

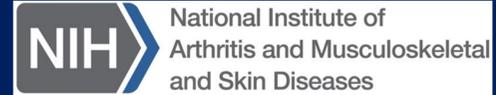


Responsiveness to Change of the Modified Rodnan Skin Score in a Phase I/II Double-Blind Randomized Trial

2617

SCLERODERMA PROGRAM
INTERNAL MEDICINE
RHEUMATOLOGY
UNIVERSITY OF MICHIGAN

Erica Bush¹, Vivek Nagaraja¹, Robert Lafyatis², Dinesh Khanna¹
¹University of Michigan Scleroderma Program, Department of Medicine, University of Michigan, Ann Arbor, Michigan, ²University of Pittsburgh School of Medicine, Pittsburgh, PA



INTRODUCTION

- Modified skin score (mRSS) is used as a primary and secondary outcome measure in different trials of diffuse cutaneous systemic sclerosis (dcSSc)¹.
- As part of a Phase I/IIa trial assessing the safety of tofacitinib 5 mg. twice a day versus placebo in dcSSc (NCT03274076)², we assessed the performance of 3 different methods of scoring the modified Rodnan Skin Score (mRSS)¹.

METHODS

- A 24 week, double-blind, randomized, placebo-controlled trial was conducted in dcSSc with a disease duration of ≤ 60 months (defined as first non-Raynaud phenomenon) and mRSS ≥ 10 and ≤ 45 units.
- Efficacy end point included the change in the mRSS at 24 weeks and 48 weeks.
- Each anatomical area was scored as: Global Average, Maximum and Representative Area. (see Fig. 1)
- Responsiveness to change was evaluated using the effect size (ES) and standardized response mean (SRM).
- For two indices, the numerator is the mean change from the baseline to 24 weeks for mRSS and the denominators are the standard deviation at baseline (ES) and the standard deviation of change (SRM).
- Cohen's rule-of-thumb for interpreting responsiveness to change where 0.20-0.49 represents a small change, 0.50-0.79 a medium change and 0.80 or greater a larger change. (see Fig.2-3)

METHODS CONTINUED

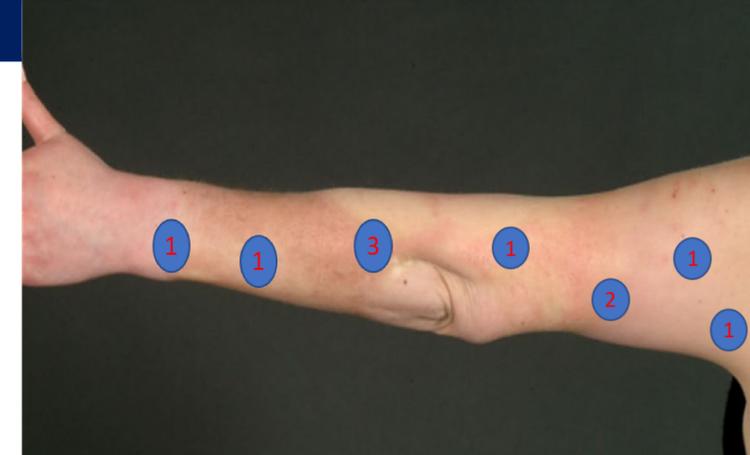
Figure 1: mRSS collection form example

Global average: The examiner scores individual areas and takes average of the area.

Representative area: The examiner scores individual areas with a score that is most representative of the involved area.

Maximum score: The examiner assigns a score to individual anatomic areas according to the most severe local involvement.

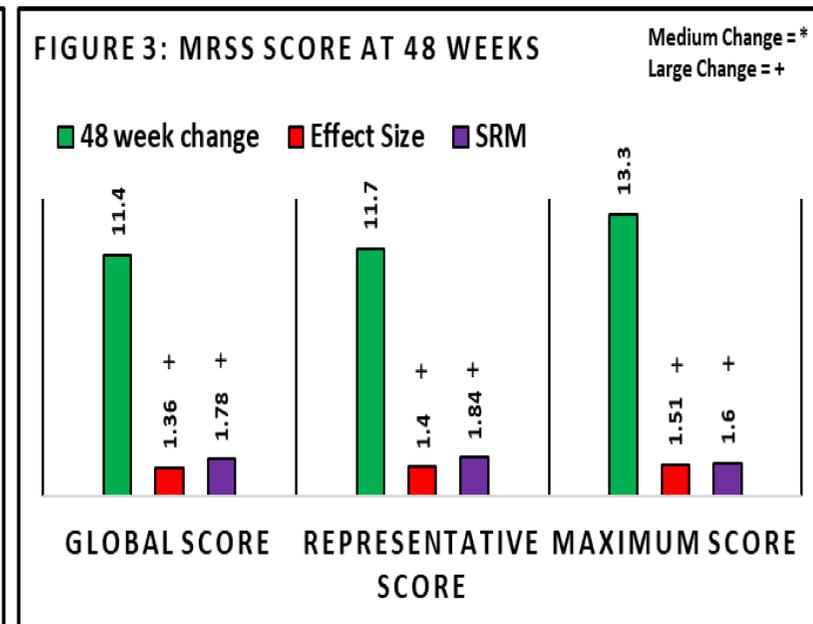
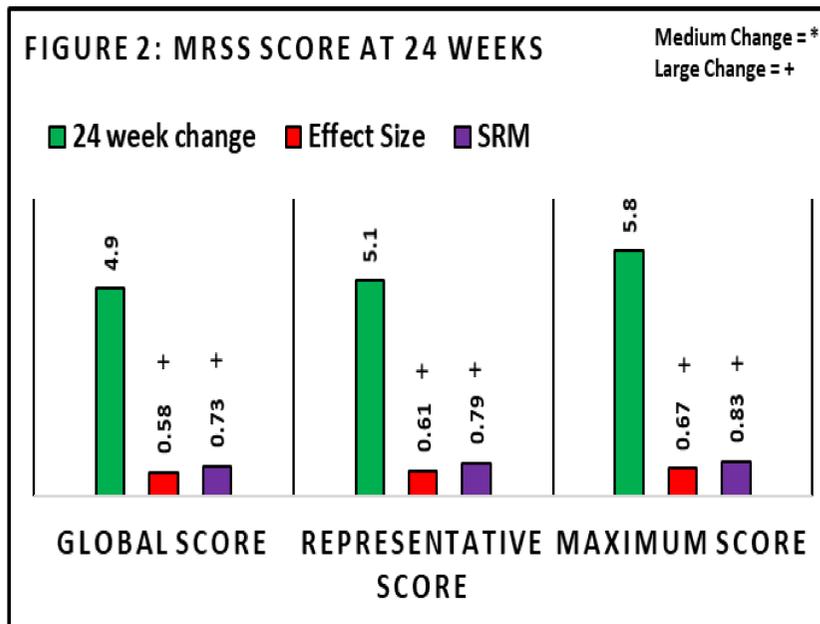
	RIGHT				Representative area	Maximum
Forearm	0. <input type="checkbox"/> 0	1. <input checked="" type="checkbox"/> 1	2. <input type="checkbox"/> 2	3. <input type="checkbox"/> 3	1	3
Upper Arm	0. <input type="checkbox"/> 0	1. <input checked="" type="checkbox"/> 1	2. <input type="checkbox"/> 2	3. <input type="checkbox"/> 3	1	2



RESULTS

Table 1: mRSS	Baseline Mean (SD)
Global Average Score	23.3 (8.4)
Representative Score	23.5 (8.3)
Maximum Score	27.0 (8.8)

Table 2. Baseline Demographics	N=15
Age, mean (SD) Years	50.8 (14.0)
% Female	10 (66.7%)
% White	14 (93.33%)
Disease Duration mean (SD), Years	2.1 (1.2)



CONCLUSION

- In a small trial of 15 participants, all 3 methods to score the mRSS yielded similar magnitude of responsiveness.
- The mRSS was conducted by experienced researchers in this trial. These results should be validated in a larger trial with multiple centers.

REFERENCES

- Khanna D, et al. JSRD 2017
- Khanna D, et al ACR Abstract #863.

Dr. Khanna was funded by the NIH/NIAID Clinical Autoimmunity Center of Excellence.