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ORIGINAL ARTICLES

Validation of a disease-specific health-related quality of life measure in adult Portuguese patients with systemic lupus erythematosus: LupusQoL-PT

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ABSTRACT

Introduction: LupusQoL is a questionnaire specifically designed to assess health-related quality of life (HRQoL) in SLE patients. We report on the translation and cross-cultural adaptation of LupusQoL into European Portuguese.
Methods: Translation and cultural adaptation were performed according to standard protocol described by the original developers. LupusQoL-PT was administered to patients during a routine visit from an outpatient clinic at a university hospital in Portugal. Content structure was validated using factorial analysis. Cronbach's alpha coefficient was computed for internal consistency. Sociodemographic were questioned during the visit and clinical data were collected during the visit and from the clinical files. Pearson's correlation, T-test, Mann-Whitney and one-way ANOVA were applied to test internal and external validation.
Results: Seventy-nine SLE patients (78 woman: 1 man) were evaluated. Most had Low disease activity (mean SLEDAI-2k = 3.49; standard deviation 4.80), 19% had moderate to severe activity and 38% had damage accrual (mean SDI = 0.75; standard deviation 1.05). Cronbach's alpha coefficient was at least 0.812, confirming good internal consistency. Correlation coefficient and test-retest correlation between the eight domains of LupusQoL-PT were strong in almost every domain ($p<0.01$). External convergent analysis showed strong correlation between LupusQoL-PT and Medical Outcome Study Short Form 36-item version 2 and visual analogic scale. Current disease activity was negative correlated with "Body Image" domain. There was no correlation between other LupusQoL-PT domains and SLEDAI-2k on divergent validity. Patients with previous neuropsychiatric and DMARDs treatment had lower HRQoL in emotional domains, while patients with renal damage accrual had HRQoL impact in both physical and emotional domains. Portuguese SLE patients had lower HRQoL than French and Italian validation cohorts' patients, and higher than Spanish cohorts.
Conclusion: LupusQoL-PT has shown adequate metric properties and should be considered an appropriate tool to evaluate HRQoL in Portuguese SLE patients.

Keywords: Quality of life; Systemic lupus erythematosus; Autoimmunity

INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic and debilitating systemic autoimmune disease. It has great clinical heterogeneity, and its impact extends beyond objective physical and laboratory findings to involve psychological, emotional, and social repercussions. The accurate characterization of this multimodal subjective dimension of the disease, generically defined as Health-Related Quality of Life (HRQoL), is increasingly recognized as essential for the global management of patients and the development of trials in SLE. In a time where a multitude of potential treatments for SLE is being developed[1], it is also important to have a complete picture of SLE morbidity to judge their efficacy.

Most patients with SLE have a reduced HRQoL compared to healthy controls[2]. This has shown to be true also for the Portuguese SLE patients, with HRQoL measured by generic questionnaires such as the Medical Outcome Study Short Form 36-item version 2 (SF-36) significantly impaired in contrast with the reference population[3]. Generic HRQoL questionnaires, such as SF-36 have demonstrated that, even with inactive disease and low damage index scores, SLE patients have poorer HRQoL[3,4]. These questionnaires, however, do

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not consider some relevant aspects for SLE patients such sleep impact, sexual function and body image.
In the face of that, several questionnaires were developed to measure the specific impact of SLE on HRQoL, such as LupusQoL[5], Systemic Lupus Erythematosus-specific QoL (SLEQoL)[6] and Simple Measure of the Impact of Lupus Erythematosus in Youngsters (SMILEY)[7]. Most questionnaires regarding HRQoL in SLE patients can only be found in English[8]. LupusQoL is translated in 77 languages to be used in 51 countries (https://lifesciences.rws.com/lupusqol/translations). It has demonstrated good psychometric properties at least in English for United Kingdom[5], European Spanish[9], French[10] and Italian[11].

LupusQoL questionnaire is not validated for European Portuguese language or patients. Our purpose is to cross-culturally adapt and validate LupusQoL into European Portuguese and test its measurement properties.

PATIENTS AND METHODS

Study design and Data Collection

Adult outpatients diagnosed with SLE by modified American College of Rheumatology (ACR) 1997[12] criteria were included in an observational cohort study conducted at Unidade de Imunologia Clínica - Centro Hospitalar e Universitário do Porto, a university-affiliated hospital in Porto, Portugal between February 2014 and March 2020. Patients with other concomitant systemic autoimmune diseases (e.g.: Sjogren's syndrome, Antiphospholipid Antibodies Syndrome, Rheumatoid Arthritis, Systemic Sclerosis) were excluded.

Sociodemographic, clinical characteristics and treatment were collected. HRQoL was evaluated using SF-36 validated for the Portuguese population[13] and an adapted (methodology below) European Portuguese version of LupusQoL – LupusQoL-PT. The questionnaires were applied by paper during their routine visit, and an interviewer sat next to the patient to clear doubts.

LupusQoL is a SLE-specific measure instrument of quality of life[5] composed by 34 items regarding eight domains (Physical Health [8 items], Pain [3 items], Planning [3 items], Intimate Relationships [2 items], Burden to Others [3 items], Emotional Health [6 items], Body Image [5 items] and Fatigue [4 items]). All questions have a 5-point Likert response format (0=all the time, 1=most of the time, 2=a good bit of the time, 3=occasionally, and 4=never). The mean raw domain score is calculated by summing the item response scores of the answered items and dividing by the number of answered items. It is obtained if at least 50% of the items are answered. A non-applicable response is treated as unanswered. Transformed domain scores represent the result for each domain after transformation to scores ranging from 0 (worst HRQoL) to 100 (best HRQoL) by dividing by 4 and then multiplying by 100. Floor and ceiling effects were calculated after frequency analysis.

The SF-36 is a 36-item non-disease specific HRQoL questionnaire consisting of eight domain scores (Physical Functioning, Bodily Pain, General Health Perceptions, Physical Role Functioning, Emotional Role Functioning, Vitality, Social Role Functioning and Mental Health) ranging from 0 (worst HRQoL) to 100 (best HRQoL). In order to facilitate SF-36 interpretation, the instrument can be further summarized into 2 component scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS)[13]. Patient-reported global health perception was evaluated, from 0 (best) to 10 (worst), by Visual Analogic Scale (VAS).

Disease activity was measured using Systemic Lupus Erythematosus Disease Activity Index [SLEDAI-2k; the score ranges from 0 (no activity) to 105 (maximal activity)][14]. Patients were considered to be Inactive if SLEDAI-2K was 0, with Low disease activity if SLEDAI was 1-4 (and no major organs was involved) and with Moderate-to-Severe activity if SLEDAI-2k was 5 or above. Chronic damage was assessed by Systemic Lupus International Collaborating Clinics / ACR (SLICC/ACR) damage index (SDI); the score ranges from 0 (no damage accrual) to 45 (maximal damage)[15].

The study was approved by the institution's Research Ethics Committee (Internal code: TA-MIM Disciplina 403/13) and all participants gave written informed consent.

Cross-cultural adaptation process

The methodology for translation and cultural adaptation of this questionnaire was conducted by RWS Life Sciences professional translators, from the original English for United Kingdom questionnaire and included: two independent forward edits of client-provider-client, one harmonized forward translation, one independent back-translation, reconciliation of back-translation and harmonized translation, review of back-translation by Survey Research Expert and review of harmonized translation by on-site sponsor representative. Cognitive debriefing was made with five native Portuguese patients with SLE (three women and two men) from our cohort who didn't enter the study sample.

Validation and reliability

Data was analysed using Statistical Package for the Social Sciences (SPSS) software version 27. Kolmogorov–Smirnov test was used to evaluate the normality of the distribution for each variable. We used the eight domains from the original score: structural validity was verified by the Keiser-Meyer-Olkin rule (should be ≥ 0.8).

Table I. Sociodemographic characterization of the participants

Variables	SLE patients (n=79)
Socio-demographic characteristics	
Male/Female (%)	1/78 (1.3/98.7)
Caucasian/Other (%)	76/3 (96.2/3.8)
Education (mean years ± SD)	12.13 ± 4.90
< 5 (%)	11 (13.9)
5-12 (%)	37 (46.8)
> 12 (%)	31 (39.3)
Occupation	
Student (%)	3 (3.8)
Employed (%)	57 (73.1)
Unemployed (%)	6 (7.7)
Retired (%)	12 (15.4)
Marital Status	
Single (%)	17 (21.5)
Married (%)	55 (69.6)
Divorced (%)	7 (8.9)
Disease features	
Current age (mean years ± SD)	43.58 ± 10.94
Age at diagnosis (mean years ± SD)	29.20 ± 9.49
Disease duration (mean years ± SD)	14.28 ± 8.14
Previous clinical involvement	
Neuropsychiatric (%)	14 (17.7)
Renal (%)	29 (33.7)
Musculoskeletal (%)	55 (69.6)
Mucocutaneous (%)	63 (79.7)
Haematological (%)	52 (65.8)
Current clinical involvement	
Neuropsychiatric (%)	2 (2.5)
Kidney (%)	6 (7.6)
Musculoskeletal (%)	10 (12.7)
Mucocutaneous (%)	6 (7.6)
Haematological (%)	11 (13.9)
Serological (%)	36 (45.6)
SLEDAI-2k index (mean ± SD)	3.49 ± 4.80
No activity (SLEDAI 0) (%)	27 (34.2)
Low activity (SLEDAI 1-4) (%)	37 (46.8)
Moderate to severe activity (SLEDAI > 5) (%)	15 (19.0)
Previous SLE treatment	
Hydroxychloroquine and Steroids only (%)	7 (8.9)
Classical Immunosupressants (%)	30 (38)
Biological Immunomodulators (%)	5 (6.3)
Current SLE treatment	
No treatment (%)	11 (13.9)
Hydroxychloroquine only (%)	23 (29.1)
Hydroxychloroquine and Steroids only (%)	17 (21.5)
Classical Immunosupressants (%)	23 (29.1)
Biological Immunomodulators (%)	1 (3.8)

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Table I. continuation

Variables	SLE patients (n=79)
SDI Index (mean ± SD)	0.75 ± 1.05
No damage accrual (%)	49 (62.0)
Damage accrual (%)	30 (38.0)
SDI specific by Organ Damage	
Neuropsychiatric (%)	14 (17.7)
Renal (%)	3 (3.8)
Lung (%)	5 (6.3)
Cardiovascular (%)	3 (3.8)
Musculoskeletal (%)	4 (5.1)
Skin (%)	4 (5.1)

Current - at the time of study; SD – standard deviation; SDI - Systemic Lupus International Collaborating Clinics / ACR (SLICC/ACR) damage index; SLE – Systemic Lupus Erythematosus; SLEDAI-2k - Systemic Lupus Erythematosus Disease Activity Index.

Internal consistency was determined using Cronbach's α coefficient computed for each component of the different domains of LupusQoL-PT; the result was considered satisfactory if ≥ 0.7[16]. Internal correlation analysis between the eight domains (inter-domain's correlation) was performed by ρ Pearson test. Correlation coefficients were considered good if between 0.15 and 0.85[16]. Test-retest reliability was assessed by intra-class coefficients (ICC), comparing LupusQol-PT scores at baseline and up to 90 days later in the 15 patients who returned by mail the self-assessed QoL questionnaires.

External validity was determined by comparing the results of LupusQoL-PT with those of SF-36 and VAS using Pearson correlation test. Spearman's correlation test was performed between SLEDAI-2k, SDI and LupusQoL-PT means by domains. T-test and One-way ANOVA were used to compare means between groups for previous and current organ involvement, previous treatment, SLEDAI-2k and SDI. Mann-Whitney test was used to non-homogenous variables. Chi-square was used to calculate the relative risk of damage accrual. p values<0.05 were considered significant.

RESULTS

Population Characterization

Seventy-nine patients responded to the questionnaires. Sociodemographic and disease characterization of the participants are described in Table I.

All but 1 patient were women (98.7%), most patients had at least 5 years of education (86.1%), were employed (73.1%) and married (69.6%). Mean and SD disease duration were long (14.28 ± 8.14 years) (range 1-37 years).

Previous organ involvement is described in Table I. Forty-four (55.7%) patients never had neuropsychiatric

Table II. LupusQoL-PT descriptive statistics

LupusQoL-PT Domains	Missing responses	Mean ± SD	Median, IQR	Minimum	Maximum	Number (%) of patients with minimum score (floor effect)	Number (%) of patients with maximum score (ceiling effect)
Physical Health	0	69.5 ± 26.97	81.3, 40.6	3.13	100	0 (0.0)	9 (11.4)
Pain	2	68.6 ± 28.90	75.0, 50.0	0	100	1 (1.3)	20 (26.0)
Planning	2	72.6 ± 28.35	83.3, 50.0	0	100	1 (1.3)	21 (26.7)
Intimate relationship	4	72.7 ± 30.67	75.0, 37.5	0	100	5 (6.7)	27 (36.0)
Burden to others	2	65.0 ± 30.50	75.0, 45.8	0	100	3 (3.9)	15 (19.5)
Emotional Health	0	69.7 ± 24.90	75.0, 37.5	8.33	100	0 (0.0)	10 (12.7)
Body Image	0	80.1 ± 23.01	90.0, 20.0	5	100	0 (0.0)	18 (22.8)
Fatigue	2	61.7 ± 26.02	62.5, 46.9	6.25	100	0 (0.0)	9 (11.7)

IQR – interquartile range; SD – standard deviation.

or renal involvement.

Mean SLEDAI-2k score and SD were 3.49 ± 4.80 (minimum and maximum values 0 and 25, respectively). Most patients had active disease, but most of them had Low disease activity (46.8%). At the time of the study, activity was mainly serological, haematological or musculoskeletal.

Less than 10% of patients never used other immunomodulators than steroids or hydroxychloroquine. At the time of the study, 34 (43%) were off steroids or any immunosuppressant.

The mean SDI score was 0.75 ± 1.05 (minimum and maximum values 0 and 5, respectively), with 38% percent of patients having damage accrual, mainly neuropsychiatric damage.

LupusQoL-PT descriptive statistics are presented in Table II. Item response rates were 98.1%. All domains of LupusQoL-PT resulted in values superior to 60. The highest mean value of responses concerned "Body Image" and the lowest mean value was related to "Fatigue". No significant floor effect was observed, but ceiling effects occurred ranging from 11.4% to 36.0%.

The mean SF-36 score and SD were 57.61 ± 21.02 and VAS score were 4.16 ± 3.21.

VALIDATION OF LupusQoL- PT

Validation and reliability

The Kaiser-Meyer-Olkin test result was 0.831 (Bartell sphericity p<0.001), suggesting the suitability of the sample.

Consistency and Internal Validity

Internal consistency of LupusQoL-PT was confirmed by a good reliability of each domain's components with Cronbach's α coefficient between 0.812 and 0.936 (Table III). Pearson's correlation confirmed a good relationship between the LupusQoL-PT 8 domains (Table III). Test-retest reliability was good (ICC range 0.789-0.947).

External Validity

Convergent validity compared results from LupusQoL-PT and SF-36 using Pearson correlation (Table IV). There is a good correlation between comparable domains (p<0.01). For non-comparable domains correlation was also good for partially related SF-36 domains, as "Intimate Relationship" with "Mental Health", "Burden to Others" with "Social function" and "Physical component summary", and "Body Image" with "Social function".

Patient-reported global health perception accessed by VAS had a significant negative strong correlation with the physical domains, medium or weak correlation with the emotional domains, medium correlation with fatigue and no correlation with "Body Image" (Table IV).

Global SLE activity measured by SLEDAI-2k negatively correlated with "Body Image" LupusQoL-PT domain (Spearman's r= -0,265, p= 0,018). There were no other correlation or significant differences between HRQoL by LupusQoL-PT domains means and activity SLEDAI-2k groups (Inactive, Low disease activity and Moderate-to-Severe patients).

Patients with global damage accrual by SDI had significant less HRQoL means in "Body Image" than patients with no damage accrual (Table V). Total damage score by SDI correlated negatively with "Pain" domain by LupusQoL-PT (Spearman's r= -0,249, p= 0,036). Previous organ involvement, current ("current" means "at the time of study") organ involvement, specific damage and previous treatment that had significant differences in LupusQoL-PT domains are presented in Table

Table III. Alpha-Cronbach's internal consistency of the 8 domains components and Pearson Correlation between the 8 domains of LupusQoL-PT

LupusQoL-PT Domains	Internal Consistency (alpha-Cronbach)	Pearson correlation LupusQoL-PT Domains							
		1.	2.	3.	4.	5.	6.	7.	8.
1. Physical Health (questions 1-8)	0.929	0.846**	0.846**	0.819**	0.611**	0.683**	0.626**	0.477**	0.715**
2. Pain (questions 9-11)	0.901	0.846**	1	0.715**	0.631**	0.616**	0.602**	0.394**	0.682**
3. Planning (questions 12-14)	0.887	0.819**	0.715**	1	0.680**	0.738**	0.669**	0.479**	0.712**
4. Intimate Relationship (questions 15-16)	0.936	0.611**	0.631**	0.680**	1	0.696**	0.680**	0.417**	0.608**
5. Burden to Others (questions 17-19)	0.906	0.683**	0.616**	0.738**	0.696**	1	0.700**	0.486**	0.691**
6. Emotional Health (questions 20-25)	0.927	0.626**	0.602**	0.669**	0.680**	0.700**	1	0.597**	0.715**
7. Body Image (questions 26-30)	0.855	0.477**	0.394**	0.479**	0.417**	0.486**	0.597**	1	0.622**
8. Fatigue (questions 31-34)	0.812	0.715**	0.682**	0.712**	0.608**	0.691**	0.715**	0.622**	1

** Correlation significance <0.01

Table IV. Pearson Correlation between LupusQoL-PT and SF-36 and Visual Analogic Scale

LupusQoL-PT domains	SF-36 domains		VAS (0-10)
		Pearson correlation (ρ)	Pearson correlation (ρ)
Physical health	Physical function	0.790**	- 0.606**
	Role physical	0.731**	
Pain	Bodily pain	0.748**	- 0.609**
Planning	Physical function	0.684**	- 0.423**
	Physical component summary	0.593**	
	Social function	0.641**	
	Mental component summary	0.512**	
Intimate Relationship	Social function	0.495**	- 0.422**
	Mental health	0.549**	
Burden to Others	Social function	0.556**	- 0.278*
	Mental component summary	0.334**	
	Physical component summary	0.593**	
Emotional Health	Mental Health	0.636**	- 0.334**
	Role emotional	0.679**	
Body Image	Social function	0.549**	- 0.235 (p=0.068)
	Role emotional	0.473**	
	Mental component summary	0.485**	
	Physical component summary	0.225**	
Fatigue	Vitality	0.728**	- 0.378**

SF-36 - Medical Outcome Study Short Form 36-item version 2; VAS – visual analogic scale. ** Correlation significance <0.01

Table V. Differences in LupusQoL-PT mean scores between different previous and current organ involvement, global and organ damage accrual, and previous treatments

LupusQoL-PT domains	HRQoL LupusQoL by Organ involvement, damage and previous treatment (Mean ± SD or Mediana)		
	Yes	No	p value
Physical Health			
vs Current Skin involvement	64.42[a]	37.99[a]	0.007*[a]
vs Renal damage	35.4 ± 45.54	70.9 ±25.55	0.025*
Pain			
vs Current Skin involvement	67.50[a]	36.59[a]	< 0.001**[a]
vs Renal damage	36.1 ± 41.11	69.9 ± 27.89	0.046*
Planning			
vs Current Skin involvement	60.25[a]	37.20[a]	0.014*[a]
vs Renal damage	38.9 ± 45.90	74.0 ± 27.03	0.035*
Intimate Relationship			
vs Previous NPSLE involvement	55.4 ± 33.51	76.7 ±28.82	0.018*
vs Current Skin involvement	62.00[a]	36.29[a]	0.008*[a]
Burden to Others			
vs Current Skin involvement	57.75[a]	37.42[a]	0.031*[a]
vs Current Haematologic involvement	58.50[a]	36.09[a]	0.003*[a]
Emotional Health			
vs Previous NPSLE involvement	56.1 ± 25.71	72.6 ± 23.98	0.024*
vs Current Skin involvement	59.67[a]	38.38[a]	0.029*[a]
Body Image			
vs Current active Arthritis	66.3 ± 27.68	82.0 ± 21.78	0.043*
vs Global damage	72.8 ± 25.76	84.5 ± 18.49	0.046*
vs Renal damage	50.0 ± 42.72	81.2 ± 21.55	0.020*
Previous biological DMARDs	49.0 ± 31.90	82.2 ± 20.97	0.001**
Fatigue			
vs Current Skin involvement	84.4 ± 20.44	59.8 ± 25.64	0.025*
vs Current Haematologic involvement	77.7 ± 17.79	59.3 ± 26.30	0.036*

T-test for homogeneous variables, aMann-Whitney for non-homogeneous variables); a – median for non-parametric variables, p value from Mann-Whitney test; Current – at the time of the study; DMARDs – disease modifying antirheumatic drugs; HRQoL – health-related quality of life; NPSLE – neuropsychiatric systemic lupus erythematosus involvement; SD – standard deviation; *p significance <0.05; **p significance <0.00

V. All had less HRQoL except current skin and haematological involvement. Patients with current skin involvement tended to have lower SLEDAI-2k and lesser global damage accrual but not statistically significant. Patients that had done previous biological DMARDs had lower mean "Body Image" HRQoL. Previously exposed to classical DMARDs' patients had more damage accrual (chi-square 16.905, p<0.001; Pearson's r 0.463, p<0.001).

DISCUSSION

LupusQoL-PT is a valid tool to assess the quality of life in SLE patients, with good reliability, internal consistency and stability, even though the retest sample was small and the interval between them was large. LupusQoL-PT correlated strongly with SF-36 domains and the physical domains with VAS, confirming the external validation of LupusQoL-PT. Despite unicentric and small, our sample represented several ages of onset of the disease, a wide range of SLE duration, several education levels, employment, and marital status, different disease activity at the time of the study and almost half of them had damage accrual, representing a wide range of female SLE Portuguese patients. As the

Table VI. Differences in LupusQOL-PT scores between groups of activity by SLEDAI-2k and damage accrual by SDI

	Pearson correlation LupusQoL-PT Domains				SDI		
LupusQoL-PT domains (Mean ± SD)	Inactive (SLEDAI 0)	Low disease activity (SLEDAI 1-4)	Moderate-to-Severe (SLEDAI > 5)	p value	No damage	Damage	p value
Physical Health	64.7 ± 31.12	74.3 ± 22.86	66.5 ± 28.19	0.329	72.0 ± 24.66	65.5 ± 30.39	0.304
Pain	64.5 ± 29.65	71.9 ± 28.30	68.3 ± 29.91	0.612	70.6 ± 26.74	65.6 ± 32.22	0.462
Planning	69.1 ± 30.30	78.6 ± 25.98	65.0 ± 29.07	0.222	75.0 ± 26.92	68.9 ± 30.55	0.360
Intimate Relationship	67.1 ± 31.99	74.3 ± 31.67	79.5 ± 25.29	0.442	75.8 ± 28.63	67.9 ± 33.43	0.276
Burden to Others	58.6 ± 29.73	68.8 ± 31.27	67.8 ± 30.19	0.403	69.1 ± 26.75	58.6 ± 35.12	0.166
Emotional Health	65.7 ± 28.46	69.5 ± 23.51	77.1 ± 21.22	0.371	73.5 ± 19.94	63.4 ± 30.81	0.118
Body Image	83.3 ± 25.42	79.9 ± 21.26	74.6 ± 23.13	0.501	84.5 ± 18.49	72.8 ± 25.76	0.046*
Fatigue	58.3 ± 29.67	63.5 ± 23.20	63.8 ± 26.43	0.709	62.8 ± 25.27	60.0 ± 27.49	0.647

SD – standard deviation; SDI - Systemic Lupus International Collaborating Clinics / ACR (SLICC/ACR) damage index; SLEDAI-2k – Systemic Lupus Erythematosus Disease Activity Index; * p significance <0.05.

original scale[5], the presence of a single male patient also constitutes a potential limitation to the generalization of LupusQoL use in male Portuguese patients.

"Body image" was the domain of LupusQoL-PT with the greatest QoL mean score and "Fatigue" was the lowest. Comparing to a South Spanish cohort[9], our patients' HRQoL was better in all domains, especially in the "Body image". Compared to a French and Italian SLE cohorts[10,11], our patients had globally worse HRQoL, scoring approximately 5 points lower, despite having similar educational level to the French cohort (data of the Italian cohort was not available). The ceiling effect was > 20% (Table II) in "Pain", "Planning", "Intimate Relationship" and "Body Image", like the original scale, the French, and the Italian validation cohorts[5,10,11]. This could explain both the differences with the other European populations as well as the lack of strong correlation with the other LupusQoL domains. Additionally, there are differences in social support and health care systems, and cultural belief and ethnical differences throughout Europe (https://ec.europa.eu).

We found no correlation between global disease activity and HRQoL (except for lower "Body Image" domain), a tendency previously reported in other cohorts [8],but surprisingly, at the time of study those who had active skin involvement had better HRQoL in both physical and emotional domains. It could be partially explained by the tendency of those patients to have less damage accrual and not due to having had active skin involvement.

Previous neuropsychiatric involvement (mood disorders, headache and mild cognitive impairment were not considered), even without neuropsychiatric damage accrual, had lower HRQoL in emotional domains ("Intimate Relations" and "Emotional Health"). As expected, renal damage accrual largely affected the HRQoL in both physical and emotional domains. Despite specific organ damage accrual impacted both physical and emotional domains, global damage accrual was only statistically significant for lower "Body Image" HRQoL.

Patients who were previous treated with biological DMARDs had significant lower "Body Image" HRQoL. Our sample includes patients with long disease duration, in whom both classical, and later, biological DMARDS were considered late in highly or persistently active patients, and higher steroids doses steroids were used, which are one of the most known contribute to damage accrual [17]. This reinforces the need to optimise treat-to-target strategies to avoid damage accrual from disease activity, treatment strategies and comorbidities.

The mean SF-36 value was significantly lower compared to a matched Portuguese general population (57.6 vs. 68.8) and mean VAS was significantly high. This probably reflects socio-psychological burden of the diagnosis, which was not evaluated, and strengthens the need for active HRQoL evaluation in SLE patients to manage the disease at all levels, including its non-biological impact.

CONCLUSION

Results from previous language adaptations of LupusQoL and the consistent results obtained from this

sample, improve our confidence that LupusQoL-PT is a useful tool to measure patient-reported quality of life in Portuguese SLE patients.

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