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ORIGINAL ARTICLE

Health-Related Quality of Life in Systemic Sclerosis as Measured by the Short Form 36: Relationship With Clinical and Biologic Markers

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Objective. **To evaluate health-related quality of life (HRQOL) in patients with systemic sclerosis (SSc) using the Short Form 36 (SF-36) and to correlate SF-36 scores with clinical and biologic markers.**
Methods. **The SF-36 was administered to 24 controls and 24 SSc patients. SSc patients also were evaluated for subset (limited SSc [lSSc] and diffuse SSc [dSSc]), age, disease duration, angiotensin-converting enzyme (ACE) levels, autoantibodies, and skin and internal organ involvement.**
Results. **The physical summary score (PSS) was lower in SSc patients than in controls ($P < 0.05$), whereas the mental summary score (MSS) was higher in dSSc than in lSSc patients ($P < 0.05$). Five of 8 single SF-36 domain scores were lower in SSc patients than in controls ($P < 0.05$). Vitality was higher in dSSc than in controls ($P < 0.001$). In SSc, elder age correlated with lower PSS; low ACE levels and high skin score correlated with higher general mental health and role limitations due to physical problems, respectively ($P < 0.05$). Patients with heart involvement had higher scores in general health perceptions ($P < 0.05$).**
Conclusion. **The SF-36 shows that HRQOL is impaired in patients with SSc. Higher scores in MSS and vitality in patients with dSSc and correlations of high SF-36 scores with specific organ involvement suggest that SSc patients with severe disease are more able to cope with HRQOL modification.**

KEY WORDS. Systemic sclerosis; SF-36; Health-related quality of life; Coping.

INTRODUCTION

Systemic sclerosis (SSc) is characterized by fibrosis of the skin and internal organs (lungs, heart, kidney, gastrointestinal tract) (1). Impairment of these organs induces a wide spectrum of functional failures and limitations, affecting general health status.

Few diseases lead to such striking and severe changes in physical aspect in a relatively short time as does SSc. Induration and retraction of skin, face modifications, telangiectasias, and microcheilia dramatically change the aesthetic aspect and influence self image. Moreover, skin changes, with articular and periarticular modifications and painful fingertip ulcers, progressively limit the functional capacity of the hands. All these internal and external physical changes lead to severe limitations in work and social activities, and to psychological distress, ultimately inducing a serious impairment in the health-related quality of life (HRQOL).

All these aspects should be addressed when dealing with a severe, chronic, and disabling illness, such as SSc. For this reason, impairment in HRQOL should be correctly evaluated and managed in SSc. In the last 10 years, various self-administered questionnaires were used to evaluate health status, functional capacity, and disability associated with rheumatic diseases. In SSc, these questionnaires

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assess the physical impact and consequences of the disease, but scarcely evaluate the psychological aspects and the HRQOL (2–5).

Health state and quality of life are determined by physical and psychological wellbeing, which are strictly related. In SSc, these 2 aspects are modified not only by general and organ-related symptoms, but also by the external modifications due to cutaneous, microvascular, and articular/periarticular changes.

The Short Form 36 (SF-36) is, to date, the most used tool that evaluates HRQOL as a subjective perception about psychological and physical limitations due to an underlying illness. The SF-36 is the short form questionnaire derived in 1990 from the Medical Outcomes Study that evaluates 40 domains on physical and mental health (6,7). The SF-36 measures 8 health domains about physical, social, usual activities, bodily pain, general mental health, emotional problems, vitality, and general health perception (8).

SF-36 administration, faster and as precise as MOS, has been successfully used to evaluate HRQOL in such rheumatic diseases as osteoarthritis (OA) (9,10), rheumatoid arthritis (RA) (11,12), Sjögren syndrome (SS) (13,14), systemic lupus erythematosus (SLE) (15–17), and fibromyalgia (FM) (17).

The aim of this preliminary study was to assess, in SSc, the HRQOL by SF-36 administration and to correlate SF-36 scores with clinical and laboratory parameters.

PATIENTS AND METHODS

Between 2000 and 2001, 24 SSc patients attending the outpatient clinic of the Division of Rheumatology of the Department of Medicine of the University of Florence (Italy), were consecutively enrolled and gave their written informed consent to participate in all the investigations included in the study (self-administration of the Italian version of the SF-36; clinical, laboratory, and instrumental testing, including radiologic and nuclear medicine investigations). They were classified as affected by limited SSc (lSSc; 15 patients) and diffuse SSc (dSSc; 9 patients) according to Le Roy et al (18). Twenty-one patients were women, 3 were men, the mean age was 53.42 years (SD 15.07 years), and the mean (± SD) disease duration, calculated from the onset of the first non-Raynaud's phenomenon symptom, was 8.30 years (± 6.60 years).

At SF-36 administration, calcium channel blockers, proton pump inhibitors, clebopride, topical glyceryl trinitrate, and intravenous prostanoids were permitted, but corticosteroids, methotrexate, cyclophosphamide, other disease-modifying antirheumatic drugs, and angiotensin-converting enzyme (ACE) inhibitors were not allowed. All SSc patients and controls were white and came from the same geographic area.

After written informed consent, the SF-36 was administrated to 24 healthy controls matched to SSc patients for sex (21 women and 3 men) and age (mean ± SD 52.71 ± 14.20 years).

SF-36. The Italian version of the self-administered SF-36 questionnaire was given to SSc patients and healthy controls to evaluate their HRQOL (19). To confirm if our control sample was representative of the general population, we verified if SF-36 scores of our healthy controls were in the range of Italian population normative data (19).

The SF-36 consists of 36 items organized into 8 domains measuring 8 health concepts: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and general mental health (8). Among these domains, physical functioning, role limitations due to physical problems, and bodily pain evaluate only physical dimensions; social functioning, role limitations due to emotional problems, and general mental health assess mental aspects; general health perceptions and vitality evaluate both physical and mental dimensions. In SF-36 domains, scores are rated so that higher values correspond to better conditions and lower scores to worse conditions (range 0–100). The 8 domains, weighted according to normative data, are also combined into a physical summary score (PSS) and a mental summary score (MSS), which are scored from 0 to 100, with higher values reflecting better HRQOL. Four blinded psychiatrists, with an expertise in evaluating HRQOL questionnaires, calculated SF-36 scores.

Clinical and hematologic assessment. An extensive clinical evaluation was performed on all SSc patients.

Skin involvement was assessed using the Rodnan modified skin score (20).

Lung involvement was evaluated by carbon monoxide diffusing capacity (DLCO) using the single-breath method standardized for hemoglobin (normal values >80%), ventilation scintiscan with ^{99m}Tc-diethylenetriaminepentaacetic acid (DTPA) radioaereosol (normal range of the alveolar capillary clearance ≥60 minutes), and high-resolution computed tomography (HRCT), according the following score: 0 = normal, 1 = ground glass appearance, 2 = diffuse interstitial fibrosis, 3 = honeycombing (21).

Heart involvement was assessed using standard electrocardiogram (EKG), 24-hour ambulatory EKG, and echocardiography (M-2D mode and Doppler). When one of these parameters was abnormal, the patient was considered positive.

ACE levels (normal value 5–12 pM/ml/minute) were measured, by fluorimetric method, as an index of endothelial derangement (22,23).

Peripheral nervous system state was assessed by neurophysiologic studies. The sensory-motor nerve conduction studies (NCS) of median, ulnar, posterior tibial, peroneal, and sural nerves were conducted using standard commercial equipment and surface electrodes (Reporter; Esa Ote-Biomedica, Florence, Italy). The technique was performed as previously reported (24). The patient was considered positive if any alteration in the assessed tests was found.

Antinuclear antibodies (ANA), anticentromere antibodies (ACA), and antitopoisomerase I antibodies (ATA) were detected as described elsewhere (25).

Statistics. Data were analyzed using SPSS 10.0 for Windows (Chicago, IL). Descriptive statistics were expressed

Table 1. Demographic and clinical characteristic of SSc patients*

	Mean ± SD	Number (%)
Age, years	53.42 ± 15.07	
Sex		
Female		21 (87.5)
Male		3 (12.5)
Disease duration, years	8.30 ± 6.60	
Subset		
lSSc		15 (62.5)
dSSc		9 (37.5)
ACE, pM/ml/minute	3.00 ± 3.03	
DTPA, minutes	39.61 ± 13.93	
DLCO	78.46 ± 24.66	
Skin score	15.21 ± 7.15	
HRCT		22
0		6 (27.27)
1		8 (36.36)
2		5 (22.72)
3		3 (13.63)
Heart involvement		24
P		12 (50)
N		12 (50)
NCS		18
+		15 (83.3)
−		3 (16.87)
ANA		24
+		24 (100)
−		0 (0)
ACA		24
+		9 (37.5)
−		15 (62.5)
ATA		24
+		9 (37.5)
−		15 (62.5)

* SSc = systemic sclerosis; lSSc = limited SSc; dSSc = diffuse SSc; ACE = angiotensin-converting enzyme; DTPA = ventilation scintiscan with ^{99m}Tc-diethylentriaminepentaacetic acid radioaereosol; DLCO = diffusing lung capacity for carbon monoxide; HRCT = high-resolution computed tomography score; 0 = normal, 1 = ground glass appearance, 2 = diffuse interstitial fibrosis, 3 = honeycombing; P = presence of electrocardiogram and/or 24-hour electrocardiogram and/or M-2D mode and Doppler echocardiography alterations; N = absence of any cardiac instrumental alteration; NCS = nerve conduction studies; ANA = antinuclear antibodies; ACA = anticentromere antibodies; ATA = antitopoisomerase antibodies.

as mean ± SD for continuous variables, and as number and percentage for categorical variables. Two-tailed Student's *t*-tests for independent samples were used to compare continuous variables. Categorical variables were analyzed using a chi-square test. Linear correlation analysis (Pearson's correlation coefficient) was used to analyze the relationship of SF-36 scores with clinical and laboratory parameters. Analysis of variance with post-hoc comparison by Bonferroni correction was used to compare SF-36 scores between patients with lSSc, dSSc, and controls. All the statistics were considered significant at $P < 0.05$.

RESULTS

Demographic, clinical, and laboratory parameters of SSc patients are shown in Table 1.

Clinical variables in patients with lSSc versus dSSc. Patients with dSSc had higher skin scores than patients with lSSc (19.77 ± 6.68 versus 12.33 ± 5.9; $P = 0.015$). No other significant difference of any demographic, clinical, or hematologic parameter was detected between the 2 SSc subsets.

SF-36 scores in SSc patients versus healthy controls. SSc patients and controls were not different in age ($P = 0.868$) or sex distribution (21 women, 87.5%; and 3 men, 12.5% in both groups). SF-36 scores of SSc patients and controls are presented in Table 2.

The PSS was significantly lower in SSc patients than in healthy controls, whereas the MSS was not different between SSc and healthy controls. The scores of 5 of 8 SF-36 domains were significantly lower in patients with SSc. In particular, physical functioning, role limitation due to physical problems, and bodily pain (all related to the physical dimension) were significantly lower in SSc patients. Among domains evaluating mental dimensions, social functioning and general mental health were significantly lower in SSc patients than in controls, whereas role limitation due to emotional problems was not significantly different from controls. No significant differences were found between SSc patients and controls in the domains evaluating both mental and physical well being (general health perception and vitality).

SF-36 scores of healthy controls were in the range of Italian population normative data, also presented in Table 2 (19).

SF-36 scores in dSSc patients versus lSSc patients versus healthy controls. SF-36 scores of dSSc and lSSc patients and controls are presented in Table 3. In both lSSc and dSSc patients, PSS was significantly lower than in healthy controls, whereas no difference was found between lSSc and dSSc patients. The MSS was significantly higher in dSSc than in lSSc patients, but neither was significantly different from controls. Interestingly, the MSS of healthy controls was higher than that found in lSSc patients and lower than in dSSc patients.

In lSSc patients, the scores of role limitations due to physical problems, bodily pain, social functioning, and general mental health were significantly lower than in controls. In dSSc patients, the scores of physical functioning, bodily pain, social functioning, and general mental health were significantly lower than in controls, whereas vitality was significantly higher. No difference in the single SF-36 domains was found in lSSc patients compared with dSSc patients.

SF-36 scores and clinical and laboratory variables in healthy controls and SSc patients. Both in controls and SSc patients, elder age was inversely correlated with lower PSS ($r = -0.565$, $P = 0.005$; $r = -0.537$, $P = 0.007$, respectively), but it did not correlate with MSS. No significant correlation between PSS and MSS with disease duration, ^{99m}Tc-DTPA, DLCO, HRCT, skin score, ANA, ACA, ATA, heart involvement, or NCS were found. Low ACE levels were inversely correlated with higher scores in gen-

Table 2. SF-36 scores in SSc versus controls and in Italian normative data*

	SSc, mean ± SD	Controls, mean ± SD	Italian normative data, normal ranges	*t*, SSc versus controls	*P*, SSc versus controls
Physical summary score	41.07 ± 10.84	50.84 ± 6.92		−3.662	0.001
Mental summary score	44.78 ± 9.92	47.07 ± 8.68		−0.841	0.405 (NS)
Physical functioning	70.71 ± 23.05	88.57 ± 14.84†	70–100	−2.40	0.021
Role limitation due to physical problems	61.34 ± 45.68	89.29 ± 21.75†	70–100	−2.71	0.010
Bodily pain	44.69 ± 19.96	73.81 ± 18.35†	60–80	−5.11	<0.001
General health perceptions	65.19 ± 15.67	68.85 ± 14.04†	50–80	−0.996	0.325 (NS)
Vitality	76.60 ± 33.13	56.43 ± 12.66†	50–80	1.96	0.059 (NS)
Social functioning	57.69 ± 22.93	81.55 ± 16.59†	60–90	−3.59	0.001
Role limitation due to emotional problems	80.29 ± 34.33	80.95 ± 30.86†	60–90	−0.75	0.457 (NS)
General mental health	44.88 ± 13.57	68.57 ± 14.10†	50–80	−5.56	<0.001

* SF-36 = Short Form 36 health survey; SSc = systemic sclerosis; NS = not significant.
† In the range of normative data.

eral mental health (r = −0.459, $P = 0.032$). High skin score values were related to higher scores in role limitations due to physical problems (r = 0.394, $P = 0.05$). Patients with heart involvement had higher scores in general health perceptions ($P = 0.039$, t = −2.21) than patients without heart involvement. No significant correlations between SF-36 domains and age, disease duration, ^{99m}Tc DTPA, DLCO, HRCT, ANA, ACA, ATA, or NCS were found.

Table 3. SF-36 scores in lSSc patients versus dSSc patients versus controls*

	SF-36 scores mean ± SD			ANOVA, overall group effect, *P*	Post-hoc paired contrasts (Bonferroni)		
	lSSc	dSSc	Controls		lSSc versus controls, *P*	dSSc versus controls, *P*	lSSc versus dSSc, *P*
Physical summary score	41.25 ± 10.13	40.83 ± 12.33	50.84 ± 6.32	0.003	0.011	0.019	1.000 (NS)
Mental summary score	40.60 ± 10.41	50.64 ± 5.46	47.07 ± 8.68	0.020	0.101 (NS)	0.858 (NS)	0.024
Physical functioning	75.77 ± 19.02*†	65.63 ± 31.67*†	88.57 ± 14.84*†	0.022	0.237 (NS)	0.027	0.805 (NS)
Role limitation due to physical problems	53.85 ± 45.47	68.75 ± 45.81	89.29 ± 21.75†	0.023	0.022	0.513 (NS)	1.000 (NS)
Bodily pain	41.92 ± 15.48	46.88 ± 26.04	73.81 ± 18.35†	<0.001	<0.001	0.005	1.000 (NS)
General health perceptions	59.38 ± 17.50	71.00 ± 11.86	68.85 ± 14.04†	0.134 (NS)	0.236 (NS)	1.000 (NS)	0.269 (NS)
Vitality	61.54 ± 42.70†	91.67 ± 23.57†	56.43 ± 12.66†	0.012	1.000 (NS)	0.010	0.060 (NS)
Social functioning	55.38 ± 22.95	60.00 ± 29.28†	81.55 ± 16.59†	0.003	0.004	0.060 (NS)	1.000 (NS)
Role limitation due to emotional problems	73.08 ± 25.44†	87.50 ± 37.80†	80.95 ± 30.86†	0.566 (NS)	1.000 (NS)	1.000 (NS)	0.908 (NS)
General mental health	45.38 ± 12.16	44.38 ± 14.99	68.57 ± 14.10†	<0.001	<0.001	<0.001	1.000 (NS)

* SF-36 = Short Form 36 health survey; lSSc = limited systemic sclerosis; dSSc = diffuse systemic sclerosis; ANOVA = analysis of variance; NS = not significant.
† In the range of normative data.

DISCUSSION

Our data show that in SSc, HRQOL, evaluated by the means of the SF-36, is impaired. Although the PSS is similarly impaired in the 2 subsets, MSS is higher in dSSc than in lSSc patients. This dichotomy could signify that people with dSSc and lSSc have different mental perceptions with respect to their disease.

In lSSc, SF-36 scores suggest that these patients experience not only limitations in physical dimensions, but also impairment in social functioning and general mental health. In dSSc, lower scores for physical functioning, bodily pain, general mental health, and higher scores for vitality indicate that these patients perceive an impairment in physical and in mental domains of SF-36 but are characterized by an elevated vitality.

SF-36 evaluates HRQOL as a subjective perception about psychological and physical limitations due to an underlying illness. For this reason, it was widely used to assess perception about psychological and physical limitations in other rheumatic diseases. SF-36 evaluated HRQOL and its modifications due to surgical and medical therapy in OA (9,10) and RA (11,12), and showed a decreased HRQOL in SS (13,14). In SLE, HRQOL measured by SF-36 was more influenced by fatigue and pain than by the presence of specific autoantibodies, organ involvement, or both (15). In SLE, SF-36 scores were significantly lower than in controls, and correlated with disease activity (16). Interestingly, patients with FM showed higher impairment than SLE patients on domains evaluating physical concepts and vitality (17). This finding reflects the difference in self-reported HRQOL between the 2 conditions. In FM, depression and psychosomatic disorders are prominent, whereas in SLE the involvement of internal organs prevails. This suggests how self-reported HRQOL may not be related to the severity of the underlying illness, but may more likely depend upon the patients' subjective perception about psychological and physical limitations and upon the capacity to cope with the disease.

In agreement with the SLE data, it may be hypothesized that dSSc patients, with a serious and disabling disease course, may cope with the disease more efficaciously than patients with lSSc, paradoxically reaching a better perception of their HRQOL and better scores in the MSS score and in the vitality domain.

The MSS is higher in dSSc than in lSSc patients, and the mental domains in which the 2 disease subsets differ from controls are distinct. This could lead to the hypothesis that a different psycopathologic profile may characterize lSSc and dSSc patients. High scores in the MSS and vitality in dSSc patients is, however, an unexpected finding. It is worth investigation with specific questionnaires if high MSS and vitality may be due to a mood switch to a euphoric status, such as in mania.

The lack of difference in the single SF-36 domains between lSSc and dSSc may be due to the lower number of dSSc patients in the study; however, this number reflects the usual ratio between the 2 disease subsets.

The coping mechanism detected in dSSc is in agreement with the HRQOL results obtained, by the means of SF-36, in other chronic and life-threatening conditions, such as renal and prostate carcinoma (26,27) and hematologic malignancies (28). Coping strategies are also observed in disabling and life-threatening primary cardiac conditions, such as heart transplant (29) and heart failure (30). In malignancies and cardiac diseases, as in dSSc, the unexpected high self-perceived HRQOL may be due to psychological adaptation and coping with the chronic and disabling underlying conditions, leading to dramatic changes of lifestyle.

Apart from the differences found in HRQOL according to disease subsets, notable associations were shown in our study between SF-36 scores and demographic and clinical characteristics. In SSc patients and in controls, lower PSS, but not MSS, is correlated with elder age. This could mean that age has a similar influence on self-perceived HRQOL in SSc patients and in controls, influencing more physical than mental aspects in both populations.

Lower ACE levels (reflecting the involvement of microvessels) and presence of heart involvement correlated with better scores in general mental health and general health perception, respectively. Higher skin scores were related to better scores in role limitations due to physical problems. All the physical changes due to microvascular, skin, and heart involvement severely limits everyday life, work, and social activities. This compels the patients, by a mechanism of coping and HRQOL modification, to adapt to the new lifestyle induced by the disease.

Up to now, attention has been dedicated to evaluating the physical impact of SSc, whereas psychological well-being was seldom assessed. In SSc, disability was evaluated by the Health Assessment Questionnaire (2), recently integrated with visual analog scales related to specific symptoms (3). Moreover, a questionnaire evaluating hand function and muscle strength, but not visceral involvement, was used to assess disability in SSc (4). The self-administered Systemic Sclerosis Questionnaire explores general and organ-specific symptoms, and covers SSc-specific functional limitations and symptoms, but its use in daily clinical practice is limited by its complexity (5).

The SF-36, instead, represents a valid and precise tool for evaluating objective disability and the overall impact of the disease on physical activities, and for assessing the subjective perceptions about the psychological limitations felt by the patients. Thus, as HRQOL is determined both by physical and mental health, SF-36 should be considered a step forward in respect to other questionnaires, because it evaluates psychological aspects as well, until now scarcely considered in SSc assessment.

In SSc patients, education level, functional ability, illness-related uncertainty, hardiness, and social support were predictive of psychosocial adjustment to the disease. Education level and functional ability explained 14% of the variance in psychosocial adjustment, whereas illness-related uncertainty, hardiness, and social support raised the explained variance to 38% (31). Mild and moderate-severe depression were found in 50% and 17% of SSc patients, respectively. Depressive symptoms were mostly present in younger patients with digital ulceration and had a stronger relationship with personality, self-rated disability, psychosocial adjustment to illness, and social support than to clinical indexes of clinical severity (32). Recently,

depression and anxiety, somatization, interpersonal sensitivity, obsessive-compulsiveness, paranoid ideation, and psychotic symptoms scores were found to be significantly increased in SSc patients (33). These works demonstrate that psychological changes are frequently found in patients with SSc.

Even if SF-36 does not specifically evaluate psychological modifications, these findings are, partly, confirmed by our study in which social functioning and general mental health scores were significantly lower in SSc patients than in controls. To the best of our knowledge, our study is the first work assessing by the means of SF-36 the subjective perceptions of patients, according to the 2 SSc subsets, about the effects of disease on disability, physical activities, and psychological limitations.

In conclusion, the SF-36 is a useful tool to evaluate HRQOL in SSc because it measures functional impairment and may indicate the psychological condition of SSc patients. Moreover, the SF-36 indicates the capacity of the patients to cope with HRQOL modifications and lifestyle adaptations made necessary by the disease.

A rapid evaluation by the self-administered SF-36 should be considered a first-step examination to assess the subjective perceptions about the changes due to their disease in patients with SSc. When a particular psychological aspect is disclosed by the SF-36, a prompt therapeutic strategy to control mania, anxiety, or depression should be started with the help of psychologists or psychiatrists. The SF-36 may be also useful in evaluating physical impairment to be managed with the help of rehabilitation therapists.

Our study is a preliminary work evaluating the SF-36 in a limited number of SSc patients. For this reason, work on larger groups are needed to confirm if the SF-36 could be useful in routine clinical activities to assess physical and psychological condition in SSc.

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