Objectives: Establishing the correlation of selected clinical, immunological and laboratory parameters with cellular composition of minor salivary glands infiltrations.

Methods: 41 pSS patients, 34 female (83%), 7 men (17%), average age 52 y.o, SD=15, with history of EBV infection, divided into two age groups (45<:≥45). The diagnostics: white blood count (WBC), rheumatoid factor (RF), erythrocyte sedimentation rate (ESR), CRP, serum concentration of γ -globulins, antinuclear antibodies ANA(IF); anti-SS-A and anti-SS-B antibodies (semi-quantitative immunoblotting evaluation), standard ELISA assays of serum cytokines levels (BAFF, APRIL, FLT-3L, LT- α , IL-21), minor salivary gland biopsy with the histopathological evaluation (focus score-FS), immunochemistry assessment of the CD3 +, CD4 +, CD19 +, CD21 +, CD35 +cells presence, ocular tests: Schirmer's test and ocular staining score (OSS); ELISA assay of antibodies against EBV specific proteins (viral capsid antigen, early antigen and Epstein-Barr nuclear antigen), ESSDAI evaluation. The Bioethics Committee approval was obtained. Statistic: U Mann-Whitney test and Spearman correlation coefficient with statistical significance set at $p<0.05$.

Results: In infiltrates CD3 +, CD4 +and CD19+cells dominated, WBC negatively correlated with CD 35+cells ($\rho=-0.323$). CD3 +and CD4+absolute cell count correlated positively with anti-SS-A antibodies, but not with ANAs and anti-SS-B antibodies. The CD19 +, CD3 +and CD4+absolute cell count correlated positively with the serum LT- α concentration (respectively $\rho=0.349$, 0.488, 0.483) and moderately negatively with Schirmer test, but not with OSS. There were no differences in FS grade between age groups. In the younger group all cell types were found, including CD21 + ($p=0.042$) and CD35 + ($p=0.036$); the older subgroup lacked dendritic cell markers. The ESSDAI positively correlated with CD3 +, CD4 +, CD19 +and CD21+cells (respectively $\rho=0.320$, 0.329, 0.28, 0.241).

Conclusions: a) Leukopenia may be associated with the dendritic cells (CD35 +) presence in the disease subsequent stage. b) The positive correlation of mononuclear cells with LT- α confirms the LT- α effect on the immune response in peripheral lymphatic organs and on T and B lymphocytes. c) The presence of CD21 +and CD 35+cells observed in younger group, may indicate an active and early phase of inflammation and the activity of both T and B-lymphocytes and dendritic cells. d) The positive correlation ESSDAI with all studied cell types confirms the observation, that organ-related complications correlate with inflammatory activity expressed in mononuclear cell infiltrates. e) The effect of EBV reactivation/previous infection on FS, CD3 +, CD4 +, CD19 +, CD21 +, CD35 +was not demonstrated.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.6061

SAT0446

SERUM CONCENTRATIONS OF 25-HYDROXYVITAMIN D AND METABOLIC SYNDROME AND ITS COMPONENTS IN NONDIABETIC SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS

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Background: Increasing evidence has suggested a protective role of vitamin D in the metabolic syndrome (MetS). However, studies addressing this issue are limited in systemic lupus erythematosus (SLE).

Objectives: We examined the relationship between serum 25-hydroxyvitamin D (25(OH)D) status and MetS in nondiabetic SLE patients.

Methods: Cross-sectional analyses of the relationship between concentrations of 25(OH)D, MetS, and its components were made in 160 nondiabetic SLE women. MetS was defined according to the NCEP-ATP III criteria. Serum 25(OH)D was measured by chemiluminescent immunoassay. Serum 25(OH)D levels were categorised into quartiles (<16.6, 16.6–21.1, 21.2–26.3, ≥26.4 ng/ml).

Results: A total of 79 (49.3%) of SLE women had MetS. Without adjusting for BMI or smoking, the odds of having MetS decreased according to increasing quartiles of vitamin D levels (P for trend=0.036). The odds ratio (OR) of having MetS was 0.39 (95% confidence interval: 0.16–0.97, $p=0.043$) for the highest vs. the lowest quartile of vitamin D levels when adjusted by age. The crude OR of having elevated hypertriglyceridemia decreased according to increasing quartiles of

vitamin D levels (P for trend=0.036). However, further adjustments for BMI and smoking removed the inverse association between vitamin D status and MetS and its individual components (Table).

Table. Multivariable-adjusted OR (95%) for metabolic syndrome according to categories of serum 25(OH)D

	Quartiles of 25(OH) ng/ml				P value
	Q1	Q2	Q3	Q4	
Number of subjects	40	41	38	41	
Median 25 (OH) ng/ml	14.9	19.2	23.3	29.2	
Metabolic syndrome	24 (60)	21 (51.2)	18 (47.3)	16 (39.0)	
Crude OR (95% CI)	1.0	0.57 (0.23–1.38)	0.54 (0.21–1.33)	0.38 (0.15–0.94)	0.036
Adjusted OR (95% CI)*	1.0	0.56 (0.23–1.38)	0.53 (0.21–1.38)	0.39 (0.16–0.97)	0.043
Adjusted OR (95% CI)†	1.0	0.59 (0.22–1.60)	0.69 (0.25–1.91)	0.49 (0.17–1.34)	0.162
Adjusted OR (95% CI) ‡	1.0	0.59 (0.22–1.60)	0.69 (0.25–1.91)	0.49 (0.17–1.34)	0.163
Triglycerides≥150 mg/dl (n,%)	25 (62.5)	25 (60.9)	18 (47.3)	16 (39.0)	
Crude OR (95% CI)	1.0	0.93 (0.38–2.69)	0.48 (0.19–1.20)	0.38 (0.15–0.94)	0.036
Adjusted OR (95% CI)*	1.0	0.92 (0.37–2.29)	0.46 (0.18–1.16)	0.40 (0.16–1.00)	0.050
Adjusted OR (95% CI) †	1.0	1.06 (0.40–2.82)	0.57 (0.21–1.54)	0.49 (0.18–1.32)	0.161
Adjusted OR (95% CI) ‡	1.0	1.07 (0.40–2.85)	0.58 (0.21–1.58)	0.49 (0.18–1.32)	0.492

* Adjusted by age, † Adjusted by age and BMI, ‡ Adjusted by age, BMI and smoking

Conclusions: In nondiabetic SLE women with mild activity, the potential inverse relationship between vitamin D status and MetS may be attributable to the joint effects of individual obesity and smoking. Prospective studies are necessary to better determine the role of 25(OH)D in the incidence of MetS in SLE patients.

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Acknowledgements: We thank David Buss for his valuable advice during this project.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.1282

SAT0447

VALIDATION OF THE 2017 ACR/EULAR CLASSIFICATION CRITERIA OF SYSTEMIC LUPUS ERYTHEMATOSUS

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Background: Two major classification criteria have been used in the clinical trials of systemic lupus erythematosus (SLE). One is American College of Rheumatology (ACR) criteria first developed in 1982 and revised in 1997 (1997 criteria)¹, and the other is Systemic Lupus International Collaborating Clinics (SLICC) criteria developed in 2012 (2012 criteria)². In the ACR annual meeting on November 2017, the new classification criteria of SLE (2017 criteria) were proposed, aiming for better specificity and sensitivity. They were made based on the agreement of expert panel³, and have not been validated in the real-world practice.

Objectives: The objective of the study is to evaluate the sensitivity of 2017 criteria when applied to real SLE cases.

Methods: We retrospectively reviewed the electronic medical record of the consecutive 100 patients who visited St. Luke's International Hospital, a tertiary care centre in Tokyo, Japan, searching back from November 13, 2017. Patients were included if they are clinically diagnosed as having SLE with board-certified doctors, and excluded if they complicated with other autoimmune disease or if they

are under 18-year-old. Each patient was evaluated if he or she satisfied the 1997, 2012, or 2017 criteria.

Results: Among the 100 cases, 9 were male and 91 were female, with wide range of age;^{18–88} mean 44.5-year-old). Asian accounted for 98%, with Hispanic 1%, and Caucasian 1%. The sensitivity of 1997, 2012, 2017 criteria are, 97%, 99%, 87% respectively. The positivity rate of each domain in the 2017 criteria was shown in table 1. The total score that the patients got in the 2017 criteria ranged from 12 to 44 (mean: 27.3). All the cases who were classified as non-SLE in the 2017 criteria had anti-nuclear antibody (ANA) <80; all of them scored more than 10 points.

Abstract SAT0447 – Table 1. Validation of the 2017 SLE classification criteria using clinically diagnosed 100 SLE cases.

Item (point)	Positivity (%)	
Entry Criteria		
ANA ≥80 (required: no point)	87.0	
Constitutional Domain		
Unexplained fever >38.3° C (2)	47.0	
Muco-Cutaneous Domain		
Non-scarring alopecia (2)	48.0	
Oral ulcers (2)	27.0	
SCLE or DLE (4)	42.0	
ACLE (6)	70.0	
Arthritis Domain		
Synovitis or tenderness in ≥2 joints or tenderness and ≥30 minutes of morning stiffness (6)	79.0	
Neurologic Domain		
Delirium (2)	0	
Psychosis (3)	4.0	
Seizure (5)	7.0	
Serositis Domain		
Pleural or pericardial effusion (5)	29.0	
Acute pericarditis (6)	0	
Hematological Domain		
Leukopenia (3)	77.0	
Thrombocytopenia (4)	26.0	
Autoimmune hemolysis (4)	14.0	
Renal Domain		
Proteinuria >0.5g / 24 hours (4)	64.0	
Renal biopsy with Class II or V lupus nephritis (8)	12.0	
Renal biopsy with Class III or IV lupus nephritis (10)	17.0	
Antiphospholipid Domain		
aCL (IgG) >40 GPL units, anti-β2-GPI >40 units, or lupus anticoagulant positive (2) *	17.0	
Complement Proteins Domain		
Low C3 or Low C4 (3)	40.0	
Low C3 and Low C4 (4)	40.0	
Highly Specific Antibodies Domain		
Anti-dsDNA antibody (6)	74.0	
Anti-Smith antibody (6) *	28.0	
Rate of the patients classified as SLE (ANA≥80 and got ≥10 points overall)		
	87.0	

*N/A in 3, *N/A in 1.

Abbreviations: ACLE, acute cutaneous lupus erythematosus; ANA, anti-nuclear antibody; anti-CL, anti-cardiolipin antibody; DLE, discoid lupus erythematosus; N/A, not available; SCLE, Sub-acute cutaneous lupus erythematosus; SLE, systemic lupus erythematosus.

*N/A in 3, *N/A in 1.

Abbreviations: ACLE, acute cutaneous lupus erythematosus; ANA, anti-nuclear antibody; anti-CL, anti-cardiolipin antibody; DLE, discoid lupus erythematosus; N/A, not available; SCLE, Sub-acute cutaneous lupus erythematosus; SLE, systemic lupus erythematosus.

Conclusions: 2017 criteria for SLE accomplished modestly high sensitivity in the real-world practice, but not as high as 1997 and 2012 criteria. They possibly miss-classify the real SLE cases as non-SLE, especially if patients have low titer (<80) of ANA.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.5721

SAT0448

REPORT OF 86 CASES OF CONGENITAL HEART BLOCK: DATA FROM THE ITALIAN REGISTRY (LU.NE REGISTRY)

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Background: Cardiac neonatal lupus is due to placental transfer of maternal anti-Ro/SSA and anti-La/SSB autoantibodies to the fetus and mainly includes congenital heart block (CHB) and dilated cardiomyopathy. The prevalence of CHB has been estimated as 1%–2% in anti-Ro/SSA women while the recurrence rate is 16%–19%.¹ This condition is associated with a high rate of fetal/neonatal mortality and in the majority of cases requires pacemaker pacing.^{2–6}

Objectives: The rarity of this condition requires the establishment of collaborative registries in order to improve our knowledge. Here we report the data of the ongoing Italian Registry of the autoimmune congenital heart block (Lu.Ne), which was created in 2016

Methods: The aim was to collect retrospective and prospective pregnancies complicated with CHB in patients with antibodies. Data regarding demography, treatment, maternal and neonatal outcome and follow-up were collected through an online electronic datasheet prepared in a Research Electronic Data Capture platform.

Maternal demography	n=82
Maternal Diagnosis at CHB detection	
Undifferentiated Connective Tissue Disease	26 (31.7)
Sjogren Syndrome	16 (19.5)
Systemic Lupus Erythematosus	4 (4.8)
Carriers Ro/SSA	18 (21.9)
Carriers Ro/SSA+La/SSB	15 (18.4)
Other	3 (3.7)
Autoantibodies profile	
Anti-Ro/SSA	78 (95)
Anti-La/SSB	47 (53)
Pregnancy Outcome	
Live birth	71 (82.5)
Intrauterine fetal death/termination of pregnancy	15 (17.5)
CHB detection	
In utero	81 (94.2)
Neonatal	5 (5.8)
Mean week of detection of CHB (±SD)	22.4±8.5
CHB degree	
II degree	17 (19.7)
III degree	59 (68.7)
II-III intermittent	4 (4.6)
Other/unknown	5 (5.8)
Therapy after in utero CHB detection	
Fluorinated steroids	45 (55)
Intravenous Immunoglobulins	19 (23)
Plasma-exchange	18 (22)
Postnatal outcome of liveborns with CHB	
At birth/Neonatal Pacemaker implantation	27 (38)
Neonatal death	3 (4.4)
Later Pacemaker implantation	23 (32.4)
Infant/childhood death	2 (3.2)

Results: Eighty-six cases of CHB were collected in 82 women with 85 pregnancies that occurred between 1969–2016. CHB was mostly detected in utero (81