Table 1. Change in cartilage thickness with sprifermin 100 μg q6mo vs placebo using automated segmentation.

<table>
<thead>
<tr>
<th>Region</th>
<th>Sprifermin 100 μg q6mo</th>
<th>Placebo</th>
<th>Mean (SD) change from baseline at Yr 2, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>TFTJ</td>
<td>0.05 (0.11)</td>
<td>-0.04 (0.08)</td>
<td>-0.09 (0.19)</td>
</tr>
<tr>
<td>MFTC</td>
<td>0.03 (0.15)</td>
<td>-0.04 (0.11)</td>
<td>-0.07 (0.17)</td>
</tr>
<tr>
<td>LFTC</td>
<td>0.07 (0.12)</td>
<td>-0.04 (0.10)</td>
<td>-0.11 (0.18)</td>
</tr>
<tr>
<td>cMT</td>
<td>0.02 (0.16)</td>
<td>-0.07 (0.17)</td>
<td>-0.05 (0.21)</td>
</tr>
<tr>
<td>cLT</td>
<td>0.09 (0.21)</td>
<td>0.05 (0.18)</td>
<td>-0.04 (0.13)</td>
</tr>
<tr>
<td>cLF</td>
<td>0.09 (0.11)</td>
<td>0.00 (0.08)</td>
<td>0.01 (0.09)</td>
</tr>
<tr>
<td>cMF</td>
<td>0.02 (0.17)</td>
<td>-0.04 (0.16)</td>
<td>-0.061</td>
</tr>
</tbody>
</table>


the Dutch Arthritis Foundation. The funding source had no role in the design and conduct of the study. Annette van der Helm - van Mil Grant/research support from: The research leading to these results has received funding from the European Research Council (ERC) under the European Union’s Horizon 2020 research and innovation programme (Starting grant, agreement No 714312) and from the Dutch Arthritis Foundation. The funding source had no role in the design and conduct of the study.


SAT0649 DEVELOPMENT AND VALIDATION OF A PATIENT-REPORTED OUTCOME ASSESSING ACTIVITY LIMITATION AND PARTICIPATION RESTRICTION OF PATIENTS WITH SYSTEMIC SCLEROSIS: THE COCHIN 17-ITEM SCLERODERMA FUNCTIONAL SCALE (CSF-17)
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Background: Few patient-reported outcomes measures (PROMs) have been specifically designed to assess the functioning of patients with systemic sclerosis (SSc), in addition, the development of currently available instruments did not fully follow current guidelines (1).

Objectives: To develop and validate a PRO assessing activity limitation and participation restriction of patients with SSc.

Methods: A provisional International Classification of Functioning, Disability and Health (ICF)-based 65-item questionnaire previously developed from interviews of SSc patients was submitted online to French patients (n=184) of the Scleroderma Patient-centered Intervention Network e-cohort (2). Items were reduced according to their metric properties, dimensional structure of the questionnaire was assessed by principal component analysis, convergent and divergent validities using the Spearman correlation coefficient (\(\rho\)), internal consistency by the Cronbach \(\alpha\) coefficient and reliability by a test-retest method using intraclass correlation coefficient (ICC) and Bland and Altman analysis.

Results: Overall, 113/184 (61.4%) patients completed the provisional questionnaire. The item-reduction process resulted in a 17-item questionnaire, the Cochin 17-item Sclerodermia Functional scale (CSF-17). Principal component analysis extracted 2 dimensions: 10 items related to mobility (CSF-17 section A) and 7 items related to general tasks (CSF-17 section B). We observed convergent validity with global activity limitation, pain, depression and aesthetic burden and divergent validity with anxiety. The Cronbach \(\alpha\) coefficient was 0.94 for section A and 0.95 for section B. ICC (n=25 patients) was 0.92 for CSF-17 total score. Bland and Altman analysis did not reveal a systematic trend for the test-retest.

Conclusion: The CSF-17 is a self-administered questionnaire assessing activity limitation and participation restriction of patients SSc with good content and construct validities.

REFERENCES


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Disclosure of Interests: None declared


SAT0650 THE INFLUENCE OF PATIENT DEMOGRAHICS ON DISEASE ACTIVITY MEASUREMENTS IN RHEUMATOID ARTHRITIS
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Rheumatology, Umeå, Sweden

Background: Several indexes have been constructed for the measurement of disease activity in rheumatoid arthritis (RA) patients, including the Disease Activity Score 28-joint count, which either includes the Erythrocyte Sedimentation Rate (DAS28ESR) or the C-reactive protein concentration (DAS28CRP), and the Clinical Disease Activity Index (CDAI). The categorization of the results of these three indexes into levels of disease activity (Remission, Low, Moderate and High) is used to assess patient outcomes, and to guide medical decisions regarding treatment. However, the different indexes can lead to somewhat different classification, and hence influence treatment decisions.

Objectives: To investigate how DAS28ESR, DAS28CRP and CDAI indexes are associated to age and sex in RA patients. To investigate the agreement between indexes and between categories of disease activity levels.

Methods: We identified a cohort of RA patients, registered in the Swedish Rheumatology Quality Register between January 1992 and December 2017. The indexes were obtained from the first visit at the time point of RA diagnosis, and at the visit registered at the start of a first ever biological treatment prescription. Linear models were used to investigate the correlation between the indexes, age and sex. The agreement between the indexes was explored with Bland-Altman plots. The agreement between disease activity levels was evaluated through kappa statistics.

Results: Data were analyzed for 3855 RA patients (2576 women, mean age ±SD=60±15) at their first diagnosis visit and for 3062 RA patients (2313 women, mean age ±SD=57±14) at the start of their first biological. Similar results for all subsequently described analyses were obtained at both time points. The correlation coefficient and 95% confidence interval (95%CI) between the indexes and age were 0.993 (0.963-0.994) for DAS28ESR and 0.995 (0.985-0.996) for DAS28CRP at the first visit, while CDAI was not correlated to age. There was no difference between men and women for CDAI and DAS28CRP, while DAS28ESR presented a mean difference of 0.1 unit between men and women. The agreement between categories of disease activity was moderate: at the RA diagnosis visit, the kappa statistics and 95% CI were: 0.63 (0.61-0.65) between DAS28ESR and DAS28CRP, 0.59 (0.57-0.61) between DAS28ESR and CDAI, and 0.55 (0.53-0.57) between DAS28CRP and CDAI. About 25% of the patients were classified differently. The Bland-Altman plot revealed that the difference between DAS28ESR and DAS28CRP depended on sex and slightly increased with age.

Conclusion: Factors related to patient demographics might influence the results of disease activity indexes. This has a potential to affect clinical decisions, as the definition into disease activity categories can differ depending on the score used. This suggests the need to consider sex and age when defining such categories and interpreting results from these indexes.

REFERENCES