

MS RACHEL DUNLAP (Orcid ID : 0000-0002-7079-581X)

DR AARON M DRUCKER (Orcid ID : 0000-0002-7388-9475)

Article type : Research Letter

**Initial validation of the Burden of Disease in Atopic Eczema instrument, a quality of life
measure for adult atopic dermatitis**

Short Title: BODE validation

Authors: A. R. Wang^{1*}, R. R. Dunlap^{1*}, M. A. Darwish³, E. L. Simpson², J. M. Hanifin²,

A. A. Qureshi¹, L. Du^{1,4}, A. M. Drucker^{1,5}

* equal contribution

¹Department of Dermatology, The Warren Alpert Medical School of Brown University, Providence,
RI 02903, USA;

²Department of Dermatology, Oregon Health and Science University, Portland, OR 97239, USA.

³No affiliation, Boston, MA, 02110, USA;

⁴Presbyterian Saint Lukes Medical Center, Denver, CO 80206, USA;

⁵Division of Dermatology, Department of Medicine University of Toronto and Division of
Dermatology, Department of Medicine and Women's College Research Institute, Women's College
Hospital, Toronto, Canada.

This article has been accepted for publication and undergone full peer review but has not
been through the copyediting, typesetting, pagination and proofreading process, which may
lead to differences between this version and the Version of Record. Please cite this article as
doi: 10.1111/bjd.16398

This article is protected by copyright. All rights reserved.

Corresponding author

Aaron Drucker, MD, ScM, FRCPC
6th Floor, Women's College Hospital
76 Grenville Street
Toronto, ON, Canada
M5S1B2 Phone: 416-323-7546
Fax: 416-323-6236 Email: aaron.drucker@wchospital.ca

Dear Editor,

The Harmonizing Outcome Measures for Eczema (HOME) initiative identified quality of life (QoL) as a core outcome domain that should be assessed in all atopic dermatitis (AD) trials.¹ However, based on a systematic review of the measurement properties of QoL instruments, HOME could not reach consensus on which QoL instrument should be recommended for adult AD.^{2,3} In response to the need for a valid QoL instrument, we developed the Burden of Disease in Atopic Eczema (BODE) instrument.

BODE was designed to address important aspects of QoL included in well-established generic QoL measures such as the SF-12, modified for patients with AD.⁴ The objectives of this study were to test item performance and internal and construct validity of BODE for the assessment of QoL in adult AD. BODE uses visual analogue scales (VAS) to measure patient-reported outcomes; a score from 0 (smallest effect) to 10 (largest effect) is derived for each question by measuring the distance from 0 along the line to the point where the patient marked, dividing that by the length of the line and multiplying by 10. BODE includes 10 items assessing physical comfort, social comfort, self-care, work, volunteer and home care, concentration, emotional health, intimacy and sleep.

A pilot version of BODE was administered to participants at two US tertiary care dermatology centres: Rhode Island Hospital, and Oregon Health and Science University (OHSU). Inclusion criteria were AD diagnosed by a board-certified dermatologist, age ≥ 18 and English-speaking. After providing informed consent, each participant completed the BODE and the Dermatology Life Quality

Index (DLQI) and Skindex-16, QoL assessments commonly used in AD trials.^{5,6} At OHSU, a dermatologist additionally performed two assessments of AD severity: an Investigator Global Assessment (IGA) and the Eczema Area and Severity Index (EASI).⁷

Sixty-six participants completed the survey, 29 males and 37 females, with a mean age of 43.2 years (SD 15.7). Median DLQI, SKINDEX-16, EASI and IGA scores are available from the authors.

We first performed exploratory factor analysis (EFA) to explore the underlying construct(s)/subdomain(scale)s/factor(s) of the BODE and to preliminarily refine the scale to include high performance items only. Confirmatory factor analysis (CFA) was then performed to validate the construct(s)/subscales, and to further refine the subscale to include high information items only. We adopted a strict item selection criterion so that only items with high information, i.e., factor loadings of greater than 0.6, will be retained in the final scale.

EFA results for BODE suggested the presence of two highly correlated ($r=0.80$) yet unique constructs/subdomains that best explain the observed item response patterns (total variance explained =70%). The two subdomains identified can be roughly categorized into “sense of well-being” and “functional independence.” CFA validated the two subdomains with all items showing statistically significant strong factor loadings on their respective subdomains (all loadings >0.6 , $P<0.001$; all data available by contacting the authors) indicating high information content. All 10 items met the selection criterion and were therefore retained.

To assess internal consistency, Cronbach's α was calculated for the subdomains of sense of well-being (0.91), functional independence (0.82), and the overall BODE (0.92), demonstrating excellent overall internal consistency and very good to excellent subscale internal consistency. Of the QoL assessments reviewed by Heintz et al. for HOME, only the QoLIAD had similar internal consistency.⁸

We hypothesized that BODE would correlate strongly with DLQI and Skindex-16 and moderately with IGA and EASI. Correlation analyses show that BODE scores are strongly correlated with DLQI (Pearson's correlation coefficient $r = 0.76$, $p < 0.001$) and Skindex-16 ($r = 0.84$, $p < 0.001$). Correlations were significant but not as strong with measures of severity of signs of AD (IGA: $r = 0.40$, $p = 0.005$; EASI: $r = 0.45$, $p = 0.001$).

The limitations of this study include a small sample size; replication in larger samples and more heterogeneous populations is needed. Development of the instrument would have been strengthened by initial qualitative interviews with patients; nevertheless, the BODE has face validity as its items assess requisite components of AD-related QoL identified at the HOME IV meeting, which included patient representatives.² Other gaps remaining in the validation of BODE include test-retest reliability, responsiveness and interpretability.

Our initial validation of the BODE (re-formatted to fit on 1 double-sided paper and emphasizing the term "current" eczema, **Figure 1**) with regard to construct validity, internal consistency and item information is promising. No currently available QoL instrument for AD shows strength in all three of these categories.³ Pending further validation, BODE may address the clinical and scientific community's need for a valid QoL measure.

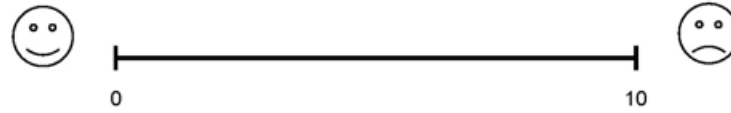
REFERENCES

- 1 Schmitt J, Williams H, Group HD. Harmonising Outcome Measures for Eczema (HOME). Report from the First International Consensus Meeting (HOME 1), 24 July 2010, Munich, Germany. *Br J Dermatol* 2010; **163**: 1166-8.
- 2 Chalmers JR, Simpson E, Apfelbacher CJ *et al.* Report from the fourth international consensus meeting to harmonize core outcome measures for atopic eczema/dermatitis clinical trials (HOME initiative). *Br J Dermatol* 2016; **175**: 69-79.
- 3 Heintz D, Prinsen CA, Deckert S *et al.* Measurement properties of adult quality-of-life measurement instruments for eczema: a systematic review. *Allergy* 2016; **71**: 358-70.
- 4 Gandek B, Ware JE, Aaronson NK *et al.* Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. International Quality of Life Assessment. *J Clin Epidemiol* 1998; **51**: 1171-8.
- 5 Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. *Clin Exp Dermatol* 1994; **19**: 210-6.
- 6 Chren MM, Lasek RJ, Quinn LM *et al.* Skindex, a quality-of-life measure for patients with skin disease: reliability, validity, and responsiveness. *J Invest Dermatol* 1996; **107**: 707-13.
- 7 Hanifin JM, Thurston M, Omoto M *et al.* The eczema area and severity index (EASI): assessment of reliability in atopic dermatitis. EASI Evaluator Group. *Exp Dermatol* 2001; **10**: 11-8.
- 8 Heintz D, Prinsen CAC, Sach T *et al.* Measurement properties of quality-of-life measurement instruments for infants, children and adolescents with eczema: a systematic review. *Br J Dermatol* 2017; **176**: 878-89.

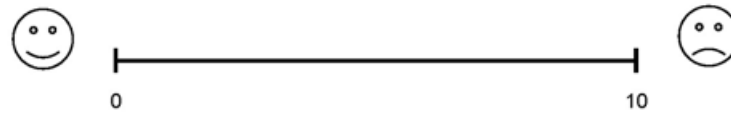
Figure 1. BODE instrument.

Burden of Disease in Atopic Eczema (BODE) tool

1. Think about your current overall health. On the scale below from 0 to 10, where 0 means the best health and 10 is the worst health you can imagine to have or death, please mark where you would rate your overall health today?

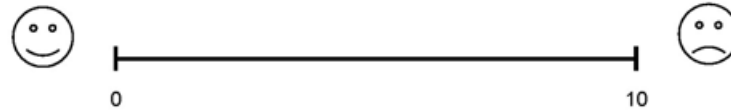


2. Think **ONLY** about your **CURRENT ECZEMA**. On a 0 to 10 scale, where 0 means no eczema at all and 10 means the worst eczema imaginable, please mark where you would rate your current eczema?

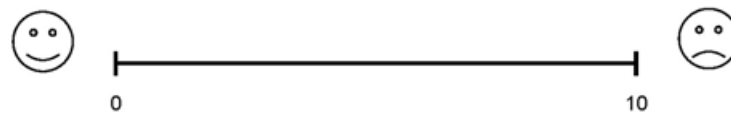


For the following questions, think **ONLY** about your **CURRENT ECZEMA**. We are going to ask you about how eczema affects different aspects of your life on a scale from 0 to 10, where **0 = eczema has the least effect**, **10 = eczema has the worst effect**.

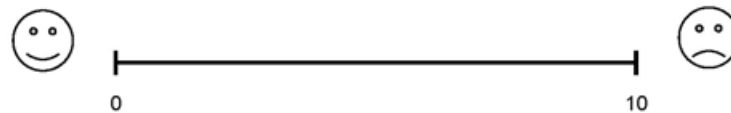
3. **Physical Comfort:** Think about your ability to be physically comfortable. This includes your ability to move around, participate in physical activity, or simply sit and be comfortable. On the scale below from 0 to 10, please mark where you would rate how *eczema* affects your ability to be physically comfortable.



4. **Social Comfort:** Think about being in a social setting – how comfortable do you feel around others with your current eczema? On the scale below from 0 to 10, please mark where you would rate how much *eczema* affects your ability to be socially comfortable.

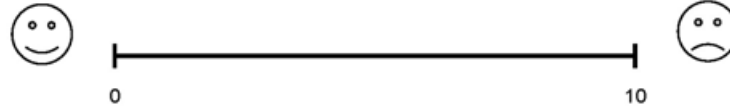


5. **Self-Care:** Think about your ability to care for yourself. This includes bathing, grooming, or shopping. On the scale below from 0 to 10, please mark where you would rate how much *eczema* affects your ability to care for yourself.

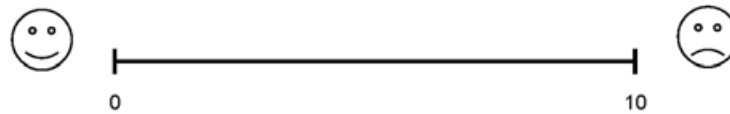


Burden of Disease in Atopic Eczema (BODE) tool

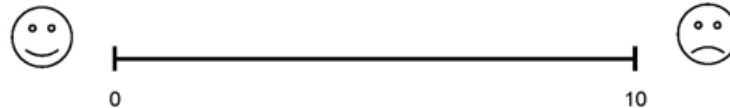
6. **Work, volunteer, home care:** Think about your ability to work, volunteer or take care of your home (for example: gardening, house cleaning). On the scale below from 0 to 10, please mark where you would rate how much *eczema* affects your ability to work, volunteer or care for your home.



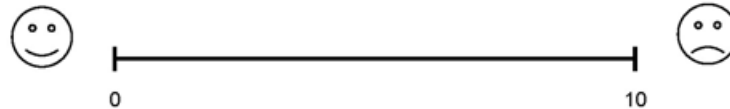
7. **Concentration:** Think about your ability to concentrate. Are you able to focus on a project, read a book or watch TV? On the scale below from 0 to 10, please mark where you would rate how much *eczema* affects your ability to concentrate.



8. **Emotional Health:** Think about your emotional health. How is your mood on a day-to-day basis? Do you feel sad, depressed, moody, angry or generally happy? On the scale below from 0 to 10, please mark where you would rate how much *eczema* affects your emotional health.



9. **Intimacy:** Think about your level of intimacy (closeness) with someone special. On the scale below from 0 to 10, please mark where you would rate how much *eczema* affects your ability to be intimate with someone close to you.



10. **Sleep:** Think about your ability to sleep. This includes your ability to fall asleep and stay asleep. Does your *eczema* cause you to wake up in the middle of the night? On the scale below from 0 to 10, please mark where you would rate how *eczema* affects your ability to sleep.

