with primary SS, 66% with secondary SS). Frequently inhomogeneity was found in all major SG (33%, 22% left and right submandibular, 77%, 44.4% left and right parotid glands) in primary SS. Both submandibular glands were symmetrically involved ($p<0.02$). Duration of disease was negatively correlated to inhomogeneity of right parotid gland ($p<0.02$).

Conclusions: Inhomogeneity in major SG in GS US was found in the majority of patients with primary and secondary SS. The symmetrical involvement of submandibular glands was significant. The inhomogeneity appears in the early period of diagnosis. No major differences were found between two groups.

References:

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SAT0665 DOES PATIENTS' OPINION OF REMISSION IN RHEUMATOID ARTHRITIS OVERLAP US "TRUE" REMISSION?

V. Vlad[1], F. Berghea[2], M. Popescu[1], V. Iorgoveanu[1], D. Predeteanu[1], R. Ionescu[2]. *[1]Rheumatology, Clinical Hospital Sf Maria Bucharest; [2]Rheumatology, UMF Carol Davila, Bucharest, Romania*

Background: Patients describe RA remission as the absence of any symptoms or return to normality. Ultrasound (US) in RA remission patients did not exactly overlap clinical evaluation of remission in previous studies (residual synovitis frequently described). US tenosynovitis evaluation and scoring seemed to better follow clinical remission scores than synovitis in RA [1].

Objectives: To verify with US/clinical evaluations if patients' reported remission is "true" remission, and if and which clinical and US scores are lowest possible in that cohort.

Methods: Forty-eight RA patients were enrolled in this pilot study between 2015–2017 according to their positive answer to the question "Are you feeling free of symptoms, like before RA started for you?"; the enrollment was regardless of the treatment they were on. Written informed consent was obtained. Clinical evaluation of tender and swollen joints was performed the same day with US evaluation of 24 joints and 26 tendon sites and with lab CRP evaluation, blinded from one another. DAS28 and SDAI were calculated after, counting VAS=1, for both physician and patients.

Results: Mean patients age was 58, 35/48 (72.9%) patients were also in remission per DAS28 criteria. Except for CRP value, no other variables (tender, swollen joints, RF, CCP, remission duration) were significantly different in the group with overlapping DAS28 remission. Considering 1.00 as the "ideal" situation (absolute overlapping of US remission and remission felt by patients), the closest was PD scoring in tenosynovitis of the ankle and feet (100%) and the furthest was GS scoring of synovitis in superior and inferior limbs (mean 17.1%)-table 1. Although residual synovitis and tenosynovitis in remission RA patients did not exhibit a statistically significant difference, PD tenosynovitis in both upper and lower limbs was found in less than 10% of patients. This confirms the results from our previous cohort [1], that tenosynovitis better overlaps RA remission than synovitis.

Table 1. Prevalence of US remission in patients with clinical remission – bootstraping for CI

MSUS Remission	DAS28 remission	SDAI Remission
PD Tenosynovitis	94.3 (5.7–100)	90.9 (77.3–100)
GS Tenosynovitis	57.1 (40.0–74.3)	54.5 (36.4–72.7)
PD Synovitis	62.9 (45.7–80.0)	59.1 (36.4–77.3)
GS Synovitis	17.1 (5.7–31.7)	13.6 (0–31.8)
PD Lower limb tenosynovitis	100 (100)	100 (100)
GS Lower limb tenosynovitis	91.4 (82.9–100)	86.4 (72.7–100)

Conclusions: The way patients perceive their disease activity is not related to either DAS28, SDAI scores or to objective US assessment of joints and tendons (GS or PD). However, PD signal especially in tendons sheaths seems to be absent in patients having a normal life, according to their own opinion. Consequently, patients in remission could benefit from US evaluation on any machine, regardless of its costs and Doppler settings. GSUS synovitis/tenosynovitis can be residual finding and does not imply any dissatisfaction in patients' health. An ongoing cohort of active RA patients is currently conducted to explore the validity of this conclusion in these cases, too.

References:

[1] Vlad V et al. Tenosynovitis US scoring systems follow synovitis and clinical scoring systems in RA and are responsive to change after biologic therapy. Med Ultrason 2015 Sep;17(3):352–60.

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SAT0666 SAMPLE SIZE FOR RA CLINICAL TRIALS USING ULTRASOUND OUTCOME MEASURES MAY BE REDUCED BY NOVEL JOINT SELECTION METHODS: A PILOT STUDY

J.C. Allen Jr[1], J. Thumboo[2,3,4], W.K. Lye[1], P.G. Conaghan[5,6], L.C. Chew[2,3,4], Y.K. Tan[2,3,4]. *[1]Office of Clinical Sciences, Centre for Quantitative Medicine, Duke-NUS Medical School; [2]Yong Loo Lin School of Medicine, National University of Singapore; [3]Duke-NUS Medical School; [4]Department of Rheumatology and Immunology, Singapore General Hospital, Singapore, Singapore; [5]NIHR Leeds Musculoskeletal Biomedical Research Unit; [6]Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, United Kingdom*

Background: Novel outcome measures selecting a reduced joint count for ultrasonography can be highly responsive in demonstrating the improvement in joint inflammation seen in rheumatoid arthritis (RA) patients on treatment [1].

Objectives: To determine whether the use of the novel methods can translate into smaller sample sizes for subject recruitment into RA clinical trials. Results from the existing methods are used for comparison.

Methods: 24 RA patients with treatment starts or escalation had clinical and ultrasound joint assessment at baseline and 3 months. The novel methods select joints based on (A) ultrasound joint findings (i.e. Individualized Ultrasound (IUS) method) or (B) a composite of ultrasound and clinical joint findings (i.e. Individualized Composite Ultrasound (ICUS) method). In contrast, the existing methods utilize pre-determined joint sites for ultrasonography. Scores at the relevant joints per patient are summed up to obtain the total inflammatory score (TIS). The effect size (ES) was measured as the mean change of the TIS divided by the standard deviation of the change in the TIS. Sample sizes were calculated from confidence intervals (CIs) on ES that reflect uncertainty in estimating ES. For a given CI on ES, sample sizes are computed as the minimum number of patients required to provide $\geq$80% power at α =0.05 for rejecting the null hypothesis (defined as no difference in the 3-month mean change in TIS comparing novel versus existing methods).

Results: Based on the 95% CI analysis, sample sizes using existing joint assessment methods in conjunction with the 12-joint approach ranged from 10 to 234. The corresponding sample sizes using the ICUS method with the 12-joint approach ranged from 7 to 39, and using the IUS method with the 12-joint approach ranged from 6 to 37. The corresponding sample sizes using the ICUS method with the 7-joint approach ranged from 6 to 24, and using the IUS method with the 7-joint approach ranged from 6 to 35.

Table 1. Summary statistics for novel versus existing methods on 3-month change in scores

Method/Approach	Sample Estimates				95% CI	
	Mean 3-month change in TIS	SD of change in TIS	Effect Size	Post-hoc Sample Size	Effect Size	Sample Size
ICUS/7-joint	0.61	0.54	1.13	9	0.61, 1.64	6, 24
ICUS/12-joint	0.87	0.91	0.96	11	0.46, 1.43	7, 39
IUS/7-joint	0.66	0.67	0.99	11	0.49, 1.47	6, 35
IUS/12-joint	0.91	0.94	0.97	11	0.47, 1.45	6, 37
Existing/7-joint	0.10	0.29	0.34	70	-0.07, 0.75	16, –[1]
Existing/12-joint	0.22	0.35	0.63	68	0.18, 1.06	10, 234

CI: Confidence Interval; SD: Standard Deviation. [1]Interval contains zero which corresponds to the null hypothesis, so upper limit cannot be calculated.

Conclusions: Our findings strongly suggest that novel ultrasound joint selection methods result in smaller sample size requirements compared to existing methods, and provide justification for larger studies to confirm these observations.

References:

[1] Tan YK et al. Novel Ultrasound Joint Selection Methods Using a Reduced Joint Number Demonstrate Inflammatory Improvement when Compared to Existing Methods and Disease Activity Score at 28 Joints. J Rheumatol. 2016;43:34–7.

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SAT0667 PRESEPSIN AND PROCALCITONIN ARE OF DIAGNOSTIC VALUE FOR BACTERIAL INFECTION IN PATIENTS WITH CONNECTIVE TISSUE DISEASES

Y. Ichimura, Y. Kawaguchi, A. Tochimoto, T. Higuchi, M. Tochihara, Y. Katsumata, H. Yamanaka. *Institute of Rheumatology, Tokyo women's medical university, Tokyo, Japan*

Background: Recently, presepsin (soluble CD14-subtype) and procalcitonin are reported as a good diagnostic markers of bacterial infection, especially sepsis. However, their utility in patients with connective tissue diseases (CTDs) has been unknown.

Objectives: To assess the diagnostic value of presepsin and procalcitonin in patients with CTDs.

Methods: We enrolled the consecutive patients with CTDs, who checked the level of procalcitonin and/or presepsin during January to September, 2016, retrospectively. We divided two groups; the infection group and non-infectious group. Infection was diagnosed by symptoms, micro-bacterial methods and the good response to antibiotics. The data analysis were assessed using IBM SPSS statistics 22.