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## Minor Salivary Glands Ultrasonography and ACR/EULAR SjöGren's Syndrome Criteria

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**Objectives** Primary Sjögren's syndrome (pSS) causes progressive functional impairment of salivary and lachrymal glands following lymphocytic infiltration in the glandular tissue. Diagnosis is performed according to the 2016 American College of Rheumatologists/European League Against Rheumatism(ACR/EULAR) criteria (Focus Score (FS)  $\geq$  1; positivity to Anti-SSA(Ro) antibodies; Ocular staining score  $\geq$  5(or van Bijsterfeld score  $\geq$  4) on at least one eye; Schirmer test  $\leq$  5 mm/5min on at least one eye; Unstimulated Salivary Flow Rate(USFR)  $\leq$  0.1ml/min). Minor salivary glands ultra-high frequency ultrasonography (UHFUS) allows the assessment of glandular alterations through the application of the Outcome Measures in Rheumatology (OMERACT) scoring system (Score 0=normal glands to 3=hypoechoic areas in the absence of normal glandular parenchyma). This study aims to assess the correlation between minor salivary glands UHFUS and ACR/EULAR items.

**Methods** Patients diagnosed with pSS following rheumatologic assessment, glandular functional tests, blood testing for anti-Ro(SSA) antibodies and minor salivary glands UHFUS and biopsy were enrolled. Study protocol was approved by the University Hospital of Pisa Ethics Committee and registered in clinicaltrials.gov (NCT06338735). The association between ACR/EULAR criteria and OMERACT scoring of UHFUS was assessed with Pearson's correlation test. Cut-offs were determined by plotting receiver operating characteristics (ROC) curves and computing the areas under the curve (AUC). **Results** 268 patients(91.8% females, mean age 55.07+13.86 years) were enrolled. OMERACT scoring showed positive correlation with histology, positive anti-Ro(SSA) antibodies and USFR. Scores 2-3 were associated to ACR/EULAR diagnosis (p<0.05). The AUC was 0.711 (sensitivity 97.3%, specificity 90.8%).

**Conclusions** OMERACT scoring of UHFUS scans is effective to characterize minor salivary glands echostructure and is a valuable predictor for FS estimation and antibodies positivity. Correspondence with histology gives insight on rethinking the necessity to perform minor salivary gland biopsy routinely in all patients with suspected pSS and holds the promise to integrate and improve pSS evaluation and diagnostic work-up.