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The Reliability of the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) Among Dermatologists, Rheumatologists, and Neurologists

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Abstract

Background—Previous studies have shown that skin disease in dermatomyositis (DM) is best assessed using the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI). Although the CDASI has been validated for use by dermatologists, it has not been validated for use by other physicians such as rheumatologists and neurologists, who also manage DM patients and assess skin activity in clinical trials. The purpose of this study is to assess the reliability of the CDASI among dermatologists, rheumatologists, and neurologists.

Methods—Fifteen subjects with cutaneous DM were assessed using the CDASI and the Physician Global Assessment (PGA) by five dermatologists, five rheumatologists, and five neurologists.

Results—The CDASI activity score means for dermatologists, rheumatologists, and neurologists were 21.0, 21.8, and 20.8, respectively. These means were not different among the specialists. The CDASI damage score means for dermatologists, rheumatologists, and neurologists were 5.3, 7.0, and 4.8, respectively. The means between dermatologists and rheumatologists were significantly different, but the means between dermatologists and neurologists were not. The intraclass correlation coefficients (ICCs) for inter-rater reliability for CDASI activity and damage were good

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to excellent for dermatologists and rheumatologists, and moderate to excellent for neurologists. The ICCs for intra-rater reliability for CDASI activity and damage were excellent for dermatologists and rheumatologists and moderate to excellent for neurologists. The PGA displayed lower inter-rater and intra-rater reliability relative to the CDASI.

Conclusions—Our results confirm the reliability of the CDASI when used by dermatologists and rheumatologists. The data was not as robust for its use by neurologists.

INTRODUCTION

Individuals with dermatomyositis (DM) present with characteristic inflammatory skin changes as well as systemic manifestations involving the muscles, joints, heart, and lungs [1]. In the past, the cutaneous manifestations of DM were among the least systematically studied aspects of this disease due to a lack of validated instruments for reliably determining the impact of therapy on cutaneous DM disease activity. The Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) was developed and validated for use by dermatologists in direct response to this need [2]. Previous studies have demonstrated that the CDASI has the best responsiveness to clinical change when compared to other outcome measures that assess cutaneous manifestations of DM [2–4].

Many clinical trials for DM include specialties other than dermatology, such as rheumatology and neurology, which have limited experience in systematically assessing cutaneous manifestations of DM. Because quantifying skin disease activity can offer early insight into the relative efficacy of an interventional agent, a cutaneous outcome measure such as the CDASI can be valuable in determining the overall efficacy of an investigational drug in clinical trials. However, the CDASI is currently validated for use by adult dermatologists only, and no clinical instrument exists that has been validated for use by DM specialists in fields such as rheumatology and neurology [2–4]. The purpose of this study is to evaluate the intra-rater and inter-rater reliability of the CDASI for use by rheumatologists and neurologists as well as dermatologists.

METHODS

This study was approved by the University of Pennsylvania Institutional Review Board. Written informed consent was obtained from all participants, including both physicians and patients, prior to study initiation.

Physician Participants

Five dermatologists, five rheumatologists, and five neurologists were invited to participate in this one-day study occurring in February 2015. With the exceptions of one rheumatology and one neurology fellow, all physicians were board-certified, attending-level physicians. All physicians were employed by academic university hospitals at the time the study was conducted. Prior to initiating the study, all physicians completed one 30-minute training session on the assessment of cutaneous DM using both the CDASI and PGA outcome instruments.

Patient Participants

Fifteen patients from the Autoimmune Skin Disease Clinic at the Hospital of the University of Pennsylvania were recruited in clinic and via telephone. Eligible patients were 18 years of age or older and had a diagnosis of DM with active skin disease. Characteristics of the patient population are summarized in Table 1.

Study Design

All physicians individually rated each patient using the CDASI and PGA. After a two-hour interval, physicians reassessed three patients using the same instruments. Reassessment was performed based on patient room availability. At the end of the study day, each physician completed a brief physician exit survey.

Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI)

The CDASI is a partially validated, clinician-scored, 1-page outcome measure used to assess skin disease in DM patients. It evaluates the skin in 15 anatomic locations and is comprised of two separate scores based on activity (erythema, scale, ulceration/erosion) and damage (poikiloderma and calcinosis). Additional factors contributing to the total score include the activity and/or damage due to Gottron's papules on the hands, recent hair loss, and periungual changes. Scores range from 0–100 for activity and from 0–32 for damage. Higher scores indicate greater disease severity. The CDASI is presented in Figure 1.

Physician Global Assessment (PGA)

The PGA is an overall rating of disease severity performed by physicians. It is completed on a 10-cm linear visual analog scale that ranges from 0 (no evidence of disease) to 10 (extremely severe disease). The PGA has been used in several other instrument validation studies for skin disorders such as lupus, pemphigus, and cutaneous sarcoidosis (Figure 2) [8–11].

Statistical Analysis

Previous studies have shown CDASI and CAT-BM scores to be normally distributed, so normality was assumed for this study [2]. Intra-rater reliability of CDASI activity and damage was estimated using the intra-class correlation coefficient (ICC), calculated from random effect ANOVA models [13]. The repeated CDASI assessments from the same patients and the same physician were included in the analysis. Two reads of the same patient by the same physician were considered to have the same normal distributions, i.e., physician-patient combinations as random effects. For any patient who was re-assessed by the same physician, only the first read was included in the following analyses.

Inter-rater reliability was estimated using the ICC, calculated from random effect ANOVA models with patient-specific random effects. For each physician group, the physician-specific ICC was estimated using the observations by the same group of physicians. Previous studies have determined an ICC between 0.50 to 0.70 as moderate, 0.70 to 0.81 as good, and > 0.81 as almost perfect [2–3, 12]. For this study, ICC scores between 0.50 and 0.70 were

considered moderate and minimally acceptable, 0.70 to 0.81 good, and >0.81 were considered excellent. Any ICC scores <0.5 were considered poor.

For the difference between dermatologists, neurologists, and rheumatologists, the group means were estimated from the fixed effects in the same ANOVA models. The difference between group means was compared using t-tests within the ANOVA models. The time spent for evaluating the CDASI was summarized within each group of physicians, and the differences from the dermatologists were tested using the Dunnett's multiple comparison method. P values less than 0.05 were considered statistically significant for all analyses. The statistical analysis was carried out using R2.15.3.

RESULTS

Skin Assessment Scores Among Specialists

The CDASI activity score for all DM patients when scored by all physicians was 21.1 ± 8.7 (mean $\pm$ s.d.) with a range of 4–38 (Table 2). The CDASI damage score for all patients when scored by all physicians was 5.7 ± 5.2 with a range of 0–23. The mean CDASI activity scores for each group of physicians were 21.0 for dermatologists, 21.8 for rheumatologists, and 20.8 for neurologists. There was no difference between the mean CDASI activity scores of dermatologists and rheumatologists ($p=0.411$) and no difference between the mean CDASI activity scores of dermatologists and neurologists ($p=0.792$). The mean CDASI damage scores were 5.3 for dermatologists, 7.0 for rheumatologists, and 4.8 for neurologists. The mean CDASI damage scores differed between dermatologists and rheumatologists ($p<0.001$) but not between dermatologists and neurologists ($p=0.253$).

The overall PGA activity score for all patients when scored by all physicians was 4.0 ± 2.2 with a range of 0.1–8.2. The overall PGA damage score was 2.5 ± 2.6 with a range of 0.0–9.4. The mean PGA activity scores were 3.8, 4.0, and 4.1 for dermatologists, rheumatologists, and neurologists, respectively, and the mean PGA damage scores were 2.6, 2.9, and 2.1. There was no statistically significant difference in mean PGA activity or damage scores between dermatologist and rheumatologists or between dermatologists and neurologists.

Inter- and Intra-rater Reliability

Inter-rater reliability yielded an ICC that was considered good for CDASI activity for dermatologists and rheumatologists (0.73 and 0.74, respectively) and moderate (minimally acceptable) for neurologists (0.56). For CDASI damage, the ICC was excellent for all groups of physicians (dermatologists 0.83, rheumatologists 0.82, neurologists 0.85). For PGA activity, the ICC was in the moderate or minimally acceptable range for dermatologists (0.61) and rheumatologists (0.69), but poor for neurologists (0.44). The ICC for PGA damage was found to be excellent for neurologists (0.85), good for rheumatologists (0.75), and moderate for dermatologists (0.58) (Table 3).

Intra-rater reliability was excellent for all physicians for CDASI activity (dermatologists 0.94, rheumatologists 0.88, neurologists 0.82). For CDASI damage, the scores were excellent for dermatologist and rheumatologists (0.92 and 0.91, respectively) and moderate

for neurologists (0.66). For the PGA activity and damage, the intra-rater reliability was excellent for dermatologists (0.89 and 0.91, respectively) and good for rheumatologists (0.75 and 0.75, respectively). For neurologists, the PGA activity was found to be good (0.74) but the PGA damage was found to be poor (0.39) (Table 4).

Convergent Validity

There was a positive association between CDASI activity and PGA activity. For each unit increase in PGA activity, the CDASI activity score increased, on average, 2.33 ($p < 0.001$) after adjusting for within-patient correlation and physician difference.

Completion Time

The CDASI had a completion time of 7.3 ± 2.6 minutes for all physicians. The mean ($\pm$ s.d.) completion time for the dermatologists was $6.3 (\pm 2.1)$ minutes, while the completion time for rheumatologists and neurologists was longer with means of ($\pm$ s.d.) $8.8 (\pm 2.7)$ minutes and $6.8 (\pm 2.7)$ minutes, respectively.

Physician Exit Survey

When asked how comfortable physicians felt using the CDASI on a scale of 1–5 (1=not comfortable at all, 5=very comfortable), the average score was 4.2 among dermatologists, 3.6 among rheumatologists, and 3.4 among neurologists. Physicians felt uncomfortable using the CDASI for the following reasons: questionable attribution of specific skin lesions (three dermatologists, five rheumatologists, and four neurologists), not enough training in skin disease (two rheumatologists and five neurologists), and not enough familiarity with the CDASI (three rheumatologists). One neurologist commented that racial differences made qualitative assessments more difficult, and one rheumatologist commented that sun damage made the skin assessments confusing. When asked whether the reassessment of patients was affected by recall of the first evaluation, five physicians answered yes, nine physicians no, and one was unsure.

DISCUSSION

The CDASI was developed and validated by dermatologists in order to provide a reliable and objective outcome instrument to assess skin manifestations of DM for use in the clinical and research settings [2]. Over the past ten years, multiple studies evaluating the CDASI, including studies comparing it to other outcome instruments such as the PGA, have consistently demonstrated its reliability and validity as well as its responsiveness to clinical change when used by dermatologists [2–4, 14–15]. This study examined the reliability and validity of the CDASI when used by rheumatologists and neurologists as well as dermatologists.

Inter-rater reliability for CDASI activity scores ranged from excellent for dermatologists and rheumatologists to moderate for neurologists. Inter-rater reliability for CDASI damage scores was excellent across all specialties. Intra-rater reliability for CDASI activity and damage scores was almost uniformly excellent for all specialties with moderate intra-rater reliability for CDASI damage scores among neurologists. These results confirm the inter-

rater and intra-rater reliability of the CDASI activity and damage scores across all specialties, with dermatologists and rheumatologists achieving good to excellent reliability.

Compared to the inter- and intra-rater reliability of the CDASI, the inter- and intra-rater reliability of the PGA was more variable. For PGA activity scores, inter-rater reliability was moderate for dermatologists and rheumatologists and poor for neurologists. Inter-rater reliability for PGA damage scores ranged from moderate for dermatologists to good for rheumatologists to excellent for neurologists. Intra-rater reliability for PGA activity and damage scores similarly ranged from excellent for dermatologists, good for rheumatologists, and poor to good for neurologists. These findings are consistent with previous studies that have shown superior inter- and intra-rater reliability of the CDASI compared to the PGA, which prior to the development of the CDASI was widely used to assess cutaneous DM manifestations [2].

Among all the specialties, the neurologists expressed the least comfort using the CDASI, with all five neurologists acknowledging lack of training in skin disease as a limiting factor in using the CDASI. A previous study evaluating the CDASI among pediatric specialists in juvenile DM yielded similar reports by the pediatric neurologists, and the inter- and intra-rater reliability of the CDASI when used by the pediatric neurologists in that study was correspondingly variable with ICC's in the poor to good range [14]. The results of the present study, however, found that the neurologists achieved at the minimum moderate, and therefore acceptable, inter- and intra-rater reliability when using the CDASI. Furthermore, mean activity and damage scores were not significantly different between dermatologists and neurologists. One possible explanation for the discrepancy in neurologists' performance between the two studies is that the neurologists recruited for the present study had all received or were in the process of receiving specialized neuromuscular training and therefore had potentially greater exposure to DM patients. Additionally, four of five of the neurologists from the present study were employed by a referral center with known expertise in DM, potentially allowing specialists at this institution to acquire greater familiarity with cutaneous manifestations of DM. Regardless, the present findings suggest that certain neurologists are able to use the outcome instrument adequately.

Limitations of this study include recall bias, with five of 15 physicians acknowledging that their reassessment of patients was affected by recall. Study day logistics required physicians to reassess patients within hours of the initial patient assessment. As a result, the nearly uniformly excellent intra-rater reliability of the CDASI activity and damage scores may be inflated. However, it is notable that the intra-rater reliability of the PGA is generally lower than the CDASI, with ICCs ranging from poor to excellent. Patients were assessed using both outcome measures at the same time, so the higher intra-rater reliability scores of the CDASI relative to the PGA should not have been affected by recall bias.

Nearly all of the physicians who participated in this study were employed by a large referral center with known expertise in DM, and the training session on the use of the CDASI and PGA was led by a known cutaneous DM expert. The generalizability of this study may therefore be limited. However, the anticipated primary use of the CDASI is in clinical trials, and given that these are often conducted at major referral centers similar to the lead

institution, the physician population expected to use the CDASI may resemble that of the physician participants in the present study. Furthermore, it is important to note that none of the physician participants in this study, save the senior author, routinely evaluate cutaneous manifestations of DM. This suggests that individuals who do not regularly evaluate cutaneous DM are capable of using the CDASI effectively, broadening the generalizability of the CDASI.

In conclusion, the CDASI activity and damage scores were found to demonstrate good to excellent inter- and intra-rater reliability among dermatologists and rheumatologists and moderate to excellent inter- and intra-reliability among neurologists. The CDASI showed good convergent validity with global skin activity and damage scores, and completion times were comparable and short across all specialties. These findings are consistent with previous studies that show that the CDASI is a reliable and valid outcome instrument to assess cutaneous manifestations of DM.

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What's already known about this topic?

- The CDASI is a reliable and valid outcome measure to assess cutaneous disease in adult dermatomyositis (DM) when used by dermatologists

What does this study add?

- The study expands the application of the CDASI in adult DM patients to use by rheumatologists
- The study suggests that neurologists are also capable of using the CDASI to assess skin in adult DM patients with neurologists achieving moderate inter-rater reliability

Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) ver02

Select the score in each anatomical location that describes the most severely affected dermatomyositis-associated skin lesion

E x t e n t	activity			damage		Anatomical Location	
	Anatomical Location	Erythema	Scale	Erosion/ Ulceration	Poikiloderma (Dyspigmentation or Telangiectasia)		Calcinosis
		0-absent 1-pink; faint erythema 2-red 3-dark red	0-absent 1-scale 2-crust; lichenification	0-absent 1-present	0-absent 1-present	0-absent 1-present	
	Scalp						Scalp
	Malar Area						Malar Area
	Periorbital						Periorbital
	Rest of the face						Rest of the face
	V-area neck (frontal)						V-area neck (frontal)
	Posterior Neck						Posterior Neck
	Upper Back & Shoulders						Upper Back & Shoulders
	Rest of Back & Buttocks						Rest of Back & Buttocks
	Abdomen						Abdomen
	Lateral Upper Thigh						Lateral Upper Thigh
	Rest of Leg & Feet						Rest of Leg & Feet
	Arm						Arm
	Mechanic's Hand						Mechanic's Hand
	Dorsum of Hands (not over joints)						Dorsum of Hands (not over joints)
	Gotttron's – Not on Hands						Gotttron's – Not on Hands

Gotttron's – Hands		Ulceration	Examine patient's hands and score if damage is present	
Examine patient's hands and double score if papules are present			Examine patient's hands and score if damage is present	
0-absent 1-pink; faint erythema 2-red erythema 3-dark red			0-absent 1-dyspigmentation 2-scarring	

Periungual	
Periungual changes (examine)	
0-absent 1-pink; red erythema/microscopic telangiectasias 2-visible telangiectasias	

Alopecia	
Recent Hair loss (within last 30 days as reported by patient)	
0-absent 1-present	

(For the activity score, please add up the scores of the left side, i.e. Erythema, Scale, Excoriation, Ulceration, Gotttron's, Periungual, Alopecia)	Total Activity Score	(For the damage score, add up the scores of the right side, i.e. Poikiloderma, Calcinosis)	Total Damage Score

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Figure 1.

The CDASI is a one-page outcome measure used to assess skin disease in DM patients. Two separate scores based on activity (erythema, scale, ulceration/erosion) and damage (poikiloderma and calcinosis) are given, and scores range from 0–100 for activity and from 0–32 for damage.

PHYSICIAN GLOBAL ACTIVITY ASSESSMENTS

1. **Global SKIN** disease assessment by drawing a vertical mark on the 10-cm line according to the following scale:

No evidence of Disease Moderate Disease Extremely active or severe disease

Global SKIN disease on a 5-point Likert scale:

☐ 0 = none

☐ 1 = mild

☐ 2 = moderate

☐ 3 = severe

☐ 4 = extremely severe

Compared to last visit, **Global SKIN** is:

☐ Improved

☐ No change

☐ Worse

☐ N/A (1st visit)

2. **SKIN** disease **activity** assessment by drawing a vertical mark on the 10-cm line according to the following scale:

No evidence of Disease activity Moderate Disease activity Extremely active or severe disease activity

SKIN disease **activity** on a 5-point Likert scale:

☐ 0 = none

☐ 1 = mild activity

☐ 2 = moderate activity

☐ 3 = severe activity

☐ 4 = extremely severe activity

Compared to last visit, **SKIN activity** is:

☐ Improved

☐ No change

☐ Worse

☐ N/A (1st visit)

3. **SKIN** disease **damage** assessment by drawing a vertical mark on the 10-cm line according to the following scale:

No evidence of Disease damage Moderate Disease damage Extremely active or severe disease damage

SKIN disease **damage** on a 5-point Likert scale:

☐ 0 = none

☐ 1 = mild damage

☐ 2 = moderate damage

☐ 3 = severe damage

☐ 4 = extremely severe damage

Compared to last visit **SKIN damage** is:

☐ Improved

☐ No change

☐ Worse

☐ N/A (1st visit)

Figure 2.

The PGA is an overall rating of disease severity and is completed on a 10-cm linear visual analog scale ranging from 0 (no evidence of disease) to 10 (extremely severe disease).

Table 1

Characteristics of the DM patient study population

Number of DM patients	15
Race, n (%)	
White/Caucasian	12 (80.0%)
African American	2 (13.3%)
Asian	1 (6.7%)
Hispanic/Latino	1 (6.7%)
Female sex, n (%)	10 (66.7%)
Age in years at study entry, mean (S.D.)	56.4 (16.0)
DM duration in years, median (IQR)	4.5, 2.6, 7.2
DM subtype, n (%)	
Classic	11 (73.3%)
Amyopathic	4 (26.7%)

Abbreviations: DM: dermatomyositis, S.D.: standard deviation, IQR: interquartile range

Table 2

Skin assessment scores in DM patients among specialties

	Dermatologists (n=5)		Rheumatologists (n=5)		Neurologists (n=5)		Overall	
	Mean (s.d.)		Mean (s.d.)	p-value*	Mean (s.d.)	p-value*	Mean (s.d.)	Range
CDASI								
Activity	21.0 (9.5)		21.8 (7.8)	0.411	20.8 (8.7)	0.792	21.2 (8.7)	4–38
Damage	5.3 (4.7)		7.0 (5.7)	<0.001	4.8 (5.1)	0.253	5.7 (5.2)	0–23
PGA								
Activity	3.8 (2.2)		4.1 (2.0)	0.393	4.1 (2.3)	0.301	4.0 (2.2)	0.1–8.2
Damage	2.6 (2.6)		2.9 (2.6)	0.237	2.1 (2.6)	0.051	2.5 (2.6)	0.0–9.4

* Mean values by t-tests compared with dermatologists

Abbreviations: CDASI: Cutaneous Dermatomyositis Disease Area and Severity Index; PGA: Physician Global Assessment

Summary: Dermatologists were the reference standard. There was no difference between dermatologists and neurologists in the CDASI and skin PGA scores, and there was a significant difference between dermatologists and rheumatologists only in the CDASI damage scores; otherwise, scores were no different between dermatologists and rheumatologists.

Table 3

Inter-rater reliability of skin assessment tools among specialists *

	Dermatologists (n=5)	Rheumatologists (n=5)	Neurologists (n=5)
CDASI			
Activity	0.73 (0.55–0.90)	0.74 (0.58–0.91)	0.56 (0.33–0.79)
Damage	0.86 (0.76–0.96)	0.82 (0.69–0.94)	0.84 (0.73–0.95)
PGA			
Activity	0.61 (0.40–0.83)	0.69 (0.50–0.88)	0.44 (0.19–0.68)
Damage	0.58 (0.46–0.81)	0.75 (0.60–0.91)	0.85 (0.75–0.96)

* Intra-class correlation coefficients (95% C.I.)

Abbreviations: CDASI: Cutaneous Dermatomyositis Disease Area and Severity Index; PGA: Physician Global Assessment

Summary: The inter-rater agreement was good to excellent for dermatologists and rheumatologists in the CDASI activity and damage scores, whereas the inter-rater agreement for neurologists was moderate for CDASI activity and excellent for CDASI damage scores.

Table 4

Intra-rater reliability of skin assessment tools amongst specialists *

	Dermatologists (n=5)	Rheumatologists (n=5)	Neurologists (n=5)
CDASI			
Activity	0.94 (0.88–1.00)	0.88 (0.76–0.99)	0.82 (0.65–0.99)
Damage	0.92 (0.83–1.00)	0.91 (0.82–1.00)	0.66 (0.37–0.95)
PGA			
Activity	0.89 (0.79–1.00)	0.75 (0.53–0.97)	0.74 (0.51–0.97)
Damage	0.91 (0.82–1.00)	0.75 (0.53–0.97)	0.39 (0.00–0.82)

* Intra-class correlation coefficients (95% C.I.)

Abbreviations: CDASI: Cutaneous Dermatomyositis Disease Area and Severity Index; PGA: Physician Global Assessment

Summary: The intra-rater agreement was excellent for dermatologists and rheumatologists in the CDASI activity and damage scores, whereas the inter-rater agreement for neurologists was moderate to excellent for the same measure.