

Reliability and Validity of the Total Joint Count and Swollen Joint Count in Early Diffuse Systemic Sclerosis

Jessica K. Gordon¹, Veronica J. Berrocal², Gandikota Girish³, Meng Zhang⁴, Chris Hatzis¹, Shervin Assassi⁵, Elana J. Bernstein⁶, Robyn T. Domsic⁷, Faye N. Hant⁸, Monique E. Hinchcliff⁹, Elena Schiopu¹⁰, Virginia D. Steen¹¹, Tracy M. Frech¹² and Dinesh Khanna¹³, ¹Rheumatology, Hospital for Special Surgery, New York, NY, ²Div of Rheumatology, University of Michigan, Ann Arbor, MI, ³Radiology, University of Michigan, Ann Arbor, MI, ⁴Epidemiology and Biostatistics, Hospital for Special Surgery, New York, NY, ⁵Rheumatology, University of Texas Medical School at Houston, Houston, TX, ⁶Rheumatology, Columbia University College of Physicians & Surgeons, New York, NY, ⁷Medicine - Rheumatology, University of Pittsburgh, Pittsburgh, PA, ⁸Dept of Medicine, Medical University of South Carolina, Charleston, SC, ⁹Division of Rheumatology, Division of Rheumatology, Northwestern University, Feinberg School of Medicine, Chicago, IL, ¹⁰University of Michigan, Ann Arbor, MI, ¹¹Rheumatology, Georgetown University Medical Center, Washington, DC, ¹²Div of Rheumatology, University of Utah, Salt Lake City, UT, ¹³Division of Rheumatology, University of Michigan, Ann Arbor, MI

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Session Title: Systemic Sclerosis, Fibrosing Syndromes and Raynaud's - Clinical Aspects and Therapeutics Poster III

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Background/Purpose: Arthropathy and tendinopathy in Systemic Sclerosis (SSc) contribute to disability and are associated with disease progression. Clinical trials in SSc sometimes include the tender joint count (TJC) and swollen joint count (SJC) as outcome measures; however, these outcomes have not yet been validated in SSc. We assessed inter and intrarater reliability of TJC and SJC and compared joint examinations with musculoskeletal ultrasound (MSK US) to determine criterion validity.

Methods: Seven patients enrolled in the Prospective Registry of Early Systemic Sclerosis (PRESS) cohort participated. Two separate 28 joint count TJC and SJC were performed on a single day by 10 rheumatologists. On the same day patients had MSK US of the bilateral hands and wrists (22 joints) which were read by a MSK radiologist for synovitis, synovial thickening, and erosions. For TJC and SJC, we computed inter and intra-rater reliability. The following values represent the following degrees of agreement: <0 – poor; 0-0.2 – slight; 0.21- 0.4 – fair; 0.41- 0.6 – moderate; 0.61-0.8 – substantial; and 0.81-1.0 – almost perfect agreement. For the validation exercise we compared the initial physician assessment of swelling or tenderness of the individual 22 joints to the MSK US. We calculated the sensitivity, specificity, positive predictive value (PPV) and negative

predictive value (NPV) for each physician compared to MSK US as a gold standard and present the mean (SD).

Results: The mean age of the patients was 41.6 ± 19.8 years and the mean disease duration from the first non-Raynaud's symptom was 2.7 ± 0.8 years. All had diffuse cutaneous (dc)SSc; 3 were female and 4 male. The mean modified Rodnan Skin Score was 14.67 ± 4.04 .

The mean TJC was 4.2 ± 2.0 (0-28 count). The interobserver reliability for the TJC was 0.97, and the intraobserver reliability for the TJC was 0.99, showing almost perfect agreement. The mean SJC was 1.3 ± 0.8 (0-28 count). The interobserver reliability for the SJC was 0.24, showing fair agreement, and the intraobserver reliability for the SJC was 0.71 denoting substantial agreement.

9.7% (15/154) of joints showed synovitis or synovial thickening on MSK US. 2% (3/150) of physician examinations of joints noted to abnormal on MSK US noted swelling, and 9.3% (14/150) noted tenderness. Additionally, in the joints that were normal on MSK-US, 4.4% (57/1302) of examinations noted swelling and 21.7% (282/1302) noted tenderness.

	Sensitivity – mean (SD)	Specificity – mean (SD)	PPV – mean (SD)	NPV – mean (SD)
Swelling of joint	0.020 (0.045)	0.956 (0.028)	0.039 (0.076)	0.894 (0.009)
Tenderness of joint	0.093 (0.034)	0.778 (0.033)	0.046 (0.014)	0.881 (0.013)

Table 1. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for the initial physician assessment of swelling and tenderness for each physician compared to the MSK US as the reference standard. These were calculated for 10 physicians and are presented as mean (SD) for the group of physicians.

Conclusion: We noted excellent inter and intrarater reliability for the TJC, substantial intrarater reliability for SJC, and fair interrater reliability for SJC in patients with early dcSSc. Examination of the joint for swelling or tenderness showed low sensitivity, but high specificity when compared with MSK US. This cohort had low prevalence of MSK US abnormalities, and this may account for the low PPV observed. Further study should assess the factors associated with SJC and TJC in early dcSSc.

Disclosure: J. K. Gordon, Bayer, 5; V. J. Berrocal, None; G. Girish, None; M. Zhang, None; C. Hatzis, None; S. Assassi, Biogen Idec, 5,Boehringer Ingelheim, 5; E. J. Bernstein, None; R. T. Domsic, Biogen-Idec, 5,Bayer, 5; F. N. Hant, None; M. E. Hinchcliff, None; E. Schiopu, None; V. D. Steen, None; T. M. Frech, None; D. Khanna, Bristol-Myers Squibb, 2,EMD Serono, 2,Genentech and Biogen IDEC Inc., 2,Bayer, 5,Biogen Idec, 5,Cytospor, 5,EMD Serono, 5,Forward, 5,Genentech and Biogen IDEC Inc., 5,Gilead, 5,Lycera, 5,Seattle Genetics, 5.

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