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Original Research Article.

Assessment of Disease Activity in Systemic Lupus Erythematosus: Validation of Four Common Clinical Indices

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ABSTRACT

Objective: Disease activity tools are important for clinical evaluation of SLE patients. Simple, less time consuming and reliable tools might help in better clinical practice. The study was aimed to assess the reliability and validity of SLEDAI, SLEDAI-2K, MEX-SLEDAI and SLAM indices response outcome.

Methods: This observational study was conducted in the SLE clinic of BSMMU Dhaka, Bangladesh from January 2012 to December 2012. The 4 tools SLEDAI, SLEDAI-2K, MEX-SLEDAI and SLAM indices were tested in 43 consecutive SLE patients fulfilling ACR criteria after having ethical clearance from IRB of BSMMU. The evaluations were done by 2 qualified physicians on 3 occasions, in an interval of 3 to 5 weeks.

Results: Out of 75 enrolled subjects' all indices were served on 3 occasions by two physicians in 43 cases. One physician evaluated 75 cases in 3 visits. 2 patients died and one patient lost to follow up during the study period. Convergent validity among instruments was R^2= 0.486 to 0.952. Reliability of instruments were SLEDAI (R^2= 0.94, 0.98, 0.90 at 1st, 2nd and 3rd visit), SLEDAI-2K (R^2= 0.92, 0.98, 0.87 at 1st, 2nd and 3rd visit), MEX-SLEDAI (R^2= 0.92, 0.94, 0.85 at 1st, 2nd and 3rd visit) and SLAM (R^2= 0.96, 0.93, 0.93 at 1st, 2nd and 3rd visit). In first and third visit SLAM showed highest reliability (R^2=0.96) and (R^2=0.93), in 2nd visit SLEDAI and SLEDAI-2K showed highest reliability (R^2=0.98). The agreement between the first to second and first to third visits were used to examine the responsiveness of 4 instruments. The SLEDAI had the best mathematical properties with sensitivity 86%, specificity 99% and overall accuracy of 94%. MEX-SLEDAI had 63% sensitivity and 96% specificity with an overall accuracy of 78%. Convergent validity was shown by the strong correlation of scores among the different instruments (R^2= 0.488 to 0.964). All instruments correlated highly with the physicians' clinical impression of disease activity. In first and third visit SLAM showed highest reliability (R^2= 0.93 and 0.86), whereas SLEDAI showed highest reliability (R^2= 0.97) in second visits. The agreement between the first to second and first to third visits were used to examine the responsiveness of 4 instruments. The SLEDAI had the best mathematical properties with sensitivity 86%, specificity 99% and overall accuracy of 94%. MEX-SLEDAI had 63% sensitivity and 96% specificity with an overall accuracy of 78%.

Conclusion: All four studied instruments are reliable and valid. In resource constrain situations MEX-SLEDAI can be considered as a clinical evaluation tool as it is simple, mostly clinical oriented, less costly and less time consuming and reliable.

Key words: SLEDAI, SLAM, Lupus Clinic, Hematuria, Proteinuria.

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INTRODUCTION

Systemic Lupus Erythematosus (SLE) is an autoimmune disease, that causes chronic inflammation in multiple systems and by periods of relapse with variable course.[1] Despite the improvement in survival over the past few decades, due to improvement of management, SLE patients still have a fivefold increased mortality than the general population. Survival of lupus patients was improved over the past few decades, due to better management, but still have a fivefold increased mortality than the general population.[2] SLE has diversity in presentation and disease activity may vary between patients and within the patient over time.[3] Organ damage usually occurs due to SLE itself or to drug therapy.[4] So assessment of the degree of disease activity in lupus

patients is essential, because many therapeutic decisions depend upon the accuracy of clinical judgment of disease activity by the physician's.[5] Considerable methodical analysis was done to determine disease activity by laboratory and clinical indices. Examples are, the British Isles Lupus Assessment Group (BILAG) developed in the United Kingdom[6], the US National Institute of Health SLE Index system(SIS)[7], the Lupus Activity Index[8], the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)[5] and the Systemic Lupus Activity Measures (SLAM) in North America[9] have been shown to share good metric properties and high reliability, validity and internal consistency.[5,8]

SLEDAI was modified by the Safety of Estrogen in Lupus Erythematosus National Assessment Group (SELENA).[10,11] This SELENA- SLEDAI version, referred to as the SLEDAI-2K (for SLEDAI-2000), was appeared as a useful index clinically.[12] (Guzzman et al 1992) developed another modification of SLEDAI, The MEX-SLEDAI.[13]

The pitfalls of these indexes are that some are lengthy; some are highly dependent on laboratory investigations and may have geographical or cultural variation.

We have taken 4 measures for the study (SLEDAI, SLEDAI-2K, SLAM, MEX-SLEDAI), because we considered that these are adequate to reflect properly the severity of the disease and to validate it in our cultural settings.

OBJECTIVES

To compare the validity and reliability of the SLEDAI, SLEDAI-2K, MEX-SLEDAI and SLAM (Systemic Lupus Activity Measure) and to establish the most valid and reliable instrument for measuring the activity in SLE patients of Bangladesh.

MATERIALS AND METHODS

This observational study was carried out in the Lupus clinic and inpatient department of rheumatology, BSMMU, Dhaka during April, 2010 to October, 2012. A total 75 consecutive patients were enrolled, after having informed consent who met the American college of rheumatology (ACR) criteria for systemic lupus erythematosus (Tan et al, 1982). Unwilling patients, including patients suffering from mixed connective tissue disease (MCTD), overlap cases, critically ill and having co-morbidity was excluded. Selected SLE disease evaluation tools used in this study were SLEDAI, SLEDAI-2K, SLAM and MEX-SLEDAI. The SLEDAI-2K was considered as gold standard tool for comparison. (Americ AG et al, 2004).

Patients were evaluated at baseline and at follow up visits separately by two investigators trained in rheumatology and observed by one expert rheumatologist. Patient follow up schedule was 4 weekly for 12 weeks. For evaluation of physician global assessment of disease activity and severity, 100-mm visual analog scales (VAS) was used. In the scale 0 for no or little activity (severity) and 100 defined most activity (severity). The relevant and necessary (FBC, urine routine and microscopic examination, S. Creatinine, SGPT, anti-ds DNA etc) laboratory investigations needed for disease evaluation at routine visit was done. Ongoing medications (e.g. prednisolone, cyclophosphamide) were allowed to continue.

Measuring Instruments

SLEDAI: Bombardier et al. developed this instrument In 1992, on the basis of the presence or absence of 24 abnormalities in 9 organ systems for identifying disease activity in lupus, as follows: 8 each for central nervous system and vascular, 4 each for renal and musculoskeletal, 2 each for serosal, dermal, immunologic, and 1 each for constitutional and hematological. The maximum score is 105. Each item recognizes disease phenomenon occurring within the 10 days prior to the evaluation. In order to differentiate from chronic lesion, the variables such as rash, alopecia, or mucus membrane lesions, and proteinuria were expressed as active only if they are new or recurrent lesion.

SLEDAI -2K: The SLEDAI-2K was developed in 2002 by modifying original SLEDAI. This index identifies disease manifestations occurring within the 10 days prior to the survey; it contains 24 specific items for different manifestations using secured weights (ranging from 1 to 8) with a maximum score of 105. In SLEDAI the rash, alopecia, or mucus membrane lesions, and proteinuria were calculated as active only if they are new or recurrent (to recognize them from chronic lesion); but, the 2K version scores the presence of any rash, alopecia, or mucosal ulcers, and a new, recurrent, or persistent proteinuria higher than 0.5 g/24 h.

SLAM: The SLE Activity Measure (SLAM) was developed in 1983 by members of American Rheumatism Association council on SLE. The items of this index can be graded. It reflects symptoms that appeared during the past month, and includes 24 clinical manifestations and 8 laboratory parameters. Immune function parameters were not included. Disease activity and disease severity are both included in the scales. Symptoms were labeled as either active or inactive.

MEX-SLEDAI: It is also a modification of SLEDAI in a simplified form, developed by Guzman, *et al* in 1992. The original 24 defined variables of SLEDAI were reduced to the 10 main variables which were clinically defined, grouped by involved organ, with maximum score of 32 points. The difference of scoring between SLEDAI and MEX-SLEDAI are mainly the followings: seizure, psychosis, organic brain syndrome, cranial nerve and cerebrovascular accident were grouped as neurological disorder, given a weight of 8; visual and lupus headache, were omitted because they are difficult to detect precisely in some cases. Vasculitis had a weight of 4, myositis had 3, and arthritis had 2. Hemolysis was added and kept with thrombocytopenia with a weight of 3. New rash, alopecia and mucus membrane were grouped as mucocutaneous disorder with a total value of 2 points. Pleurisy and pericarditis were kept with peritonitis and called serositis, given a value of 2. Leukopenia or lymphopenia received 1 point and fever or fatigue had 1 point.

Analysis: Patients demographics were expressed in percentages, mean and standard deviation.

Average scores of measuring tools at baseline observed by two physicians were determined by using Mann-Whitney U test, which reflects reliability of the indices.

Reliability

The correlations between visits of two physicians were analyzed by Spearman rank correlation coefficient test which also reflects reliability.

Validity was tested comparing each index score against physicians' VAS and the other indices' scores using Spearman rank correlation coefficient test.

Validity

Validity was tested by comparing each total score against SLEDAI-2K using Spearman rank correlation coefficient.[14]

We noticed index score changes over time within each patient and calculated a coefficient of responsiveness. The mean changes of index score were assessed in each group. Improvement of coefficient of responsiveness was acquired by the standard deviation of stable patients according to following formula:

$$CR = \frac{\mu \text{ (mean change)}}{\sigma \text{ (SD in stable patients)}}$$

{μ = previous index score – present index score}

Worsening of coefficient of responsiveness was obtained with the same formula, using the scores of the patients who also worsened instead of patients who improved; any CR > 1 indicated sensitivity to detect clinical change.[15] Random probabilities of less than 5% ($p < 0.05$) was used as significant. All data was processed with the Statistical Package for Social Sciences (SPSS), version 16.0.

RESULTS

A total 75 patients were enrolled out of them 43 completed study period and followed up by 2 physicians. As 2nd physician did not evaluate 32 patients they were excluded from analysis. Physician 1 evaluated all 43 patients in 3 visits. Physician 2 evaluated same 43 patients, among them 22 patients had 1 visit, 11 patients had 2 visits and 10 patients had 3 visits.

All of the patients were female and range of age was (26.2 ± 8.7). Each and every patient was tested with all four indices for their disease activity. Two physicians evaluated each patient separately with total 3 evaluations were done at an interval of 3 to 5 weeks.

Reliability: In first and third visit SLAM showed highest reliability (R^2=0.96) and (R^2=0.93), in 2nd visit SLEDAI and SLEDAI-2K showed highest reliability (R^2=0.98).

Validity: The correlation with physician's VAS was highly significant for SLEDAI, SLEDAI-2K, MEX-SLEDAI and also for SLAM. This evidence supports the presence of convergent validity.

Table I: Baseline characteristics of the patient [Measuring index variable]. There is no significant difference on Mann-Whitney U test in perception of disease activity between physician 1 and 2.

	Physician-1 (n=43)		Physician-2 (n=43)		P-value
	Mean ± SD	Median	Mean ± SD	Median	
SLEDAI	14.0 ± 6.8	14	13.2 ± 7.2	13	0.06
SLEDAI 2K	14.1 ± 6.8	14	13.5 ± 7.2	13	0.20
MEX SLEDAI	7.2 ± 3.8	7	6.9 ± 4.2	7	0.23
SLAM	13.2 ± 5.6	14	12.7 ± 6.0	13	0.05

Table II: Baseline Responses of different variables (clinical and laboratory) of the patient as evaluated by both physician-1 and physician-2. (Data in the parenthesis indicates percentage)

	Physician-1 (n=43)				Physician-2 (n=43)			
CONSTITUTIONAL	**Absent/normal**	**Mild**	**Moderate**	**Severe**	**Absent/normal**	**Mild**	**Moderate**	**Severe**
Weight loss	27 (62.8)	15 (34.9)	0 (0.0)	1 (2.3)	29 (67.4)	12 (27.9)	0 (0.0)	2 (4.7)
Fatigue	10 (23.3)	19 (44.2)	0 (0.0)	14 (32.6)	17 (39.5)	15 (34.9)	0 (0.0)	11 (25.6)
Fever	32 (74.4)	8 (18.6)	0 (0.0)	3 (7.0)	34 (79.1)	6 (14.0)	0 (0.0)	3 (7.0)
Oral Ulcer	23 (53.5)	20 (46.5)	0 (0.0)	0 (0.0)	26 (60.5)	16 (37.2)	0 (0.0)	1 (2.3)
Alopecia	17 (39.5)	19 (44.2)	7 (16.3)	0 (0.0)	19 (44.2)	16 (37.2)	8 (18.6)	0 (0.0)
Erythematous, rash or discoid lupus, or lupus profundus, or bullous lesions	28 (65.1)	9 (20.9)	5 (11.6)	1 (2.3)	28 (65.1)	11 (25.6)	3 (7.0)	1 (2.3)
Vasculitis	33 (76.7)	9 (20.9)	1 (2.3)	0 (0.0)	33 (76.7)	9 (20.9)	1 (2.3)	0 (0.0)
EYE								
Cytoid	39 (90.7)	4 (9.3)	0 (0.0)	0 (0.0)	38 (88.4)	4 (9.3)	1 (2.3)	0 (0.0)
Hemorrhages	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)
Papillias	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)
RETICULOENDOTHELIAL								
Diffuse	24 (55.8)	15 (34.9)	4 (9.3)	0 (0.0)	23 (53.5)	15 (34.9)	5 (11.6)	0 (0.0)
Hepato	41 (95.3)	2 (4.7)	0 (0.0)	0 (0.0)	41 (95.3)	2 (4.7)	0 (0.0)	0 (0.0)
PULMONARY								
Pleural	39 (90.7)	2 (4.7)	1 (2.3)	1 (2.3)	40 (93.0)	1 (2.3)	1 (2.3)	1 (2.3)
Pneumonia	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
CARDIOVASCULAR								
Raynaud's	31 (72.1)	12 (27.9)	0 (0.0)	0 (0.0)	32 (74.4)	11 (25.6)	0 (0.0)	0 (0.0)
Hypertension	36 (83.7)	7 (16.3)	0 (0.0)	0 (0.0)	35 (81.4)	8 (18.6)	0 (0.0)	0 (0.0)
Carditis	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)

GASTROINTESTINAL								
Abdominal pain	38 (88.4)	5 (11.6)	0 (0.0)	0 (0.0)	38 (88.4)	4 (9.3)	1 (2.3)	0 (0.0)
Stroke syndrome	42 (97.7)	0 (0.0)	0 (0.0)	1 (2.3)	41 (95.3)	0 (0.0)	0 (0.0)	2 (4.7)
Seizure	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)
Cortical dysfunction	17 (39.5)	22 (51.2)	3 (7.0)	1 (2.3)	22 (51.2)	17 (39.5)	4 (9.3)	0 (0.0)
Headache	35 (81.4)	1 (2.3)	7 (16.3)	0 (0.0)	35 (81.4)	0 (0.0)	8 (18.6)	0 (0.0)
Myalgia	28 (65.1)	12 (27.9)	3 (7.0)	0 (0.0)	29 (67.4)	7 (16.3)	6 (14.0)	1 (2.3)
Joint pain	13 (30.2)	14 (32.6)	7 (16.3)	9 (20.9)	15 (34.9)	15 (34.9)	4 (9.3)	9 (20.9)
Others	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	43 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
LABORATORY								
Hematocrit	15 (34.9)	17 (39.5)	7 (16.3)	4 (9.3)	14 (32.6)	18 (41.9)	8 (18.6)	3 (7.0)
WBC	40 (93.0)	3 (7.0)	0 (0.0)	0 (0.0)	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)
Lymphocyte	28 (65.1)	9 (20.9)	5 (11.6)	1 (2.3)	28 (65.1)	9 (20.9)	5 (11.6)	1 (2.3)
Platelet	40 (93.0)	2 (4.7)	1 (2.3)	0 (0.0)	42 (97.7)	1 (2.3)	0 (0.0)	0 (0.0)
ESR	5 (11.6)	16 (37.2)	9 (20.9)	13 (30.2)	5 (11.6)	16 (37.2)	9 (20.9)	13 (30.2)
S. creatinine	34 (79.1)	5 (11.6)	4 (9.3)	0 (0.0)	36 (83.7)	4 (9.3)	3 (7.0)	0 (0.0)
Urine sediment	19 (44.2)	10 (23.3)	14 (32.6)	0 (0.0)	19 (44.2)	11 (25.6)	12 (27.9)	1 (2.3)

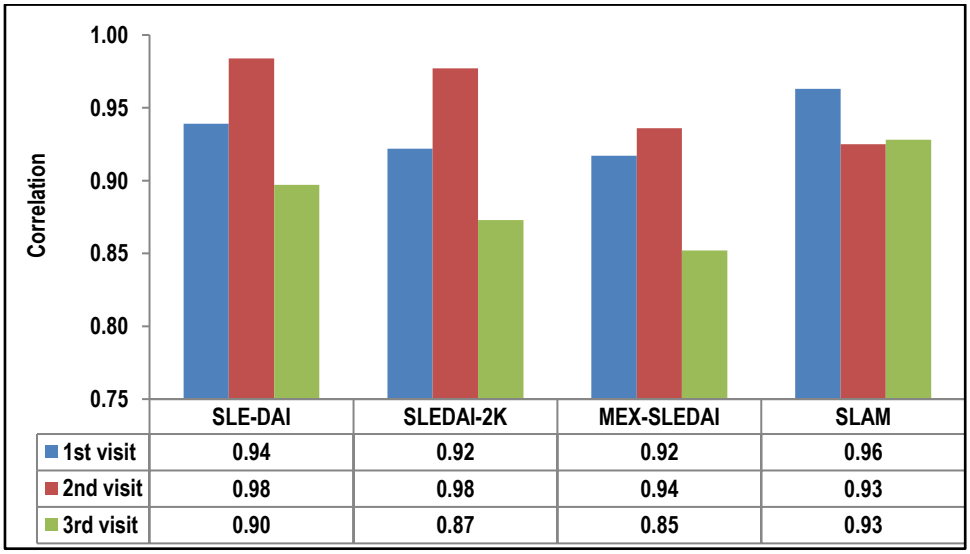

Figure 1: Inter observer correlations (R^2) in all 3 visits for instruments and physician's VAS (by Spearman rank correlation coefficient test) (Reliability).

Table III: The correlation between the mean scores for each subject on each instrument ranged from 0.486 to 0.952.

		Physician 2				
		SLEDAI	**SLEDAI 2K**	**MEX SLEDAI**	**SLAM**	**Physician VAS**
Physician 1	**SLEDAI**	0.952	0.945	0.519	0.791	0.634
	SLEDAI 2K	0.952	0.935	0.525	0.806	0.633
	MEX SLEDAI	0.526	0.514	0.902	0.486	0.685
	SLAM	0.83	0.836	0.499	0.927	0.625
	Physician VAS	0.646	0.669	0.561	0.61	0.918

Table IV: Mean score change and Coefficient of responsiveness (CR) in first visit to 2nd visit and 3rd visit of each index

			SLAM	**SLEDAI**	**SLEDAI-2K**	**MEX-SLEDAI**
First to 2nd visit	**Mean score change**	**Worsening**	3.8	6.2	5.1	3.3
		Improvement	5.8	8.1	7.3	4.2
		P-value	0.0	0.0	0.0	0.0
	CR	**Worsening**	0.68	0.9	0.7	0.9
		Improvement	1.0	1.2	1.2	1.1
First to 3rd visit	**Mean score change**	**Worsening**	2.8	6.7	5.4	1.9
		Improvement	7.4	10.2	9.5	4.6
		P-value	0.0	0.0	0.0	0.0
	CR	**Worsening**	0.6	1.3	0.7	0.8
		Improvement	1.3	1.5	1.5	1.2

Table V: Change in the mean scores in all indices in first, second and third visits

Visit	SLEDAI	SLEDAI 2K	MEX -SLEDAI	SLAM
1st	13.5 ± 6.3	13.6 ± 6.3	7.2 ± 3.6	13.6 ± 5.2
2nd	9.4 ± 7.6	10.4 ± 7.2	5.6 ± 4.6	10.8 ± 6.1
3rd	6.1 ± 6.6	7.4 ± 6.3	3.8 ± 3.7	7.2 ± 5.0

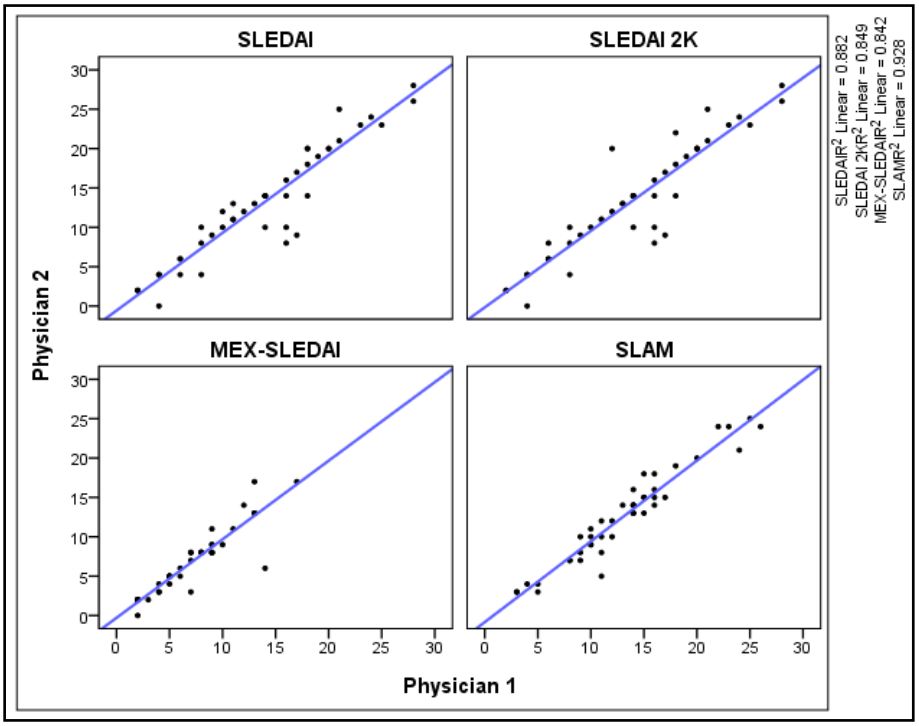

Figure 2: Physicians' VAS in SLEDAI, SLEDAI- 2K, MEX-SLEDA and SLAM showed significant agreement among physician- 1 and physician- 2 (R^2 = 0.882, 0.849, 0.842, 0.928 respectively) (By Spearman rank correlation coefficient test).

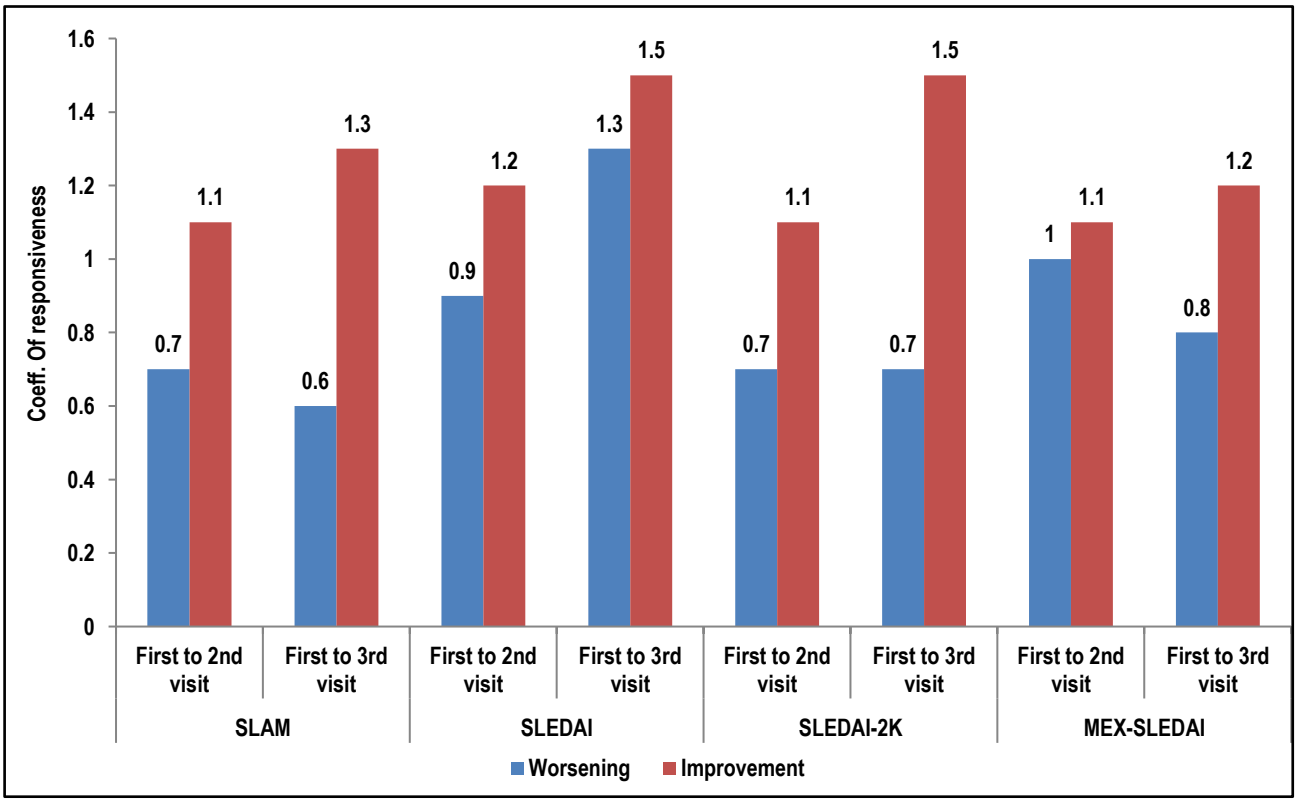

Figure 3: The agreement between the first to second and first to third was used to examine the responsiveness. All 4 indices had higher coefficients of responsiveness for improvement than for worsening. SLEDAI was more sensitive to change than others in both first to second and first to third visits. Coefficient of responses ranged from 1.1 to 1.5 for improvement and 0.6 to 0.9 for worsening

Table VI: The SLEDAI had the best metric properties with an overall accuracy of 94%, sensitivity 86% and specificity 99%. MEX-SLEDAI has high specificity (96%) but relatively low sensitivity than SLEDAI and SLAM.

	SLAM	SLEDAI	MEX-SLEDAI
Sensitivity	77	86	63
Specificity	84	99	96
Predictive value positive	71	99	96
Predictive value negative	88	91	68
Overall accuracy	82	94	78

SLEDAI-2K, is considered the gold standard[16]

DISCUSSION

Exact pathophysiology of SLE is not fully understood, so assessment of disease activity can only be done indirectly for validation of any clinical system. During evaluation of disease activity and research purpose, clinician's judgment should correlate with disease activity scores, and when multiple observers are involved, activity scores should be reproducible. This study evaluated mathematical information on the validity and reliability of 4 measures of SLE activity (SLEDAI, SLEDAI-2K, MEX-SLEDAI and SLAM). All of them proved to have adequate convergent validity. The correlation between each instrument in all three visits were:

Convergent validity among instruments was R^2= 0.486 to 0.952. The correlation with physician's VAS was significant for SLEDAI, SLEDAI-2K, MEX-SLEDAI and also for SLAM. This evidence supports the presence of convergent validity.

Reliability of instruments were SLEDAI (R^2= 0.94, 0.98, 0.90 at 1st, 2nd and 3rd visit), SLEDAI-2K (R^2= 0.92, 0.98, 0.87 at 1st, 2nd and 3rd visit), MEX-SLEDAI (R^2= 0.92, 0.94, 0.85 at 1st, 2nd and 3rd visit) and SLAM (R^2= 0.96, 0.93, 0.93 at 1st, 2nd and 3rd visit). In first and third visit SLAM showed highest reliability (R^2=0.96) and (R^2=0.93), in 2nd visit SLEDAI and SLEDAI-2K showed highest reliability (R^2=0.98). All instruments had shown high correlation with the physicians' clinical impression of disease activity

In this study, MEX-SLEDAI was as reliable as the original SLEDAI (r_s = 0.894 vs. 0.867), and its correlation with expert's VAS was similar (0.678 for the MEX-SLEDAI) (Guzzman et al.1992). In this series, inter-rater reliability was very good. The P value was 0.55 for SLEDAI, 0.199 for SLEDAI-2K, 0.179 for MEX-SLEDAI, 0.060 for SLAM, 0.919 for physician's VAS of SLAM, 0.889 for physician's VAS for SLEDAI. This result was consistent with the study done by Bombardier et al, 1992, Liang et al, 1989 and Guzzman et al, 1992. The correlation between the patients' and physicians' global assessment suggests that the simple visual analog rating by either the doctor or the patient could be used when it is not feasible to use the expanded scales. The agreement between the first to second and first to third visits were used to examine the responsiveness. The four indices had higher coefficients of responsiveness for improvement than for worsening. SLEDAI appeared more sensitive to change than others in both first to second and first to third visits As the SLEDAI-2K was considered as gold standard (Americ A G et al, 2004) we have seen that SLEDAI showed highest sensitivity (86%) and specificity (99%) with an overall accuracy of 94% and maintained its metric properties very well. MEX-SLEDAI had 63% sensitivity and 96% specificity with an overall accuracy of 78%. Our observation is near similar to that of Americ A G et al, 2004, who had shown that MEX-SLEDAI had a sensitivity of 58%, a specificity of 93% and overall accuracy of 89%, which is near similar to our study.

LIMITATION

The limitation of the study was that most patients had mildly active disease.

RECOMMENDATION

High inter-rater agreement in this study may be as; both the raters were also treating the patients. We did relevant investigations only for management purpose. Urine sediment as a variable may be redefined. i.e., In SLAM proteinuria was also included as sediment. Whereas in MEX-SLEDAI cast, hematuria and proteinuria altogether were designated as renal disorder. It creates difficulty in multiple regression analysis.

CONCLUSION

This study proved that SLEDAI, SLEDAI-2K, MEX-SLEDAI and SLAM indices are valid and reliable tools for the assessment of disease activity in patients with SLE. The SLEDAI maintained its best metric properties. In developing country like Bangladesh, where fund constrain is an issue, MEX-SLEDAI can be considered, because it is valid, reliable, simple, more clinically oriented, less costly and less time consuming.

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