

Associated Factors Correlate with Disability in Long-Standing Systemic Sclerosis Patients

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Background: *The disability of systemic sclerosis (SSc) correlates with disease severity. Long-standing SSc patients with the low disease activity suffer from incapacity as a consequence of tissue damage. The factors correlating with disability in long-standing SSc patients have not been emphasized.*

Objective: *To analyze the body composition, physical function, and nutritional status in SSc patients and determine the parameters correlated with disability.*

Material and Method: *Sixty of SSc patients characterized into three subgroups as: 1) diffuse SSc (dSSc; n = 46), 2) limited SSc (lSSc, n = 6), and 3) SSc with overlap syndrome (SSc-overlap, n = 8) were enrolled. Clinical data, body composition, physical function, and disability were evaluated.*

Results: *There were no difference in clinical characteristics, functional assessment, body composition, and disability among three subgroups of SSc patients. The data analysis demonstrated the parameters strongly correlated with disability were factors related to: 1) disease activity (ESR; $R = 0.413$, $p = 0.001$ and the dose of prednisolone; $R = 0.314$, $p = 0.014$), 2) physical function (6-meter walk test; $R = 0.402$, $p = 0.001$, and peak expiratory flow rate; $R = -0.27$, $p = 0.37$), 3) body composition (skeletal mass; $R = -0.257$, $p = 0.047$), and 4) nutritional status (phase angle; $R = -0.274$, $p = 0.043$ and serum albumin; $R = -0.424$, $p = 0.001$).*

Conclusion: *Disease activity, physical function, body composition, and nutritional status associate with disability in long-standing SSc patients. Our findings revealed the factors that should be corrected to lessen the disability in SSc patients.*

Keywords: *Systemic sclerosis, Disability, Disease activity, Nutrition, Body composition, Physical function*

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Systemic sclerosis (SSc) is a chronic autoimmune disease that affects the skin, extracutaneous, and vascular systems. The immunotherapeutic treatment can improve the survival of SSc patients⁽¹⁾. However, the challenge for long-term care of SSc patients is to differentiate between the persistence of disease activity and disease damage, which cause disability. The assessment of disability using the Health Assessment Questionnaire Disability Index (HAQ-DI) has been verified in SSc⁽²⁾ and correlates with skin thickening, proximal muscle weakness, and tendon friction rubs⁽³⁾. SSc can be categorized into two groups, limited cutaneous SSc (lSSc) and diffuse cutaneous

SSc (dSSc). SSc may also present features of other autoimmune diseases, so-called "overlap syndrome". Each group of SSc may have preferential involvement of skin and musculoskeletal system that may contribute to various body composition and affect the disability.

Sarcopenia is a condition characterized by losing of muscle mass and strength⁽⁴⁾. The increase of pro-inflammatory cytokines (IL-6, TNF-alpha, and IL-1 β) can induce sarcopenia and reduce muscle strength^(5,6). Lower limb muscle strength is correlated with impaired functional performance and quality of life in patients with SSc⁽⁷⁾.

The abnormal of nutritional status representing by low phase angle has been shown as a marker for disease activity and severity in patients with SSc⁽⁸⁾. However, the correlation between nutritional factors, body composition, and disability in SSc patients has never been assessed. The identified correlating factors

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will provide knowledge that physicians can use to monitor disability in SSc and arrange the appropriate care to decrease disability.

Material and Method

Patient enrollment

Patients with SSc were recruited from the rheumatology clinic in Ramathibodi Hospital between June 2014 and January 2015. These patients were classified according to the criteria of LeRoy et al as having lSSc or dSSc⁽⁹⁾. In addition, the SSc patients with overlap syndrome (SSc-overlap syndrome) were included in the present study. The exclusion criterion was the inability to walk. The study was approved by the Ramathibodi Hospital Ethics Committee and conducted according to the guidelines of the Declaration of Helsinki. Each participant gave a written informed consent before enrollment.

Clinical assessment

The medical records of patients were reviewed to collect the clinical characteristics data. The severity of skin involvement in all patients was evaluated using modified Rodnan skin score (mRSS). The grade of skin thickness is on a scale from 0 to 3 (0 = normal, 1 = mild thickening, 2 = definite thickening, and 3 = severe thickening) in 17 different body areas⁽¹⁰⁾. Disability was assessed by the HAQ-DI in Thai version which related to everyday activities in eight categories: grooming, getting up/down, eating and cooking, walking, body cleaning, reaching for articles, holding and gripping, and other activities. Each category had a score of 0 to 3 and the final score was calculated by summing the highest score of each category and dividing it by 8. A mean HAQ-DI score was 0 to 3 continuous scale, and the higher score means the more disability^(11,12). Peak expiratory flow (by a peak flow meter), and six-meter walk test/gait speed are parameters for muscle strength and physical function, respectively⁽⁴⁾.

Definition

Sarcopenia is a condition of low skeletal muscle mass and muscle strength. Sarcopenic obesity is the reduction of muscle mass with the increase of fat mass⁽⁴⁾. The low physical function states when the six-meter walk test is less than 1 meter per second. Low respiratory muscle strength defines as the peak expiratory flow less than the expected peak expiratory flow (normal values based on a person's sex, age, and height; EU scale).

Body composition measurements

The studies show the proper correlation of measuring body composition between dual X-ray absorptiometry (DXA) and Bioelectrical Impedance analysis (BIA)⁽¹³⁻¹⁵⁾. In the present study, body composition of our patients was assessed by the BIA, using an InBody S10. The measurement method was direct segmental multi-frequency BIA (DSM-BIA). BIA obtained the value of total fat mass, the percentage of body fat, protein mass, soft lean mass, skeletal muscle mass, and phase angle.

Statistical analysis

Descriptive statistics (means, standard-deviation (SD), and proportions) were used to characterize the demographics and measured variables. Demographic data and body composition parameters in patients were compared in each of the three groups using one-way analysis of variance for normally distributed continuous variables and Pearson's Chi-square test for categorical variables. The correlation analysis among multi-parameters was assessed by Pearson correlation (2-tailed). All analyzes were performed using SPSS statistical software, version 20.

Results

Patient demographics and clinical characteristics in subtypes of SSc

Sixty of SSc patients were enrolled in the present study. The clinical characteristics were categorized into diffuse (dSSc 46/60 or 76.6%), limited (lSSc 6/60 or 10%), and overlapping (SSc overlap syndrome 8/60 or 13.3%) as shown in Table 1. The majority of patients were female (54/60 or 90%), and disease characteristics of these three subgroups were not statistically significant different except for the higher of mRSS and interstitial lung involvement, which significantly associated with dSSc (Table 1). The current daily dosages of prednisolone, cyclophosphamide, and azathioprine were almost the same among these SSc subgroups; however, there was a trend that higher numbers of patients with dSSc and SSc overlap syndrome that received prednisolone, and most of the dSSc patients (76.1%) exposed to immunosuppressive agents (Table 1).

Functional assessment in SSc

To identify the difference of function ability between the subgroups of SSc, the physical function, respiratory muscle strength, and disability score were assessed (Table 2). The 6-meter gait speed and the

percentages of low physical function (defined by 6-meter gait speed less than 1 meter/second) were comparable among these SSc subgroups (Table 2). Peak expiratory flow rate (representing respiratory muscle strength), percentages of low respiratory muscle strength (peak expiratory flow rate less than predicted value), and disability index (Thai HAQ-DI score) were similar between these groups (Table 2).

Body compositions in SSc

Most of the patients had a normal body mass index (BMI). The analysis of body composition in three subgroups did not reveal any differences regarding BMI, protein mass, fat mass, soft lean mass, skeletal

muscle mass, and phase angle (Table 3). Of interest, body fat mass was significantly different between dSSc and ISSc ($p = 0.04$), and between ISSc and SSc-overlap syndrome ($p = 0.022$), but this difference was not observed in dSSc and SSc-overlap syndrome (Table 3). None of the patients in the present study had sarcopenic obesity condition.

Correlation between physical disability and multi-parameters in SSc

To identify the parameters that associated with disability in SSc patients (regardless of the type of SSc), the correlation of Thai-HAQ-DI (representing disability)⁽¹¹⁾ and multiple parameters were performed

Table 1. Patient demographics and clinical characteristics in subtypes of systemic sclerosis (SSc)

	All (n = 60)	dSSc (n = 46)	ISSc (n = 6)	SSc-overlap (n = 8)	p-value
Age (years)	50.4±13.3	49.8±13.4	59.0±7.4	47.4±14.7	0.225
Female, n (%)	54 (90.0)	40 (86.9)	6 (100)	8 (100)	0.781
Disease characteristics					
Disease duration (years)	7.02±5.81	6.62±5.53	5.98±5.31	7.87±8.22	0.907
ILD, n (%)	44 (73.3)	38 (82.6)	2 (33.3)	4 (50.0)	0.011
mRSS	10.1±8.7	12.0±9.0	4.8±3.0	2.9±2.4	0.005
ESR (mm/hour)	35.2±24.2	37.1±26.1	17.8±9.4	37.1±13.9	0.181
CRP (mg/L)	3.2±6.8	3.65±2.53	1.9±1.8	2.1±2.1	0.704
Serum albumin (g/L)	38.3±3.3	37.9±3.3	38.2±3.8	40.1±2.2	0.243
Cholesterol (mg/dl)	199.4±43.1	194.9±72.6	210.8±97.8	214.4±52.8	0.427
Creatine kinase (U/L)	115.8±72.9	118.7±80.1	115.2±51.8	99.7±36.9	0.801
Prednisolone					
Current use, n (%)	36 (60.0)	29 (63.0)	2 (33.3)	5 (62.5)	0.372
Current daily dose (mg)	2.6±3.4	2.8±3.6	1.7±2.6	2.0±2.5	0.648
Immunosuppressive drugs					
Current use, n (%)	43 (71.7)	35 (76.1)	3 (50.0)	5 (62.5)	0.339
Cyclophosphamide					
Current use, n (%)	34 (56.7)	29 (63.0)	1 (16.7)	4 (50.0)	0.175
Current daily dose (mg)	23.9±24.3	27.3±24.8	4.2±10.2	19.6±22.8	0.077
Azathioprine					
Current use, n (%)	8 (13.3)	6 (13.0)	1 (16.7)	1 (12.5)	0.897
Current daily dose (mg)	7.1±20.2	7.6±21.6	8.3±20.4	3.5±10.1	0.867

dSSc = diffuse SSc; ISSc = limited SSc; ILD = interstitial lung disease; mRSS = modified Rodnan skin score; ESR = erythrocyte sedimentation rate; CRP = C-reactive protein

Data presented as mean ± standard deviation or proportions (%), the three groups were compared using one-way analysis of variance

Table 2. Functional assessment in SSc

	All (n = 60)	dSSc (n = 46)	ISSc (n = 6)	SSc-overlap (n = 8)	p-value
Physical function					
6-meter gait speed (m/second)	1.0±0.3	1.1±0.3	0.9±0.1	0.9±0.2	0.238
Low physical function, n (%)	24 (40.0)	20 (43.5)	2 (33.3)	2 (25.0)	0.579
Respiratory muscle strength					
Peak expiratory flow (L/minute)	344.2±78.8	345.7±84.1	315.0±55.8	357.5±60.4	0.574
Low muscle strength, n (%)	39 (65.0)	31 (67.4)	4 (66.7)	4 (50.0)	0.633
Disability					
Thai HAQ-DI score	0.41±0.55	0.48±0.61	0.13±0.11	0.20±0.26	0.177

Thai HAQ-DI = Thai Health Assessment Questionnaire Disability Index

Data presented as mean ± standard deviation or proportions (%), the three groups were compared using one-way analysis of variance

Table 3. Body compositions in SSc

Parameters	All (n = 60)	dSSc (n = 46)	ISSc (n = 6)	SSc-overlap (n = 8)	p-value
BMI (kg/m ²)	21.6±3.5	21.8±3.4	19.8±1.9	22.2±4.9	0.401
Protein mass (kg)	7.6±1.2	7.8±1.2	6.7±0.8	7.2±1.1	0.060
Fat mass (kg)	14.6±6.9	14.9±6.5*	10.5±3.3	16.4±10.3**	0.268
Soft lean mass (kg)	37.0±5.8	38.3±5.5	32.7±4.1	33.4±7.0	0.051
Skeletal muscle mass (kg)	20.7±3.4	21.2±3.41	18.1±2.3	19.6±3.3	0.071
Sarcopenia, n (%)	20 (33.0)	13 (28.3)	3 (50.0)	3 (37.5)	0.308
Phase angle	6.6±2.2	6.5±2.3	7.8±1.9	6.5±1.6	0.796

BMI = body mass index

* $p = 0.04$ (diffuse SSc vs. limited SSc), ** $p = 0.022$ (limited SSc vs. overlap syndrome)

Data presented as mean ± standard deviation or proportions (%), the three groups were compared using one-way analysis of variance, Chi-square, or Fisher's exact test with posthoc Bonferroni correction for multiple comparisons

using Pearson correlation analysis. Among the analyzed parameters from the SSc patients, erythrocyte sedimentation rate (ESR), the dose of prednisolone, peak expiratory flow rate, 6-meter walk, skeletal muscle mass, phase angle, and serum albumin correlated with the disability in these SSc patients (Table 4). Of interest, disease duration, mRSS, and the presence of interstitial lung disease (ILD) did not correlate with disability in these patients.

Among the parameters that associated with disability, we could simply categorize those factors into three types of parameters, which were related to: 1) disease activity, 2) physical function, and 3) body composition/ nutritional status (Fig. 1).

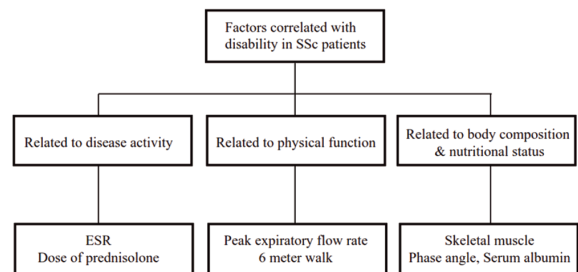
Table 4. Correlation between disability and multi-parameters in SSc patients

Parameters	Correlation coefficient (R)	p-value
Disease duration (years)	-0.205	0.133
mRSS	0.232	0.074
ILD involvement	-0.200	0.126
ESR**	0.413	0.001
Dose of prednisolone (mg)*	0.314	0.014
Peak expiratory flow rate*	-0.270	0.037
6-meter walk (minute)**	0.402	0.001
Protein mass (kg)	-0.220	0.091
Body fat mass (kg)	-0.095	0.471
Skeletal mass (kg)*	-0.257	0.047
Phase angle*	-0.274	0.043
Serum albumin**	-0.424	0.001

* Correlation is significant at the 0.05 level (2-tailed, Pearson correlation)

** Correlation is significant at the 0.01 level (2-tailed, Pearson correlation)

The Health Assessment Questionnaire-Disability Index (HAQ-DI) represents disability

**Fig. 1** Categorized parameters associated disability in SSc patients.

Discussion

Demographic data of SSc patients enrolled in the present study were comparable between the three subtypes (dSSc, ISSc, SSc overlap syndrome) except mRSS and ILD, which are higher in dSSc (Table 1). The vast number of cases suffered from ILD in SSc, which tended to guide the physicians to prescribe more prednisolone and immunosuppressants to dSSc compared with ISSc patients (although it was not a significant difference due to a small number of non-dSSc patients). However, we observed a minor increase in acute phase proteins (ESR and C-reactive protein, CRP) in patients at the time of enrollment, which suggested inactive or low disease activity in our enrolled subjects. The discrepancy between the high incidence of ILD and low disease activity could be the effect of immunotherapeutic treatment for ILD in dSSc patients for a significant period (mean disease duration 6.62 years).

SSc-overlap and dSSc patients similarly suffer from musculoskeletal symptom more frequently than ISSc, which can cause disability⁽¹⁶⁾, however, the assessment of physical function, respiratory muscle strength, and disability in our patients showed no difference between the three subtypes of SSc.

Comparing with other autoimmune diseases, the disability scores in dSSc are higher than ISSc but do not differ from rheumatoid arthritis and dermatomyositis patients⁽¹⁷⁾. Our dSSc patients demonstrated higher HAQ-DI than ISSc patients but it did not show a statistical significant difference, which possibly due to small numbers of ISSc patients.

The analysis of body composition revealed that mean of fat mass was significantly different between groups. We observed the higher level of fat mass in dSSc and SSc-overlap syndrome when compared with ISSc (Table 3). Prednisolone dosage is an independent predictor for the increase in fat mass after renal transplantation⁽¹⁸⁾. In the present study, patients with dSSc or SSc-overlap syndrome had a tendency to receive prednisolone more often than ISSc patients (Table 1), so prednisolone usage may promote the increase of fat mass in SSc patients.

We hypothesized that subtypes of SSc might create different body composition, which may cause functional disability. The analysis of physical function and body composition between the three subtypes of SSc in our patients did not show significant difference (Table 2, 3). This could be due to the small sample sizes in the groups of ISSc and SSc-overlap, or the three subtypes did not have a real difference in those parameters.

Sarcopenia relates to disability in elderly⁽¹⁹⁾. Longer disease duration is a risk factor of sarcopenia in SSc patients while a higher mRSS is a predictor of the lower relative skeletal mass index in patients with dSSc⁽²⁰⁾. High level of CRP correlates with mRSS, disease activity and HAQ⁽²¹⁾. However, the analysis of parameters that correlated with disability in our SSc patients showed no correlation with disease duration, mRSS, and interstitial lung disease. The result from the extensive usage of immunotherapeutic drugs in our patients could induce SSc to low disease activity, which represented the small level of CRP in most of our SSc patients at the time of enrollment. Otherwise, these patients were at the later stage of SSc (average disease duration is around seven years).

The previous study has shown that the disability correlated with disease severity⁽³⁾. The analyzed parameters that positively correlated with a disability were ESR, dose of prednisolone, and 6-meter walk test, The parameters that negatively correlated were peak expiratory flow, skeletal muscle mass, serum albumin, and phase angle. The previous study shows the dose of prednisolone may promote the loss of muscle mass or create low bone mass density (BMD),

which correlates with disability^(18,22). Skeletal muscle mass was the only body composition tested here that correlated with disability. In our study, we did not see the correlation between prednisolone dosage and skeletal muscle mass (data not shown). Prednisolone may induce osteoporosis in our patients and create disability. However, we did not perform DXA to determine BMD in our patients to confirm this notion.

The skeletal muscle mass, 6-meter walk test, and peak expiratory flow significantly correlated with disability. These data suggested the caretakers can use these two simple physical assessments to evaluate disability and should encourage the patients to do the exercise for strengthening skeletal muscle including respiratory muscle to reduce disability in SSc patients.

Low phase angle representing nutritional status correlates with force vital capacity (FVC), mRSS, and ESR in SSc patients⁽⁸⁾. The phase angle correlated negatively with disability in our SSc patients as well. We did not evaluate the gastrointestinal (GI) involvement in our patients and determine the correlation between GI involvement and low phase angle. Nevertheless, we found serum albumin, a marker of nutritional status, also associated with disability outcome.

Here, we categorized the factors correlated to disability into three subsets as followed. First, the parameters related to disease activity, which was the dosage of prednisolone (tended to be prescribed in active disease) and high ESR. Second, the factors related to a physical function, which was peak expiratory flow rate and the 6-meter walk test. Third, the components related to body composition, which was skeletal muscle mass, and to nutritional status, which was phase angle and serum albumin.

Conclusion

The results provide information for a rheumatologist caring for an SSc patient to improve the quality of life and reduce disability. For example: 1) physical training, especially expiratory muscle strength exercise should be a part of the treatment plan in SSc patients to improve muscle mass and strength, 2) usage of steroid should be minimized in long-standing SSc, and 3) caretakers should encourage SSc patients to improve their nutritional status.

What is already known on this topic?

The previous study has been shown that the disability in SSc patients correlated with disease severity⁽³⁾, which was measured by the extent of skin

thickening, proximal muscle weakness, and tendon friction rubs. However, the study that demonstrated the parameters correlated with disability in chronic stage of disease have not been shown.

What this study adds?

We demonstrated the parameters that associated with disability in long-standing SSc patients with low disease activity in which disability was the consequence of inflammation or damage. The parameter identified in the present study can guide the health care providers to improve the quality of life and prevent disability in SSc patients. For example: 1) physical training, especially expiratory muscle strength exercise should be a part of the treatment plan in SSc patients to improve muscle mass and strength, and 2) usage of steroid should be minimized in long-standing SSc.

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Potential conflicts of interest

None.

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ปัจจัยที่มีความสัมพันธ์กับภาวะทุพพลภาพในผู้ป่วยโรคหนังแข็ง

วิมล จังสมบัติศิริ, อรุณี ไชยฤทธิ, มนต์จันทร์ วนิชย์พันธุ์, ธนัชพร กาฝากส้ม, สุภา อ่อนเข้ม, นิชาภา เดชาปภาพิทักษ์, มาลินี ทองดี, วาสนา อ่ำรัมย์, ดร.ณิวัทย์ วัชรอมวิจิตร, ประภาพร พิธิษฐ์กุล

ภูมิหลัง: ภาวะทุพพลภาพในผู้ป่วยโรคหนังแข็งสัมพันธ์กับความรุนแรงของโรค ในผู้ป่วยที่เป็นโรคนานและความรุนแรงของโรคลดลงก็ยังสามารถพบภาวะทุพพลภาพเป็นผลจากการที่เนื้อเยื่อถูกทำลายไป

วัตถุประสงค์: หาค่าความสัมพันธ์ระหว่างส่วนประกอบของร่างกาย ความสามารถของร่างกาย และภาวะโภชนาการกับภาวะทุพพลภาพในผู้ป่วยโรคหนังแข็งที่เป็นโรคนาน

วัสดุและวิธีการ: ศึกษาผู้ป่วยโรคหนังแข็งจำนวน 60 ราย ได้แก่ 1) diffuse SSc 46 ราย, 2) limited SSc 6 ราย และ 3) SSc with overlap syndrome 8 ราย โดยประเมินข้อมูลทางคลินิก ความสามารถของร่างกาย และภาวะทุพพลภาพ

ผลการศึกษา: ผู้ป่วยทั้ง 3 กลุ่ม ไม่มีความแตกต่างระหว่างลักษณะทางคลินิก สมรรถภาพทางกาย และส่วนประกอบของร่างกาย การศึกษานี้พบว่ามีความสัมพันธ์ของภาวะทุพพลภาพกับ 1) ความรุนแรงของโรค (ESR; $R = 0.413$, $p = 0.001$ และ dose of prednisolone; $R = 0.314$, $p = 0.014$), 2) ความสามารถของร่างกาย (6-meter walk speed; $R = 0.042$, $p = 0.001$ และ peak expiratory flow rate; $R = -0.27$, $p = 0.037$), 3) ส่วนประกอบของร่างกาย (skeletal mass; $R = -0.257$, $p = 0.047$) และ 4) ภาวะโภชนาการ (phase angle; $R = -0.274$, $p = 0.043$ และ serum albumin; $R = -0.424$, $p = 0.001$)

สรุป: ปัจจัยที่เกี่ยวข้องกับความรุนแรงของโรค สมรรถภาพทางกาย ส่วนประกอบของร่างกาย และภาวะโภชนาการมีความสัมพันธ์กับภาวะทุพพลภาพในผู้ป่วยโรคหนังแข็งที่เป็นมานาน จากข้อมูลนี้แสดงให้เห็นว่าปัจจัยดังกล่าวควรได้รับการแก้ไขเพื่อลดภาวะทุพพลภาพในผู้ป่วยโรคหนังแข็ง