

PO.7.144 ASSESSLE- A NEW TOOL TO ASSESS SLE DISEASE ACTIVITY- THE PATIENTS' PERSPECTIVE

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Purpose Systemic lupus erythematosus (SLE) is a heterogeneous, waxing and waning, multisystem autoimmune disease. The complexity and clinical unpredictability of SLE challenge the assessment of disease activity over time, especially in every day clinical practice. Multiple clinical disease monitoring instruments have been developed, however they are limited in ability to detect change in disease activity over time, too cumbersome to be utilized in daily practice and do not include patient reported outcomes (PROs).

We aimed to construct a new disease activity score which will simplify and improve disease activity assessment in daily practice, and include PROs. Here we present the PRO component.

Methods The new instrument for the assessment of SLE activity is comprised of 7 visual analogue scales (VAS), which separately address the physician's global assessment and 6 organ systems. The PRO consists of 5 VAS questions which address general well-being, global disease activity, activities of daily living, medication compliance and mood. The ASSESSLE PRO is compared to the Short Form Health Survey (SF-36) which is a 36-item, patient reported survey of patient health. We applied the ASSESSLE PRO to 46 consecutive patients with SLE attending the rheumatology clinic in 2 tertiary medical centers in Israel.

Results Psychometric evaluation of the reliability of all 5 PRO questions indicated that question 4, regarding compliance, poorly correlated with the other items and lowered the

reliability (Cronbach's $\alpha = 0.80$ 95% CI [0.74,0.85]). Following omission of question 4, Cronbach's α was recalculated, leading to increased internal reliability (Cronbach's $\alpha = 0.86$, 95% CI [0.82, 0.90]). All other remaining items had satisfactory correlation with the other items ('item-other' correlation between 0.58–0.70). Therefore, the score was computed as the mean of the 4 remaining questions. Aiming to compare the ASSESSLE PRO to the SF-36 survey, Spearman correlation coefficient between absolute scores was computed and a strong and significant effect was found ($R=0.85$, $p<0.0001$) (figure 1).

Conclusions The ASSESSLE PRO is a short PRO which allows a reliable, reproducible and simple PRO form showing excellent correlation with the SF-36. Following omission of question 4, regarding patient compliance, the ASSESSLE PRO consists of only 4 questions, as compared to the SF-36 which requires a response to 36 items. The ASSESSLE PRO seems to have significant advantages due to its intuitive VAS questions and brevity which allows use of this PRO in every day practice and may increase validity of disease activity evaluation of SLE when combined with the physician's assessment.

PO.7.145 ACTIVE SKIN INVOLVEMENT IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: ANALYSIS OF THE IMPACT ON HEALTH-RELATED QUALITY OF LIFE AND PATIENT PERCEPTION OF HEALTH STATUS

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Purpose skin involvement can severely alter body image thus representing a major concern for patients with Systemic Lupus Erythematosus (SLE).

The aim of this study was to analyze the impact of active skin involvement on Health-Related Quality of Life (HRQoL), mood disorders and self-perception of disease activity in a monocentric cohort of SLE patients.

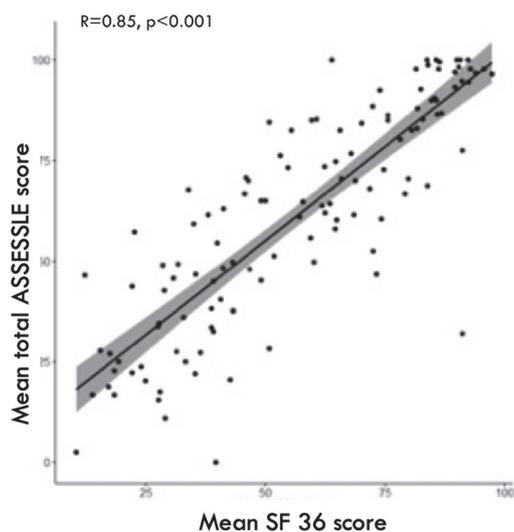
Methods a cross-sectional study including consecutive outpatients with SLE with active skin involvement. The severity of skin lesions was assessed through the CLASI index.

Consecutive SLE outpatients with at least one active disease manifestation, but without active skin involvement or irreversible skin damage served as a control group.

The following data have been collected: demographics, clinical and laboratory data, SLEDAI-2K and SLICC-DI. Each patient completed the following Patient-Reported Outcomes (PROs): SF-36, FACIT-F, LIT for disease burden, SLAQ for self-assessment of disease activity; the HADS for anxiety and depression was available for a subgroup of patients. Patients with skin involvement also completed the SKINDEX-16 (a questionnaire for the evaluation of HRQoL in patients with dermatological conditions).

Results we enrolled 72 consecutive SLE patients, 38 with active skin lesions ('skin group') and 34 without active mucocutaneous manifestations or irreversible skin damage ('no-skin group'); 88.9% were female, 94.4% Caucasians. Mean age at enrollment was 43.9 ± 12.2 years and median disease duration was 11.5 (IQR 7–18.5) years. In the 'skin group' the

Correlation between SF-36 score and ASSESSLE score



Abstract PO.7.144 Figure 1

median CLASI activity score was 5 (IQR 3–7.5) and the median CLASI damage score was 1 (IQR 0–4).

In the ‘no-skin group’, we found a significantly higher percentage of patients with active hematological and renal manifestations ($p < 0.01$).

No other significant differences emerged between the two groups with respect to age, disease duration, disease activity and damage, ongoing treatment and fibromyalgia.

By comparing PROs results between the two groups, we found no significant differences for the SF-36, the LIT and the FACIT-F. However, although the SLEDAI score did not significantly differ between the two groups, we found that patients in the ‘skin group’ had a significantly higher score of the SLAQ questionnaire compared to patients in the ‘no-skin group’ ($p < 0.01$).

The HADS questionnaire was available for 50 patients: patients with active skin involvement presented significantly higher scores for depressive symptoms compared to patients without skin manifestations ($p = 0.01$).

Finally, among patients with active skin lesions, we did not demonstrate a significant correlation between the CLASI activity score and the scores of all PROs used, not even with the SKINDEX, which is specific for dermatological conditions.

Conclusion although skin involvement is not generally considered a severe disease manifestation in SLE, it seems to be strongly associated with patients’ perception of higher disease activity and with depressive symptoms. These results underline as skin involvement still represents an unmet need in the management of patients with SLE, with a potentially negative impact on patient satisfaction with the care process.

PO.7.146 SENSITIVITY ANALYSIS OF EQ-5D-3L INDEX SCORES IN RELATION TO DISCRIMINATIVE AND KNOWN-GROUPS VALIDITY IN SYSTEMIC LUPUS ERYTHEMATOSUS

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Purpose To investigate the ability of different EQ-5D-3L index scores to discriminate between verum drug and placebo (discriminant validity) as well as between responders and non-responders (known-groups validity) in the SLE patient population of two phase III clinical trials of belimumab.

Methods Data from the BLISS-52 (NCT00424476) and BLISS-76 (NCT00410384) trials (N = 1684), which both showed superiority of belimumab to placebo, were utilised. Responders were defined as SLE Responder Index 4 (SRI-4) achievers at week 52. The Pearson’s χ^2 and Mann-Whitney U tests were used for comparisons, and logistic regression analysis was used for adjustments for confounders and assessment of independence.

Results While full health state (FHS; EQ-5D index score 1) showed the best ability to discriminate between belimumab and placebo (adjusted OR: 1.47; 95% CI: 1.1–2.0; $P = 0.008$) and between SRI-4 responders and non-responders (adjusted

OR: 3.47; 95% CI: 1.3–11.0; $P = 0.020$), the discriminative ability of EQ-5D index scores 0.800 or more reached statistical significance for both discriminant validity (adjusted OR: 1.29; 95% CI: 1.0–1.6; $P = 0.036$) and known-groups validity (adjusted OR: 3.08; 95% CI: 1.2–9.7; $P = 0.034$).

Conclusions Overall, higher EQ-5D index scores were associated with increasing ability to discriminate between belimumab and placebo, and between responders and non-responders. EQ-5D index scores less stringent than FHS may be clinically relevant treatment targets in patients with SLE, introducing the concept of EQ-5D adequate health state.

PO.7.147 OBESITY AND TOBACCO SMOKING ARE INDEPENDENTLY ASSOCIATED WITH POOR PATIENT-REPORTED OUTCOMES IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS FROM A SWEDISH TERTIARY REFERRAL CENTRE

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Purpose To investigate associations of obesity and tobacco smoking with SLE patients’ health-related quality of life (HRQoL), pain, fatigue and functional disability.

Methods Patients from the Linköping University Hospital with an SLE diagnosis according to the 1982 ACR or the 2012 SLICC criteria (n=325) were included in the present cross-sectional analysis of data captured at visits between January 2008 and September 2021. Among consecutive visits, the first visit with complete demographic, clinical and patient-reported data was selected for the present analysis.

Body mass index categories were based on the WHO classification: underweight (BMI < 18.5 kg/m²), normal weight (18.5 ≤ BMI < 25 kg/m²), pre-obesity (25 ≤ BMI < 30 kg/m²) and obesity (BMI ≥ 30 kg/m²). Smoking status was self-reported and categorised as never, prior and ongoing smoker. HRQoL was self-reported using the 3-level EuroQoL 5-Dimension (EQ-5D-3L) index scores. Visual analogue scales (VAS; 0–100) were used to self-report fatigue, pain and well-being within the preceding 7 days. Functional disability was evaluated using the Swedish version of the Health Assessment Questionnaires Disability Index (HAQ-DI). Disease activity was evaluated using the clinical (c)SLEDAI-2K (serology excluded). Comparisons of continuous data between different BMI and smoking categories were performed using the Mann-Whitney U test and Kruskal-Wallis test. Multivariable linear regression analysis was employed to assess independence and priority of contributors to HRQoL and functional impairment.

Results In total, 111 patients were pre-obese and 55 were obese, whereas 103 were prior smokers and 39 were ongoing smokers. Compared with normal weight, obese individuals reported lower EQ-5D-3L index score [0.73 (0.36–0.80) versus 0.78 (0.68–0.85); $P = 0.014$], as well as higher VAS fatigue [50.0 (27.0–72.5) versus 32.0 (6.5–59.5); $P = 0.008$], VAS pain [40.0 (11.0–67.0) versus 20.5 (5.3–46.5); $P = 0.011$] and HAQ scores [0.63 (0.13–1.13) versus 0.13 (0.0–0.63); $P < 0.001$]. Similarly, ongoing smokers reported higher VAS fatigue [56.0 (28.0–78.0) versus 32.0 (8.0–58.0); $P = 0.001$], VAS pain [45.0 (18.0–62.0) versus 18.0 (5.0–39.8); $P = 0.001$] and HAQ scores