

# Results of the Health Assessment Questionnaire for Japanese patients with systemic sclerosis - measuring functional impairment in systemic sclerosis versus other connective tissue diseases

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## Abstract

### Objective

*To evaluate the physical functional impairment in patients with systemic sclerosis (SSc) using the Health Assessment Questionnaire (HAQ) and to estimate the correlation of HAQ scores with the severity of SSc.*

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### Method

*One hundred and twenty-four outpatients with connective tissue disease, including 50 patients with SSc, were evaluated using the HAQ. Twelve patients were classified as having diffuse cutaneous SSc (dSSc) and 38 limited cutaneous SSc (lSSc). The severity classification and the guidelines for treatment (2004) were applied to Japanese SSc patients in order to evaluate the relationship between HAQ scores and disease activity in patients with multiple organ involvement.*

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### Results

*In dSSc the HAQ category scores for eating, walking, grip, activity and the HAQ-disability index (HAQ-DI) showed the greatest deficits in all disease groups. The severity of disease activity correlated significantly with the scores for walking, reach, and the HAQ-DI. The severity of joint, heart, and pulmonary hypertension were correlated independently with the HAQ-DI score by multiple linear regression analysis.*

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### Conclusion

*Patients with dSSc suffer greater functional impairment than patients with other connective tissue diseases, and improvements in hand use and walking represent very important targets for both drug development and rehabilitation. As improvement in organ involvement (joints, heart as well as pulmonary hypertension) can lead to reduced functional impairment, they constitute an important target for therapy in SSc.*

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### Key words

Connective tissue disease, Health Assessment Questionnaire, functional impairment, systemic sclerosis.

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## Introduction

Systemic sclerosis (SSc) is characterized by thickening of the skin, fibrotic changes in the joints, muscles, and visceral organs, abnormalities in the microcirculation, and autoimmunity. There are two subsets of SSc based on the degree of skin thickening – limited cutaneous SSc (lSSc) and diffuse cutaneous SSc (dSSc) – and the SSc subset is closely correlated with the prognosis (1). The clinical course and the severity of organ involvement can vary widely in patients with SSc. In Europe and the United States, a scoring system to assess disease severity for each organ system in SSc has been published (2). In Japan, the classification of severity and the guideline for treatment of patients with SSc has recently been developed with support from the Ministry of Health and Welfare of Japan (3).

Self-administered questionnaires are a practical and valid method for objectively measuring the health status in some connective tissue diseases (4). The Arthritis Impact Measurement Scales (AIMS) (5), the Health Assessment Questionnaire (HAQ) (6), the Functional Status Questionnaire SF36 (7), and others are commonly used. The HAQ is a well-known self-administered questionnaire, which is unaffected by most social, mental, or environmental aspects, that can be used to evaluate physical functional impairment in patients with chronic diseases (6).

The purpose of this study was to determine the physical functional impairment in patients with SSc and other connective tissue diseases using the HAQ and to estimate the correlation of the HAQ with the disease severity of each organ system in SSc.

## Materials and methods

### Selection of patients

This study included 124 outpatients with one of the following connective tissue diseases: systemic lupus erythematosus (SLE) (n = 40), dermatomyositis (DM) (n = 14), Sjögren syndrome (SjS) (n = 14), rheumatoid arthritis (RA) (n = 6), or SSc (n = 50) classified as dSSc (n = 12) and lSSc (n = 38). Patients were examined at the Department of Dermatology, Nagoya University School of

Medicine. There were 114 females and 10 males in total; their age ranged from 22 to 82 years, with a mean of  $55 \pm 14$  years (Table I). The healthy controls (n = 25) were matched for age (mean age;  $62 \pm 10$  years) and sex (23 females and 2 males) to the patients with SSc. Written informed consent was obtained from each subject, and this study was approved by the local Ethics Committee.

### Procedure

The standard disability index of the HAQ (HAQ-DI) (6) is a self-administered questionnaire that contains 20 components (each scored 0-3), classified into eight categories of daily activity: dressing, rising, eating, walking, hygiene, reach, grip, and activity. The highest scores from each category are summed and then divided by 8 to determine the HAQ-DI. This score is calculated as a continuous variable that ranges from 0 (no disability) to 3 (severe disability).

The HAQ was modified to match the Japanese life-style by the research project for systemic sclerosis supported by the Ministry of Health and Welfare of Japan. For example, one of the original questions in the eating component was: 'Are you able to cut your meat?' The question was revised to: 'Are you able to eat with chopsticks?' (8).

We examined the organ involvement in patients with SSc according to the Japanese classification of severity and the guideline for treatment (2004) (3). This guideline identifies eight organ systems and the variables for each that are used to define severity. These systems are: general condition, vasculature, skin, joint, upper and lower digestive tract, lung (interstitial pneumonia, pulmonary hypertension), heart, and kidney. We scored the performance of each system on a scale of 0-4, where 0 = normal, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe.

The severity of the general condition was based on the percentage of body weight loss. The severity of vasculature dysfunction was determined by the presence of Raynaud's phenomenon, digital pitting ulcers, other skin ulcerations or digital gangrene. As the severity of skin sclerosis was based on

Competing interests: none declared.

**Table I.** Patient profiles.

Disease	Number	Sex	Age yrs.	mean $\pm$ standard deviation
		male : female		
SSc*	50	4 : 46	39 - 82	62 $\pm$ 10
ISSc	38	2 : 36	39 - 82	63 $\pm$ 10
dSSc	12	2 : 10	42 - 74	59 $\pm$ 10
SLE	40	2 : 38	24 - 75	47 $\pm$ 14
DM	14	4 : 10	22 - 73	53 $\pm$ 15
SjS	14	0 : 14	31 - 70	52 $\pm$ 13
RA	6	0 : 6	54 - 78	64 $\pm$ 10
Healthy controls	25	2 : 23	46 - 84	62 $\pm$ 10

\*Total data on limited and diffuse SSc patients.

SSc: systemic sclerosis; ISSc: limited cutaneous SSc; dSSc: diffuse cutaneous SSc; RA: rheumatoid arthritis; SLE: systemic lupus erythematosus; DM: dermatomyositis; SjS: Sjögren syndrome.

a modified Rodnan total skin thickness score (TSS) (9), we also examined TSS. The severity of joint mobility was based on the range of motion bilaterally in the wrist, cubital, and knee joints. The severity of upper digestive tract impairment was scored based on the presence of distal esophageal hypoperistalsis, aperistalsis, reflux esophagitis, and esophagostenosis. The severity of lower digestive tract impairment was scored based on the need for antibiotics to limit bacterial growth, the requirement for intravenous hyperalimentation, and the presence of abnormal bowel series, malabsorption syndrome, or pseudoobstruction. The severity of interstitial pneumonia was based on the percentage vital capacity (%VC) and fibrosis on radiograph or computed tomography. The severity of pulmonary hypertension was based on the mean pulmonary artery pressure and New York Heart Association Functional Classification (NYHA). The severity of heart dysfunction was based on the electrocardiogram, ejection fraction, and NYHA findings. The severity of kidney dysfunction was determined from the serum level of creatinine and the amount of urine protein. Overall, the disease activity was defined the highest score among the skin, lung, heart, kidney and digestive tract evaluations.

#### Statistical analysis

The HAQ scores of the disease groups were compared by ANOVA (Bonferroni test). The comparison of HAQ scores for dSSc versus healthy controls was

performed using the Student's t-test (2-tailed, unpaired). Pearson correlation coefficients were calculated based on the correlation between the HAQ score and the disease severity of each organ system in SSc. A multiple linear regression analysis using a stepwise method was performed to identify those variables of organ involvement that were independently associated with the HAQ-DI. Statistical analyses were performed using SPSS Ver. 11 statistical software from SPSS Japan Inc. A *p* value less than 0.05 was considered statistically significant.

#### Results

##### HAQ category scores for the disease groups

Table II shows the mean disability index, as well as the mean score, for each category as evaluated in the patients with various diseases. In dSSc patients the scores for dressing, rising, and reach were lower than those in RA patients, but higher than the scores in patients with other diseases. In almost all categories, the scores for dSSc patients were the highest, followed in descending order by RA, DM, ISSc, SLE, and SjS. In all categories except reach, the scores of healthy control were the lowest.

##### The HAQ category scores for SSc versus other diseases

The HAQ category scores for patients with dSSc versus those with other diseases are compared in Table III. The HAQ-DI for dSSc was significantly higher than for ISSc, SLE, SjS and

healthy controls, but not different from the index in DM and RA. The category scores for ISSc also were compared to other diseases (data not shown). The scores for reach (*p* < 0.05) in ISSc were significantly lower than in DM. However, there were no significant differences in any of the categories between ISSc and SLE/SjS.

##### The severity of organ involvement in SSc patients

Table IV shows the distribution of mean severity for each organ system in SSc, ISSc, and dSSc patients. The patients with dSSc had significantly higher scores than patients with ISSc in terms of skin, joint, and heart involvement, interstitial pneumonia and disease activity, including TSS.

##### Correlation of HAQ scores with the severity of organ involvement in SSc

The correlation coefficients of each HAQ score with the severity of organ system disability are shown in Table V. The severity of joint, heart and skin involvement, pulmonary hypertension, and general condition correlated significantly with the HAQ-DI. Joint severity was strongly correlated with the HAQ scores in all categories. Cardiac involvement was significantly correlated with 5 categories (dressing, walking, hygiene, reach, activity) and pulmonary hypertension with 3 categories (eating, walking, reach). Although the severity of skin abnormalities showed no or little correlation with the HAQ scores, TSS correlated with the HAQ scores in all categories except for hygiene. General condition was significantly correlated with 3 categories (walking, reach, activity). Vasculature and kidney involvement correlated with grip alone. However, the severity of interstitial pneumonia and digestive tract problems did not correlate with any category. The total score for disease activity was significantly correlated with walking, reach and HAQ-DI.

##### Multiple regression analysis in SSc

In single variable analysis, the severity of joint, heart and skin involvement, pulmonary hypertension, and gen-

**Table II.** HAQ scores in 124 patients with connective tissue diseases.

Disease	HAQ categories								HAQ-DI
	Dressing	Rising	Eating	Walking	Hygiene	Reach	Grip	Activity	
SSc	0.24	0.32	0.64	0.44	0.3	0.64	0.68	0.6	0.48
ISSc	0.16	0.24	0.5	0.24	0.18	0.37	0.5	0.34	0.32
dSSc	0.5	0.58	1.1	1.1	0.67	1.5	1.3	1.4	1
SLE	0.05	0.18	0.38	0.25	0.08	0.5	0.48	0.5	0.3
DM	0.43	0.43	0.71	0.64	0.43	1	0.86	0.71	0.65
SjS	0.07	0.14	0.29	0.14	0.07	0.21	0.5	0.14	0.2
RA	0.83	0.83	0.83	0.83	0.67	1.7	0.83	1	0.94
Control	0	0.16	0.12	0.08	0	0.36	0.28	0.12	0.14

SSc: systemic sclerosis; ISSc: limited cutaneous SSc; dSSc: diffuse cutaneous SSc; RA: rheumatoid arthritis; SLE: systemic lupus erythematosus; DM: dermatomyositis; SjS: Sjögren syndrome; HAQ: Health Assessment Questionnaire; HAQ-DI: HAQ disability index.

**Table III.** Comparative analysis of the HAQ category scores for diffuse cutaneous SSc versus other diseases using ANOVA.

Disease	HAQ categories								HAQ-DI
	Dressing	Rising	Eating	Walking	Hygiene	Reach	Grip	Activity	
ISSc	NS*	NS*	NS*	$p < 0.01$	$p < 0.05$	$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.001$
SLE	$p < 0.001$	NS*	NS*	$p < 0.05$	$p < 0.001$	$p < 0.01$	NS*	$p < 0.05$	$p < 0.01$
DM	NS	NS	NS	NS	NS	NS	NS	NS	NS
SjS	NS*	NS*	NS*	NS*	$p < 0.05$	$p < 0.01$	NS*	$p < 0.01$	$p < 0.01$
RA	NS	NS	NS	NS	NS	NS	NS	NS	NS
Controls**	$p < 0.001$	$p < 0.05$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.01$	$p < 0.001$	$p < 0.001$

SSc: systemic sclerosis; ISSc: limited cutaneous SSc; SLE: systemic lupus erythematosus; DM: dermatomyositis; SjS: Sjögren syndrome; RA: rheumatoid arthritis; HAQ: Health Assessment Questionnaire; HAQ-DI: HAQ disability index; NS: not significant.

\*Not significant on ANOVA, but  $p < 0.05$  using Student's t-test (2-tailed, unpaired):

\*\*Comparative analysis of the HAQ category scores for diffuse cutaneous SSc versus controls was performed using the Student's t-test (2-tailed, unpaired).

**Table IV.** Distribution of the mean severity of organ involvement in SSc patients.

Disease	General condition	Vasculature	Skin	TSS*	Severity of organ involvement					Heart	Kidney	Disease activity
					Joint	Upper digestive tract	Lower digestive tract	Lung (interstitial pneumonia)	Lung (pulmonary hypertension)			
SSc	0.26	1.24	1.1	5.98	0.28	1.2	0.18	0.72	0.1	0.2	0.1	1.96
ISSc	0.18	1.2	0.87	3.8	0.08	1.2	0.16	0.55	0.05	0.03	0.08	1.76
dSSc	0.5	1.3	1.8	13	0.92	1.2	0.25	1.3	0.25	0.75	0.17	2.58
<i>P**</i>	NS	NS	< 0.001	< 0.001	< 0.001	NS	NS	< 0.01	NS	< 0.01	NS	< 0.01

\*TSS: Total skin thickness score was added to assess the severity of skin involvement.

\*\*Comparing the scores between ISSc and dSSc.

SSc: systemic sclerosis; ISSc: limited cutaneous SSc; dSSc: diffuse cutaneous SSc.

eral condition correlated significantly with the HAQ-DI. To identify those variables for organ involvement that were independently associated with the HAQ-DI, multiple linear regression analysis using a stepwise method was performed. The severity scores for joint involvement (standard partial regression coefficient: standardized  $\beta = 0.518$ ,  $p < 0.001$ ), heart involvement ( $\beta = 0.436$ ,  $p < 0.001$ ), and pulmonary hypertension ( $\beta = 0.323$ ,  $p = 0.001$ ) were associated independently with the

HAQ-DI, although the association of the severity of skin involvement with the HAQ-DI was not significant.

### Discussion

The HAQ-DI is a self-administered instrument that has been used to examine a broad range of outcomes such as quality of life, health care utilization, pain, and disability (10) that are correlated with the severity and activity of connective tissue diseases (CTDs). The HAQ-DI is valid for determining

physical disability in patients with RA, as well as SLE and osteoarthritis (11). Poole and Steen first reported in 1991 that 221 patients with SSc had a relatively high degree of functional impairment and that the HAQ-DI displayed a strong correlation with TSS (12). More recently, Steen and Medsger reported that the HAQ-DI was strongly correlated with skin thickening, cardiac involvement, renal involvement, finger contractures, and tendon friction rubs in 1,000 patients. The highest corre-

**Table V.** Correlation coefficients of each HAQ score with the severity of organ involvement in SSc patients.

Organ involvement	HAQ categories								
	Dressing	Rising	Eating	Walking	Hygiene	Reach	Grip	Activity	HAQ-DI
General condition	0.14	-0.01	0.15	0.34**	0.15	0.34**	0.17	0.39***	0.28*
Vasculature	0.07	0.14	0.15	0.15	0.24	0.09	0.55****	0.21	0.26
Skin	0.24	0.22	0.2	0.30*	0.21	0.25	0.22	0.25	0.29*
TSS#	0.31*	0.33*	0.31*	0.30*	0.28	0.33**	0.33*	0.33**	0.39***
Joint	0.28*	0.39***	0.50****	0.29*	0.45****	0.39****	0.51****	0.43***	0.51****
Upper digestive tract	-0.08	0.06	0.09	0.06	0.14	0.09	-0.01	0.03	0.06
Lower digestive tract	0.09	0.01	0.07	0.07	0.003	0.08	0.01	0.1	0.07
Lung (interstitial pneumonia)	0.02	0.08	0.03	0.01	0.06	0.13	0.1	0.13	0.09
Lung (pulmonary hypertension)	0.17	0.23	0.34***	0.38***	0.13	0.36***	0.28	0.16	0.33**
Heart	0.46****	0.17	0.25	0.58****	0.41***	0.62****	0.14	0.58****	0.50****
Kidney	0.03	0.06	0.06	0.15	0.07	0.15	0.35**	0.16	0.17
Disease activity	0.21	0.13	0.20	0.39**	0.28	0.42***	0.15	0.30	0.33*

\* $p < 0.05$ , \*\* $p < 0.02$ , \*\*\* $p < 0.01$ , \*\*\*\* $p < 0.001$ .

#Total skin thickness score (TSS) was added to assess the severity of skin involvement.

lation was observed with life expectancy in multivariate analysis (13). In Japanese patients with SSc, the HAQ score in every category except eating was generally much lower (8) than the scores reported in the United States (12). This discrepancy might be due to differences in the distribution of disease subsets and in the mean disease duration between the two populations. In this study, we evaluated the physical functional impairment in Japanese patients with SSc compared to other CTDs. First, our results indicate that patients with dSSc have more functional impairment than patients with RA or other CTDs. As shown in Table II, the mean HAQ-DI score was higher in dSSc patients (1.0) than in patients with RA or other CTDs. Although dSSc accounted for only 24% of all SSc cases, the HAQ-DI in our study was higher than that of another study because of the higher mean age (61 years) of our patients (14). Scores greater than 1.0 were found for the following categories: grip, eating, walking, and activity (Table II). These results illustrate the importance of improvements in hand function and walking in the treatment of patients with dSSc.

Criteria for determining the severity of organ dysfunction in SSc have been published (2). However, these criteria do not consider racial differences in the clinical symptoms or the immunologic abnormalities of SSc (15). Therefore, the new Japanese criteria were config-

ured to more accurately evaluate the severity in Japanese patients with SSc (3). The new criteria lowered the standard values for TSS, interstitial pneumonia and pulmonary hypertension.

Joint involvement was correlated with all categories of the HAQ in SSc (Table V), possibly because the HAQ was designed originally to evaluate patients with RA. Heart involvement was correlated with the categories of dressing and walking, in which the correlation with joint function was less significant (Table V). Indeed, patients with SSc often have cardiac conduction defects. Kaburagi *et al.* demonstrated a correlation between electrocardiographic abnormalities and high HAQ-DI scores in patients with SSc (16). In contrast, interstitial pneumonia did not correlate with any of the categories (Table V). Some studies have reported that %VC is correlated with the HAQ-DI (8, 13), while others have shown no correlation between lung function and the HAQ-DI (16, 17). Our results for interstitial pneumonia may result from the fact that lung disease in most cases was not progressive at examination. In addition, the %VC range used to determine the severity of interstitial pneumonia might be inappropriate for evaluating functional impairment. While TSS correlated with most HAQ categories, there was no significant correlation between the severity of skin sclerosis and the HAQ score in our study. Considering the fact that

the classification of the severity of skin sclerosis is based on the TSS, the present ranges of TSS for severity might not be appropriate for evaluating functional impairment.

Because the HAQ was not designed for patients with SSc, some of the items in the questionnaire may not detect functional impairment in SSc patients. For example, peripheral circulatory disorders (Raynaud's phenomenon, finger ulcers), digestive symptoms (heart burn, diarrhea) and respiratory symptoms (cough, shortness of breath) are often seen in SSc, but generally cannot be estimated by the HAQ. In fact, involvement of the digestive tract, vasculature, kidney and lung (interstitial pneumonia) did not correlate with the HAQ-DI in our analysis. Alternatively, the scleroderma HAQ (SHAQ) combines the HAQ-DI and five scleroderma-specific visual analog scales and is useful as specific tool linked to SSc (18).

In conclusion, our data indicates that patients with dSSc have greater functional impairment than patients suffering from other connective tissue diseases. In patients with dSSc, improvement in functional impairment associated with the hands and walking are of high priority. As improvement in joint, heart, and lung involvement (pulmonary hypertension) can lead to lower functional impairment, they can be important targets for therapy in patients with SSc.



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