Usefulness of the Skindex-29 Questionnaire for Quality of Life Assessment in Patients with Lower-Limb Ulcers of Vascular Aetiology

Przydatność kwestionariusza Skindex-29 do oceny jakości życia chorych z owrzodzeniem kończyny dolnej o etiologii naczyniowej

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Summary

Aim of the study: The aim of the study was to verify the psychometric characteristics and usefulness of the Skindex-29 instrument for quality of life assessment in patients with lower-limb ulcers of vascular.

Material and methods: Consecutive patients who referred to the Venous Ulceration Outpatient Clinic and the Department and Clinic of General Surgery were enrolled. The inclusion criterion of the study was the presence of a lower limb ulcer. Patients with ulcers of venous (n = 101), arterial (n = 98), or arteriovenous aetiology (n = 99) were enrolled. The reliability of the Skindex-29 in the group of patients with lower limb ulcers was evaluated based on its internal consistency, determined by Cronbach’s α index values and using the split-half method. Diagnostic accuracy of the scale was assessed on the basis of the correlation between its results and the values of an external standard measuring the same or similar parameters (correlation between the results of the Skindex-29 and the Acceptance of Illness Scale).

Results: The reliability of the Skindex-29, expressed by Cronbach’s α index, amounted to 0.94 for the global score, 0.93 for the physical symptoms subscale, and 0.94 for both emotions and psychosocial functioning subscales. The diagnostic accuracy of Skindex-29 was verified based on the correlation between its scores and the results of AIS. The correlation proved significant (r = –0.47, t = –9.21552, p < 0.05).

Conclusions: Skindex-29, the instrument for quality of life assessment in individuals with dermatological disorders, was characterised by good psychometric parameters in the sample of patients with lower-limb ulcers.

Key words: lower limb ulceration, quality of life, Skindex-29, psychometric parameters.
Introduction

Lower-limb ulcers affect approximately 0.3-3.5% of adult patients from highly-industrialised countries [1, 2]. It is estimated that 95% of the wounds are of vascular origin, including as many as 70-85% of venous origin. According to the literature, the number of causes of lower limb ulcers ranges from 40 to about 100 [2, 3]. Venous disorders, complications of diabetes, and peripheral atherosclerosis are the most common aetiological factors of ulcers in the United States and European countries. Active or healed venous ulcers exist in more than 3% of the Polish population [1]. The exact epidemiological data on the prevalence of the ulcers of ischaemic or other origin are lacking. The number of patients with ulcers is known to increase with age, similarly to the number of comorbidities involved in the complex aetiology of this condition.

Irrespective of their aetiology, the presence of skin lesions is a common feature of all lower-limb ulcers. Venous ulcers are nearly always accompanied by local disorders typical for advanced stages of venous insufficiency. These include brownish discoloration, so-called haemosiderosis of the skin, and lipodermatosclerosis [4]. The skin around the ulceration can be thinned, inflamed, or macerated by the wound exudate. The exudate is usually intense, especially if accompanied by swelling, and has an unpleasant, difficult to eliminate smell. Susceptibility of the skin to allergic reactions and contact eczema is a problem in many patients [5]. Sometimes areas of vascular atrophy, so-called white atrophy, are observed in the skin.

In the atherosclerosis of lower limbs and so-called limb ischaemia, the skin shows typical signs of ischaemia; it is dry, thin, and shiny, and often lacks the adnexa and hair. Distal parts of the ischaemic limb are pale and cold. The nails become thicker due to decreased perfusion and slow growth. Also, muscles and subcutaneous tissue can be involved with the atrophy. Skin and more deeply located tissues are susceptible to injury and secondary infection. Even a small injury can be a starting point of a severe, non-healing wound [2, 6]. Most patients with ischaemic ulcers experience pain associated with the primary condition, present constantly or during activity, including nursing and medical procedures. In turn, the venous and arteriovenous ulcers combined pathology associated with chronic venous insufficiency with that of the arteriosclerosis of lower limbs [4, 6].

Chronic dermatological disorders, including trophic and ulcerative lesions of the lower limbs, can modulate the mood of the patients, their functional capacity, ability to work, and social activity [7, 8]. The quality of life in patients with lower-limb ulcers was revealed to be significantly worse than in the general population [9]. Evaluation of the influence of skin lesions on the quality of life of ulcer patients requires a reliable measurement tool. We used the Skindex-29 questionnaire for this purpose because it contains statements corresponding to lesions associated with lower-limb ulcers.

The aim of the study was to verify the psychometric characteristics and usefulness of the Skindex-29 instrument for the quality of life assessment in patients with lower-limb ulcers of vascular aetiology, i.e. venous, arterial, or arteriovenous. The results presented in this paper constitute part of a larger project, whose other parts were published elsewhere [10-12].

The protocol of the study was approved by the Local Bioethical Committee of the L. Rydygier Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Toruń. Permission was obtained from the author of the Polish version of Skindex-29, K. Janowski, to use the instrument in this study. All the participants gave their informed, voluntary consent to participate in the project.

Material and methods

Characteristics of the Skindex-29 questionnaire

Skindex-29 is an instrument intended for the assessment of the quality of life in individuals with dermatological disorders. The first version of the instrument was developed in 1996 in the United States by M. Chren, R. Lasek, et al. (1996) [13]. It included 61 items grouped into eight subscales corresponding to various dimensions of the quality of life. The new, revised version of the Skindex (1997) comprises 29 statements (items) reflecting the effect a disease exerts on the quality of life. The items are grouped into three subscales, which describe [13,14]:

- Physical symptoms – seven items (hurting, burning or stinging, itching, bothering by water [bathing]), irritation, sensitivity, and bleeding of the skin),
- Emotions – 10 items (worrying that the condition may be serious, feeling depressed, worrying about getting scars, feeling ashamed, worrying that the condition may get worse, being angry, being embarrassed, being frustrated, being humiliated, and being annoyed by the condition);
- Psychosocial functioning, including everyday activities, role functioning, and social contacts – 12 items (quality of sleep, work and hobbies, social life, tendency to stay at home, being close with others, tendency to do things alone, showing affection, interaction with others, being a problem for loved ones, desire to be with people, interference with sex life, and being tired).

The Polish adaptation of Skindex-29 was developed by K. Janowski in 1999, with the approval of the authors of the original instrument [15]. The answers to the Polish version of Skindex-29 are scored analogically as in the American version of the instrument. The re-
spondents choose an answer corresponding to the frequency (never, rarely, sometimes, frequently, all the time) with which they have experienced any of the problems during the last month. The answers are scored between 1 and 5 points, respectively. The points are summed and the quality of life score is obtained, ranging between 29 points (highest quality of life – the lack of negative effects of the condition) and 145 points (the worst quality – maximum negative influence of the condition).

Characteristics of the Acceptance of Illness Scale (AIS) as an external standard used to verify the diagnostic accuracy of the Skindex-29 questionnaire

The Acceptance of Illness Scale (AIS), developed by Felton et al. (New York, 1984), is used to determine the degree of a disease acceptance. The version adapted to Polish conditions (Z. Juczyński, 2001) is characterised by high reliability and accuracy [16]. The AIS scale is intended for the examination of adult patients, currently affected, irrespective of the condition. The scale consists of eight statements referring to the negative consequences of poor health. They include four aspects associated with the disease: limitations imposed by the condition, lack of self-sufficiency, feeling of being dependent on other people, and lowered self-esteem. The respondents score each statement using a five-item scale: from 1 (definite agreement) to 5 (definite disagreement). The sum of points reflects the overall level of the acceptance of illness. The global score can range between 8 and 40 points. Low scores correspond to the lack of illness acceptance, poor adjustment, and the strong feeling of discomfort. High scores reflect a definite lack of agreement with the statements of the scale, and corresponds to the acceptance of a disease, better adjustment, and lower level of psychological discomfort [16, 17]. Similarly to the quality of life assessment with Skindex-29, the examination of illness acceptance refers to patients’ experiences from the last month.

| Table 1. Clinical and sociodemographic characteristics of the study participants |
|------------------------------|-----------------|-----------------|-----------------|-----------------|
| Analysed parameters          | Venous ulcers   | Arterial ulcers | Arteriovenous ulcers | p-value (level of significance) |
|------------------------------| (n = 101)       | (n = 98)        | (n = 99)          |
| Age (years)                  | 66.2 (±11.3)    | 65.7 (±9.8)     | 67.8 (±10.2)     | 0.659 |
| Gender                       |                 |                 |                 |
| Women (n)                    | 69 (68.3%)      | 34 (34.7%)*     | 69 (69.7%)       | 0.000 |
| Men (n)                      | 32 (31.7%)      | 64 (65.3%)*     | 30 (30.3%)       |       |
| Marital status               |                 |                 |                 |
| Maiden/bachelor (n)          | 12 (11.9%)      | 18 (18.4%)      | 8 (8.1%)         | 0.431 |
| Married /common law (n)      | 64 (63.4%)      | 63 (64.3%)      | 61 (61.6%)       |       |
| Widowed (n)                  | 25 (24.8%)      | 17 (17.3%)      | 30 (30.3%)       |       |
| Place of residence           |                 |                 |                 |
| Countryside (n)              | 20 (19.8%)      | 22 (22.4%)      | 19 (19.2%)       | 0.089 |
| Town to 30,000 (n)           | 8 (7.9%)        | 19 (19.4%)      | 11 (11.1%)       |       |
| Town 30,000-100,000 (n)      | 8 (7.9%)        | 21 (21.4%)      | 13 (13.1%)       |       |
| City >100,000 (n)            | 65 (64.4%)      | 36 (36.7%)      | 56 (56.6%)       |       |
| Educational level            |                 |                 |                 |
| Primary (n)                  | 18 (17.8%)      | 35 (35.7%)      | 24 (24.2%)       | 0.344 |
| Vocational (n)               | 48 (47.5%)      | 32 (32.7%)      | 50 (50.5%)       |       |
| Secondary (n)                | 32 (31.7%)      | 22 (22.4%)      | 20 (20.2%)       |       |
| Higher (n)                   | 3 (3.0%)        | 9 (9.2%)        | 5 (5.1%)         |       |
| Professional activity        |                 |                 |                 |
| Professionally active (n)    | 11 (10.9%)      | 4 (4.1%)        | 4 (4.0%)         | 0.553 |
| Professionally inactive (n)  | 90 (89.1%)      | 94 (95.9%)      | 95 (96.0%)       |       |
| Characteristics of the ulcer |                 |                 |                 |
| Ankle-brachial index         | 1.15 (±0.80)*   | 0.59 (±0.15)    | 0.74 (±0.08)     | 0.032 |
| Wound surface (cm²)          | 7.0 (2.5-15.75) | 6.5 (3.0-12.5)  | 5.5 (2.25-12.5)  | 0.666 |
| Duration (months)            | 36 (8-96)       | 18 (7-60)       | 36 (11-120)      | 0.716 |

*mean value, *significant differences between groups
The selection of AIS as the external standard resulted from the documented relationship between the level of quality of life and the degree of adjustment and acceptance of a disease [9, 16, 17].

Qualification criteria

Psychometric analysis of the instrument was conducted in the group of patients with lower-limb ulcers of vascular aetiology. Consecutive patients who referred to the Venous Ulceration Outpatient Clinic and the Department and Clinic of General Surgery, Dr. J. Biziel Memorial University Hospital No. 2 in Bydgoszcz were enrolled.

The inclusion criterion of the study was the presence of a lower-limb ulcer, defined as discontinuity of the skin associated with loss of tissue. Patients with ulcers of venous (n = 101), arterial (n = 98), or arteriovenous aetiology (n = 99) were enrolled. The patients were qualified to the study on the basis of an established diagnosis of chronic venous insufficiency (CVI, venous aetiology) and/or lower limb atherosclerosis (LLA, arterial aetiology), and relevant values of the ankle-brachial index. Overall, 298 patients were enrolled.

The exclusion criteria included ulcers with non-arterial, non-venous, or non-arteriovenous aetiology, ulcers of unknown aetiology, chronic comorbidities other than CVI and LLA, and incomplete medical documentation.

Clinical and sociodemographic characteristics of patients included in the statistical analysis are presented in Table 1.

Statistical analysis

The reliability of Skindex-29 in the group of patients with lower-limb ulcers was evaluated on the basis of its internal consistency, determined by Cronbach’s alpha index values and using the split-half method. Diagnostic accuracy of the scale was assessed based on the correlation between its results and the values of an external standard measuring the same or similar parameters (correlation between the results of Skindex-29 and the Acceptance of Illness Scale).

The calculations were carried out with the Statistica 7 package (StatSoft®).

Results

The reliability of Skindex-29, expressed by Cronbach’s alpha index, amounted to 0.94 for the global score, 0.93 for the physical symptoms subscale, and 0.94 for both emotions and psychosocial functioning subscales. Correlations between the scores of various items of the scale and its global score are presented in Table 2. The scores of nearly all items were consistent with the global score, showing moderate or strong correlation, i.e. between 0.43 and 0.77. Two items (16 and 28) showed lower correlation with the global score: 0.21 in the case of item 16 (included in the physical symptom subscale and referring to bothering the skin by water [bathing]) and 0.24 in the case of item 28 (included in the psychosocial functioning subscale and referring to the interference with sex life). However, after excluding these two items, the value of Cronbach’s alpha index did not differ considerably from the baseline level.

The split-half reliability of the whole scale was 0.92. The results of analysis with the split-half method are presented in Table 3.

The diagnostic accuracy of Skindex-29 was verified on the basis of the correlation between its scores and the results of AIS. The correlation proved significant (r = –0.47, t = –9.21552, p < 0.05).

Discussion

The quality of life of patients with lower limb ulcers has been the subject of many studies [2, 8, 9, 18]. They involved generic instruments, such as the Nottingham Health Profile (NHP) or Short-Form Health Survey (SF-36). Both of them are characterised by high reliability and diagnostic accuracy in the examination of adult patients. They represent the measures that are most commonly determined in health-related research [19].

Additionally, many instruments adjusted to the primary condition, most commonly chronic venous insufficiency (e.g. Hyland questionnaire, Quality of Life Questionnaire in Chronic Lower Limb Venous Insufficiency – CIVIQ, or Tübinger Questionnaire for measuring Quality of Life in patients with CVI – TLQ-CVI) were used for the specific examination of patients with lower limb wounds. Searching available literature, we did not find any specific instruments for the quality of life assessment in patients with ulcers of various aetiology. The quality of life of patients with venous, arterial, and mixed, i.e. arteriovenous, ulcers has not yet been confirmed. The modified Skindex-29 questionnaire for the quality of life assessment in dermatological conditions (Venous Leg Ulcer Quality of Life Questionnaire, VLU-QoL) was used in one study [20, 21]. However, this instrument was adjusted solely for the determination of the quality of life in patients with venous ulcers, which precludes its use in the comparative analysis of patients with ulcers of various etiology.

Validation of the Polish version of Skindex-29 was carried out in 1999 to use this instrument for the psychological examination of individuals with dermatological disorders and diseases of the skin. The questionnaire was used for the quality of life assessment of patients with psoriasis and common acne, among others [15, 22, 23].
Irrespective of their aetiology, lower limb ulcers are associated with trophic changes of the skin and subcutaneous tissue. They are accompanied by typical local signs and disorders, such as itching, maceration or peeling of the skin, and swelling. The ulcer is defined as discontinuity and loss of the skin. In our previous studies we revealed that factors impairing the everyday functioning and comfort of patients with ulcers are similar to those observed in the course of dermatological conditions [24, 25]. These findings constituted an argument for using Skindex-29 in the group of patients with lower limb ulcers. We used this instrument in our previous studies, e.g. in the comparative analysis of the quality of life in patients in whom chronic venous
insufficiency was associated with trophic disorders of the skin (without a wound) and in those with ulcers [26,27]. In this study we verified the psychometric characteristics of the instrument in the group of patients with lower-limb ulcers, not only those associated with chronic venous insufficiency and pro-thrombotic state, but also those resulting from arterial or arteriovenous conditions (arteriovenous ulcers).

The reliability of Skindex-29 was based on its internal consistency, determined on the basis of the Cronbach’s alpha index values and the split-half reliability index. The values of both the indices can range between 0.00 and 1.00. The closer to 1.00 is the value of the index, the higher is the internal consistency of the instrument and guaranteed precision of the results [17]. The values of Cronbach’s alpha (\( \alpha = 0.94 \)) and split-half reliability indices (\( r_{tt} = 0.92 \)), documented in our sample of patients with lower limb ulcers, were high. This pointed to high internal consistency and reliability of the method. The values of Cronbach’s alpha index for various subscales amounted to \( \alpha = 0.94 \) for both psychosocial functioning and emotions subscales, and \( \alpha = 0.92 \) for physical symptoms subscale. These values are comparable with those of the original American version of the instrument (\( \alpha = 0.96, \alpha = 0.94, \) and \( \alpha = 0.87, \) respectively) as well as with those characterising the Polish version tested in patients with psoriasis (\( \alpha = 0.96 \)) [15, 22]. According to the literature, only instruments showing certain psychometric characteristics are acceptable for the quality of life assessment. Reliability, characterised by Cronbach’s alpha index, should reach at least 0.65-0.85. The values documented in our study were higher and thus confirmed good psychometric characteristics of the instrument. Only two items of the scale were characterised by a weak correlation with its global score; however, it did not markedly affect the overall reliability of the scale.

We determined the diagnostic accuracy of Skindex-29 on the basis of the correlation between the values of this scale and those of an external standard, the Acceptance of Illness Scale (AIS). According to literature, the acceptance of illness is a good predictor of health-related quality of life, and it corresponds to satisfaction with life and self-assessment of current health status [16, 17]. Based on our findings we conclude that Skindex-29 can be used for the quality of life assessment in patients with lower-limb ulcers of venous aetiology. We postulate the following interpretation criteria for this group of patients: 29-58 points (25% of the global score) as corresponding to a high level of quality of life, 59-87 (26-50% of the global score) as corresponding to a moderate level of quality of life, and more than 87 points (more than 50% of the global score) as corresponding to a low level of quality of life. Similar criteria should be used for the interpretation of various components of the questionnaire, the physical symptoms, emotions, and psychosocial functioning subscales.

### Table 3. Split-half reliability of the Skindex-29 questionnaire

<table>
<thead>
<tr>
<th>Item</th>
<th>1st half</th>
<th>2nd half</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of items</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Mean</td>
<td>46.48993</td>
<td>38.32886</td>
</tr>
<tr>
<td>Sum</td>
<td>13854.00</td>
<td>11422.00</td>
</tr>
<tr>
<td>SD</td>
<td>9.912151</td>
<td>9.501333</td>
</tr>
<tr>
<td>Variance</td>
<td>98.25074</td>
<td>90.27533</td>
</tr>
<tr>
<td>Alpha</td>
<td>0.8941485</td>
<td>0.8994363</td>
</tr>
</tbody>
</table>

Cronbach’s alpha, complete scale: 0.94328, standardised alpha: (Spreadsheet 1)
Correlation between the 1st and 2nd half: 0.851308, corrected for attenuation: 0.949285
Split-half reliability: 0.919683, Guttman split-half coefficient: 0.919238

### Conclusions

Skindex-29, the instrument for the quality of life assessment in individuals with dermatological disorders, was characterised by good psychometric parameters in the sample of patients with lower-limb ulcers. Therefore, this instrument can be used to assess the quality of life in patients with lower-limb ulcers of vascular, venous, arterial, or arteriovenous aetiology.

The authors declare no conflict of interest.

### References


