20] summarizes that, in order to improve the current evidence-based knowledge regarding excess skin liable tools are required. An overall conclusion is, regardless of which questionnaires are used, they should be reliable and validity tested [19,21–23]. As previously mentioned, there are several studies that focus on studying QoL in this patient population. The BODY-Q, like SESQ, evaluate patients experience of excess skin after weight loss and/or body contouring [24]. However, BODY-Q covers both QoL and excess skin which makes it a comprehensive and rather time-consuming questionnaire. A previous study in our research group [25], concluded that it seems like the two questionnaires complement each other.

Strength and limitations

Since SESQ has been used in many different studies, we have data from several different patient cohorts and it is obviously a great strength and advantage when we now have tested internal consistency and known group comparison. Another strength is that SESQ is validated to BODY-Q [25]. The two questionnaires have some similarities but are different in focus, structure and response options. The correlation analyses revealed that there were generally good correlations ($r_s > 0.6$) between the scores in BODY-Q and SESQ, for both assessment of experience of the excess skin and discomfort from it.

There are some limitations of the study. There are several aspects of both reliability and validity and in this study, we have not studied for example construct validity, content validity or criterion validity. Thus, the validation process has not been performed in accordance to COSMIN methodology. Furthermore, the questionnaire was not based on inductive approach but clinical experience and clinical questions and it would have been better

to research it from the start with validity and reliability testing during the introduction.

But, finally, not only the statistical analysis indicates that SESQ is a valid questionnaire, the patients' also support its clinical and significant relevance.

Conclusion

SESQ has a high face validity and high validity regarding internal consistency and known group comparison as a questionnaire addressing excess skin in post-bariatric patients. The updated version of the SESQ is both accurate and user-friendly.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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