



# Physician and Patient Assessment of Disease Severity in Systemic Sclerosis (SSc).

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## Abstract

### Rationale:

Systemic sclerosis is a complex disorder with differing modes of presentation and diverse evolution of disease features. A methodological factor limiting the progress of interventional research in scleroderma has been the lack of validated measures of outcome. Identification of disease characteristics which correlate with physician and patient assessment of severity of the disease can be a contributing step in the development of a composite measure of severity of disease in SSc.

### Methods and Patients:

Clinical data from 100 ambulatory SSc patients, 51 with limited and 49 with diffuse disease, was obtained by medical record review. 87 (87%) were female. Mean age was  $51 \text{ y} \pm 12$  and disease duration  $7 \text{ y} \pm 7$ . Patients completed the SF36 and SHAQ-DI. The measure of disease severity by physician and patient was a 1-item VAS.

### Results (See Table):

Physician Assessment of disease severity was found to correlate moderately with DLco, RV, TLC, FVC, and Total Joint Count in the total sample. In the Limited SSc group correlations were found with TLC, FVC, Total Joint Count, and SHAQ-DI. In the Diffuse SSc groups correlations were found with Esophageal symptoms, Skin score, and SHAQ-DI. Patient Assessment of disease severity was found to correlate moderately with RVSP, EF, DLco, TLC, SHAQ-DI, SF-36 Physical, and very highly with all other VAS. In the Limited SSc group moderate correlations were found with DLco, TLC, digital pitting, SF-36 Physical, and very high correlations with several of the VAS. In the Diffuse SSc group correlations were significant with RVSP, EF, DLco, SF-36 Physical. In the diffuse groups high correlations were also found between the patient assessment of severity and other VAS.

### Conclusions:

There is no correlation between Patient and Physician Assessment of Disease Severity. Patient and Physician Assessment of Disease Severity correlate with different disease measures in the Limited and Diffuse SSc groups reinforcing the need for the development of composite

### Conclusions Continued:

disease measures in SSc. Few correlations with physician assessment of disease severity are significant and when they are, they are modest in magnitude. Very high correlations between patient assessment of severity and other VAS measures can be explained by the similarity of the scales. This finding together with the significant correlations with the SF-36 Physical Scale indicate that all patient-reported measures correlate well in all groups. Overall, these results also indicate the need for further model building to assess which factors contribute to patients' and physicians' severity assessment.

## Rationale

To identify disease characteristics which correlate with physician and patient assessment of severity of disease.

- SSc is a complex disease
- Disease presentation and evolution is not uniform
- A need exists for validated measures of outcome
- A need exists for a composite measure of disease severity in SSc
- Identifying disease characteristics which correlate with physician and patient assessment of severity of disease can be a contributing step.

## Methods

### Subjects:

- 100 patients with diagnosis of SSc by ACR classification criteria
  - Patient characteristics:
  - 51 patients with limited and 49 with diffuse SSc
  - Age:  $51 \text{ y} \pm 12$
  - Gender: 87 (87%) females
  - Duration of Disease :  $7 \text{ y} \pm 7$

### Survey Instruments:

- SF-36
- SHAQ-DI
- Disease Severity: 1 item VAS

### Clinical Disease Data:

- RVSP
- Ejection Fraction
- DLCO
- RV
- TLC
- FVC
- Sreat
- Esopsym
- Digital Pitting
- Total Joint Count
- Skin Score

## Results

Correlations between Patient and Physician Assessment of Severity of Disease and Clinical Features in SSc

	Combined		Limited SSc		Diffuse SSc	
	Patient	Physician	Patient	Physician	Patient	Physician
RVSP	.306*	.128	.192	.170	.469*	.172
Ejection Fraction	-.313*	.029	-.075	.002	-.552**	-.044
DLco	-.295**	-.262*	-.345*	-.277	-.291*	-.198
RV	-.211	-.363**	-.296	-.300	-.112	-.167
TLC	-.239*	-.300**	-.390*	-.461**	-.156	-.060
FVC	-.191	-.329**	-.115	-.325*	-.198	-.180
Esophageal Symptoms	-.039	-.021	.025	-.024	-.082	.387**
Digital Pitting	-.148	-.057	-.335*	-.081	-.098	.022
Total Joint Count	.194	.292**	.096	.429**	.256	-.021
Skin Score	-.010	-.023	.155	.118	-.167	.428**
SHAQ-DI	.674**	.167	.638**	.310*	.672**	.311*
Raynaud VAS	.929**	.031	.623**	.149	.959**	.011
Digital VAS	.432**	-.037	-.039	-.039	.483**	-.009
Gastrointestinal VAS	.908**	.031	.298*	-.098	.964**	.008
Pulmonary VAS	.939**	-.033	.566**	-.074	.967**	.048
Pain VAS	.935**	.400	.511**	.196	.970**	.024
SF-36 Physical Function	-.425**	-.086	-.629**	-.166	-.398**	-.272
SF-36 Mental Health	-.056	-.047	-.269	-.089	.020	-.191
<b>Physician Severity</b>			.236		.070	

\*  $P \leq .01$  (2-tailed), \*\*  $P \leq .05$  level (2-tailed)

## Conclusions

- No correlation between Patient and Physician Assessment of Disease Severity.
- Patient and Physician Assessment of Disease severity correlate with different disease measures in Limited and Diffuse SSc patients.
- Physician Assessment of Disease Severity: very few correlations with other disease measures
- Patient Assessment of Disease Severity:
  - \* Correlate nicely with all patient-reported outcome measures for both disease groups
  - \* Significant correlations with SF-36 Physical Scale
  - \* High correlatons with other VAS measures (might be due to similarity of the scales)
- Need further model building to assess which factors contribute to patient and/or phsycian assessment of severity of disease