

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  $\chi^2$  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/m<sup>2</sup>), normal weight (18.5 ≤ BMI < 25 kg/m<sup>2</sup>), pre-obesity (25 ≤ BMI < 30 kg/m<sup>2</sup>) and obesity (BMI ≥ 30 kg/m<sup>2</sup>). 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

[0.63 (0.13–1.13) versus 0.13 (0.0–0.63);  $P=0.001$ ] compared with individuals who were never exposed to tobacco smoking. There were no differences across groups regarding cSLEDAI-2K scores.

In multivariable linear regression models, obesity and current tobacco smoking were independently associated with lower EQ-5D-3L index scores ( $\beta=-0.12$ ;  $P=0.021$  and  $\beta=-0.11$ ;  $P=0.029$ , respectively), and higher VAS fatigue ( $\beta=12.8$ ;  $P=0.007$  and  $\beta=17.5$ ;  $P<0.001$ ), VAS pain ( $\beta=12.1$ ;  $P=0.004$  and  $\beta=15.5$ ;  $P<0.001$ ), VAS well-being ( $\beta=9.6$ ;  $P=0.028$  and  $\beta=9.8$ ;  $P=0.035$ ) and HAQ scores ( $\beta=0.30$ ;  $P=0.001$  and  $\beta=0.27$ ;  $P=0.007$ ), but not with cSLEDAI-2K ( $\beta=-0.73$ ;  $P=0.189$  and  $\beta=0.34$ ;  $P=0.572$ ).

**Conclusions** In a Swedish SLE population, obesity and tobacco smoking were independently associated with worse outcomes - compared with normal weight patients and individuals who never smoked, respectively - regarding HRQoL, fatigue, pain and functional disability but not with clinical disease activity.

#### PO.7.148 PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND THEIR EXPERIENCE WITH VACCINATION AGAINST COVID-19: A DESCRIPTIVE AND EXPLANATORY STUDY

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**Purpose** A pandemic emergency could represent a source of concern for Systemic Lupus Erythematosus (SLE) patients and their rheumatologists; the unexpected arrival of the COVID-19 emergency could determine the loss of health status control, with anxiety and stress development. Here, we performed a descriptive and explanatory study to describe the expectations and potential concerns related to COVID-19 vaccination in SLE subjects, by using a narrative approach and thus providing the patients' perspectives.

**Methods** SLE patients filled out an anonymous self-administered web-based questionnaire consisting of four questions regarding their experience with SLE over the past year and with vaccination, as reported below:

1. How have you experienced your condition as a Lupus patient in the last year?
2. How did you feel when you were called for the vaccination? What did it mean for you to be called for the vaccination?;
3. Describe the day of vaccination;
4. Do you think anything will change in your life now that you have been vaccinated? (If so, what?).

Furthermore, the Positive and Negative Affect Schedule (PANAS) and the Generic Risk Perception (GRP) were performed in all the patients.

**Results** Thirty-one patients were recruited [M/F 29/2; mean age 45.2 years (SD 8.9)]. The experience during the last year was described with a predominantly negative connotation, referring to the fear of infection, feelings of fear or anxiety, concern for own frailty or for contracting the virus. Concerning the question on vaccination, people basically answered in two ways, referring either to the fear or concern related to the risk to their health and possible side effects, or to the feeling of relief, opportunity/freedom/health protection and gratitude for having received the vaccine.

The application of PANAS questionnaire referring to the period before and after vaccination demonstrated a significant improvement in the majority of investigated positive items and the reduction of those negative. In detail, we observed the significant improvement in the following positive items: determined ( $p=0.03$ ), active ( $p=0.001$ ), enthusiastic ( $p=0.0005$ ), alert ( $p=0.01$ ), and strong ( $p=0.02$ ). Finally, a substantial change in the risk perception was observed: in particular the proportion of patients perceiving high risk of being infected with SARS-Cov2 decreased from 29.4% to 2.9%.

**Conclusion** The present descriptive and explanatory study provides information about the experience with vaccination against COVID-19 of SLE patients. Our results indicated that vaccination substantially changed the patients' perspective, with a positive direction towards the future.

#### PO.7.149 ASSOCIATIONS BETWEEN ABNORMAL BMI AND PATIENT-REPORTED HEALTH-RELATED QUALITY OF LIFE BEFORE AND AFTER THERAPEUTIC INTERVENTION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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**Purpose** To investigate whether abnormal body mass index (BMI) is associated with patient-reported health-related quality of life (HRQoL) impairments in terms of experienced diminutions in different dimensions of the 3-level Euro Quality of Life 5-dimensions (EQ-5D-3L) questionnaire, before and after a 52 week-long therapeutic intervention for moderately to severely active systemic lupus erythematosus (SLE) within the frame of phase III clinical trials.

**Methods** We conducted a post-hoc analysis of data from two phase III clinical trials which evaluated the efficacy of belimumab in SLE patients, i.e. BLISS-52 (NCT00424476; N=865) and BLISS-76 (NCT00410384; N=819). Abnormal BMI was defined as underweight (BMI <18.5 kg/m<sup>2</sup>), pre-obesity (25 ≤ BMI <30 kg/m<sup>2</sup>), and obesity (BMI ≥30 kg/m<sup>2</sup>). HRQoL impairments were defined as experiencing problems (some/moderate; severe/extreme) in each one of the five dimensions of the descriptive system of EQ-5D-3L. Pearson's chi-square tests were used to determine potential associations between abnormal BMI and experiencing problems in EQ-5D-3L at baseline and week 52, using normal weight as the comparator. Multivariable logistic regression models were used to adjust for potential confounders, i.e. age, ethnicity, SLE disease activity, and prednisone dose. Results at week 52 were also adjusted for baseline EQ-5D-3L responses and belimumab use to capture whether BMI independently affected the post-treatment EQ-5D outcome.

**Results** EQ-5D-3L data were available in a total of 1655 patients. Proportions of patients reporting problems at baseline (table 1) were greater among pre-obese versus normal-weighted patients, with the highest difference regarding mobility (47.1% versus 35.4%; odds ratio (OR): 1.63; 95%