Health-related quality of life in Italian patients with systemic lupus erythematosus. I. Relationship between physical and mental dimension and impact of age

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Objective. To examine health-related quality of life (HRQOL) in Italian patients with systemic lupus erythematosus (SLE) and compare it with that of healthy people, and to investigate relationships among different dimensions and subscales of a generic health status measure.

Methods. The Medical Outcomes Study Short Form-36 (SF-36) was applied in a cohort of 126 consecutive SLE patients and 96 healthy controls. At the time of HRQOL testing, all patients underwent clinical and laboratory evaluation.

Results. Both physical (PCS) and mental (MCS) component summary scores of the SF-36 were reduced in patients compared with controls. In SLE great variability in all the subscales was observed. Significant correlations between PCS and MCS and between many different subscales were observed in patients but not in controls. The PCS was higher than MCS more frequently in controls than in SLE patients (81 *vs* 48.4%, $P < 0.00001$). In SLE, HRQOL tended to worsen with age.

Conclusion. Both PCS and MCS contribute to the decrease in HRQOL in SLE patients. In SLE the mutual interaction between these two dimensions seems to be more relevant than in healthy people.

KEY WORDS: SF-36, Health-related quality of life, Mental health, Physical health, Systemic lupus erythematosus.

Over the past few years, the assessment of health-related quality of life (HRQOL) in systemic lupus erythematosus (SLE) has become a relevant tool in defining disease prognosis and the effectiveness of therapeutic intervention [1, 2].

During the last decade, several studies on the HRQOL of SLE patients have been carried out which have recognized the importance of the disease assessment not only from a biological but also from a psychosocial point of view [3, 4]. In order to select the most suitable tools for defining health status in SLE patients, some authors have analysed different generic health status instruments designed to summarize a spectrum of HRQOL that applies to many different impairments, patients and populations [5]. Apart from their broad applicability, they may be able to detect unexpected beneficial and adverse effects on disease remission and progression that can easily be missed by specific measures. The Medical Outcomes Study Short Form-20 (SF-20) and the Short Form-36 (SF-36) were the generic health status instruments which performed better in SLE [6]. In view of the comprehensiveness of the SF-36, its widespread use and international validation for a wide range of medical conditions, we choose it as a patient life-impact assessment, although it is not yet known what degree of change in SF-36 score is clinically important.

Our objectives were to examine health status in Italian SLE patients using SF-36, compared with that of healthy controls, and to study the relationships among its different health dimensions and the impact of age class. Our findings may help patient management in clinical practice.

Patients and methods

Patients with SLE

We considered 126 consecutive out-patients affected with SLE seen in the rheumatology unit at the Division of Rheumatology, Padua University. They were all Caucasians. There were 110 females and 16 males, mean age was 38.9 ± 11.9 yr (range 18–65) and mean disease duration 9.9 ± 6.3 yr (range 1–32).

All patients satisfied at least four of the American College of Rheumatology (ACR) criteria for the classification of SLE [7] and had always been followed up according to the diagnostic and therapeutic guidelines reported by ACR [8].

SLE clinical and laboratory parameters, disease activity and cumulative damage, and treatment were evaluated.

For definitions of SLE-specific features, we used those included in the ACR criteria [7].

Antinuclear antibodies (ANA) and anti-double-stranded DNA (dsDNA) were detected with the indirect immunofluorescence technique, using as a substrate HEp-2 cells and *Crithidia luciliae* respectively. Antibodies against extractable nuclear antigens (anti-Sm, anti-nRNP, anti-Ro/SSA, anti-La/SSB) were tested with the

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counterimmunoelectrophoresis technique, using as control sera those provided by the Center for Disease Control (Atlanta, GA, USA). Lupus anticoagulant was detected by means of the Russell viper venum time method, and anticardiolipin antibodies by an enzyme-linked immunosorbent assay.

SLE disease activity was measured with the European Consensus Lupus Activity Measure (ECLAM) score [9] and cumulative damage with the Systemic Lupus International Collaborating Clinic/American College of Rheumatology (SLICC/ACR) damage index [10]. An ECLAM score greater than 2 was considered indicative of active disease.

Ninety-six subjects, selected by the Department of Rheumatology, University of Ancona, were considered as controls. The control group was chosen randomly from a list of 430 hospital personnel, and included 80 females and 16 males (mean age 43 ± 7.5 yr; range 26–58 yr). All controls were healthy with no coexistent disease; this was determined from their medical records, which included reports of a complete physical examination, routine blood and urine tests, and chest radiographs. The study was done according to the Declaration of Helsinki. All the patients and controls gave informed consent.

Quality of life assessment

HRQOL was assessed using the SF-36 questionnaire. The SF-36 is a generic instrument with scores that are based on responses to individual questions, which are summarized into eight scales, each of which measures a health concept [11]. These scales include function domains and aspects of well-being, as follows: physical function (PF), limitations in physical activities because of health problems; role–physical (RP), limitations in usual role activities because of physical health problems; bodily pain (BP), influence of pain on daily activities; vitality (VT), energy level and fatigue; role–emotional (RE), limitations in usual role activities because of emotional problems; mental health (MH), psychological distress and well-being; social function (SF), limitations in social activities because of physical or emotional problems; general health (GH), subjective perception of health status.

These eight scales, weighted according to normative data, are scored from 0 to 100, higher scores reflecting better HRQOL [12]. The SF-36 survey also includes a single-item measure of health transition, which is not used to score any of the eight multi-item scales. The SF-36 has been validated for use in Italy [13] and it can be completed within 10 min by most people. Recently, the originators of the SF-36 have developed algorithms to calculate two psychometrically based summary measures: the physical component summary (PCS) score and the mental component summary (MCS) score [14, 15]. The PCS and MCS provide greater precision, reduce the number of statistical comparisons needed, and eliminate the floor and ceiling effects noted in several of the subscales [16, 17].

Statistical analysis

Scores are variables measured on an ordinal scale and their distributions showed a significant difference from normality, especially in the SLE group; consequently a non-parametric statistic was used. The Mann–Whitney U test was used for independent samples. Linear correlation between variables was checked using Spearman's ρ. Dichotomous variables were analysed using the Pearson's χ^2 test. Statistical significance was set at $P < 0.05$. The median and range and the mean ± S.D. are presented. All analysis were performed using the statistical software package Statistica (Statsoft, Tulsa, OK, USA).

Results

The prominent clinical and serological features of our out-patients are reported in Table 1. At the time of our evaluation the patients had an average ECLAM score of 1.67 ± 1.12 (range 0–6). Twenty-five patients (18%) had damage in at least one of the organ systems considered in the SLICC/ACR damage index. The mean damage index score in our 126 patients was 0.33 ± 0.84 (range 0–5). Taking into account only the 25 patients with damage, the score was 1.68 ± 1.14 (range 1–5).

In SLE patients, the PCS and the MCS scores were both lower than in controls. PCS was 67.73 ± 21.02 in SLE and 82.47 ± 5.07 in controls ($P < 0.00001$), and MCS was 67.86 ± 20.09 in SLE and 77.58 ± 5.01 in controls ($P < 0.04$).

In Table 2, the mean scores obtained in each of the eight SF-36 subscales in the patient and control groups are reported. In all subscales the mean scores were lower in SLE patients than in controls. The differences were statistically significant for all subscales except RP and SF. The major differences were observed in GH and VT scores (both $P < 0.00001$). In healthy subjects, the frequencies of each score obtained in all subscales followed a distribution with the mode located in the range of the highest

TABLE 1. Prominent SLE features overall and at the time of evaluation in 126 patients enrolled in the study

	Cumulative		At the time of evaluation	
	n	(%)	n	(%)
Arthritis	94	(74.6)	9	(7.14)
Artralgias	110	(87.3)	33	(26.2)
Skin rash	67	(53.2)	9	(7.14)
Raynaud's phenomenon	59	(46.8)	27	(21.4)
Serositis	33	(26.2)	7	(5.5)
Haematological involvement	103	(81.7)	62	(49.2)
Renal involvement	49	(38.9)	27	(21.4)
CNS involvement	13	(10.3)	4	(3.2)
Anti-dsDNA	96	(76.2)	64	(50.8)
Anti-RNP	53	(42.1)	37	(29.4)
Anti-Ro/SSA	54	(42.8)	37	(29.4)
Anti-La/SSB	15	(11.9)	9	(7.14)
Anti-aCL	39	(30.9)	48	(38)
LAC	27	(21.4)	20	(15.9)

For definitions of SLE specific features, we used those included in the ACR criteria [7].

CNS, central nervous system; anti-dsDNA, anti-double-stranded DNA antibody; anti-aCL, anticardiolipin antibody; LAC, lupus anticoagulant.

TABLE 2. Mean and standard deviation of the eight SF-36 subscales in the patient and control groups

SF-36 subscale	Mean ± S.D.		$P <$
	SLE (126 cases)	Controls (96 cases)	
PF	83.2 ± 17.3	90.1 ± 9.1	0.015
RP	69.8 ± 37.9	81.7 ± 8.5	n.s.
BP	68.7 ± 26.3	78.8 ± 11.0	0.011
GH	49.1 ± 22.7	79.3 ± 7.4	0.00001
VT	57.9 ± 19.6	71.2 ± 10.7	0.00001
SF	74.0 ± 26.1	81.7 ± 8.7	n.s.
RE	72.0 ± 38.3	80.9 ± 9.8	0.020
MH	67.6 ± 21.0	76.5 ± 8.4	0.022

Significance was tested with the Mann–Whitney U test (n.s., not significant).

PF, physical function; RP, role–physical; BP, bodily pain; GH, general health; VT, vitality; SF, social function; RE, role–emotional; MH, mental health.
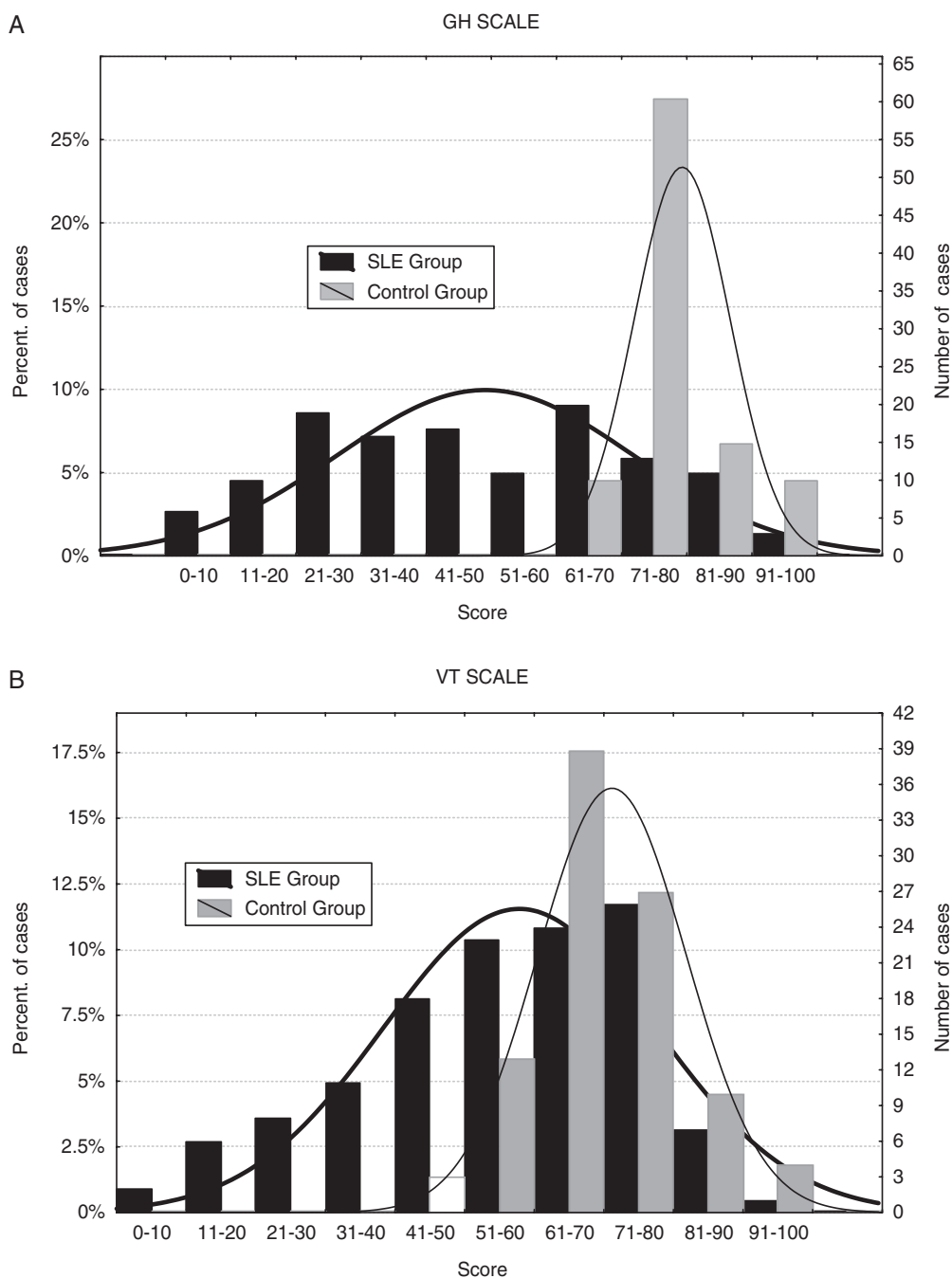
A

GH SCALE

B

VT SCALE

Fig. 1. (A) Frequencies of scores on the GH (general health) scale in patients and controls. (B) Frequencies of scores on the VT (vitality) scale in patients and in controls.

scores, whereas in SLE the frequencies were spread along the whole scale (Fig. 1A and B).

Looking at the effect of age on these measures, we observed a significant inverse linear correlation for all subscales and PCS and MCS in SLE group, whereas no linear correlations were found in the control group (Table 3 and Fig. 2).

In Table 4, the values of PCS and MCS distributed according to age class are reported. In SLE, compared with controls, the PCS score was lower in the age class 35–44 yr ($P = 0.04$), 45–54 yr ($P = 0.0001$) and the MCS score was lower in the age class 45–54 yr ($P = 0.001$), whereas no differences were noted in the age class 25–34 yr, i.e. the most common age class for disease onset.

While in the control group we observed very few correlations among the different subscales (Table 5A), in SLE we noticed a

significant correlation among the scores obtained in the different subscales (Table 5B). In particular, in SLE, the VT subscale was correlated with three of the four subscales of PCS: PF, RP and BP.

There was a significant linear correlation ($\rho = 0.64$, $P < 0.00001$) between the PCS and the MCS score in the patient group, which was lacking in the control group ($\rho = 0.18$, $P = 0.07$).

The PCS was higher than MCS in 81% of the controls and in 48.4% of the patients ($\chi^2 = 24.6$, $P = 0.00001$).

Discussion

We considered a group of SLE patients regularly followed in our division. Since they were all out-patients their mean disease activity

was low, as expected. The mean damage index was also low, probably due to their young mean age and their Caucasian race. In this cohort of patients, HRQOL was lower than that observed in healthy subjects. Our data concur with those reported by others [6, 18–21] who considered a cohort of patients similar to our cohort in term of disease activity and damage. However, other authors [22, 23] observed an even lower HRQOL in groups of patients with higher disease activity and damage index scores (Table 6).

The high standard deviation we observed in our SLE patients, but not in our controls, suggests that SLE has a variable impact on the patient's life [24, 25]. This difference could be due to two types of factors: the variability of the disease characteristics and course, and the influence of the patient's personality. The latter influences, positively or negatively, adaptation to the illness.

Moreover, if we analyse the distribution of the scores of the single subscales, we can see that low scores are frequently observed in SLE patients, probably because some of them are forced to drastically reduce or even discontinue activities usually considered an essential part of daily life such as work, school or social relationships. The most compromised scales were GH and VT. In GH the patient expresses a global evaluation of his/her own health

TABLE 3. Linear correlation between age and SF-36 subscale scores in the SLE and control groups

SF-36 subscale	SLE patients (126 cases)		Controls (96 cases)	
	ρ	$P<$	ρ	P
PF	−0.33	0.0002	0.07	n.s.
RP	−0.24	0.009	0.14	n.s.
BP	−0.29	0.001	0.08	n.s.
GH	−0.22	0.013	−0.07	n.s.
VT	−0.35	0.00005	−0.18	n.s.
SF	−0.20	0.03	0.08	n.s.
RE	−0.21	0.02	0.11	n.s.
MH	−0.22	0.015	0.04	n.s.
PCS	−0.32	0.0005	0.04	n.s.
MCS	−0.27	0.002	−0.01	n.s.

PF, physical function; RP, role–physical; BP, bodily pain; GH, general health; VT, vitality; SF, social function; RE, role–emotional; MH, mental health; PCS, physical component summary; MCS, mental component summary; n.s., not significant.

and its decrease underlines a sensation of general reduction of physical wellbeing. The worsening of VT has even more severe implications: being an index of the energy level experienced by the subject, its reduction can be due to physical causes as well as to the sensation that even the psychological energies necessary to face both everyday reality and planning of the future are missing.

SLE is traditionally considered a disease with great impact on all aspects of health status. In patients, but not in controls, we observed a progressive decrease in both PCS and MCS scores, starting from age class 25–34 yr and continuing to decrease in the 45–54 and 55–64 classes. These progressive changes in HRQOL could be due to several factors, such as SLE progression along the years, continuously coping with a chronic illness, and practical management items that may be required (frequent medical visits, laboratory examinations, etc.). However, it is worth noting that in the age group 18–24 yr HRQOL was lower than that observed in the age groups 25–34 and 35–44 yr, apparently in contrast with what we have stated previously. A possible explanation is that the diagnosis of a chronic illness has a stronger effect in terms of compromising HRQOL at an age at which physical, psychological and social stability has not yet been reached.

The difference we noted in the PF scale may be due to the combined influence of age and the effect of the illness: both factors can contribute in limiting the physical activities that a patient can carry out freely.

It is worth noting that VT was influenced by the age class in SLE patients but not in healthy people, probably because the latter do not have to spend energy in balancing the physical limitations due to illness.

In the SLE group, the subscale of VT significantly correlated with three of the four scales of the PCS. Therefore it seems that this scale, in the presence of illness, works as a link between physical and mental aspects, probably because VT has both physical (fatigue, weakening) and psychological (demotivation, depressed mood, tension) characteristics. It is interesting to note that, in our sample, fatigue evaluated by the clinician and defined as a symptom which limits daily life activities, was observed in only seven patients among 126 (5.5%), whereas VT was, together with GH, the most compromised subscale according to the patients' perspective [16]. This observation confirms the strong impact that subjectivity has in modulating the effects of an event on everyday life.
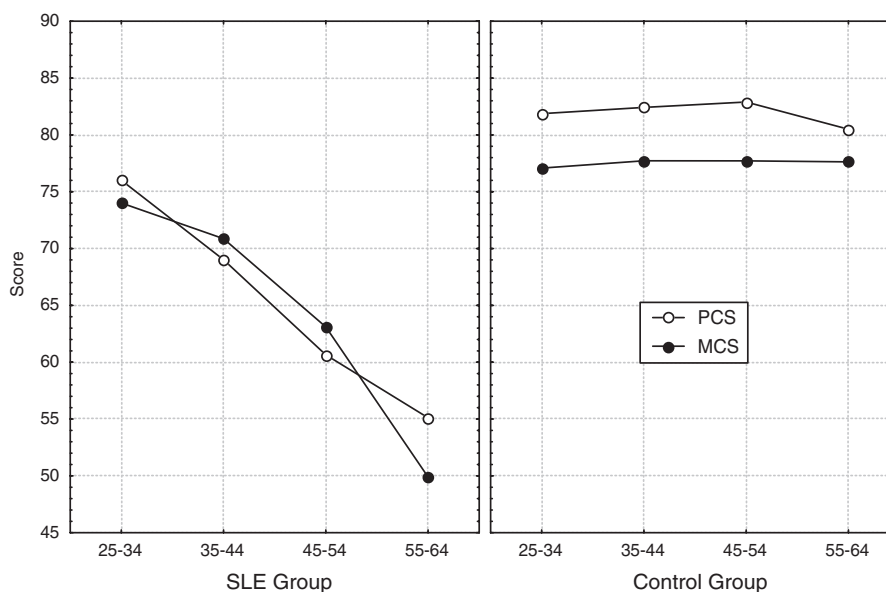

FIG. 2. Trend of the mean of the two total scales for age classes and groups. PCS, physical component summary; MCS, mental component summary.

TABLE 4. Mean and S.D. of total scores (physical and psychological) in the two groups, divided into age classes

Age class (yr)	Patients (n)	Controls (n)	PCS			MCS		
			Patients	Controls	P	Patients	Controls	P
18–24	9	0	64.4 ± 18.4			67.6 ± 18.0		
25–34	49	19	76.0 ± 16.4	81.9 ± 5.7	n.s.	74.0 ± 19.4	77.1 ± 5.5	n.s.
35–44	27	24	69.0 ± 20.4	82.4 ± 4.3	0.04	70.9 ± 18.8	77.7 ± 5.6	n.s.
45–54	23	49	60.6 ± 24.1	82.9 ± 5.1	0.0001	63.1 ± 19.7	77.7 ± 4.7	0.001
55–64	16	4	55.1 ± 23.0	80.5 ± 6.5	n.s.	49.9 ± 23.3	77.6 ± 5.0	n.s.
65–74	2	0	44.7 ± 11.3			76.1 ± 3.0		

PCS, physical component summary; MCS, mental component summary.

TABLE 5. Correlation coefficients between the eight subscales

SF-36 subscale	PCS				MCS			
	PF	RP	BP	GH	VT	SF	RE	MH
(A) Control group								
PF	1.00	0.11	0.19	0.02	0.08	0.08	−0.07	0.05
RP		1.00	−0.01	0.09	**−0.22**	**0.34**	0.08	0.10
BP			1.00	0.06	**0.25**	−0.02	−0.15	−0.01
GH				1.00	0.12	0.13	**0.26**	−0.04
VT					1.00	−0.09	0.07	−0.16
SF						1.00	0.05	0.09
RE							1.00	0.32
MH								1.00
(B) Patient group								
PF	1.00	**0.59**	**0.55**	**0.41**	**0.60**	**0.38**	**0.27**	**0.27**
RP		1.00	**0.67**	**0.41**	**0.62**	**0.48**	**0.49**	**0.36**
BP			1.00	**0.44**	**0.58**	**0.51**	**0.34**	**0.43**
GH				1.00	**0.48**	**0.49**	**0.34**	**0.47**
VT					1.00	**0.54**	**0.49**	**0.61**
SF						1.00	**0.47**	**0.49**
RE							1.00	**0.48**
MH								1.00

Bold type indicates *P* < 0.05.
PF, physical function; RP, role–physical; BP, bodily pain; GH, general health; VT, vitality; SF, social function; RE, role–emotional; MH, mental health; PCS, physical component summary; MCS, mental component summary.

TABLE 6. Comparison of SF-36 scores, damage and activity indices in our patients and in other published series

Author (reference)	Patients (n)	SF-36		SLICC/ACR: mean ± S.D. or median (range)	Disease activity	
		MCS	PCS		Score: mean ± S.D. or median (range)	Activity index
Thumboo [20]	90	69.2 ± 19.4	65.1 ± 19.9	0 (0–6)	2 (0–19)	BILAG
Stoll [21]	60	64.4 ± 19.1	n.r.	0.5* (0–5)	4.8 (1–11)	BILAG
Da Costa [22]	59	46.1 ± 11.5	37.6 ± 11.1	1.5 ± 1.9 (0–8)	6.6 ± 3.5	SLAM-R
					6.2 ± 5.1	SLEDAI
Wang [23]	54	43.1 ± 12.3	38.6 ± 10.9	1.8 ± 2.8	6.3 ± 4.1	SLAM-2
Present study	126	67.9 ± 20.1	67.7 ± 21.0	0.33 ± 0.84 (0–5)	1.7 ± 1.1	ECLAM

*S.D. not reported; n.r., not reported.
PCS, physical component summary; MCS, mental component summary.

Unlike what was observed in healthy subjects, in SLE patients PCS and MCS and the single subscales were strongly correlated with each other. Suffering from a chronic illness probably has a central role in the patient's life, since he/she could be forced to revise some aspects of everyday life, including social relationships as well as job adjustment [21, 26]. These changes are due to physical reasons, but they can influence the psychosocial life of the patient.

In fact, if we consider the fact that PCS was higher than MCS more frequently in the control group compared with the patients, in agreement with other authors [21, 27], we can hypothesize that it

is PCS which influences MCS in SLE patients. In fact, the most relevant factor in differentiating the two groups is indeed health. While in healthy subjects the mental dimension is probably influenced by various factors of everyday life, in an ill person attention is focused on health problems, which in turn amplify the everyday discomfort that everyone has to face.

There are some limitations of this study that should be considered and addressed in future research studies. The cross-sectional design prevented us from measuring any change in HRQOL that may have occurred over time. A longitudinal study is

needed to validate our findings and to explore the causal relationship between physical involvement and mental factors.

In conclusion, HRQOL is significantly reduced in SLE patients, both in its physical and mental components, and this decrease is characterized by a high correlation between the two dimensions. It is likely that suffering from an organic illness reduces mental well-being. However, once this negative connection is settled, the influence might become mutual. This means that, along with the progression of the illness, attention has to be focused on the way physical symptoms influence the patient's everyday life, in order to prevent psychosocial difficulties from amplifying clinical complaints. For this purpose it might be useful to look at the VT as a reference index because it represents a connection between the physical and mental dimensions. In addition, since age causes a worsening of HRQOL greater than expected in patients, greater attention should be paid to this process as patients gets older.

Rheumatology	Key messages
	• In patients with SLE psychosocial difficulties may amplify clinical complaints.
	• Thus, it is important to evaluate not only the severity of the physical symptoms but also their influence on the patient's everyday life.
	• VT may be used as a reference index because it represents a connection between the physical and mental dimensions.

The authors have declared no conflicts of interest.

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