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Clinical Correlates of Quality of Life in Systemic Sclerosis Measured with the World Health Organization Disease Assessment Schedule II

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Abstract

Background To identify the clinical characteristics of systemic sclerosis (SSc) that best correlate with the health-related quality of life (HRQoL) of patients with SSc, using the World Health Organization Disease Assessment Schedule II (WHODAS II) as the measure of HRQoL.

Methods Cross-sectional, multi-center study of 337 patients from the Canadian Scleroderma Research Group Registry. Patients were assessed with the WHODAS II and detailed clinical histories and medical examinations. Hierarchical multiple linear regression was used to assess the relationship between selected clinical variables and HRQoL.

Results The mean WHODAS II score (range 0-100) was 23.7, with the greatest impairments in the subscales measuring life activities, mobility and participation in society. In multivariate analysis, significant clinical predictors of the WHODAS II were skin scores, shortness of breath, number of gastrointestinal problems, fatigue, pain and depression. The final model explained 61% of the variance in the WHODAS II scores.

Conclusions The clinical characterisitics identified in this study as significant correlates of HRQoL in SSc should each be targets of intervention in order to improve the HRQoL of patients with this disease.

Systemic Sclerosis (SSc) is a chronic, multi-system disorder characterized by thickening and fibrosis of the skin and internal organs[1, 2]. It affects mainly women[3, 4] in the prime of their life[3, 4] and is associated with significant morbidity, including disability and depression[5, 6], increased mortality (relative survival as low as 35% at 20 years, compared to age, sex and race matched individuals)[7] and high costs[8]. SSc is thought to affect over 16,000 Canadians and up to 100,000 Americans[9-13]. In the absence of a cure[14], the major objective of medical care for patients who suffer from this chronic disease is to ensure optimal health related quality of life. However, little is known on the clinical features of the disease that contribute most to HRQoL. Identifying these factors would help to identify the targets for intervention that, short of being curative, would have the greatest impact in terms of improving the HRQoL of SSc patients.

The *International Classification of Functioning, Disability and Health* (ICF) is the World Health Organization's (WHO) revised classification of functioning and disabilities that is based on a biopsychosocial model[15]. The *World Health Organization Disease Assessment Schedule II* (WHODAS II) is a generic HRQoL instrument developed to operationalize the core dimensions of the ICF[16]. It is a multidimensional instrument that has six domains: understanding and communicating, getting around, self care, getting along with others, household and work activities, and participation in society. It distinguishes itself from other HRQoL instruments in that it is based on an international classification system, it has been tested in multiple cultures, and it treats all disorders at parity when determining the level of functioning. Furthermore, it assesses some functional and health-related issues, including participation in society and sexuality,

which are not addressed in the Medical Outcomes Study Short Form 36 (SF 36)[17, 18]. Given that the morbidity of SSc results from an interplay of biopsychosocial factors, the WHODAS II may be particularly well-suited to assess HRQoL in this condition. We recently evaluated the psychometric properties of the WHODAS II in SSc and found that it had good convergent validity and that it discriminated well between patients with mild and severe disease (manuscript accepted, Arthritis Care and Research).

The purpose of this study was to identify the clinical characteristics of SSc that best correlate with the HRQoL of patients with SSc, using the WHODAS II as the measure of HRQoL.

Methods

Design. Cross-sectional study of a national cohort of patients with SSc.

Study subjects The study subjects consisted of those enrolled in the Canadian Scleroderma Research Group Registry. Patients in this Registry are recruited from 15 centers across Canada. They must have a diagnosis of SSc made by the referring rheumatologist, be $\geq$ 18 years of age and be fluent in English or French. The patients included in this study were those whose baseline visit was between September 2004 and August 2006 and whose complete data was entered into the database as of August 2006.

Study instrument The self administered WHODAS II consists of 36 Likert formatted questions covering six domains: Understanding and Communicating (cognition and conversation), Getting Around (mobility), Self Care (attending to one's hygiene, dressing, eating and staying alone), Getting Along with Others (interpersonal interactions and sexuality), Life Activities (divided between household responsibilities and work/school activities), and Participation in Society (joining in community activities) during the last 30 days. Using SPSS syntax available through the WHO, each domain is weighted and scored separately. An overall score can also be generated. The scores range from 0 (best) to 100 (worst). Permission to translate the english version of the WHODAS II into Canadian French and to use both versions was obtained from the WHO. In prior analyses,[19] we found that the WHODAS II has good psychometric properties in SSc (good convergent validity (correlation with the SF 36 Physical Component Summary score *r* -0.44, the SF 36 Mental Component Summary score *r* -0.41 and measures of

function *r* 0.54, depression *r* 0.44, pain *r* 0.40 and fatigue *r* -0.49, all $p < 0.0001$) and discriminated well between patients with mild and severe disease).

Predictor variables Patients recruited into the Registry underwent an extensive medical evaluation with standardized reporting of history, physical evaluation, and laboratory investigations. Skin involvement was assessed using the modified Rodnan skin score ranging from 0 to 51[20]. Shortness of breath was assessed using the disease specific question of the Scleroderma-Health Assessment Questionnaire (S-HAQ)[21]. For this question, patients were asked to rate the severity of their shortness of breath in the past week. The question was anchored by the adjectives "does not interfere" and "very severe limitation". Unlike the visual analogue scales originally used for the S-HAQ, the assessment in this study was made using 11-point numerical rating scales (NRS) ranging from 0 to 10[22, 23]. Joint examinations were done using the simplified 28 jount count[24] and tender points of fibromyalgia were assessed using American College of Rheumatology criteria[25]. Patients also completed self-administered questionnaires to measure depression using the Center for Epidemiologic Studies - Depression Scale (CES-D)[26,27], pain using the Short Form McGill Pain Questionnaire (MPQ)[28, 29, 30] and fatigue using the vitality subscale of the Medical Outcomes Study Short Form 36 (SF 36)[17, 18].

Statistical Analysis Descriptive statistics were used to summarize the baseline characteristics of the patients. Bivariate correlations between the WHODAS II and various sociodemographic and predictor variables were assessed using Kendall's tau correlation coefficients. Multiple regression analysis was performed to identify the

independent predictors of HRQoL in patients with SSc as measured by the WHODAS II. The distribution of WHODAS II scores was significantly skewed. Thus, a square root transformation was carried out in order to meet regression assumptions of linearity and normality of regression residuals[31]. Similar analyses were also carried out for each of the six WHODAS II subscales.

We performed hierarchical multiple linear regression modeling. We believe that it is important that a theoretically-driven model which controls for variables that differ across patients (regardless of their significance) be used rather than only significant variables. In fact, it is well-known and robustly demonstrated that regression models that only include significant variables, either by pre-screening univariate associations or through methods such as stepwise regression, capitalize on variability unique to a given sample, radically underestimate the degrees of freedom used to determine estimates in regression models, often generate substantially inflated type I error rates and artifactually small p values, and do not consistently produce replicable findings[32, 33].

We built our hierarchical model in the following way. In block one, we entered sociodemographic variables, namely age, gender and education status. In block two, we added a variable to control for disease duration. In block three, we added clinical variables that represented a spectrum of common disease manifestations that were likely to influence HRQoL. These were Modified Rodnan skin scores, fingertip to palm distance, number of fingertip ulcers, shortness of breath (assessed by the patient on the S-HAQ), number of gastrointestinal symptoms (weight loss, anorexia, dysphagia, reflux, pyrexia, choking at night, early satiety, bloating, nausea/vomiting, constipation, diarrhea, malabsorption, fecal incontinence, antibiotics for bacterial overgrowth,

hyperalimentation), swollen joint count, tender joint count and number of tender points of fibromyalgia. Because fatigue, pain and depression can be both process and outcome variables, we added them separately in block four. However, we did not include other variables such as working status, income and function or measures of disease severity because they likely represent outcomes of SSc for many patients and their inclusion could artifactually underestimate the role of the selected clinical variables in the evaluation of the patients' HRQoL. For each step, individual variable parameters are shown, including unstandardized regression coefficients (B) and their standard errors, as well as standardized regression coefficients (β), and p values. In addition, overall model fit statistics and a P value for the change in variance accounted for (Δ R) are shown for each step. Unstandardized regression coefficients (B) represent the expected unit change in the outcome variable per unit of change in the predictor variable. Standardized regression coefficients (β) represent partial correlations between a predictor variable and the outcome variable after removing the shared association between the predictor variable and other predictor variables.

For exploratory purposes, we reran all models stratified by extent of skin involvement, with limited and diffuse disease defined according to Leroy et al[34].

Data are presented in the text as means (± standard deviation). All tests of significance were 2-tailed, and all statistical analyses were performed with SPSS v. 15 (Chicago, IL).

Ethical considerations Ethics committee approval for this study was obtained at each site and each patient provided informed written consent to participate in this study.

Role of the funding sources The funding sources had no role in the design of the study, analysis of the data, preparation of the manuscript and decision to submit for publication.

Results

There were 337 patients included in this study, of which 294 (87%) were women, mean age was 56 (± 13) years, and mean disease duration since the onset of the first non-Raynaud's disease manifestation was 11 (± 9) years (Table 1). Mean WHODAS II score, out of a possible 100, was 23.7 (± 17.2), with the greatest impairments in the subscales measuring life activities, mobility and participation in society.

In bivariate analysis, the WHODAS II was significantly correlated with all of the selected disease-related variables except the number of swollen joints (Table 2). The correlations were moderate with shortness of breath and number of gastrointestinal symptoms (Kendall's tau 0.37 and 0.32, respectively) and relatively high with fatigue, pain and depression (Kendall's tau -0.50, 0.41 and 0.43, respectively). The negative correlation with fatigue is explained by the fact that, for that variable, low scores represent worse fatigue.

In multivariate analysis, after controlling for age, gender and disease duration, the significant clinical predictors of the WHODAS II were skin scores, shortness of breath and number of gastrointestinal problems (Table 3). Fatigue, pain and depression were also significant predictors of the WHODAS II. The final model explained 61% of the variance in the WHODAS II scores. Almost identical results were obtained when only the significant variables were retained in the final model (R^2 0.60)

For exploratory purposes, we reran models for limited and diffuse patients separately and found similar results with only minor differences. For limited patients (N 183, 54.3%), all predictors were the same, except number of gastrointestinal symptoms (p = .452) and skin score (p = .258). For diffuse patients (N 154, 45.7%), all predictors were the same except pain (p = .159) and age (p = .013). However, we have less confidence in these findings because of the smaller number of patients in these analyses.

We examined the associations between the predictor variables and the six individual WHODAS II subscales in separate but identical hierarchical models. In general, the variables that predicted the overall WHODAS II score also predicted the subscales (Table 4), with only small but predictable differences (eg. depression predicted understanding and communicating, getting along with people and participation in society but not getting around, self care and life activities).There were only 3 other significant predictors, each for one subscale, namely age for getting around and life activities, gender for self care and fingertip ulcers for participation in society.

Discussion

This is the largest study to date to assess the correlates of HRQoL in patients with SSc. We found that skin involvement, shortness of breath and number of gastrointestinal symptoms were independent correlates of HRQoL, as measured with the WHODAS II. Fatigue, pain and depression also contributed independently to HRQoL. The variables selected for these models explained a large amount of the variance in the WHODAS II, validating our *a priori* selection of variables and suggesting that we have identified some of the most important factors that contribute to HRQoL in SSc. The associations between the clinical variables and the individual subscales of the WHODAS II were very similar to those of the main analysis using the overall WHODAS II score, with some theoretically predictable differences. Given that seven regressions models with 13 variables were run altogether, it is not unexpected that small differences may arise. It remains that the results of the models for the subscales are highly consistent with that of the overall score and point to the robustness of our results.

The relevance of this study is twofold. First, it lies in its ability to identify foci of intervention for SSc. Although clinicians have some symptomatic treatments for dyspnea and gastrointestinal symptoms, there are currently no effective treatments for the skin disease. This remains a serious lacuna. Also, little attention has been given to date to fatigue, pain and depression in SSc. Identifying these contributors of HRQoL in SSc gives a strong signal to the research community that, short of curative treatments, we need to develop better symptomatic treatments for this devastating disease.

Second, this study allows us to gain further experience with the WHODAS II. HRQoL is an important outcome in chronic diseases. Although HRQoL in SSc has so far

been measured with the SF 36, concerns about the validity of this measure in patients with chronic illness have recently been raised[35] and experts have called on more research in the area of HRQoL in patients with SSc[36]. The WHODAS II is a multi-dimensional instrument that has face and content validity in so far as SSc is concerned. We also recently showed that it has good psychometric properties in patients with SSc[19] . In this study, the WHODAS II allowed us to identify correlates of HRQoL in SSc that make intuitive sense. In time, the WHODAS II may become the instrument of choice for measuring HRQoL in SSc.

This study is not without limitations. Most importantly, the cross sectional design prevents us from examining the mechanisms by which some variables may relate and how this influences outcome. In other words, how are skin involvement, gastrointestinal symptoms, dyspnea, depression, pain and fatigue related and how do these relationships affect HRQoL? Longitudinal studies examining these relationships are currently under way. In addition, it is possible that concurrent measurement of self-report variables, including pain, fatigue, depression, and HRQoL may have inflated estimates of their association. Finally, the patients included in this study had longstanding disease and mild to moderate disease (Table 1). Thus, our results may not be generalizable to patients with earlier or more severe disease.

In conclusion, this study allowed us to identify important clinical correlates of HRQoL in SSc, namely skin and gastrointestinal involvement, dyspnea, pain, fatigue and depression. Longitudinal studies must be done to confirm these relationships. The importance of these studies lies in their ability to identify targets of intervention and help

set the research agenda in the field of SSc if we hope to effectively improve the HRQoL of patients with this disease.

Table 1 Baseline characteristics of patients with systemic sclerosis enrolled in the Canadian Scleroderma Research Group Registry

	% or mean (SD)
Women	87.2%
Mean age, years	55.6 (12.8)
Education (more than high school)	46.3%
Mean disease duration, years*	10.6 (8.5)
Diffuse skin involvement	45.7%
Modified Rodnan skin scores (range 0-51)	11.2 (10.4)
Fingertip to palm distance, centimetres	1.2 (2.0)
Number of fingertip ulcers	1.3 (2.5)
Shortness of breath (range 0-10)	2.1 (2.5)
Number of swollen joints	0.9 (3.1)
Number of tender joints	2.0 (4.6)
Number of gastrointestinal symptoms (range 0-15)	3.9 (2.9)
Number of tender points of fibromyalgia (range 0-18)	3.6 (5.6)
Fatigue (range 0-100)**	46.1 (10.7)
Pain (range 0-45)**	6.6 (7.7)
Depression (range 0-60)**	13.4 (10.2)
WHODAS II score** (range 0-100)	23.7 (17.2)
Understanding and communicating	12.6 (15.8)
Getting around	29.9 (24.2)
Self care	14.3 (19.9)
Getting along with people	14.9 (16.2)
Life activities	35.5 (27.5)
Participation in society	25.6 (19.0)

*Since onset of first non-Raynaud's manifestation of SSc.

**Lower scores represent better and higher scores represent worse outcomes for pain, depression and WHODAS II scores. On the contrary, for fatigue, lower scores represent more and higher scores less fatigue.

Table 2 Correlations between WHODAS II and sociodemographic and disease-related variables

	Correlation coefficient	p value
Male (compared to female)	0.07	0.127
Age	-0.03	0.502
More than high school education *vs* high school or less	-0.09	0.05
Mean disease duration in years since onset of first non-Raynaud's manifestation	0.05	0.149
Modified Rodnan skin score	0.13	<0.001
Number of fibromyalgia tenderpoints	0.15	<0.001
Fingertip to palm distance	0.14	0.001
Number of fingertip ulcers	0.10	0.021
Shortness of breath	0.37	<0.001
Number of swollen joints	0.07	0.106
Number of tender joints	0.19	<0.001
Number of gastrointestinal symptoms	0.32	<0.001
Fatigue	-0.50	<0.001
Pain	0.41	<0.001
Depression	0.43	<0.001

Table 3 Hierarchical linear regression predicting the WHODAS II in SSc patients

Step	Variables	df	B	SE B	β	p	R^2	Adjusted R^2	Δ R^2	p
1	Age		.000	.009	-.003	.955				
	Gender		.507	.321	.086	.115				
	Education	3, 333	-.447	.219	-.113	.042	.020	.012	.020	.077
2	Age		-.003	.009	-.021	.704				
	Gender		.527	.321	.089	.101				
	Education		-.444	.218	-.112	.043				
	Disease duration	1, 332	.021	.013	.089	.107	.028	.016	.008	.051
3	Age		.004	.007	.024	.622				
	Gender		.325	.270	.055	.231				
	Education		-.132	.178	-.033	.457				
	Disease duration		.006	.011	.027	.572				
	Skin score		.040	.010	.211	<.001				
	Shortness of breath		.292	.037	.371	<.001				
	# gi symptoms		.169	.034	.249	<.001				
	FTP distance		.037	.049	.038	.455				
	# fingertip ulcers		.013	.038	.016	.736				
	# fibromyalgia tender point		.023	.017	.064	.180				
	# swollen joints		.002	.035	.003	.951				
	# tender joints	8, 324	.044	.024	.102	.064	.386	.363	.358*	< .001
4	Age		.011	.006	.069	.080				
	Gender		.165	.219	.028	.451				
	Education		-.027	.146	-.007	.854				
	Disease duration		.003	.009	.014	.720				
	Skin score		.033	.008	.174	<.001				
	Shortness of breath		.152	.032	.193	<.001				
	# gi symptoms		.058	.028	.086	.041				
	FTP distance		.026	.040	.027	.518				
	# fingertip ulcers		.018	.030	.024	.546				
	# fibromyalgia tender point		-.006	.014	-.016	.677				
	# swollen joints		-.007	.028	-.010	.812				
	# tender joints		.023	.019	.054	.231				
	Fatigue		-.070	.008	-.381	<.001				
	Pain		.034	.011	.135	.003				
	Depression	3, 321	.035	.009	.180	<.001	.610	.592	.224*	< .001

For each step, individual variable parameters are shown, including unstandardized regression coefficients (B) and their standard errors (SE), as well as standardized

regression coefficients (β) and p values. In addition, overall model fit statistics (R^2) and a P value for the change in variance accounted for (ΔR^2) are shown for each step.

*p < .001

GI – gastrointestinal; FTP – fingertip to palm distance

Table 4 Standardized betas (p values) for significant sociodemographic and clinical correlates of the WHODAS II subscales in separate multivariate models using the subscale scores as outcome variables

	Understanding and communicating	Getting around	Self care	Getting along with people	Life activities	Participation in society
Age		.184 (<.001)			.150 (.002)	
Gender			.106 (.022)			
Education						
Disease duration						
Skin score		.108 (.023)	.313 (<.001)		.199 (<.001)	.152 (.002)
Shortness of breath		.267 (<.001)	.164 (.001)		.186 (<.001)	.181 (<.001)
# gi symptoms		.114 (.018)	.132 (.011)			
FTP distance						
# fingertip ulcers						.093 (.036)
# fibromyalgia tender point						
# swollen joints						
# tender joints						
Fatigue	-.232 (<.001)	-.354 (<.001)	-.141 (.013)	-.234 (<.001)	-.417 (<.001)	-.272 (<.001)
Pain	.114 (.044)	.158 (.002)	.203 (<.001)			.144 (.027)
Depression	.351 (<.001)			.230 (<.001)		.260 (<.001)

GI – gastrointestinal; FTP – fingertip to palm distance

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