Original article

# Indices of the Scleroderma Assessment Questionnaire (SAQ) can be used to demonstrate change in patients with systemic sclerosis over time

Predrag Ostojic*, Nemanja Damjanov

*Clinical Rheumatology III, Institute of Rheumatology, School of Medicine, University of Belgrade, Serbia*

## Abstract

*Objective*: This study aims to estimate the value of the Scleroderma Assessment Questionnaire (SAQ) to demonstrate change in patients (pts) with systemic sclerosis (SSc) over time.

*Methods*: Sixty pts with SSc were evaluated at two occasions, 12 months apart. Pts were divided into three subgroups according to criteria of improved, unchanged or deteriorated status of vascular, respiratory, gastrointestinal and musculosceletal system. All pts filled in the SAQ as part of both evaluations, and the Index of Vascular Status (IVS), Index of Respiratory Status (IRS), Index of Gastrointestinal status (IGS) and Index of Musculoskeletal Status (IMSS) were calculated. Average index scores for particular organ system at the beginning and after the follow-up period in all subgroups of pts were compared.

*Results*: The mean value of IVS decreased significantly in pts with objectively improved vascular status (1.91 vs. 1.29, $p = 0.01$), but increased in pts with deteriorated status (1.54 vs. 2.13, $p = 0.003$). In the subgroup of pts with unchanged vascular morphology or function, the IVS did not change significantly either (1.84 vs. 1.77, $p = 0.36$). The mean value of IRS decreased significantly in pts with objectively improved lung function (1.08 vs. 0.62, $p = 0.027$), and increased in pts with deteriorated function (0.69 vs. 1.12, $p = 0.012$). In the subgroup of pts with unchanged pulmonary function, the IRS did not change significantly (0.13 vs. 0.14, $p = 0.18$). A statistically significant decrease in mean IGS value was found in pts who were treated with prokinetics (1.20 vs. 0.70, $p < 0.001$). In pts who were not treated with prokinetics, an increase of IGS was observed (0.58 vs. 0.76, $p = 0.002$). Differences between mean values of the IMSS were statistically significant in subgroups of pts with improved (1.28 vs. 0.90, $p = 0.004$) or deteriorated musculoskeletal status (0.98 vs. 1.44, $p = 0.012$), but not in pts with unchanged condition of this organ system (0.72 vs. 0.68, $p = 0.498$).

*Conclusion*: The SAQ is a sensitive measurement to demonstrate change in patients with SSc over time.

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*Keywords:* Systemic sclerosis; Questionnaire; Functional ability; Disease status

## 1. Introduction

Systemic sclerosis (SSc) is a clinically heterogeneous generalized disorder which affects the connective tissue of the skin and internal organs such as gastrointestinal tract, lungs, heart and kidneys. It is characterized by alterations of the microvasculature, disturbances of the immune system and by massive deposition of collagen.

SSc is a chronic disease with usually slow progression of damage. In many patients it is almost impossible to differentiate exacerbation and remission of the disease, since inflammation is very mild and laboratory parameters, like C-reactive protein or erythrocyte sedimentation rate, are usually normal. For these reasons, it is very difficult to follow disease activity and functional ability in patients with SSc. However, criteria of disease activity in SSc have been recently defined by Valentini and coworkers, and the value of the test has been assessed in a multicenter study [1]. On the other hand, a severity scale

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* Corresponding author. Institute of Rheumatology, Clinical Rheumatology III, School of Medicine, University of Belgrade, Resavska 69, 11000 Belgrade, Serbia.

*E-mail address:* ostojic@net.yu (P. Ostojic).

for individual organ involvement, based on objective signs of damage, has been developed and tested by Medsger et al. [2]. Some questionnaires, which are developed to assess disease severity and functional ability in SSc, based on patient's subjective complaints, are also published. The Health Assessment Questionnaire Disability Index (HAQ-DI), at first created for patients with rheumatoid arthritis, correlates with some parameters of functional ability also in patients with SSc, but not with objective signs of lung, heart or kidney involvement [3,4]. Steen and Medsger added special-generated Visual Analogue Scales (VAS) to the HAQ, in order to evaluate specific organ symptoms, like Raynaud's phenomenon, gastrointestinal and lung involvement, pain, and overall disease severity [5]. This questionnaire is known as the Scleroderma Health Assessment Questionnaire (SHAQ). Rouf and coworkers [6] developed and tested the Systemic Sclerosis Questionnaire (SySQ), whereas Silman et al. [7] published the Scleroderma Functional Assessment Questionnaire (SFAQ). The SHAQ draws most attention, and a French version of the questionnaire is already validated [8]. But until now none of these questionnaires is widely in use. We have recently published a new questionnaire for SSc patients, the Scleroderma Assessment Questionnaire (SAQ). In a previous article [9], we have assessed face validity, reproducibility and content validity of the test. This study aims to estimate the value of the SAQ to demonstrate change in patients with SSc over time.

## 2. Methods

Development of the SAQ, item generation and selection, structure and contents of the questionnaire, are systematically described in our previous paper [9]. Briefly, the SAQ consists of 23 questions divided into four subgroups: four items related to vascular dysfunction, six items to respiratory, five items to gastrointestinal and eight items to musculoskeletal dysfunction. Some items are derived from the SySQ questionnaire, with permission of authors. An English translation of the original Serbian language questionnaire, which is validated in this study, is shown in Table 1. There is a multiple choice of four answers to each question. As in HAQ, the answers are assessed on a 0–3 scale: answers referring to the intensity of symptoms (no = 0, some = 1, moderate = 2, very intensive = 3), answers referring to the frequency of symptoms (never = 0, sometimes = 1, frequently = 2, always = 3) and answers referring to the ability to perform activities (without difficulty = 0, with some difficulty = 1, with much difficulty = 2, not able to do = 3). The *Index of Vascular Status* (IVS), *Index of Respiratory Status* (IRS), *Index of Gastrointestinal status* (IGS) and *Index of Musculoskeletal Status* (IMSS) are calculated, dividing the total score for particular group by number of questions for that group. The range of all indices is from 0 to 3. A higher index value indicates more severe damage of particular organ system.

Sixty consecutive SSc patients were included in this study. The characteristics of patients are shown in Table 2. At the start and after 12 months, established indicators of vascular, respiratory, gastrointestinal and musculoskeletal damage were assessed as follows: capillaroscopic findings, presence

Table 1
Structure and the contents of the Scleroderma Assessment Questionnaire (SAQ)

| Subgroup of questions | Questions (English version) | Answering category |
|---|---|---|
| Vascular dysfunction | Do you feel pain in fingers when they are exposed to a cold environment? | B |
| | Do your fingers change colour (turn white or blue) when they are exposed to a cold environment? | A |
| | Do you feel pain in chest when the weather is cold?? | A |
| | **Do you feel pain in your fingers when touching or holding objects** | A |
| Respiratory dysfunction | Do you feel you are short of breath while climbing twenty stairs? | A |
| | **Do you feel you are short of breath when walking on the flat ground?** | A |
| | **Do you feel you are short of breath when dressing?** | A |
| | Do you feel you are short of breath when sitting? | A |
| | **Do you cough?** | B |
| | **Do you cough up phlegm?** | B |
| Gastrointestinal dysfunction | Does a bite of a firm food (for example bread) lag behind your breastbone when you swallow? | B |
| | Does a sip of liquid (for example water or tea) lag behind your breastbone when you swallow? | B |
| | **Do you have heartburn?**? | B |
| | **Do you feel pain when swallowing?** | A |
| | Do you have constipation or diarrhea | B |
| Musculoskeletal dysfunction | Do you drop objects frequently when holding them (for example a bar of soap, a glass or a pack of cigarettes)? | B |
| | Are you able to open your mouth wide enough to bite an apple? | C |
| | Are you able to hold a pen and write? | C |
| | Are you able to do and undo your shirt buttons? | C |
| | Are you able to hold a knife and cut bread? | C |
| | Are you able to get out of bed without someone's help? | C |
| | Are you able to dry your entire body with a towel? | C |
| | Are you able to make your bed? | C |

Bold items are derived from the SySQ with permission of authors. All items are scored from 0 to 3.
Answering categories: A. intensity of symptoms (no = 0, some = 1, moderate = 2, very intensive = 3), B. frequency of symptoms (never = 0, sometimes = 1, frequently = 2, always = 3), C. ability to perform activities (without difficulty = 0, with some difficulty = 1, with much difficulty = 2, no able to do = 3).

of finger-tip ulcers, finger-tip osteolysis (estimated by hand radiography), interstitial lung fibrosis (estimated by chest radiography), forced vital capacity (FVC), carbon-monoxide diffusing capacity (DLCO), modified Rodnan skin score, finger-to-palm distance (distance between the tip of the third finger and the distal palmar crease), muscle weakness and arthritis (estimated by physical examination). At this two