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# Recent trends in disease severity and quality of life instruments for patients with atopic dermatitis: A systematic review



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**Background:** A significant number of instruments exist that are aimed at quantifying atopic dermatitis (AD) outcomes.

**Objective:** We sought to assess recent trends in the use of disease severity and quality of life (QOL) outcome instruments in randomized controlled trials (RCTs) conducted on patients with AD between July 2010 and July 2015.

**Methods:** A total of 540 nonduplicate records were identified through searches of Scopus and Ovid MEDLINE. Included studies were RCTs conducted on humans with AD that were published in English between July 2010 and July 2015 and that reported the results of disease severity or QOL outcome measures.

**Results:** All of the 135 included studies assessed disease severity. Only 45 studies assessed QOL. Sixty-two disease severity measures and 28 QOL scales were identified.

**Limitations:** This study was limited by its timeframe of 5 years and by the exclusion of non-RCTs and gray literature.

**Conclusion:** Disease severity and QOL outcome measures are instrumental in evaluating AD treatment efficacy. The number of such tools used in RCTs on patients with AD continues to rise. Standardization of outcomes instruments is essential for comparability among studies and improved quality of evidence. (J Am Acad Dermatol 2016;75:906-17.)

## INTRODUCTION

Atopic dermatitis (AD; also known as atopic eczema or eczema) is a chronic inflammatory, pruritic skin disease with significant quality of life (QOL) consequences for both patients and families.<sup>1-3</sup> Affecting  $\leq 30\%$  of children and 10% of adults,<sup>4</sup> AD presents a major global public health concern of increasing magnitude.<sup>5,6</sup> Recent advances in

understanding the molecular phenotype of AD have opened the door to potential new treatment avenues,<sup>7</sup> making the use of reliable outcomes measures in AD therapeutic trials more important than ever.

A plethora of instruments aimed at quantifying AD outcomes exist. Given the often concurrent physiologic and psychological burdens of AD,<sup>1-3</sup> both disease severity and QOL measures are fundamental to

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patient evaluation and care. A systematic review by Rehal and Armstrong<sup>8</sup> identified a total of 20 disease severity scales and 14 QOL indices used in 382 randomized controlled trials (RCTs) of AD treatment between 1985 and July 2010. The most frequently used disease severity scale was the Scoring Atopic Dermatitis (SCORAD) index,<sup>9</sup> followed in frequency of use by the Eczema Area and Severity Index (EASI),<sup>10</sup> both of which increased in use between 2005 and 2010. While only 67 RCTs reported QOL outcomes, the use of such instruments expanded over the time period studied, possibly indicating an increased recognition of the need to account for QOL when evaluating patient welfare. To our knowledge, there has been no systematic review describing trends in outcomes measures of AD trials published since July 2010.

The purpose of this study was to assess by systematic review recent trends in disease severity and QOL outcome instruments used in RCTs on patients with AD that were conducted between July 2010 and July 2015. Specifically, we sought to establish the following: 1) the proportion of reviewed studies using disease severity or QOL outcome measures; 2) the total number and frequency of use of disease severity scales; and 3) the total number and frequency of QOL instruments used.

### Search strategy and criteria

Comprehensive searches of the literature were conducted by two authors (MKH and AKP) using the Scopus, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, and Ovid MEDLINE bibliographic databases for the period of January 1, 2010 through July 31, 2015. Searches used combinations of the key terms “atopic dermatitis,” “randomized controlled trial,” “quality of life,” and “severity of illness index” (Tables I and II). Two reviewers (MKH, AKP) independently assessed the eligibility of identified records. Included studies were human subject RCTs on AD published in English between July 1, 2010 and July 31, 2015 that reported the results of disease severity or QOL outcome measures. The search databases were filterable by time periods of years but not months (Tables I and II), and studies published between January 2010 and July 2010 were therefore manually excluded.

### Study selection

Six hundred forty-six records were identified (175 from Scopus and 471 from Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, and Ovid MEDLINE), of which 540 were non-duplicate records (Fig 1). Of the 405 studies excluded, 53 were published before July 2010, 195 were not RCTs, 58 did not investigate AD treatment, 39 were not human studies, 17 were not in English, and 43 did not report disease severity or QOL outcome measures. The remaining 135 RCTs<sup>12-146</sup> were included in the systematic review.

### RESULTS

All of the 135 included RCTs assessed disease severity. Sixty-seven (50%) included studies used >1 disease severity scale. Only 45 (33%) studies reported QOL

outcomes. Fifteen (11%) studies used >1 QOL measure. The proportion of published RCTs that assessed QOL peaked in 2012 (Fig 2).

Sixty-two disease severity scales were used in the 135 reviewed RCTs (Table III). The most frequently used disease severity scale was the SCORAD index,<sup>9</sup> which was used in 79 studies. The second most common disease severity instrument was the visual analogue scale (VAS) for pruritus (n = 30). These were closely followed by the Investigator's Global Assessment (IGA) tool (n = 29) and the EASI<sup>10</sup> (n = 28). There were no discernable trends in use of the top four disease severity scales by publication year. Forty-five of the identified disease severity scales were used in only 1 study.

From the 45 studies that assessed QOL, a total of 28 QOL measures were identified (Table IV). The most common QOL instrument, the Dermatology Life Quality Index (DLQI),<sup>147</sup> was used in 20 RCTs. The second most frequent measure, the Infants' Dermatology Quality of Life Index (IDQOL),<sup>148</sup> was used in only 8 RCTs. These were followed by the Children's Dermatology Life Quality Index<sup>149</sup> (CDLQI; n = 6) and the Dermatitis Family Impact (DFI) questionnaire<sup>150</sup> (n = 5). Twenty-one of the identified QOL instruments were used in only 1 study.

### DISCUSSION

Our systematic review identified a total of 62 disease severity scales from the 135 included studies. This is a drastic increase from the 20 disease severity

### CAPSULE SUMMARY

- Many available measures exist for quantifying atopic dermatitis outcomes.
- This systematic review identified 62 disease severity and 28 quality of life instruments used in randomized controlled trials on atopic dermatitis between July 2010 and July 2015.
- The increasing heterogeneity of reported outcomes hinders their comparability and translation to clinical practice.

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