Quantitative Data for Care of Patients with Systemic Lupus Erythematosus in Usual Clinical Settings: A Patient Multidimensional Health Assessment Questionnaire and Physician Estimate of Noninflammatory Symptoms

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ABSTRACT. ***Objective.*** To analyze quantitative data in patients with systemic lupus erythematosus (SLE), seen in usual care, from a patient Multidimensional Health Assessment Questionnaire (MDHAQ) with routine assessment of patient index data (RAPID3) scores and from a physician global estimate of noninflammatory symptoms; and to compare results to self-report Systemic Lupus Activity Questionnaire (SLAQ) scores and 4 SLE indices: SLE Disease Activity Index-2K (SLEDAI-2K), British Isles Lupus Assessment Group (BILAG), Systemic Lupus Activity Measure (SLAM), and European Consensus Lupus Activity Measurement (ECLAM).

Methods. Fifty consecutive patients with SLE were studied in usual care of one rheumatologist. All patients completed an MDHAQ/RAPID3 in this setting. Each patient also completed a SLAQ. The rheumatologist scored SLEDAI-2K, BILAG, SLAM, ECLAM, and 2 physician global estimates, one for overall status and one for noninflammatory symptoms. Patients were classified into 2 groups: "few" or "many" noninflammatory symptoms. Scores and indices were compared using correlations, cross-tabulations and t tests.

Results. The patients included 45 women and 5 men. MDHAQ/RAPID3 and SLAQ scores were significantly correlated. RAPID3 scores were significantly higher in patients with SLE index scores above median levels, and in 34 patients scored by the rheumatologist as having "few" noninflammatory symptoms. MDHAQ/RAPID3 and SLAQ were significantly higher in 16 patients scored as having many noninflammatory symptoms.

Conclusion. MDHAQ/RAPID3 and SLAQ subscale scores appear to reflect disease activity in patients with SLE, but not in patients with many noninflammatory symptoms. A physician scale for noninflammatory symptoms is useful to interpret MDHAQ/RAPID3, SLAQ, and SLE index scores. (First Release April 1 2011; J Rheumatol 2011;38:1309–16; doi:10.3899/jrheum.101091)

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SYSTEMIC LUPUS ERYTHEMATOSUS SYSTEMIC LUPUS ACTIVITY QUESTIONNAIRE
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Diagnosis and management of systemic lupus erythematosus (SLE) is complicated by the absence of a single "gold standard" measure that may be applied to each individual patient. Therefore, pooled indices[1] have been developed that include data from patient history, physical examination, and laboratory tests. Prominent SLE indices include the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)[2,3]; SELENA-SLEDAI[4,5,6]; SLEDAI-2K[7]; British Isles Lupus Assessment Group index (BILAG)[8,9]; Systemic Lupus Activity Measure (SLAM)[10]; and the European Consensus Lupus Activity Measurement (ECLAM)[11]. These indices have been widely used in clinical trials and clinical research, but are too complex and time-consuming for usual clinical care. Ironically, the only quantitative measures generally available in medical records of SLE patients seen in usual care are laboratory tests, the limitations of which were the initial impetus to develop indices that also include, in addition to laboratory tests, information from a patient history and physical examination.

Laboratory tests clearly are critical to diagnosis and management of SLE. Nonetheless, a patient history provides a primary source of many management decisions in SLE, as in

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many chronic diseases[12,13,14,15]. Components of a medical history such as standard, quantitative scores may be provided by a patient self-report questionnaire. The Systemic Lupus Activity Questionnaire (SLAQ) is a simple one-page patient self-report questionnaire based on the SLAM, developed in recognition that available SLE indices "are impractical, time-consuming, require a professional, and are costly"[16]. Nonetheless, the SLAQ also is not used in most usual care settings, in part because collection of different patient self-report questionnaires in busy clinical settings generally is pragmatically ineffective. The most effective approach is to ask each patient to complete the same questionnaire at each visit, regardless of diagnosis[17].

The Health Assessment Questionnaire (HAQ)[18] has been used extensively in rheumatology over the last 3 decades, and adapted for usual care settings in a multidimensional format (MDHAQ)[19,20]. The MDHAQ includes scoring templates for an index of physical function, pain, and patient global estimate, termed routine assessment of patient index data (RAPID3), which is correlated significantly with the Disease Activity Score (DAS28) and Clinical Disease Activity Index (CDAI) in patients with rheumatoid arthritis (RA)[21,22]. Although most reports of data from the HAQ and MDHAQ have involved patients with RA[23], the MDHAQ has been used effectively in patients with all rheumatic diseases in certain settings[24,25]. In this report, we analyze the MDHAQ in 50 patients with SLE seen at the Seligman Center for Advanced Therapeutics of the NYU Hospital for Joint Diseases, New York.

MATERIALS AND METHODS

Patients. A cross-sectional study was conducted in 50 consecutive patients with SLE seen in usual care by one rheumatologist (ADA). All patients met the 1997 American College of Rheumatology (ACR) revised criteria for SLE[26,27]. The study was approved by the Institutional Review Board of New York University School of Medicine. Consent for this specific study was requested from each patient with SLE seen between June and November 2009; 3 patients declined to participate and 50 patients provided informed consent to participate.

Measures. All patients complete an MDHAQ upon registration for each visit at the Seligman Center for Advanced Therapeutics, in the infrastructure of care, prior to seeing the rheumatologist. The MDHAQ includes scales for physical function (FN; 0–10); visual analog scales for pain (PN; 0–10), patient global estimate (PATGL; 0–10), and fatigue (FT; 0–10); and a review of systems checklist (PATSX; 0–60)[19,20]. RAPID3 is a composite index of three 0–10 scores for FN, PN, and PATGL, scored 0–30[28].

All patients enrolled in the study completed the SLAQ. Four scores were assigned for the SLAQ, as described in the initial report[16]: SLAQ total (SLAQt) of 0–44; symptom score based on a 0–24 count of positive responses; patient global assessment based on a 0–3 score for severity of lupus flare; and patient numerical rating scale based on a 0–10 scale for global disease activity.

The rheumatologist (ADA) conducted a clinical encounter: a full history including all common SLE symptoms, physical examination including all common SLE signs, and laboratory evaluation including but not limited to complete blood count (CBC), chemistry profile with urinalysis, erythrocyte sedimentation rate, C-reactive protein, DNA antibodies, and complement levels. The rheumatologist assigned a physician global estimate of SLE disease activity (DOCGL) on a 0–3 scale in 0.1 increments, 0 = no disease activity through 3 = severe disease activity. The rheumatologist also estimated a global level of noninflammatory symptoms (DOCNON) on a 0–3 scale in 0.1 increments, 0 = minimal noninflammatory symptoms through 3 = high level of noninflammatory symptoms, based on the patient history, physical examination, and laboratory evidence of presence or absence of inflammatory or autoimmune features of SLE activity. The rheumatologist did not review the patient global score (PATGL) prior to assigning a DOCGL or DOCNON score. The rheumatologist, who has extensive expertise in management of SLE and has participated in more than 10 SLE clinical trials that require certification for assessment of SLE indices, then recorded the clinical components of 4 standardized indices of SLE activity, SLEDAI-2K[7], BILAG[8,9], SLAM[10], and ECLAM[11]. Index scores were completed after laboratory data became available.

Statistical analysis. All statistical analyses were performed using SPSS for Macintosh version 16.0 and Stata 11.0 for Windows (StataCorp LP, College Station, TX, USA). Mean and median levels of demographic, clinical and laboratory variables, patient questionnaire scores from the MDHAQ (FN, PN, PATGL, RAPID3, FT, PATSX) and SLAQ (SLAQ-total, symptom score, patient global "flare" score, patient numerical rating scale), DOCGL, DOCNON, and physician-assessed indices SLEDAI-2K, BILAG, SLAM and ECLAM were computed. Mean levels are presented for variables that are normally distributed, and median levels are presented for variables not normally distributed.

MDHAQ/RAPID3 and SLAQ scores were compared in patients above and below the median value for the SLAQ and each SLE index. Spearman rank-order correlations were computed to compare patient self-report scores, DOCGL, DOCNON, and SLE indices.

SLE patients with physician-assigned noninflammatory symptom scores (DOCNON) ≥ 0.5 on a 0–3 scale were classified as patients with "many noninflammatory symptoms," while those with scores < 0.5 were classified as patients with "few noninflammatory symptoms." Mean and median values of demographic, clinical and laboratory variables, patient self-report questionnaire MDHAQ/RAPID3 and SLAQ scores, and physician-scored SLE indices were compared for subgroups of patients with "many noninflammatory symptoms" (DOCNON ≥ 0.5) versus patients with "few noninflammatory symptoms" (DOCNON < 0.5). MDHAQ/RAPID3 and SLAQ scores were compared in patients above and below the median value for the SLAQ and each SLE index, and Spearman rank-order correlations were computed, to compare patient and physician variables in subgroups of patients with many or few noninflammatory symptoms.

Median values also were analyzed according to 4 ethnic groups, African American, Asian, Hispanic, and white. Statistical significance was analyzed using the Mann-Whitney and Kruskal-Wallis tests. Correlations are interpreted according to guidelines of 0.10 indicating no correlation, 0.10–0.29 low, 0.30–0.49 moderate, and ≥ 0.50 high correlation[29]. All p values are reported unadjusted for multiple comparisons[30], and the adjusted p value is given in each table.

RESULTS

Patients. The study patients included 45 women and 5 men, mean age 38.7 years, mean duration of disease 7.3 years, mean level of formal education 14.8 years, 18% African American, 18% Asian, 26% Hispanic, 36% white, and 2% other ethnicity (Table 1). All patients had third-party insurance, and completed English-language questionnaires.

Mean (± SD) MDHAQ 0–10 scores for FN were 1.4 ± 1.9, for PN 3.2 ± 2.9, and for PATGL 3.2 ± 2.8; mean RAPID3 (0–30) score was 7.8 ± 7, mean FT (0–10) 3.9 ± 2.8, and mean PATSX (0–60 scale) 9.9 ± 8.7 (Table 2). Mean SLAQ scores included 10.2 ± 6.8 for total SLAQ (0–44 scale), 9.6 ± 6.5 for symptom score (0–24 scale), 1 ±

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Table 1. Demographic, clinical characteristics, laboratory and medication data of 50 patients with SLE, including 34 with few and 16 with many noninflammatory symptoms. Continuous variables are expressed as mean (± standard deviation); categorical variables expressed as n (%).

	All Patients, n = 50	Patients with Few Noninflammatory Symptoms, n = 34	Patients with Many Noninflammatory Symptoms, n = 16	p*
Demographic characteristics				
Age, yrs	38.7 (± 13.2)	37.9 (± 13)	40.5 (± 13.6)	0.48
Female, n (%)	45 (90)	30 (88.2)	15 (93.8)	0.54
Mean disease duration, yrs	7.3 (± 6.7)	7.3 (± 7.4)	7.3 (± 5.1)	0.69
Ethnicity, n (%)				
African American	9 (18)	9 (26.5)	0	
Asian	9 (18)	8 (23.5)	1 (6.2)	
Hispanic	13 (26)	8 (23.5)	5 (31.2)	0.03
White	18 (36)	9 (26.5)	9 (56.2)	
Other	1 (2)	0	1 (6.2)	
Third-party insurance	50 (100)	50 (100)	50 (100)	
Education level, yrs	14.8 (± 3.4)	14.7 (± 3.7)	15.3 (2.4)	0.73
Clinical manifestations				
Rash	12 (24)	9 (26.5)	3 (18.8)	0.55
Alopecia	2 (4)	2 (5.9)	0	0.32
Oral ulcers	2 (4)	2 (5.9)	0	0.32
Raynaud's phenomenon	24 (48)	18 (52.9)	6 (37.5)	0.31
Arthritis	19 (38)	10 (29.4)	9 (56.2)	0.06
Serositis	4 (8)	0	4 (25)	0.002
Nephritis	3 (6)	3 (8.8)	0	0.22
Vasculitis	1 (2)	0	1 (6.2)	0.14
Laboratory data				
Leukopenia (< 3000)	5 (10)	4 (11.8)	1 (6.2)	0.54
Thrombocytopenia (< 100,000)	0	0	0	
Low complement	24 (48)	17 (50)	7 (43.8)	0.68
Elevated anti-DNA antibody	21 (42)	17 (50)	4 (25)	0.09
ESR	22.3 (± 29)	27.1 (± 33.1)	11.2 (± 10)	0.27
CRP	3.9 (± 7.1)	5.4 (± 8.1)	0.7 (± 1.3)	0.01
Medications				
Prednisone	18 (36)	14 (41)	4 (25)	0.31
Hydroxychloroquine	38 (76)	24 (70.6)	14 (87.5)	0.19
Immunosuppressors	23 (46)	15 (44)	8 (50)	0.70

* Chi-square for categorical variables; Mann-Whitney for continuous variables. No differences are significant at $p < 0.0023$, the adjusted p value equivalent to $p < 0.05$ for 21 comparisons. ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

1 for patient global "flare" (0–3 scale), and 3.6 ± 2.7 for patient numerical rating scale (0–10 scale). These scores indicate low to moderate SLE activity.

MDHAQ and SLAQ scores compared to quantitative SLE indices. MDHAQ scores for FN, PN, PATGL, RAPID3, FT, and PATSX were significantly correlated with total SLAQ scores (rho = 0.43–0.63, $p < 0.001$; Table 3). RAPID3 scores were significantly correlated with SLAQ total (rho = 0.59, $p < 0.0001$), SLAQ symptom score (rho = 0.58, $p < 0.0001$), patient global "flare" (rho = 0.40, $p < 0.01$), and patient numerical rating scale (rho = 0.76, $p < 0.001$).

Physician-scored SLE indices were significantly correlated with DOCGL (rho = 0.59–0.72, $p < 0.0001$; Table 3). Correlations of RAPID3, PATGL, SLAQ global flare, and SLAQ numerical rating scale scores with SLE indices were lower, but generally > rho = 0.3, other than for SLEDAI, and significant in unadjusted analyses for BILAG and SLAM (rho = 0.38, 0.47, $p < 0.01$), but not significant for SLEDAI or ECLAM (rho = 0.20, 0.30, nonsignificant), or with any SLE index, adjusted for multiple comparisons. Total SLAQ, SLAQ symptom score, and MDHAQ PATSX scores were not correlated significantly with any SLE index. DOCGL was not correlated significantly with any patient measure or index (Table 3). Mean RAPID3 score was considerably higher in patients above compared to those below the median levels for SLE indices and SLAQ (Table 4). These data suggest that RAPID3 appears to reflect inflammatory activity in patients with SLE.

Comparison of patients with many and those with few noninflammatory symptoms on a physician scale (DOCNON). The rheumatologist estimated a level of noninflammatory symptoms in each patient, on a scale of 0–3 in 0.1 increments (DOCNON), without knowledge of the patient questionnaire scores. Sixteen patients were estimated to have DOCNON ≥ 0.5, and were classified as having "many noninflammatory symptoms." By contrast, 34 patients were estimated to have DOCNON < 0.5, and were classified as having "few noninflammatory symptoms." SLE patients with many compared

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Table 2. Differences in mean and median values of MDHAQ scores, SLAQ, SLE indices, and laboratory tests between SLE patients with few versus many noninflammatory symptoms.

Measure/Index	All Patients, n = 50		SLE with Few Noninflammatory Symptoms, n = 34		SLE with Many Noninflammatory Symptoms, n = 16		p (Mann-Whitney)
	Mean (± SD)	Median (R)	Mean (± SD)	Median (R)	Mean (± SD)	Median (R)	
Physical function (FN; 0–10)	1.4 (± 1.9)	0.7 (0–6.3)	0.7 (± 1.2)	0 (0–5.3)	2.7 (± 2.4)	2.7 (0–6.3)	< 0.01
Pain (PN) VAS (0–10)	3.2 (± 2.9)	2.2 (0–9)	2.5 (± 2.6)	1.7 (0–9)	4.9 (± 2.7)	5 (0–9)	< 0.02
PATGL (0–10)	3.2 (± 2.8)	3 (0–9.5)	2.2 (± 2.5)	1.2 (0–9.5)	5.4 (± 2.2)	5.5 (1.5–9)	< 0.01
Fatigue (FT) VAS (0–10)	3.9 (± 2.8)	3.2 (0–10)	2.8 (± 2.5)	2 (0–9)	6.3 (± 2.1)	6.5 (3–10)	< 0.01
No. symptoms (PATSX; 0–60)	9.9 (± 8.7)	8 (0–38)	6.6 (± 6.8)	5 (0–31)	16.9 (± 8.2)	17.5 (6–4)	< 0.001
RAPID3 (0–30)	7.8 (± 7)	5.5 (0–23)	5.4 (± 5.9)	3 (0–22.8)	13 (± 6.7)	12.4 (4.5–23)	< 0.01
SLAQ-total (0–44)	10.2 (± 6.8)	9.5 (0–27)	7.1 (± 5.3)	6.5 (0–18)	16.9 (± 4.5)	16 (10–27)	< 0.001
Symptom score (0–24)	9.6 (± 6.5)	8 (1–24)	6.47 (± 4.9)	5 (1–23)	16.2 (± 4.1)	16.5 (8–24)	< 0.01
Patient global "flare" (0–3)	1 (± 1)	1 (0–3)	0.81 (± 1.1)	0 (0–3)	1.2 (± 0.8)	1 (0–2)	< 0.01
Patient numerical rating scale (0–10)	3.6 (± 2.7)	3 (0–9)	3.0 (± 2.8)	2 (0–8)	4.8 (± 1.9)	4.5 (2–9)	< 0.01
DOCGL (0–3)	1.1 (± 0.6)	1.2 (0–2.2)	1.1 (± 0.6)	1.1 (0–2.20)	1.1 (± 0.5)	1.2 (0.3–2)	0.98
SLEDAI-2K (0–105)	5 (± 3.7)	4 (0–16)	5.1 (± 3.9)	4 (0–16)	4.8 (± 3.6)	4 (0–12)	0.83
BILAG	4.6 (± 4.3)	3.5 (0–15)	4.2 (± 4.2)	2.5 (0–15)	5.4 (± 4.6)	4 (0–15)	0.27
ECLAM	2 (± 1.4)	2 (0–6)	1.9 (± 1.3)	1.5 (0–4)	2.2 (± 1.6)	2 (0–6)	0.65
SLAM	3.9 (2.9)	3 (0–12)	3.7 (± 3.2)	3 (0–12)	4.2 (± 2.3)	4 (1–10)	0.32
SLAM-no laboratories	2.1 (1.8)	2 (0–7)	1.6 (± 1.6)	1 (0–5)	3.2 (± 1.8)	3 (0–7)	< 0.01

Only differences in PATSX and SLAQ total are significant at $p < 0.003$; the adjusted p value equivalent to $p < 0.05$ for 16 comparisons. FN: physical function on MDHAQ; PN: pain; VAS: visual analog scale; PATGL: patient global estimate; FT: fatigue; RAPID3: Routine Assessment of Patient Index Data 3; PATSX: number of symptoms reported by patient on MDHAQ review of systems (total = 60); SLAQ: Systemic Lupus Activity Questionnaire; DOCGL: physician global assessment; SLEDAI-2K: Systemic Lupus Erythematosus Activity Index-2K; BILAG: British Isles Lupus Assessment Group; ECLAM: European Consensus Lupus Activity Measurement; SLAM: Systemic Lupus Activity Measure; SD: standard deviation; R: range (minimum-maximum).

Table 3. Spearman correlations between the MDHAQ and SLAQ items with the SLAQ total (SLAQt), RAPID3, patient global assessment (PATGL), physician global assessment (DOCGL), and the SLE indices.

Measure	Patient Measures		Global Measures		SLE Indices				
	SLAQt	RAPID3	PATGL	DOCGL	SLEDAI-2K	BILAG	ECLAM	SLAM	SLAM (no laboratories)
SLAQ									
SLAQ-total (0–44)	—	0.59*	0.60*	–0.08 NS	–0.01 NS	–0.04 NS	–0.01 NS	0.08 NS	0.34†
Symptom score (0–24)	0.93*	0.58*	0.57*	–0.07 NS	–0.02 NS	0.02 NS	–0.00 NS	0.10 NS	0.37†
Patient global "flare" (0–3)	0.29 NS	0.40†	0.38†	0.28 NS	0.28†	0.40†	0.34†	0.35†	0.30†
Patient numerical rating scale (0–10)	0.54*	0.76*	0.70*	0.34 NS	0.22 NS	0.37†	0.31 NS	0.49*	0.54*
MDHAQ									
Physical function (FN) (0–10)	0.43*	0.75*,[a]	0.58*	0.11 NS	0.01 NS	0.21 NS	0.17 NS	0.26 NS	0.41†
Pain (PN) VAS (0–10)	0.48*	0.94*,[a]	0.80*	0.11 NS	0.22 NS	0.37†	0.29 NS	0.46†	0.64*
PATGL (0–10)	0.60*	0.93*,[a]	—	0.14 NS	0.20 NS	0.38†	0.29 NS	0.43†	0.61*
RAPID3 (0–30)	0.59*	—	0.93*,[a]	0.14 NS	0.17 NS	0.38†	0.30 NS	0.47†	0.64*
Fatigue (FT) VAS (0–10)	0.63*	0.82	0.79*	0.01 NS	0.09 NS	0.30 NS	0.27 NS	0.41†	0.64*
No. symptoms (PATSX; 0–60)	0.62*	0.73*	0.67*	0.02 NS	0.08 NS	0.20 NS	0.24 NS	0.27 NS	0.48*
DOCGL									
DOCGL	–0.08 NS	0.14 NS	0.14 NS	—	0.72*	0.71*	0.59*	0.64*	0.27 NS

* $p < 0.0001$; † $p < 0.01$; NS: not significant. [a] Higher correlations reflect inclusion of these items in the RAPID3. SLAQ: Systemic Lupus Activity Questionnaire; VAS: visual analog scale; PATGL: patient global estimate; RAPID3: Routine Assessment of Patient Index Data 3; DOCGL: physician global assessment; SLEDAI-2K: Systemic Lupus Erythematosus Activity Index-2K; BILAG: British Isles Lupus Assessment Group; ECLAM: European Consensus Lupus Activity Measurement; SLAM: Systemic Lupus Activity Measure.

to few noninflammatory symptoms did not differ in age, duration of disease, or formal education level (Table 1).

Mean (median) MDHAQ scores for FN, PN, PATGL, FT, PATSX, and RAPID3, as well as mean scores for total SLAQ and SLAQ subscales for symptoms, global flare, and numerical rating scale, were substantially lower in 34 patients with few noninflammatory symptoms compared to 16 patients with many noninflammatory symptoms (Table 2). Scores for the SLAM, SLEDAI, BILAG, and ECLAM did not differ significantly in the 2 patient groups (Table 2).

RAPID3 scores, SLAQ numerical rating scale, PATGL, and DOCGL were correlated at substantially higher levels

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Table 4. Mean RAPID3 scores in patients whose SLE index scores are below and above median levels, according to physician estimates of few versus many noninflammatory symptoms.

Index	Level of Noninflammatory Symptoms	Median Index Score	Patients Below Index Median		Patients Above Index Median		p (Mann-Whitney)
			n	RAPID3, mean (range)	n	RAPID3, mean (range)	
SLEDAI-2K	Few	4	23	2.3 (0–22.8)	11	7.5 (0–14.8)	0.07
	Many	4	11	14.16 (4.5–23)	5	10 (5.2–21.3)	0.82
	All patients	4	34	3.8 (0–23)	16	8.7 (0–21.3)	0.21
BILAG	Few	2	17	2 (0–22.8)	17	7.5 (0–16.7)	0.009
	Many	4	9	16.3 (4.5–21.3)	7	10 (5.3–23)	0.71
	All patients	3	25	3 (0–22.8)	25	10 (0–23)	0.007
ECLAM	Few	1	17	2 (0–16.7)	17	7 (0–22.8)	0.02
	Many	1	7	10.6 (4.5–18.8)	9	14.2 (5.2–23)	0.49
	All patients	1	24	3.25 (0–18.8)	26	8.8 (0–23)	0.024
SLAM	Few	2	16	2 (0–8.5)	18	7.3 (0–22.8)	0.005
	Many	3	7	14.2 (4.5–18.8)	9	10.7 (5.2–23)	0.56
	All patients	3	26	3 (0–18.8)	24	10.3 (0–23)	0.01
SLAQ	Few	6	17	2.2 (0–14.3)	17	4 (0–22.8)	0.04
	Many	16	9	14.2 (4.5–23)	7	8 (5.3–21.3)	0.53
	All patients	9	25	2.5 (0–14.3)	25	11.3 (0–23)	0.0001

Only differences in SLAQ are significant at $p < 0.003$, the adjusted p value equivalent to $p < 0.05$ for 16 comparisons. RAPID3: Routine Assessment of Patient Index Data 3; SLEDAI-2K: Systemic Lupus Erythematosus Activity Index-2K; BILAG: British Isles Lupus Assessment Group; ECLAM: European Consensus Lupus Activity Measurement; SLAM: Systemic Lupus Activity Measure.

with SLE indices in patients with few noninflammatory symptoms compared to those with many noninflammatory symptoms, while little difference was seen between the 2 groups for SLAQt, fatigue VAS, or PATSX (Table 5). These data suggest that RAPID3, SLAQ numerical rating scale, PATGL, and DOCGL reflect inflammatory activity in patients with few noninflammatory symptoms, but not in patients with many noninflammatory symptoms, while SLAQ total, fatigue VAS, and PATSX appear to be independent of SLE indices in all patients and both subgroups.

Analyses according to ethnic group. As noted above, among the 50 study patients, 9 (18%) were African American, 9 (18%) Asian, 13 (26%) Hispanic, 18 (36%) white, and 1 (2%) other ethnicity (Table 1). The 34 patients who had few noninflammatory symptoms fortuitously included 9 African American, 8 Asian, 8 Hispanic, and 9 white patients. The Hispanic patients generally had higher scores than the other groups, although only the differences between Hispanic and Asian patients for pain, MDHAQ patient global, RAPID3, and SLAQ patient global flare were statistically significant in unadjusted analyses, and none were significant adjusted for multiple comparisons (Table 6). Scores were similarly high in Hispanic and white patients with many noninflammatory symptoms, and no significant differences were seen between the 2 groups (Table 6).

DISCUSSION

MDHAQ/RAPID3 data have been reported primarily in RA. However, the MDHAQ appears informative to assess and monitor patients with SLE, and possibly any rheumatic diagnosis[25]. Functional disability, pain, and global distress are common in all rheumatic diseases.

MDHAQ scores for physical function, pain, patient global estimate of status, RAPID3, fatigue, and number of symptoms were significantly correlated with total SLAQ scores; and RAPID3 scores were correlated with SLAQ subscores for symptoms, global flare, and numerical rating scale. These data suggest that MDHAQ/RAPID3 and SLAQ address similar constructs.

MDHAQ scores for RAPID3, pain, patient global estimate of status, and SLAQ global "flare" and numerical rating scales are correlated at higher levels than MDHAQ physical function, fatigue and patient symptoms, SLAQ total, and SLAQ patient symptom score with SLE indices. These findings are consistent with other evidence that simpler scales often are more informative than complex scales in clinical settings[31,32]. However, complex scales are needed in research studies to elucidate mechanisms of a problem such as pain or fatigue.

RAPID3 and patient MDHAQ and SLAQ global scores other than fatigue were correlated at levels above 0.3 with BILAG, ECLAM, and SLAM, and with all SLE indices, and appear to reflect SLE inflammatory activity in all patients and in those with few noninflammatory symptoms. By contrast, all correlations in patients with many noninflammatory symptoms were rho < 0.12. These data suggest that the physician scale for noninflammatory symptoms (DOCNON) may have considerable value in interpreting data from the MDHAQ, SLAQ, and other sources. RAPID3 scores and some, but not all, MDHAQ and SLAQ scores

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Table 5. Spearman correlations, in patients with few versus many noninflammatory symptoms (DOCNON), between SLAQ and MDHAQ items with SLAQ total (SLAQt), RAPID3, patient global assessment (PATGL), physician global assessment (DOCGL), and the SLE indices.

Index	Patient Measures		Global Measures		SLE Indices				
	SLAQt	RAPID3	PATGL	DOCGL	SLEDAI-2K	BILAG	ECLAM	SLAM	SLAM (no laboratories)
Few DOCNON (n = 34)									
SLAQ									
SLAQ-total (0–44)	—	0.46†	0.41*	–0.07 NS	–0.02 NS	–0.20 NS	–0.09 NS	0.00 NS	0.15 NS
Patient numerical rating scale (0–10)	0.45†	0.71*	0.62*	0.45†	0.27 NS	0.38 NS	0.34 NS	0.57*	0.54*
MDHAQ									
RAPID3 (0-30)	0.46†	—	0.89*	0.27 NS	0.32 NS	0.42†	0.38 NS	0.56*	0.65*
Fatigue (FT) VAS (0–10)	0.43†	0.82*	0.76*	0.11 NS	0.18 NS	0.34 NS	0.26 NS	0.39 NS	0.61*
No. symptoms (PATSX; 0–60)	0.45†	0.76*	0.62*	0.05 NS	0.08 NS	0.18 NS	0.21 NS	0.24 NS	0.40 NS
PATGL	0.41†	0.89*	—	0.31 NS	0.39 NS	0.49†	0.40 NS	0.54†	0.62*
DOCGL	–0.07 NS	0.27 NS	0.31 NS	—	0.76*	0.80*	0.67*	0.72*	0.30 NS
Many DOCNON (n = 16)									
SLAQ									
SLAQ-total (0–44)	—	–0.04 NS	0.04 NS	–0.18 NS	0.16 NS	–0.11 NS	0.06 NS	–0.16 NS	–0.08 NS
Patient numerical rating scale (0–10)	–0.02 NS	0.84*	0.75*	0.18 NS	0.31 NS	0.41 NS	0.38 NS	0.28 NS	0.37 NS
MDHAQ									
RAPID3 (0–30)	–0.04 NS	—	0.91*	–0.13 NS	0.00 NS	0.07 NS	0.12 NS	–0.04 NS	0.06 NS
Fatigue (FT) VAS (0–10)	0.21 NS	0.34 NS	0.36 NS	–0.35 NS	0.20 NS	0.20 NS	0.37 NS	0.40 NS	0.39 NS
No. symptoms (PATSX; 0–60)	0.13 NS	0.05 NS	–0.03 NS	0.01 NS	0.27 NS	0.17 NS	0.51 NS	0.33 NS	0.03 NS
PATGL	0.04 NS	0.91*	—	–0.08 NS	0.12 NS	0.09 NS	0.19 NS	0.06 NS	0.09 NS
DOCGL	–0.18 NS	–0.13 NS	–0.08 NS	—	0.62†	0.47 NS	0.42 NS	0.44 NS	0.25 NS

* $p < 0.0001$; † $p < 0.01$; NS: not significant. SLAQ: Systemic Lupus Activity Questionnaire; MDHAQ: Multidimensional Health Assessment Questionnaire; RAPID3: Routine Assessment of Patient Index Data 3; FT: fatigue; VAS: visual analog scale; PATGL: patient global estimate; PATSX: number of symptoms reported by patient on MDHAQ review of systems; DOCGL: physician global assessment; SLEDAI-2K: Systemic Lupus Erythematosus Activity Index-2K; BILAG: British Isles Lupus Assessment Group; ECLAM: European Consensus Lupus Activity Measurement; SLAM: Systemic Lupus Activity Measure; DOCNON: physician estimate of level of noninflammatory symptoms.

Table 6. Differences in median values between SLE patients of different ethnicities, in all patients, those with few noninflammatory symptoms (DOCNON < 0.5), and many noninflammatory symptoms (DOCNON ≥ 0.5) (Kruskal-Wallis). All comparisons adjusted for multiple comparisons required $p < 0.002$; therefore all adjusted comparisons are not statistically significant.

	N	RAPID3 (0–30)	Patient Global "Flare" (0–3)	SLEDAI-2K	BILAG	ECLAM	SLAM
All patients							
African American	9	3 (0.33–16.6)	1 (0–1)	4 (0–10)	3 (0–9)	1 (0–4)	3 (0–8)
Asian	9	3 (0–14.2)	0 (0–1)	4 (2–16)	4 (0–10)	2 (0–4)	3 (0–5)
Hispanic	13	7.48 (2.5–22.8)	1 (0–3)	6 (0–14)	4 (0–15)	2 (1-4)	5 (1–10)
White	18	6.17 (0–23)	1 (0–3)	4 (0–11)	3.5 (0–13)	1 (0–6)	2.5 (0–12)
p value (all groups)	—	0.09	0.10	0.37	0.46	0.36	0.30
p (Asian vs Hispanic)	—	0.01	0.02	0.20	0.17	0.56	0.07
DOCNON < 0.5							
African American	9	3 (0.33–16.6)	1 (0–1)	4 (0–10)	3 (0–9)	1 (0–4)	3 (0–8)
Asian	8	2.58 (0–7.66)	0 (0–1)	4 (2–16)	2 (0–12)	1.5 (0–4)	3.5 (0–5)
Hispanic	8	7.24 (2.5–22.8)	1 (0–3)	5 (0–14)	5 (0–15)	2 (1–4)	6 (1–10)
White	9	2 (0–11.3)	0 (0–3)	4 (2–11)	2 (0–13)	1 (0–4)	2 (0–12)
p value (all groups)	—	0.02	0.03	0.55	0.37	0.66	0.09
p (Asian vs Hispanic)	—	0.06	0.19	0.85	0.74	0.73	0.37
DOCNON ≥ 0.5							
Hispanic	5	17.2 (5.2–21.3)	2 (0–2)	2 (0–10)	5 (0–10)	1 (0–6)	3 (1–10)
White	9	10 (4.5–23)	1 (0–2)	7 (4–12)	4 (3–14)	3 (1–3)	4 (2–7)
p (Hispanic vs white)	—	0.64	0.66	0.03	0.90	0.11	0.46

No differences are significant at $p < 0.002$, the adjusted p value equivalent to $p < 0.05$ for 13 comparisons. No African American patient and 1 Asian patient had DOCNON ≥ 0.5; therefore, no comparisons were made for these subsets. RAPID3: Routine Assessment of Patient Index Data 3; DOCNON: physician estimate of level of noninflammatory symptoms; SLEDAI-2K: Systemic Lupus Erythematosus Activity Index-2K; BILAG: British Isles Lupus Assessment Group; ECLAM: European Consensus Lupus Activity Measurement; SLAM: Systemic Lupus Activity Measure.

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reflected SLE indices, but not in patients with many noninflammatory symptoms.

Most patients with many noninflammatory symptoms had clinical manifestations of fibromyalgia, although formal criteria[33,34] were not applied in this study. Fibromyalgia is considerably more common in patients with rheumatic diseases than in the general population[35,36], consistent with the finding of 32% of SLE patients with "many noninflammatory symptoms" in our study. Patient questionnaire scores have been found to distinguish patients with noninflammatory symptoms from those with RA[37,38], as well as patients with RA who have many or few noninflammatory symptoms[38].

The discordance seen between patient and physician global estimates is similar to previous reports in patients with SLE[39,40,41]. By contrast, patient and physician global estimates are correlated at levels of 0.6 and higher in patients with RA[42]. Further analysis of this discordance is beyond the scope of this study, but would appear to be of value regarding improved management of patients with SLE.

Several limitations are seen in this study. This was a cross-sectional assessment of only 50 patients with SLE in one practice, scored by only one rheumatologist. Almost all differences seen are not statistically significant in formal statistical adjustments for multiple comparisons, although 10 of 10 comparisons with rho < 0.05 in the same direction, as seen for differences in MDHAQ and SLAQ patient questionnaire scores in patients with many or few noninflammatory symptoms as judged by a physician (DOCNON), are most likely significant. Further, the results appear clinically plausible. Possible analyses of subgroups were limited due to small numbers, e.g., whether differences between Hispanic and white patients might be disproportionately higher according to patient-scored or physician-scored indices. The data may be regarded as hypothesis-generating, rather than hypothesis-testing. Further multicenter studies involving larger numbers of rheumatologists and cohorts of SLE patients, with estimates of DOCGL and levels of noninflammatory symptoms such as DOCNON assessed by different observers, would be of interest. Studies that include longitudinal monitoring appear desirable to further characterize use of the MDHAQ in usual care of patients with SLE.

Available SLE indices were designed for clinical research rather than for usual care, and also add relatively little guidance for treatment of clinical manifestations of disease. Self-report questionnaires appear to be of value to help identify patients with high activity levels, particularly when used together with a physician score for noninflammatory symptoms. Availability of such a score may be of value to prevent intensification of antiinflammatory therapies in patients whose symptoms are likely to have a largely noninflammatory basis[37,38,43]. Nonetheless, scores from an MDHAQ, SLAQ, or any measure must be interpreted in the context of a complete patient history, physical examination, laboratory tests, ancillary studies, and other elements of a physician evaluation to enhance clinical decisions.

The RAPID3 on an MDHAQ is calculated in 5 seconds[22]. Several advantages are seen in having a patient complete a questionnaire in the clinic beyond the data in RAPID3 or other specific scales. Completion of an MDHAQ prior to seeing a physician helps the patient to focus on the visit, enhancing discussion with the physician[44]. Availability of patient scores as well as the symptom checklist and recent medical history saves time for the physician to focus on details and nuances of the patient history[45]. A practice of asking a patient to complete a questionnaire while waiting to see the clinician does not prevent further quantitative assessment from a physical examination, laboratory test, ancillary study, or composite index. Further study of the use of MDHAQ in patients with SLE should clarify its longterm potential value to improve patient outcomes.

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