



Abstract 1120 Figure 1 Receiver Operating Characteristic (ROC) curve of Δ PGA for predicting flare. AUC = Area under the curve.

between 2-3. The ROC curve for the performance of Δ PGA in predicting flare is shown in figure 1. The area under the curve was 0.774 (SE .034), $p < 0.001$. A Δ PGA of 0.3 is associated with the highest Youden's index.

Conclusion Preliminary results from this small observational study suggest that the MCID for the PGA is 0.3. Larger studies evaluating the Δ PGA and flare, scored by multiple physicians are necessary.

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EVALUATION OF COMORBIDITIES AND DAMAGE IN CANADIAN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease with a wide array of clinical manifestations, treated with corticosteroids and long term immunosuppressants to reduce the disease activity and damage. Our objectives were to examine a Canadian cohort of SLE patients in comparison to the general Canadian population to examine potential risk factors for comorbidities and disease damage in SLE patients. We hypothesize that SLE patients accumulate more damage and comorbidities with greater disease activity and corticosteroid exposure over time compared to the general population.

Methods We explored the Canadian Network for Improved Outcomes in SLE (CaNIOS) registry, a multi-centred cohort of Canadian SLE patients, to identify prevalence of damage using the SLICC SLE Damage Index (SDI) and comorbidity using the Charlson Comorbidity Index (CCI). We also performed an age-matched data analysis to compare the comorbidities prevalence between the CaNIOS registry and the general Canadian population (Canadian Community Health Survey). Exploratory analysis was done using descriptive statistics. Univariable analysis was performed to identify potential predictors of comorbidities and damage in the CaNIOS SLE population at

baseline. Variables that were significant at the univariable level were included in Generalized Linear Model (GLM).

Results 603 SLE patients from the CaNIOS registry were included, mean age 50.9 years (SD=14.6), average disease duration 14.2 years (SD=11.9), 91% being female. Mean SLE disease activity score (SLEDAI) was 3.1 (SD 3.5) and mean ACR classification criteria 5.3 (1.5). Mean CCI was 1.33 (SD=0.69), and mean SDI was 1.34 (SD=2.04). The most common comorbidities in CaNIOS patients were cerebrovascular disease (6.5%), followed by solid tumours (5.8%). Compared to their age-matched general population counterparts, SLE patients had higher rates of cancer (7.8% vs 2%) and cerebrovascular disease (6.5% vs 1.8%) ($p < 0.0001$). Multivariable GLM showed age to be a significant predictor for increased comorbidities ($p < 0.05$). Baseline risk factors associated with increased damage (SDI) were age, longer disease duration, higher ACR scores, current smoking and prednisone use within the last year ($p < 0.05$). Female gender ($p < 0.0160$), a recent onset of disease (< 12 months) ($p < 0.0001$) and intravenous steroid use ($p < 0.0286$) were found to be associated with less disease damage.

Conclusions Canadian lupus patients have a greater burden of certain comorbidities compared to the general population. Identifying the risk factors associated with comorbidities and greater disease damage is a very important step in treating those patients.

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VALIDATION OF A NOVEL LUPUS MULTIVARIABLE OUTCOME SCORE AS AN OUTCOME MEASURE FOR SYSTEMIC LUPUS ERYTHEMATOSUS TRIALS

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Background Development of effective new Systemic Lupus Erythematosus (SLE) treatments requires a validated responder index responsive to clinically meaningful change and relevant to clinical practice. To address this challenge, we have recently developed a new Lupus Multivariable Outcome Score (LuMOS) to optimize discrimination between outcomes of actively treated patients *versus* those on placebo.¹ We now report on external validation of LuMOS in two independent SLE clinical trials.

Methods Validation was carried out in the Illuminate trials that evaluated tabalumab (TB) in SLE. All participants in both Illuminate 1 and 2 trials met the ACR classification criteria for SLE and all were included in our analyses. To adapt LuMOS for use with laboratory results assessed on different platforms than used in the trials of belimumab employed to generate the original LuMOS outcome score.¹ we calculated a standardized score using z-score transformations. For validation, in each of the Illuminate trials, we calculated LuMOS scores at week 52 for all participants receiving either placebo or one of 2 dosage regimens of TB. Cohen D Effect Size (ES), with 95% confidence intervals (CI), assessed the ability of LuMOS to discriminate between outcomes in active

Abstract 1122 Table 1 Comparison of Effect Sizes for TB vs Placebo groups between LuMOS and SRI-5

Trial	Group (n)	LuMOS: Effect Size (95% CI)	SRI-5: Effect Size (95% CI)
ILLUMINATE-1	TB-q4weeks (n=378)	0.44 (0.30; 0.59)	0.13 (- 0.02; + 0.27)
ILLUMINATE-1	TB-q2weeks (n=381)	0.42 (0.27; 0.56)	0.05 (- 0.09; + 0.20)
ILLUMINATE-2	TB-q4weeks (n=376)	0.54 (0.39; 0.68)	0.15 (+0.01; +0.30)
ILLUMINATE-2	TB-q2weeks (n=372)	0.69 (0.53; 0.83)	0.23 (+0.08; +0.37)

treatment groups *versus* placebo, and compared it with SRI-5 responder index used in the original trials.

Results LuMOS using standardized z-score transformed laboratory data worked comparably to the original LuMOS model in the analyses of original belimumab trials and was then applied to the Illuminate data sets. LuMOS-based ES for both TB groups in both trials indicated highly significant ($p < 0.0001$), moderately strong treatment effects ($ES > 0.4$), in contrast to weak effects ($ES < 0.25$) based on SRI-5, that were statistically *non*-significant for Illuminate-1, as reflected by the 95% CI's that included 0 (table 1).

Conclusion LuMOS improves the ability to detect statistically significant treatment effects. Further validation in SLE trials of non-B cell directed treatments is necessary to document utility as an outcome measure independent of drug mechanism.

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REFERENCE

1. Abrahamowicz et al. *Arthritis Rheumatol.* 2018;70:1450-58.

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REMISSION AND LUPUS LOW DISEASE ACTIVITY STATE (LLDAS) ARE ASSOCIATED WITH A LOWER PROBABILITY OF FLARES IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS. DATA FROM THE ALMENARA LUPUS COHORT

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Background Remission and LLDAS have been proposed as the treatment goal for SLE patients. Different investigators have reported that achieving these states prevent damage accrual; however, their independent impact on the occurrence of flares has been only scarcely evaluated. The aim of this study was to evaluate the independent impact of remission and LLDAS on flares.

Abstract 1123 Table 1 Factors associated with flares. Univariable and multivariable models

	OR (95%CI)	p value	OR (95%CI)	p value
Disease activity state				
Active	Ref.		Ref.	
LLDAS	0.405 (0.182-0.903)	0.027	0.358 (0.152-0.841)	0.018
Remission	0.604 (0.400-0.912)	0.017	0.595 (0.387-0.916)	0.018
Age at diagnosis, years	1.001 (0.987-1.016)	0.846	1.002 (0.986-1.180)	0.791
Female gender	1.234 (0.482-3.159)	0.661	1.379 (0.564-3.373)	0.481
SES				
Low	Ref.		Ref.	
Medium	1.212 (0.788-1.863)	0.382	1.140 (0.672-1.935)	0.627
High	0.935 (0.488-1.792)	0.839	0.792 (0.276-2.274)	0.665
Educational level, years	0.989 (0.919-1.063)	0.756	0.977 (0.861-1.109)	0.722
Disease duration	0.989 (0.963-1.017)	0.443	0.988 (0.956-1.021)	0.469
SDI	1.044 (0.929-1.173)	0.468	1.047 (0.928-1.180)	0.456
Antimalarial use				
Current	Ref.		Ref.	
Past	1.027 (0.553-1.908)	0.933	1.076 (0.578-2.003)	0.558
Never	1.287 (0.285-5.808)	0.743	1.533 (0.367-6.400)	0.818

OR: Odds ratio. LLDAS: Lupus low disease activity state. SES: Socioeconomic status. SDI: SLICC/ACR damage index.

Methods SLE patients from a single center cohort with at least two visits were included. Visits were performed every six months. Disease activity state was defined as three independent states: remission defined as a SLEDAI-2k (excluding serology) = 0, physician global assessment (PGA) < 0.5, prednisone daily dose ≤ 5 mg/d and immunosuppressive drugs on maintenance dose (based on 2021 DORIS definition); LLDAS defined as a SLEDAI-2k ≤ 4 with no activity in major organ systems, with no new features of lupus disease activity compared to the previous assessment, physician global assessment (PGA) ≤ 1.0, prednisone daily dose ≤ 7.5 mg/d; and the rest were defined as active. Flares were defined as an increase of at least four points in the SLEDAI-2k between two consecutive visits. Generalized estimating equations were performed, using as outcome the occurrence of a flare in the subsequent visit, and the activity state in the previous visit; multivariable models were adjusted for possible confounders [age, gender, socioeconomic status, educational level, disease duration, antimalarial use and SLICC/ACR damage index (SDI)]. All the confounders were measured in the same visit than the activity state.

Results Two hundred and eighty-one patients were included, they were followed-up for 2.7 (1.1) years. A total of 1346 visits were included, 730 (54.2%) of them were on remission, 190 (14.1%) were on LLDAS, and 426 (31.6%) were active. One hundred and one flares occurred during the follow-up among these 281 patients; 197 of them (70.1%) did not present flares, 67 (23.8%) presented one flare and 17 (6.0%) presented two flares. Remission and LLDAS were associated with a lower probability of flares. Univariable and multivariable models are depicted in table 1.

Conclusions Remission and LLDAS are independently associated with a lower probability of flares. These results reinforce the importance of these states as the goals of SLE treatment.