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 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. 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 ACR-SLE 1997 (ACR97) criteria.

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OP0095

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 saliadenitis 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 FSG≥1, or against biopsy based on an absolutely low predicted risk.

Objectives: To build a decision model of LG biopsy based on B-mode ultrasoundography (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 echostructure of each gland on a scoring system scaled 0 to 4 (US score), and SWE which described the elasticity of each gland on a scoring system (SWE score). 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 echostructure of each gland on a scoring system scaled 0 to 4 (US score), and SWE which described the elasticity of each gland on a scoring system (SWE score).

Results: (1) 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 FSG≥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.

(2) 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 different. In the study group, 75% of patients showed equal US scores between two glands.

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higher than those of US score 0, while SWE values in glands of US score 4 became declined and showed no significant difference from those with US score 0 (Figure 1A).

(3) Heatmap showed US scores in either major salivary gland of patients with FS≥1 on LG biopsy were significantly higher than those with FS<1 (all p<0.001, Figure 1B). ROC curve showed a total US score (including bilateral PG and SMG)≥30 could significantly recognize patients with FS≥1, respectively with specificity of 100% and 93% (Figure 1C). In this cohort, among 51 patients with a total US score ≥9 and/or a total SWE value≥30, 49 patients (96%) showed FS≥1 on LG biopsy; while two outliers showed total US scores were both 8 although combined SWE values≥30. Other 29 patients showed total US scores≥6 with total SWE values <30 and only one patient (3%) showed FS≥1 on LG biopsy. The remaining 11 patients showed total US scores were 8 with total SWE values <30 and 64% of them (n=7) showed FS≥1.

Conclusion: A preliminary decision model of LG biopsy based on B-mode US with SWE in patients with suspected SS were built in Table 1. For example, rheumatologists should reassess the need for biopsy if the incidence of FS≥1 would be <5%. Another cohort of patients with suspected SS is needed for further validation.

Table 1. A preliminary decision model of LG biopsy based on B-mode US with SWE in patients with suspected SS

<table>
<thead>
<tr>
<th>Algorithm*</th>
<th>Comments on the decision of LG biopsy</th>
</tr>
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<tbody>
<tr>
<td>A total US score≥9 and/or a total SWE≥30</td>
<td>The specificity of FS≥1 on biopsy is ~90%. Biopsy is recommended. In some special cases (e.g. contraindicated to biopsy), this item is a potential alternative to LG biopsy. It is hard to predict the result of FS, so biopsy is strongly recommended.</td>
</tr>
<tr>
<td>A total US score 7–8 with a total SWE &lt;30</td>
<td>The incidence of FS≥1 would be ~5%. Rheumatologists should reassess the need for biopsy.</td>
</tr>
<tr>
<td>A total US score≥6 with a total SWE &lt;30</td>
<td></td>
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</table>

Figure 1: B-mode ultrasonography (US) with shear-wave elastography (SWE) in 91 patients with suspected SS. A: SWE values in 182 parotid glands (PG, left) or 182 submandibular glands (SMG, right) of US score 0 to 4. B. Heatmap showed US scores in either major salivary gland of 57 patients with FS<1 on left gland biopsy and 54 patients with FS<1. C. ROC curve was used to evaluate the predicting role of a total US score (including bilateral PG and SMG), a total SWE (including bilateral PG and SMG) and anti-SSA positive on the incidence of FS≥1 on salivary gland biopsy.

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