

FRI0355

### PREDICTIVE ABILITY OF AVAILABLE 10 YEARS CARDIO-VASCULAR RISK ALGORITHMS IN SYSTEMIC LUPUS ERYTHEMATOSUS: A RETROSPECTIVE STUDY ON 2 ITALIAN LUPUS COHORT

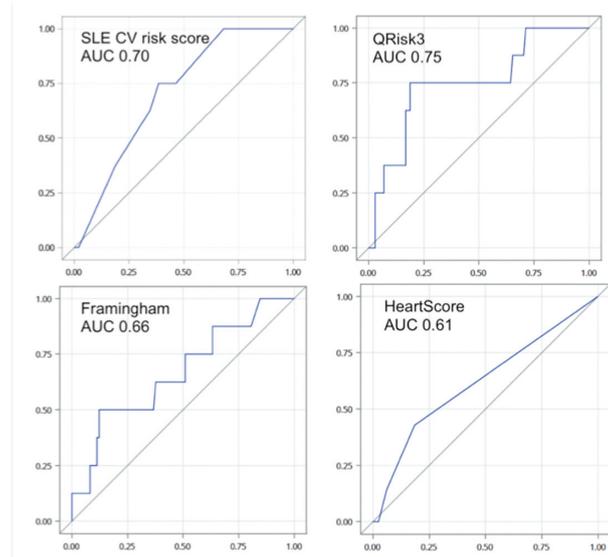
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**Background:** Patients with Systemic Lupus Erythematosus (SLE) present an increased incidence of Cardio-Vascular Events (CVE) compared to general population, and the difference with healthy subjects is particularly evident in young SLE women.

**Objectives:** The aim of this study is to assess the predictive ability of established 10 years CV risk models in SLE

**Methods:** A retrospective analysis of two Italian SLE prospective cohorts was performed. SLE patients without previous CVE, with age  $\geq 25$  years, a minimum continuative follow-up of 10 years and sufficient data to calculate the 10 years risk scores were enrolled. The 10 years CVE risk scores were calculated at the first observation and all CVE were prospectively recorded in the following 10 years. We calculated the following scores: the QRisk3, the Framingham CV disease 10 years score, the HeartScore (Europe Low Risk) and the SLE CV Risk Score proposed by Petri et al. Discriminatory ability for CV risk prediction was estimated by the area under the receiver operating characteristic curve. Hosmer-Lemeshov (HL) tests was used to evaluate calibration comparing the observed versus expected number of events

**Results:** Analysis was performed on 131 SLE patients (mean baseline age of 37  $\pm 11$  years). We observed 10 CVE during the 10 years follow-up from baseline (3 acute coronary syndrome, 4 stroke, 1 transitory ischaemic attack and 2 peripheral artery disease). The AUC values were 0.75 (95% CI 0.55–0.94) for QRisk3, 0.66 (0.45–0.88) for Framingham score, 0.62 (0.41–0.82) for the HeartScore and 0.7 (95% CI 0.55–0.85) for the SLE CV risk score. The p values of HL test were 0.8 for QRisk3 and SLE CV score and 0.4 for Framingham score and HeartScore, suggesting a good model fit for all the CV risk scores. Considering scores with better discriminative ability and calibration, 20% of CVE were observed with QRisk3 score lower than 3.6% and with SLE CV risk score between 6% and 8%. Discriminative ability and calibration were not improved by multiplying by 2 the Framingham score and the HeartScore.



**Conclusions:** The available CV risk scores demonstrate a moderate predictive ability of 10 years CVE in SLE. We observed a better model fit for QRisk3 and SLE CV risk score. Nevertheless, a considerable proportion of patients, with very low predicted CV risk, developed CVE during follow-up.

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FRI0356

### ORGAN DAMAGE IN SYSTEMIC LUPUS ERYTHEMATOSUS IS CONSISTENTLY ASSOCIATED WITH INCREASED MORTALITY: A META-ANALYSIS

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**Background:** More than half of all patients with systemic lupus erythematosus (SLE) develop organ damage over time, including damage to the kidney, skin, cardiovascular, musculoskeletal and central nervous systems. Several mechanisms have been associated with organ damage, including long-term steroid use. SLE organ damage, like comorbid disease, may contribute to increased mortality.

**Objectives:** We conducted a systematic literature review and meta-analysis of the association between organ damage in SLE and mortality.

**Methods:** A literature search (January 2000–February 2017) of PubMed, EMBASE, Cochrane Library, and Latin American and Caribbean Health Sciences Literature from four continents evaluating organ damage by the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SDI) and mortality was conducted. Exclusion criteria included non-English language articles and study designs that did not report original, population-level measures of association. We used a random-effects meta-analysis to evaluate studies that modelled SDI as a continuous predictor of mortality and reported hazard ratios (HR) associated with a 1-unit SDI increase.

**Results:** The search yielded 10 420 articles, of which, 21 prospective cohort studies were selected. Ten studies evaluating SDI as a continuous variable and reporting HR as measure of association were pooled and meta-analysed. The pooled HR of mortality for a 1-unit increase in SDI was 1.34 (95% confidence interval [CI]: 1.21–1.44;  $p < 0.001$ ). A study of 213 patients followed for 13 years in China yielded the greatest risk of mortality for a 1-unit SDI increase (HR 3.65, [95% CI: 1.52–8.76]). When excluded from the meta-analysis, the pooled HR of mortality for a 1-unit increase in SDI was 1.32 (95% CI: 1.25–1.42;  $p < 0.001$ ). Four studies that evaluated SDI as binary variable reported HR for various SDI reference groups: SDI=0: HR 5.10 (95% CI: 1.99–13.03); SDI<1: HR 3.8 (95% CI: 1.30–16.40); SDI<3: HR 4.74 (95% CI: 1.55–14.51); and SDI<5: HR 55.12 (95% CI: 19.15–158.63). Two studies reported odds ratios (OR) as the measure of association; for a 1-unit SDI increase, the OR was 19.7 (95% CI: 5.30–72.50), and for SDI=0 as reference group, the OR was 12 (95% CI: 1.60–92.00).

**Conclusions:** Organ damage in SLE is consistently associated with increased mortality across studies from various countries, regardless of how it is modelled. Novel therapies that are potentially disease modifying and steroid sparing could reduce organ damage, improve overall outcomes, and decrease mortality in patients with SLE.

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FRI0357

### VALIDATION OF A DISEASE-SPECIFIC HEALTH – RELATED QUALITY OF LIFE MEASURE FOR RUSSIAN ADULT PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: LUPUSQOL-RUSSIAN

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**Background:** Improvements in the survival of patients with systemic lupus erythematosus (SLE) in Russia have to some extent paralleled that seen worldwide over the last 20 years, but have at times come at the cost of increased morbidity and reduction in health-related quality of Life (HRQoL). Recently, a specific questionnaire to evaluate HRQoL in adult SLE patients (LupusQoL) has been developed and validated in United Kingdom and in several European countries.

**Objectives:** To assess the validity of a LupusQoL-Russian in adult SLE patients **Methods:** The LupusQoL-Russian was administered to a cohort of Russian patients affected with SLE. To perform a control, QoL was evaluated also with SF-36. The Russian version of LupusQoL questionnaire was developed by the University of Central Lancashire and the East Lancashire Hospitals NHS Trust ([www.lupusqol.com](http://www.lupusqol.com)), after a linguistic validation process. Disease activity was evaluated by the SLEDAI-2K, and chronic damage by the Systemic Lupus International

Collaborating Clinics Damage Index score (SDI). Internal consistency and test-retest reliability, convergent and discriminant validity were examined.

**Results:** 328 Russian SLE patients were enrolled in the study (M/F 30/298, mean age 34.4±11.5 years, mean disease duration 106.3±97.9 months; mean SLEDAI 2K 9.6±8.0; mean SDI 0.2±0.6). The LupusQoL-Russian demonstrated substantial evidence of construct validity. Each domain showed good correlation when compared with equivalent domains of the SF-36 ( $p<0.001$  for all comparisons). LupusQoL-Russian discriminated between patients with different degrees of disease activity according to SLEDAI 2K: Lupus-QoL domains showed a trend to lower values in patients with higher disease activity (SLEDAI-2K $\geq$ 4) compared with those with lower disease activity (SLEDAI 2K<4), reaching statistically significant difference when considering the domains "Pain", "Planning", "Intimate relationship" and "Body image" ( $p=0.007$ ,  $p=0.0004$ ,  $p=0.0003$  and  $p=0.007$ , respectively).

LupusQoL-Russian was significantly lower for "Physical health", "Planning" and "Fatigue" in patients with SDI $\geq$ 1 ( $p=0.002$ ,  $p=0.03$ , and  $p=0.03$ ) respectively (table 1). Test-retest reliability was good to excellent between baseline and day 3 (intra-class correlation coefficient (ICC) 0.7–0.9)

Abstract FRI0357 – Table 1. External divergent validity (N=328)

Domain	SLEDAI-2K $\leq$ 4 (n=113)	SLEDAI-2K $\geq$ 4 (n=215)	p-value	SDI $\leq$ 1 (n=142)	SDI $\geq$ 1 (n=186)	p-value
Physical health, mean $\pm$ SD	70,1 $\pm$ 22,0	64,9 $\pm$ 23,6	0,07	71,01 $\pm$ 22,5	63,3 $\pm$ 23,1	0002
Pain, mean $\pm$ SD	74,7 $\pm$ 23,6	67,5 $\pm$ 24,8	0007	72,3 $\pm$ 24,2	68,2 $\pm$ 24,8	0,1
Planning, mean $\pm$ SD	71,1 $\pm$ 27,9	60,1 $\pm$ 28,0	0,0004	67,7 $\pm$ 27,3	60,9 $\pm$ 29,0	0,03
Intimate relationship, mean $\pm$ SD	78,3 $\pm$ 28,7	69,9 $\pm$ 31,7	0003	76,06 $\pm$ 28,4	70,6 $\pm$ 32,5	0,22
Burden to others, mean $\pm$ SD	61,2 $\pm$ 26,8	54,2 $\pm$ 28,0	0,03	55,7 $\pm$ 28,4	57,4 $\pm$ 27,3	0,68
Emotional health, mean $\pm$ SD	67,3 $\pm$ 24,8	63,2 $\pm$ 24,6	0,13	66,2 $\pm$ 25,2	63,3 $\pm$ 24,3	0,24
Body image, mean $\pm$ SD	71,1 $\pm$ 24,7	62,02 $\pm$ 28,5	0007	66,6 $\pm$ 27,9	64,03 $\pm$ 27,3	0,33
Fatigue, mean $\pm$ SD	65,0 $\pm$ 24,5	65,09 $\pm$ 24,8	0,22	65,7 $\pm$ 25,3	60,35 $\pm$ 24,0	0,03

**Conclusions:** The LupusQoL-Russian is valid to assess quality of life in SLE patients

**Disclosure of Interest:** None declared

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#### FRI0358 FACTORS ASSOCIATED WITH PULMONARY MANIFESTATIONS IN SJÖGREN SYNDROME

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**Background:** Primary Sjögren's Syndrome (pSS) is a systemic autoimmune disorder characterised by lymphocytic infiltration of the exocrine glands resulting in dry syndrome. Approximately one-third of patients have extraglandular systemic findings, such as respiratory symptoms (43%–75%), that are also considered to be a cause of morbidity and conditioning quality of life. The aim of the study is to estimate the prevalence of pulmonary manifestations in pSS, and to identify factors associated with its development.

**Methods:** SJOGREN-SER (Spanish Rheumatology Society Registry of pSS) is a multicenter cross-sectional study of pSS patients under active follow-up at 33 rheumatology departments through Spain. Patients fulfilled the European-American consensus criteria of 2002. Airway disease (dry cough, xerotrachea, bronchial, hyperresponsiveness and airway obstruction) and pulmonary involvement (ILD, pulmonary amyloidosis, pulmonary arterial hypertension, vasculitis and pleural involvement) were considered according to the definition contained in EULAR Sjögren's Disease Activity Index (ESSDAI), as well as Sjögren's

Syndrome Disease Damage Index. Bivariate logistic regression models and multivariate analysis were used to establish the independent effect of patient characteristics associated with pulmonary manifestations. The results were considered significant when the P value was less than 0.05.

**Results:** The SJOGREN-SER registry included 437 patients (95% women, median age at inclusion 59 years [50–68 years] and mean of ESSDAI 2 (IQR 0–4)). One hundred and seventeen patients (26.8%) had pulmonary manifestations (19.2% airway disease and 9.8% pulmonary involvement). Ten patients presented both. Sociodemographic characteristics were: mean age 59.5 years (SD: 11.46), 94.9% women and 19.6% smokers or former smokers. Patients with pulmonary manifestations had higher ESSDAI score (6 (SD 6) vs 4 (SD 5)), prolonged disease duration (10.05 years (SD: 7.15) vs 7.7 (SD 6.3)) and were ANA positive more frequently (94.9% vs 62.2%). Airway involvement preceded or occurred at the time of diagnosis in 46.4% of patients. Pulmonary involvement occurred 5 years after the diagnosis of pSS in 37.2% of them. [RS1] Twenty-nine patients (6.6%) were diagnosed with ILD. The most frequent radiological patterns were: Non-Specific Interstitial Pneumonia n=14, Usual Interstitial Pneumonia n=5, Lymphocytic Interstitial Pneumonia n=5 and Cryptogenic Organised Pneumonia n=2. Stepwise multivariate analysis was performed including the following variables: sex, age, laboratory findings, disease duration, smoking and ESSDAI. Disease duration (OR of 1.05 (95% CI, 1.006–1.083)), ESSDAI score (OR of 1.044 (95% CI, 1.006–1.083)) and positivity for ANA (OR of 3.725 (95% CI, 1.141–12.159)) were found to be associated factors with pulmonary involvement in pSS.

**Conclusions:** Prevalence of pulmonary manifestations in this cohort of pSS patients is substantial due to both airway disease and pulmonary involvement. Disease duration, activity of pSS according to ESSDAI score and ANA positivity were factors associated with the development of pulmonary manifestation.

**Disclosure of Interest:** None declared

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#### FRI0359 ROUTINE CLINICAL PATHOLOGY MEASUREMENTS ARE ASSOCIATED WITH RISK OF ORGAN DAMAGE ACCRUAL IN SLE

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**Background:** Prevention of permanent organ damage, a major predictor of morbidity and mortality, is a key goal in the treatment of SLE. Physician-measured disease activity scores, which entail some subjectivity, are associated with damage accrual risk, but there have been few studies of objective measures as indicators of organ damage risk. Routine pathology laboratory measurements provide objective biological data, but their association with damage accrual in SLE has not been studied.

**Objectives:** To evaluate the association of objective pathology laboratory measurements with risk of organ damage accrual in SLE.

**Methods:** A dataset of SLE patients between 2007–2017 from the Australian Lupus Registry and Biobank was studied. Variables recorded prospectively included disease activity (SLEDAI-2k), drug treatment and 16 routine pathology measurements at each visit, and organ damage (SLICC-SDI) annually. Longitudinal patient data was split into annual periods, and each visit classified as being either in a "transition" or "non-transition" period based on whether SDI increased during that period. Time adjusted means (TAMs) of the variables were calculated for each period, and multivariable logistic regression analysis of the association with being in a "transition" period (adjusting for age, gender, race, previous organ damage and prednisolone dose) was performed, with Holm-Bonferroni correction. An "odds ratio plot" was generated to depict the effect on risk of organ damage accrual at each threshold of the continuous variables.

**Results:** 893 periods, comprising 5082 visits from 245 patients (85.6% female, 50.2% Caucasian), were analysed. Five out of 16 laboratory variables: estimated glomerular filtration rate (eGFR), creatinine ( $p<0.01$ ), urine protein:creatinine ratio ( $p<0.01$ ), ESR ( $p<0.001$ ), and haemoglobin ( $p<0.001$ ) were significantly associated with risk of damage increase. Moreover, the odds of damage increase were approximately proportional to the deviation of each of these variables from its respective normal range. SLEDAI-2k was also significantly associated with damage increase ( $p<0.001$ ), but the association of SLEDAI-2k with damage did not exhibit this proportionality.