Inter- and Intra-Observer Reliability of Modified Rodnan Skin Score Assessment in Thai Systemic Sclerosis Patients: A Validation for Multicenter Scleroderma Cohort Study

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Background: *Assessment of the severity of skin tightness by the modified Rodnan skin score (mRSS) for systemic sclerosis (SSc) has been found feasible, valid, and reliable. Despite being a major clinical outcome, it has not yet been validated by Scleroderma Research Group.*

Objective: *To (a) determine the inter-observer variability vis-à-vis mRSS assessment by members of the Scleroderma Research Group before and after mRSS-assessment training by an experienced rheumatologist and (b) determine intra-observer variability.*

Material and Method: *Between June and August 2013, we conducted a descriptive study of Thai adult SSc patients and all rheumatologists in the Scleroderma Research Group at Srinagarind Hospital, Khon Kaen University, Northeast Thailand. Eleven rheumatologists assessed the mRSS of 22 SSc patients three times (i.e., before and after training, and eight weeks after training). The intra-class correlation coefficient (ICC) and its 95% CI were estimated at week 8 after training.*

Results: *The mean and standard deviation (SD) of mRSS for inter-observer variability analysis was slightly decreased from before training, after training (by an experienced rheumatologist), and at week 8 after training (17.3±11.9, 16.5±11.1, and 16.2±10.3, respectively). Intra-observer variability had moderate agreement before training (ICC 0.59; 95% CI 0.38-0.78), which increased to good agreement after training and at week 8 after training (ICC 0.60; 95% CI 0.42-0.76 vs. 0.68; 95% CI 0.53-0.82, respectively).*

Conclusion: *Inter-observer variability for mRSS assessment decreased after training and the reduction persisted for eight weeks after training. The ICC rose from moderate agreement at baseline to good agreement at the end of the study. The mRSS assessment by members of the Scleroderma Research Group was reliable.*

Keywords: *Systemic sclerosis, Scleroderma, Modified Rodnan skin score, Validation, Inter-observer variability, Intra-observer variability*

Scleroderma or systemic sclerosis (SSc) is a rare disease. The respective prevalence and incidence is 13 to 280 cases per million adults and two to 20 per million per year[1-4]. Skin tightness is the major presenting characteristic of SSc, classified as (i) limited cutaneous systemic sclerosis (lcSSc) and (ii) diffuse cutaneous systemic sclerosis (dcSSc). The lcSSc includes skin tightness of the face, hands, feet, forearms, and legs, while dcSSc includes skin tightness of the trunk and both extremities. The dcSSc, associated with internal organ fibrosis and prognosis, is more severe than the limited type.

The assessment of the severity of skin tightness by modified Rodnan skin score (mRSS) is practicable, feasible, and reliable[5-7]. Since mRSS

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reflects skin thickness from a skin biopsy accurately[8,9], it is used for outcome measurement in clinical trials of SSc[10,11]. The mRSS assesses skin in 17 areas, including the face, chest, abdomen, arms, forearms, hands, fingers, thighs, legs, and feet. Assessment is rated as 0 (normal skin thickness), 1 (mild but definite skin thickness), 2 (moderate thickness), and 3 (severe thickness with inability to pinch a fold of skin). The mRSS is calculated by sum of the rating score from all 17 areas (range, 0-51). The mRSS is a clinical predictor of physical health status in SSc patients[12]. The skin pattern during follow-up can be (a) rapid progression, (b) slow progression, (c) slow progression to a peak or maximum then slow regression, (d) intermediate progression, and (e) slow progression to peak then intermediate regression. A high skin score is associated with digital ulcer(s) and capillary nailfold deletion[13-16]. Internal organ involvement occurs in patients with extensive skin tightness[5].

Skin scoring is a subjective outcome assessment. Assessors only use their finger to perceive skin thickness. Owing to its subjectivity, validation is needed. The mRSS has been validated at many centers[6,17,18] but never in Thailand. Before starting the Scleroderma Cohort Trial (for which the mRSS is a clinical outcome parameter), members of the Scleroderma Research Group wanted to assess inter-observer variability before and after mRSS-assessment training by an experienced rheumatologist.

The objectives of the current study were to (a) determine inter-observer variability of mRSS assessment by members of the Scleroderma Research Group before and after assessment training by an experienced rheumatologist and (b) determine intra-observer variability.

Material and Method

We conducted a descriptive study of Thai adult SSc patients as well as the member rheumatologists of the Scleroderma Research Group. The study was performed at Srinagarind Hospital, Khon Kaen University, Northeast Thailand between June and August 2013. All of the included patients were over 18 years old and had a diagnosis of SSc. We included both the dcSSc subset and the lcSSC subset. We excluded patients who had overlap syndrome, were functional class IV, needed oxygen therapy at rest, and were not available for skin assessment (i.e., limb amputation).

Eleven participant rheumatologists assessed the mRSS of all 22 SSc patients (1 participant assessed 22 patients) without any information, instructions, or discussion with the other rheumatologists. The skin score was assessed using the mRSS technique. After finishing the first round of mRSS assessment, all participants were instructed and trained by an experienced rheumatologist on accurate assessment of mRSS. The trainer and all participants were free for discussion during the training and agreed on the appropriate technique. Then a second round of mRSS assessment of the same patients was performed (Fig. 1). Inter-observer variability was evaluated after finishing the second round. As for evaluating intra-observer variability, all of the participants were asked to reassess the patients with the same technique at week 8 after training.

Operational definitions

A diagnosis of SSc was based on the American College of Rheumatology criteria[19]. SSc was classified as the limited or diffuse type as per the classification of LeRoy et al[20]. The mRSS was assessed at 17 sites; viz., the face, chest, abdomen, arms, forearms, hands, fingers, thighs, legs, and feet. Assessment was rated as 0 (normal skin thickness), 1 (mild but definite skin thickness), 2 (moderate thickness), or 3 (sever thickness with inability to pinch a fold of skin). The score was calculated by summing the rating score from all 17 areas (range, 0-51)[6].

Sample size

Bearing in mind the primary objective of the study, the sample size was calculated based on the intra-class correlation coefficient used to quantify the reliability among the 11 assessors for the mRSS score ranging between 0 and 51. The method proposed

mRSS = modified Rodnan skin score
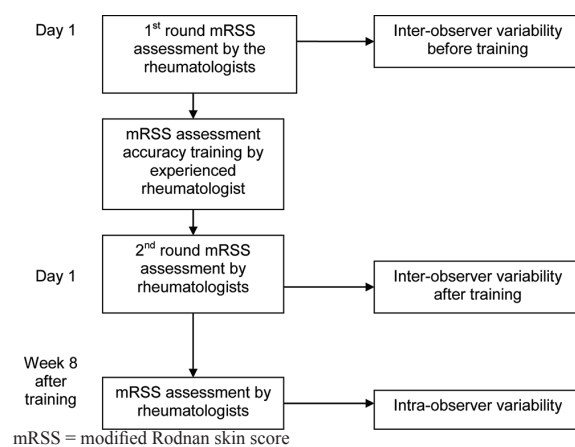
Fig. 1   Study flow chart.

by Walter et al (1998) was used[21]. A sample size of 22 subjects with 11 assessors per subject would achieve 90% power for detecting an intra-class correlation of 0.80 under the alternative hypothesis when the intra-class correlation under the null hypothesis was 0.60, using an F-test with a significance level of 0.05.

Statistical analysis

Demographic characteristics of the patients as well as the assessors were presented using the mean and standard deviation for continuous data and the number and percentage for the categorical data.

To answer the research question, the inter-observer variability was tested by calculating the overall mean and standard deviation (SD) of the mRSS after finishing the second round of mRSS assessment. The intra-class correlation coefficient (ICC) and its 95% confidence interval were estimated at week 8 after training. The calculation was based on a 2-way random effect model where patients and assessors were fully crossed, thereby forming the data matrix.

All of data analyses were performed using STATA version 13 (StataCorp, College Station, TX, USA).

The study was designed by the authors and approved by the Human Research Ethics Committee at Khon Kaen University as per the Helsinki Declaration and the Good Clinical Practice Guidelines (HE561049). All of the patients signed informed consent before being enrolled in the study.

Results

Eleven rheumatologists from seven tertiary care centers were included as assessors and 22 SSc patients. The demographic characteristics of the assessors and SSc patients were presented in Table 1.

The respective mean and SD of the mRSS for the inter-observer variability analysis (a) before training, (b) after training by an experienced rheumatologist, and (c) at week 8 after training was 17.3±11.9, 16.5±11.1, and 16.2±10.3 (Table 2).

Intra-class correlation had a moderate agreement before training (ICC 0.59). This slightly increased to good agreement after training (ICC 0.60) and trended upward again at week 8 after training (ICC 0.68) (Table 3).

Discussion

The mRSS is widely used as an outcome measure in clinical trials for assessing the severity and extent of skin thickness in SSc[10,11]. The mRSS has

been demonstrated valid and reliable[5-7]. Although mRSS is useful in daily practice and in clinical trials, it is a subjective assessment. Therefore, it is necessary to validate the mRSS before starting any clinical, multicenter study, which the Scleroderma Research

Table 1. Demographics of patients and assessors

Characteristics	Number, n (%)
Characteristics of patients	n = 22
Age in years, mean ± SD (min-max)	51.3±9.4 (32.1-67.0)
Duration of disease in years, mean ± SD (min-max)	5.8±3.9 (0.7-13.9)
Sex	
Female	13 (59.1)
Male	9 (40.9)
Subset	
dcSSc	15 (68.2)
lcSSc	7 (31.8)
Characteristics of assessors	n = 11
Age in years, mean ± SD (min-max)	38.2±7.1 (32.2-55.4)
Sex	
Female	6 (54.5)
Male	5 (45.5)
Experience in rheumotology <5 years	7 (63.6)

SD = standard deviation; dcSSc = diffuse cutaneous systemic sclerosis; lcSSc = limited cutaneous systemic sclerosis

Table 2. Overall mean and SD of mRSS assessment

Occasion	Mean	Within patient SD
mRSS assessment before training by experienced rheumatologist	17.3	11.9
mRSS assessment after training by experienced rheumatologist	16.5	11.1
mRSS assessment at week 8 after training	16.2	10.3

SD = standard deviation; mRSS = modified Rodnan skin score

Table 3. Calculating intra-class correlation

Occasion	ICC	95% CI
mRSS assessment before training by experienced rheumatologist	0.59	0.38 to 0.78
mRSS assessment after training by experienced rheumatologist	0.60	0.42 to 0.76
mRSS assessment at week 8 after training	0.68	0.53 to 0.82

ICC = intra-class correlation coefficient; CI = confidence interval; mRSS = modified Rodnan skin score

Group plans to do. The study, therefore, aimed to validate the mRSS assessment of members of the Scleroderma Research Group.

The inter-observer variability after training by an experienced rheumatologist at week 8 after training was 16.2 ± 10.3 while the intra-observer variability by ICC was 0.68 (95% CI, 0.53 to 0.82). These values are comparable with previous validation studies in which agreement by ICC for inter-observer variability ranged from 0.38 to 0.87[6,22-25] and for intra-observer variability 0.71 to 0.72[22,23]. Although agreement among all studies (including ours) were moderate (ICC 0.4 to 0.6) to good (0.6 to 0.8), it was still acceptable.

Inter- and intra-observer variability is predictably high at baseline before training and decreases with training. The results revealed a reduction of the mean of different for mRSS assessment among assessors over time as well as an improvement of ICC agreement. The change from before training to after training was less than 5% and from after training to week 8 was less than 2%. Notwithstanding, overall inter-observer variability only slightly changed from before training to week 8 after training (i.e., 6%). The slight reduction in inter-observer variability might be explained by the comparable baseline knowledge of mRSS assessment and self-confidence in doing assessments among the assessors.

The intra-class correlation improved according to the learning curve. The study documented an improvement of intra-observer variability over time - from moderate agreement at baseline to good agreement after training and at week 8 after training. The ICC was much higher at week 8 after training when compared to D1 after training, which was opposite to inter-observer variability. The difference is probably explained by the self-learning curve of each assessor over time.

A limitation of the study was that we could not do more than two mRSS assessments because of financial and patients limitation. Consequently, we could not determine the remote intra-class correlation. Notwithstanding, the study included SSc patients of various ages, subsets, and durations of disease; thereby representing general SSc patients in daily practice.

Conclusion

Inter-observer variability for mRSS assessment decreased after training and the reduction persisted. The ICC rose from moderate agreement at baseline to good agreement at the end of the study. The

mRSS assessment by members of the Scleroderma Research Group proved reliable.

What is already known on this topic?

The mRSS is a subjective outcome assessment. Assessors only use their finger to perceive skin thickness. Owing to its subjectivity, validation is needed. The mRSS has been validated at many centers but never in Thailand. The inter- and intra-observer variability among all previous studies was moderate to good agreement and were generalized acceptable. Before starting the Scleroderma Cohort Trial (for which the mRSS is a clinical outcome parameter), members of the Scleroderma Research Group were assessed inter-observer variability before and after the mRSS-assessment training by an experienced rheumatologist.

What this study adds?

Inter-observer variability for the mRSS assessment of the study decreased after training and the reduction persisted. Intra-class correlation rose from moderate agreement at baseline to good agreement at the end of the study. The mRSS assessment by members of the Scleroderma Research Group proved reliable to be a clinical outcome parameter in the Scleroderma Research Group Cohort Trial.

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Appendix 1. Assessment form

Participant number

Assessment [1] 1st round [2] 2nd round [3] week 8

Each participant (Pt 1 – Pt 24) is assessed on the following body regions with scores 0, 1, 2, 3 recorded for Right and Left sides, with a Total box.

Body regions assessed:
- Face — Right (0 1 2 3) / Left (0 1 2 3)
- Chest — Right (0 1 2 3) / Left (0 1 2 3)
- Abdomen — Right (0 1 2 3) / Left (0 1 2 3)
- Arm — Right (0 1 2 3) / Left (0 1 2 3)
- Forearm — Right (0 1 2 3) / Left (0 1 2 3)
- Hand — Right (0 1 2 3) / Left (0 1 2 3)
- Finger — Right (0 1 2 3) / Left (0 1 2 3)
- Thigh — Right (0 1 2 3) / Left (0 1 2 3)
- Leg — Right (0 1 2 3) / Left (0 1 2 3)
- Foot — Right (0 1 2 3) / Left (0 1 2 3)

Total □□

(This assessment grid is repeated for Pt 1 through Pt 24.)

ความผันแปรของการประเมินคะแนนความแข็งตึงของผิวหนังในผู้ป่วยโรคหนังแข็งด้วยวิธี *modified Rodnan* ระหว่างผู้ประเมินและภายในตัวผู้ประเมิน: การประเมินความแม่นยำสำหรับการศึกษาโรคหนังแข็งแบบสหสถาบัน

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ขวัญฤทัย ศรีพวาทกุล, วิริยา เชื้อลี, บดินทร์ บุตรธรรม, ปฐพงศ์ โตวิวัฒน์, พัชรวรรณ สืบมี, กิตติกร ดวงกำ, ดรุณี คงแป้น,
จินตาหรา มังคะละ, รัตนวดี ณ นคร

ภูมิหลัง: การประเมินความแข็งตึงของผิวหนังในโรคหนังแข็งด้วยวิธี *modified Rodnan skin score (mRSS)* ทำได้ง่าย มีความแม่นยำ และเชื่อถือได้ ทั้งที่การประเมินวิธีนี้เป็นการประเมินผลการดำเนินโรคหลัก แต่ยังไม่เคยมีการประเมินความแม่นยำโดยกลุ่มวิจัยโรคหนังแข็ง

วัตถุประสงค์: เพื่อศึกษาความผันแปรของการประเมินคะแนนความแข็งตึงของผิวหนังระหว่างผู้ประเมิน *(inter-observer variability)* และภายในตัวผู้ประเมิน *(intra-observer variability)* ในสมาชิกกลุ่มวิจัยโรคหนังแข็งก่อนและหลังการฝึกอบรมโดยอายุรแพทย์ผู้เชี่ยวชาญโรคข้อ

วัสดุและวิธีการ: การศึกษาแบบพรรณนาดำเนินการในเดือนมิถุนายน ถึง สิงหาคม พ.ศ. 2556 ในผู้ป่วยโรคหนังแข็งผู้ใหญ่และอายุรแพทย์โรคข้อที่เป็นสมาชิกในกลุ่มวิจัยโรคหนังแข็ง ณ โรงพยาบาลศรีนครินทร์ มหาวิทยาลัยขอนแก่น ภาคตะวันออกเฉียงเหนือ ประเทศไทย อายุรแพทย์โรคข้อจำนวน 11 คน ทำการประเมินความแข็งตึงของผิวหนังด้วยวิธี *mRSS* ในผู้ป่วยโรคหนังแข็งจำนวน 22 ราย เป็นจำนวน 3 รอบ (ก่อนการฝึกอบรม หลังการฝึกอบรม และที่สัปดาห์ที่ 8 หลังการฝึกอบรม) ค่าสัมประสิทธิ์ *intra-class* และช่วงความเชื่อมั่นร้อยละ 95 ได้รับการประเมินที่สัปดาห์ที่ 8 หลังจากการฝึกอบรม

ผลการศึกษา: ค่าเฉลี่ยและส่วนเบี่ยงเบนมาตรฐานของคะแนนที่ได้จากการประเมินผิวหนังแข็งตึงด้วยวิธี *mRSS* สำหรับการประเมินความผันแปรระหว่างผู้ประเมินลดลงเล็กน้อยจากก่อนการฝึกอบรม หลังการฝึกอบรม และที่สัปดาห์ที่ 8 หลังการฝึกอบรม (17.3±11.9, 16.5±11.1 และ 16.2±10.3 ตามลำดับ) ค่าความผันแปรภายในตัวผู้ประเมินก่อนการฝึกอบรมเป็น *moderate agreement* (ค่าสัมประสิทธิ์ *intra-class* 0.59, ช่วงความเชื่อมั่นร้อยละ 95: 0.38-0.78) และเพิ่มขึ้นเป็น *good agreement* หลังการฝึกอบรม และที่สัปดาห์ที่ 8 (ค่าสัมประสิทธิ์ *intra-class* 0.60, ช่วงความเชื่อมั่นร้อยละ 95: 0.42-0.76 และค่าสัมประสิทธิ์ *intra-class* 0.68, ช่วงความเชื่อมั่นร้อยละ 95: 0.53-0.82 ตามลำดับ)

สรุป: ค่าความผันแปรระหว่างผู้ประเมินในการประเมินผิวหนังแข็งตึงด้วยวิธี *mRSS* ลดลงภายหลังจากที่ฝึกอบรม และยังคงลดลงต่อเนื่องจนถึงสัปดาห์ที่ 8 หลังจากที่ฝึกอบรม ขณะเดียวกัน ค่าสัมประสิทธิ์ *intra-class* เพิ่มขึ้นจาก *moderate agreement* ณ วันแรกที่ประเมินไปเป็น *good agreement* ณ วันสิ้นสุดการประเมิน การประเมินผิวหนังแข็งตึงด้วยวิธี *mRSS* โดยสมาชิกกลุ่มวิจัยโรคหนังแข็งเป็นที่น่าเชื่อถือ