Validation of outcome measures and biomarkers

### POS1448

**DKCKOP HOMOLOG 3 (DKK3) AS A PROGNOSTIC MARKER IN LUPUS NEPHRITIS: A PROSPECTIVE MONOCENTRIC EXPERIENCE**

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**Background:** Lupus nephritis (LN) is a major cause of mortality/morbidity in patients affected by systemic lupus erythematosus (SLE). Reliable prognostic markers, especially related to the degree of interstitial fibrosis, are still lacking and renal biopsy still represents the gold standard. Recent data suggests a role of Dickkopf homolog 3 (Dkk3) as a marker of tissue fibrosis in different diseases, however its role in autoimmune diseases still needs to be elucidated.

**Objectives:** To investigate DKK3 serum levels in SLE patients with and without LN, assessing its changes in relation to kidney function, flares and interstitial renal fibrosis, as well as its association with the IFN signature.

**Methods:** 132 SLE patients, 57 of whom diagnosed with LN, were included in this study, as well as 50 healthy donors. DKK3 and Myxovirus resistance protein 1 (Mxa) were measured in serum samples, using enzyme-linked immunosorbent assays. Biopsies were evaluated for glomerular involvement, interstitial renal fibrosis and tubular atrophy according to 2003 International Society of Nephrology/Renal Pathology Society (ISN/RPS) classification and the revised 2018 version. Patients were followed-up for at least 36 months.

**Results:** DKK3 serum levels were significantly higher in patients with biopsy-proven LN when compared to those without (median[min:max]: 215ng/ml [81-341] vs 21.1ng/ml [1-69], p<0.01). When focusing on patients with LN, DKK3 levels resulted to be associated with the presence of chronic kidney disease (OR: 4.31/[C.1.2.0.16.6.1] per DKK3 doubling, p<0.01), higher chronicity index at biopsy (OR: 1.75/[C.I. 1.59-2.13] per DKK3 doubling, p<0.01) and flares rate (OR: 1.45/[C.I. 1.15-1.71] per DKK3 doubling, p=0.044). DKK3 levels correlated with the IFN signature as expressed by Mxa (correlation coefficient: 0.71, p<0.037).

**Conclusion:** While kidney biopsy remains the gold standard for diagnostic and prognostic assessment in LN, DKK3 could represent an additional useful prognostic tool to monitor SLE patients and eventually to guide therapeutic choices.

**Disclosure of Interests:** None declared

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### POS1449

**VALIDATION OF THE GERMAN LUPUSPRO QUESTIONNAIRE TO MEASURE LUPUS-SPECIFIC HEALTH-RELATED QUALITY OF LIFE IN LUPUS ERYTHEMATOSUS PATIENTS**

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**Background:** To date, there is no validated lupus-specific questionnaire for health-related quality of life (HRQoL) in German language. Regular assessment of health-related quality of life is recommended for monitoring and outcome in current management guidelines [1][2]. Given that about 20% of the EU population are native German speakers, it is therefore essential to validate a Lupus-specific questionnaire in German.

**Objectives:** The aim of this study is to present the validity (content, construct, and criterion) and reliability (internal consistency and test-retest) of the German translation of the LupusPro questionnaire, which captures both generic and lupus-specific HRQoL domains.

**Methods:** The German LupusPRO was professionally translated and then administered to consecutive patients with systemic lupus erythematos treated at our tertiary centre. At each visit, clinical and laboratory data were collected, including disease activity and damage (SLEDAI-2K resp. SLICC/SDI). Additional questionnaires were used for validity testing, including questionnaires for HRQoL (SF-36v2), fatigue (FACIT), depression (CES-D), sleep (PSQI) and health impairments (IMET).

We calculated Cronbach’s alpha to test reliability. An alpha >0.70 is considered acceptable. Test-retest reliability was tested by evaluating the consistency between the LupusPro at two time points (T0 and T1 after 2-3 days). Criterion and construct validity was assessed by comparing the results of the LupusPRO with the generic HRQoL questionnaire, established clinical endpoints (disease activity, disease damage), and the domains of the additional questionnaires. The confirmatory factor analysis was performed with the Lavaan package (Ver. 0.6-9) in R using the relative fit indices, the Tucker-Lewis index (TLI) and the comparative fit index (CFI).

**Results:** 148 patients with confirmed SLE took part in the study of which 111 participated in the test-retest analysis. About 84% were female with a mean age of 45.5 (SD 12.0) and mean disease duration of 17.7 (SD 9.7) yrs. The mean SLEDAI-2K was 3.1 (SD 3.2) and SLICC/SDI 1.4 (SD 2.1).

The LupusPro domain's internal consistency by Cronbach’s alpha exceeded >0.7 except for the domains lupus symptoms (α=0.64), lupus medication (α=0.59), procreative ability (α=0.58), and coping strategies (α=0.43). The overall test-retest correlation was excellent (ICC=0.94). The correlation of the corresponding LupusPRO and SF-36v2 domains were moderate to strong (ρ=0.34–0.78), whereas correlation with disease activity and damage (SLEDAI-2K and SLICC/SDI) was weak (ρ=0.23 resp. -0.08). Correlation of the selected LupusPRO domains with the above mentioned other dedicated outcome measure instrument emphasized construct and criterion validity.

The results of the confirmatory factor analysis showed good construct validity of the LupusPRO. The observed model fit for the hypothesized item-scale relationships was very good (CFI = 0.96, TLI = 0.98). Items generally had loadings of >0.6 with their respective factor. Exceptions were especially the domain coping strategies where all items loaded <0.4.

**Conclusion:** The GermanLupusPRO is a valid instrument for measuring health-related quality of life. It shows comparable psychometric properties as the original versions. Minor difference in individual domains may be explained by sociocultural factors.

**REFERENCES:**

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