

## CLINICAL REPORT

# Usefulness of Rajka & Langeland Eczema Severity Score in Clinical Practice

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**Simple, validated eczema severity scores are required for the evaluation of interventions. The Rajka & Langeland (R&L) scale is based on 3 domains (extent, course, and intensity); however, its validity is not yet confirmed. The aim of this study was to investigate the quality aspects of the R&L scale in clinical practice. In the first part of the study, experts and consumers judged the content validity of the scale. The second part of the study was performed with 87 children during a 4-month eczema school. Construct validity, internal consistency, sensitivity to change, time consumption and health-related quality of life variables were investigated. The content of the R&L scale was considered valid by 45 panellists. Inter- and intra-observer reliability was very good. Divergent construct validity was adequate, while convergent construct validity and internal consistency were inadequate. The R&L scale was able to define a significant improvement in eczema during the eczema school. The time required for completing the R&L assessment was significantly shorter than for objective Scoring of Atopic Dermatitis (SCORAD). The R&L scale is a simple, fast, valid, reliable and sensitive tool for scoring of atopic dermatitis in everyday clinical practice. *Key words: eczema school; measurement; quality of life; objective SCORAD.***

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Atopic dermatitis (AD), or eczema according to the World Allergy Organization (1), is a chronic inflammatory skin disease that affects at least one-third of Scandinavian children (2, 3). The burdens of childhood AD are many and can interfere with the child's and family's life, with substantial effects on the patients' health-related quality of life (HRQoL) (4, 5). Various forms of eczema school have been shown to improve eczema and HRQoL (6–9).

For those patients referred to eczema schools or participating in controlled clinical trials there is a need to monitor their eczema severity. A systematic review of outcome measurement scales in AD showed that 3

outcome measurement scales performed adequately (10). These scales are the Scoring of Atopic Dermatitis (SCORAD) (11), the Eczema Area and Severity Index (EASI) (12) and the Patient-Oriented Eczema Measure (POEM) (13). Recently an international group of researchers has collaborated to agree on outcome measures for use in all clinical trials of AD (14). The major areas covered are signs, symptoms, long-term control and quality of life in patients with AD.

The Rajka & Langeland (R&L) eczema severity score was constructed to enable a simple assessment of AD severity as well as the classification of AD into mild, moderate or severe at a single clinical visit (15). The score is based on the grading of: (i) eczema extent according to the rule of 9, (ii) eczema course based on the number of months with eczema during the previous year, and (iii) eczema intensity expressed in terms of nocturnal sleeplessness due to itch. However, the R&L scale has not yet been thoroughly evaluated (10).

The aim of the present study was to investigate various quality aspects of the R&L eczema severity score, including its usefulness in everyday clinical practice.

## MATERIALS AND METHODS

### General concept

The complete Materials and Methods are set out in Appendix S1<sup>1</sup> and the structure of the study is summarized in Fig. S1<sup>1</sup>. The aims of first part of the study (pre-eczema school studies) were to ensure that the R&L domains were perceived as adequate by experts and consumers, and to train and evaluate participating nurses. In the second part (eczema school studies) the R&L scale performance was evaluated by using it on children in our regular eczema school. The objective SCORAD was used as gold standard (16). The study was performed in parallel at 2 departments of dermatology. The study was approved by the Regional Ethical Review Board in Lund (number 2012/417). Informed consent was obtained from all participants.

### Pre-eczema school studies

To investigate whether the R&L scale covers adequate domains, i.e. content validity, a questionnaire with 15 different items of eczema was distributed to 45 persons; senior dermatologists,

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dermatology nurses, adults and children with eczema and parents of children with eczema (Table S1<sup>1</sup>). Inter-observer reliability was investigated on 7 children with AD. The intra-observer reliability was studied using a test–retest procedure. Intra-class correlation (ICC) was computed as a measure of inter- and intra-observer reliability.

#### Eczema school studies

The second part of the current study was performed in 87 children during a 4-month eczema school. Construct validity, internal consistency, sensitivity to change, time consumption and HRQoL variables were investigated.

#### Statistical analysis

Prior to the study a power calculation (with statistical power 0.9, significance level 0.05, standard deviation (SD) 1.6, and clinical relevant decrease in R&L score 0.8) showed that 85 patients were required in the eczema school study. The statistical methods for the different quality items are presented next to the description of each variable (see Appendix S1<sup>1</sup>). ICC was computed using analysis of variance (ANOVA) (18). The changes in HRQoL scores between 0 and 4 months were analysed with paired *t*-tests. *p*-values <0.05 were considered statistically significant. Stata 12 (StataCorp LP, College Station, TX, USA) statistical software was used.

## RESULTS

#### Pre-eczema school studies

**Content validity.** Of the 15 items, all but one (skin odour) were considered as important or very important by the panellists (Fig. 1). There was no significant difference between consumers and professionals. The 5 items ranked as most important by consumers were itch intensity, eczema extent, skin pain, skin dryness and eczema localization. The 5 items ranked as most important by professionals were itch intensity, eczema extent, eczema oozing, skin erythema and eczema localization. Thus, the panellists ranked 2 of the R&L domains as the most important items; namely itch intensity and eczema extent. The third domain, eczema course, was considered important and ranked as number 6.

**Inter- and intra-observer reliability.** The inter-observer (ICC 0.86) and the intra-observer (median ICC 0.97, range 0.89–0.98) reliability were very good for R&L.

#### Eczema school studies

**Construct validity.** The correlation coefficient between extent and course was 0.12, between extent and intensity 0.35, and between course and intensity 0.15. Thus, divergent construct validity was adequate, while convergent construct validity was inadequate.

**Internal consistency.** Cronbach's alpha was 0.40 when all R&L ratings were included (*n*=261). Thus, the different domains of the scale, i.e. extent, course and intensity, were not interrelated.

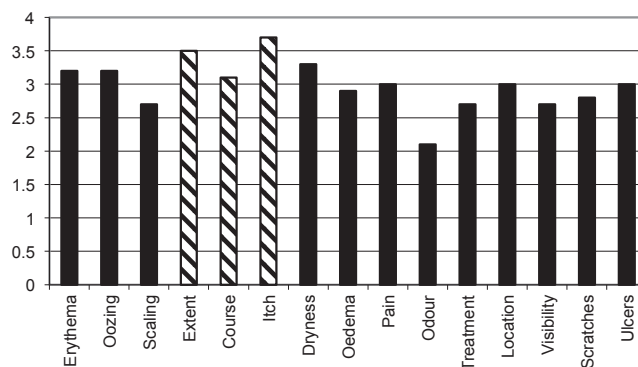


Fig. 1. Panellists' ranking of the importance of different eczema score items (See App. S1 for details). A median rating of "important" or "very important" was required to rate a domain or item as adequate for content validity. The Rajka & Langeland eczema score domains (hatched bars) fulfilled this. Solid bars are items not included in the score. 0=unimportant, 1=rather unimportant, 2=neither–nor, 3=important, 4=very important.

#### Sensitivity to change (including HRQoL)

At baseline the R&L mean score  $\pm$  SD was  $5.60 \pm 1.41$  and the mean objective SCORAD was  $17.51 \pm 8.44$  (*n*=87). The corresponding values at 4 months were  $4.55 \pm 0.92$  and  $9.93 \pm 6.62$ , respectively. The correlation coefficient between changes in R&L and objective SCORAD from 0 to 4 months was 0.39. There was a significant reduction for both scales from baseline to 4 months (*p*<0.00001, Fig. 2), i.e. the R&L scale was able to detect significant improvement in eczema during the eczema school. In addition, both HRQoL scale values (Infants' Dermatitis Quality of Life Index (IDQoL) and Children's Dermatology Life Quality Index (CDLQI)) were significantly improved from baseline to 4 months (IDQoL: *n*=40, baseline =  $8.15 \pm 5.48$ , 4 months =  $3.85 \pm 2.91$ , *p*<0.00001; CDLQI: *n*=47, baseline =  $7.38 \pm 4.53$ , 4 months =  $3.66 \pm 3.12$ , *p*<0.00001). The relationship between HRQoL and the eczema scores is shown in Fig. 3. The correlation coefficient between changes in HRQoL instruments and R&L 0–4 months was 0.38 for children aged 2–4 years and 0.58 for children aged 5–15 years. The corresponding values for objective SCORAD were 0.19 and 0.28, respectively.

#### Time consumption

The time required for completing the R&L assessment was significantly shorter than for SCORAD (R&L mean  $\pm$  SD =  $1.02 \pm 0.17$  min vs. SCORAD  $2.50 \pm 0.82$  min, *p*<0.001).

## DISCUSSION

The validation and standardization of outcome measures in clinical research are key issues. Few outcome measures of eczema perform adequately (10, 24). The R&L eczema severity score was introduced many years ago, but nevertheless it has not been validated previously.

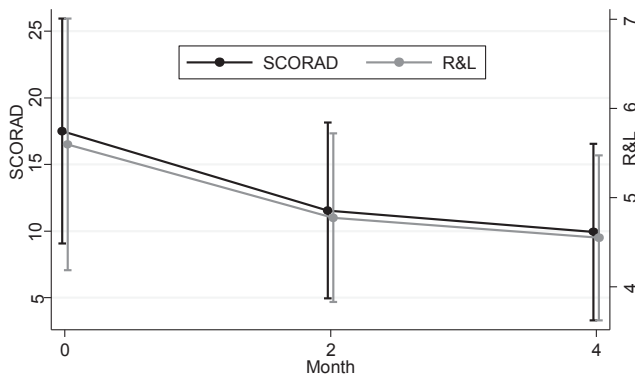


Fig. 2. Eczema severity score (mean  $\pm$  SD) assessed with objective SCORAD and Rajka & Langeland (R&L) from baseline to 4 months. There was significant reduction in eczema score for both scales ( $p < 0.00001$ ).

The present study showed that the R&L scale has adequate content validity, very good inter- and intra-observer reliability, and adequate divergent construct validity, sensitivity to change and time consumption. Concerning content validity, both experts and consumers ranked all 3 R&L domains as important or very important. The most important of all 15 items were itch intensity and eczema extent. Furthermore, there was no disagreement between the opinions of experts and consumers. With very good inter- and intra-observer reliability after prerequisite initial training, the scale can be used with reliable ratings in different settings and by different professionals. The divergent construct validity measures whether 2 outcome measurements that are presumed to measure different constructs are unrelated. As expected, the divergent construct validity was adequate (see below). The correlation coefficient between changes in the R&L and objective SCORAD scores from 0 to 4 months was only 0.39, which may be explained by the very few scale steps in the former compared with the latter. However, the R&L scale was sensitive enough to detect a highly significant and clinically relevant improvement in eczema score after

a 4-month period of eczema school in children aged 2–15 years. It also correlated with 2 HRQoL instruments (Fig. 3), further supporting its sensitivity. In everyday clinical practice, the time to administer the measurement is of greatest importance. A scoring duration of less than 3 min is adequate in everyday clinical practice (10). The R&L scale was very rapid in use and required only approximately 1 min, which is a major benefit compared with SCORAD, which requires almost 3 min. An advantage with SCORAD is, however, that it is available electronically, free of charge, in many languages. Taken together, all the above-mentioned variables fulfil the quality criteria for an adequate rating.

The convergent construct validity and internal consistency of the R&L scale were inadequate. The convergent construct validity describes whether 2 outcome measurements that are presumed to measure the same latent construct are related. The R&L scale has only 3 domains (extent, course, and intensity) and the correlation coefficients between these domains were at best 0.35, whereas an acceptable value should be at least 0.6 (10). However, we did not expect the domains to measure the same constructs, because the R&L scale mixes both signs and symptoms, which may not necessarily co-vary. For example, eczema can be very localized with a short duration, but still disturb sleep at night to a high degree. The same arguments are also valid for the low internal consistency.

We have identified some shortcomings of the R&L scale. It has rather few scale steps, ranging from 3 to 9. Thus the scale lacks a zero point, which means that a person in remission will still have a score of 3, making the interpretation of the value 3 difficult. The extent is based on the investigator's assessment of the affected body surface area in percent at the visit, i.e. it includes no retrospection. On the other hand, assessment of affected body surface area is a very difficult task (25). Assessment of the course and the intensity is made retrospectively by the consumer. For the course, the time period is the previous year, whereas the time period for the intensity is not clearly stated. Therefore patients with eczema duration less than 12 months cannot be rated appropriately. For this reason we excluded children younger than 2 years of age from our study. It is our impression that the time period for intensity rating was the last week or some weeks. To increase the precision of the scale we suggest a time period of 2 weeks for rating of the intensity.

Strengths of the study were the initial assessment training of the staff, the broad approach highlighting several aspects of the R&L scale, and the prospective design, where children were evaluated in the everyday clinical practice of eczema school. One limitation of the study was that no adults were included. Another limitation was that only 2 dermatology clinics in only one country participated, and that the number of nurses involved was limited.

HOME (Harmonizing Outcome Measures for Eczema) is an international, multiprofessional project also inclu-

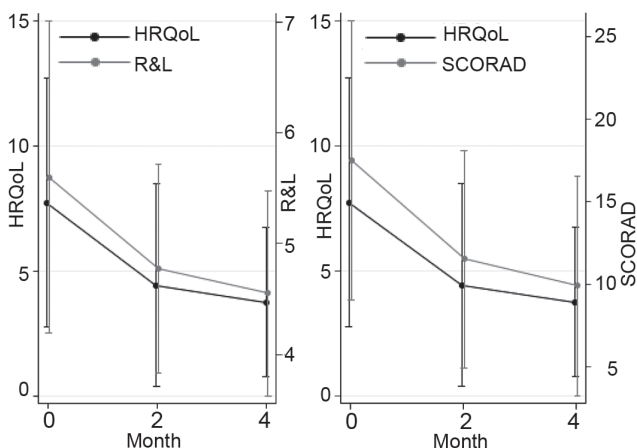


Fig. 3. Changes in health-related quality of life (HRQoL) and the 2 eczema scores Rajka & Langeland (R&L) and objective SCORAD (mean  $\pm$  SD) in 87 children participating in eczema school.

ding patients (26). Four prioritized research topics have been identified: signs, symptoms, long-term control and quality of life. For measurement of clinical signs in eczema trials, the preferred standardized core instrument is the Eczema Area and Severity Index (EASI) (27). However, in a systematic review of the best outcome measurements in eczema it was concluded that both SCORAD and EASI have been sufficiently tested and perform adequately (10). No recommendations have yet been made for symptoms, long-term control and quality of life (28). The R&L scale integrates 3 of the topics above; namely, signs (extent), symptoms (intensity) and long-term control (course), which may be a great advantage in a busy clinic.

In conclusion, the R&L scale is a simple, fast, valid and reliable tool, which is sensitive enough for scoring of eczema in everyday clinical practice, such as an eczema school for children.

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