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EULAR-ACR 2019 CLASSIFICATION CRITERIA FOR SLE: CAN WE CLASSIFY USING LABORATORY TESTS ALONE?

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Background: The EULAR-ACR 2019 (EULAR19) classification criteria for systemic lupus erythematosus (SLE) were developed to improve the sensitivity and specificity of previous criteria. Notably, both the EULAR19 and existing SLICC-SLE 2012 (SLICC12) criteria can classify patients as having SLE by the presence of immunology and haematological abnormalities in the absence of any signs or symptoms.

Objectives: To validate the EULAR19 criteria, with comparison to existing criteria, in a large cohort of patients with an established systemic autoimmune rheumatic disease (SARD).

Methods: We recruited 227 adult patients who were ANA positive with ≥1 clinical feature suggestive of a SARD, from three hospitals in the North West of England. Clinician diagnosis was used as gold standard; we then applied the EULAR19, SLICC12 and the ACR-SLE 1997 (ACR97) criteria.

Results: Of the 227 patients recruited, by clinician diagnosis, 89 patients (36%) had SLE, 43 (17%) primary Sjögren's (pSS), 62 (25%) undifferentiated CTD (UCTD), 25 (10%) systemic sclerosis (SSc) and 8 (3%) an inflammatory myositis. The characteristics of these patients and the breakdown of the EULAR19 criteria are outlined in figure 1.

	SLE n=89	pSS n=43	UCTD n=62	SSc n=25	Myositis n=8
Female N (%)	82 (92)	42 (98)	53 (85)	24 (96)	8 (100)
Age, mean (SD) /years	44 (13)	52 (12)	47 (13)	60 (9)	53 (7)
Disease duration, mean (SD) /years	12 (10)	6 (5)	5 (7)	9 (11)	3 (3)
SLE classification criteria					
EULAR SLE 2019, N (%)	75 (84)	10 (23)	20 (32)	1 (4)	0
ACR SLE 1997, N (%)	77 (87)	9 (21)	21 (34)	2 (8)	1 (13)
SLICC SLE 2012, N (%)	84 (94)	15 (35)	33 (53)	4 (16)	2 (25)
EULAR-ACR 2019 criteria					
Constitutional, N (%)	10 (11)	2 (5)	1 (2)	0	1 (13)
Neuropsychiatric, N (%)	3 (3)	0	1 (2)	1 (4)	0
Mucocutaneous, N (%)	71 (80)	13 (30)	27 (44)	2 (8)	2 (25)
Serosal, N (%)	13 (15)	1 (2)	2 (3)	0	0
Musculoskeletal, N (%)	52 (58)	14 (33)	22 (35)	3 (12)	3 (38)
Renal, N (%)	30 (34)	0	0	1 (4)	0
Haematological, N (%)	44 (49)	12 (28)	10 (16)	3 (12)	0
Antiphospholipid antibodies, N (%)	43 (48)	7 (16)	17 (27)	4 (16)	0
Low complement, N (%)	48 (54)	10 (23)	10 (16)	3 (12)	1 (13)
Anti-Sm, N (%)	19 (21)	2 (5)	4 (6)	1 (4)	0
Anti-dsDNA, N (%)	50 (56)	8 (19)	12 (19)	0	1 (13)

Figure 1. Baseline characteristics and classification criteria compared across five SARD diagnoses.

The sensitivity and specificity of the EULAR19 is similar to ACR97 (sensitivity 84% (95% CI 75-91%) vs. 87% (95% CI 78-93%) and specificity 78% (95% CI 70-84%) vs. 76% (95% CI 68-83%) respectively). The SLICC12 criteria by contrast are more sensitive (94% (95% CI 87-98%)) and less specific (61% (95% CI 52-69%)) in this cohort.

Figure 2 illustrates patients with a clinician diagnosis of SLE or UCTD who meet each of the classification criteria. Of the 89 patients with a clinician diagnosis of SLE, 39 (44%) patients would have sufficient points to meet EULAR19 criteria on blood test results alone in the absence of clinical symptoms. Four pSS patients and 4 UCTD patients would also meet EULAR19 criteria from positive blood results alone.

Figure 2. Venn diagrams illustrating patients with SLE and UCTD who meet the EULAR19, ACR97 and SLICC12 classification criteria. No criteria refers to the patients not meeting any of the three SLE classification criteria.

Conclusion: These results suggest that the EULAR19 criteria perform comparably to the ACR97 criteria when applied to an established cohort of SARDs.

Similar to SLICC12, it is possible to classify patients as having SLE using the EULAR19 criteria by haematological and other laboratory tests. To what extent haematological abnormalities can be potentially used as the sole 'clinical criteria' needs consideration.

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Disclosure of Interests: Sarah Dyball: None declared, John Reynolds: None declared, Eoghan McCarthy: None declared, Sahena Haque: None declared, Ariane Herrick: None declared, Hector Chinoy: None declared, Ellen Bruce: None declared, Ben Parker Grant/research support from: GSK and Sanofi Genzyme, Consultant of: GSK, AstraZeneca, UCV, Abbvie, Pfizer, BMS, Celltrion, Ian N. Bruce Grant/research support from: Genzyme Sanofi, GSK, and UCB, Consultant of: Eli Lilly, AstraZeneca, UCB, Ilto, and Merck Serono, Speakers bureau: UCB

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A DECISION MODEL OF LABIAL GLAND BIOPSY BASED ON B-MODE ULTRASONOGRAPHY WITH SHEAR-WAVE ELASTOGRAPHY IN PATIENTS WITH SUSPECTED SJÖGREN'S SYNDROME

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Background: Focal lymphocytic sialadenitis defined as focus score (FS) ≥1 on labial gland (LG) biopsy plays an integral role in various classification criteria of Sjögren's syndrome (SS). However, suspected patients often hesitate to receive a biopsy; and rheumatologists hope a decision for biopsy based on a high predicted incidence of FS≥1, or against biopsy based on an absolutely low predicted incidence.

Objectives: To build a decision model of LG biopsy based on B-mode ultrasonography (US) with shear-wave elastography (SWE) in patients with suspected SS.

Methods: Patients who had at least one symptom of oral dryness (based on AECG questions) or had anti-SSA positive were recruited and signed a written informed consent. Bilateral parotid (PG) and submandibular glands (SMG) were examined with B-mode US which graded the echotexture of each gland on a scoring system scaled 0 to 4 (US score), and SWE which described the elasticity of glands. Then LG biopsy was performed.

Results:

- Ninety-one patients whose mean age was 43±15 years were enrolled and 93% of them were female. Anti-SSA was detected in 77 patients (85%) and 28 patients (31%) showed unstimulated whole saliva flow rate (USFR) ≤0.1mL/min. There were 57 patients (63%) showing FS≥1 on LG biopsy. Sixty-three patients (69%) were classified as primary SS, 10 patients (10%) were secondary SS, 18 patients (20%) were uCTD and one patient was RA without SS.
- US scores were equal between PG and SMG in 59 patients (65%), while the rest patients showed different US scores between two glands: 7 patients (8%) showed higher US scores in PG and 25 patients (27%) showed higher scores in SMG. In each pair of glands US scores were equal. SWE values in PG or SMG of US score 1, 2 or 3 were significantly