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Investigator and Patient Global Assessment Measures for Psoriasis Clinical Trials: A Systematic Review on Measurement Properties from the International Dermatology Outcome Measures (IDEOM) Initiative

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- Lourdes M. Perez-Chada (1) View author's OrcID profile (View OrcID profile)
- Nicole F. Salame (2)
- Adam R. Ford (3)
- Kristina Callis Duffin (4)
- Amit Garg (5)
- Alice B. Gottlieb (6)
- John Latella (7)
- Joseph F. Merola (1) (8)
- April W. Armstrong (9) Email author (armstrongpublication@gmail.com)

1. Department of Dermatology, Brigham and Women's Hospital, , Boston, USA
2. Irvine School of Medicine, University of California, , Irvine, USA
3. Keck School of Medicine of the University of Southern California, , Los Angeles, USA
4. Department of Dermatology, University of Utah, , Salt Lake City, USA
5. Department of Dermatology, Hofstra Northwell School of Medicine, , New Hyde Park, USA
6. Department of Dermatology, Icahn School of Medicine at Mount Sinai, , New York, USA
7. International Dermatology Outcome Measures (IDEOM), , Windsor, USA
8. Department of Medicine, Division of Rheumatology, Brigham and Women's Hospital, , Boston, USA
9. Department of Dermatology, Keck School of Medicine of the University of Southern California, , Los Angeles, USA

Systematic Review
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Abstract

Background and Objective

The International Dermatology Outcome Measures (IDEOM) has defined a core set of domains to be measured in all psoriasis clinical trials. This set comprises the following domains: skin manifestations, psoriasis and psoriatic arthritis symptoms, health-related quality of life, investigator global, patient global, and treatment satisfaction. The next step is to define how to measure these domains. The objective of this article was to evaluate the quality of available instruments to assess 'investigator global' and 'patient global' domains to identify the most appropriate instruments.

Methods

Reviewers conducted a systematic literature review to retrieve studies on the measurement properties of instruments including either an investigator global assessment or a patient global assessment. Following the COnsensus based standards for the Selection of health Measurement INstruments (COSMIN) checklist, three independent reviewers rated the quality of each study. We then performed a qualitative synthesis of the evidence.

Results

We identified nine investigator global assessments and three patient global assessments, reflecting substantial variability in global assessment instruments. Overall, most measures lacked evidence for content validity and feasibility. The Lattice System-Physician Global Assessment, Product of the Investigator Global Assessment and Body Surface Area, and the professional-Simplified Psoriasis Index had higher levels of evidence for validity, reliability, and/or responsiveness than the 5- and 6-point investigator global assessments. The self-assessment-Simplified Psoriasis Index was the only patient global assessment with evidence for validity, reliability, and responsiveness.

Conclusions

The 5- and 6-point investigator global assessments, which are the most widely used investigator global assessments in registered clinical trials, have less evidence for measurement properties as compared with the Lattice System-Physician Global Assessment, professional-Simplified Psoriasis Index, and the Product of the Investigator Global Assessment and Body Surface Area. However, all instruments lack evidence for

content validity and feasibility. Further validation studies of investigator global assessments and patient global assessments are required to recommend the best global measure for psoriasis clinical trials.

L. M. Perez-Chada and N. F. Salame are co-primary authors.

Electronic supplementary material

The online version of this article (https://doi.org/10.1007/s40257-019-00496-w (https://doi.org/10.1007/s40257-019-00496-w)) contains supplementary material, which is available to authorized users.

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Notes

Compliance with Ethical Standards

Funding

International Dermatology Outcome Measures (IDEOM) funded the conduct of this study.

Conflict of interest

Dr. Garg is a consultant/advisor for Abbvie, Pfizer, UCB, and Asana Biosciences and received a grant from UCB. Dr. Gottlieb is an advisor/consultant for Janssen Inc., Celgene, Beiersdorf, BMS, Abbvie, UCB, Novartis, Incyte Corporation, Lilly, Reddy Labs, Valeant, Dermira, Allergan, Sun Pharmaceutical Industries, XBiotech, Leo, Avotres Therapeutics, and Boeringer Ingelheim. She received research/educational grants from Janssen, Incyte Corporation, XBiotech, Novartis, Boeringer Ingelheim, and UCB. In addition, she participated in the development of the National Psoriasis Foundation Psoriasis Score, an instrument discussed in the present study. John Latella is an advisor for Boehringer Ingelheim and Glaxo Smith Kline. Dr. Duffin serves as an advisory board/consultant/investigator for Amgen, Abbvie, Celgene, Novartis, Lilly, Pfizer, Stifle, Janssen, Ortho Dermatologic, and Boehringer Ingelheim. In addition, she has participated in validation studies of the IGA×BSA, an instrument discussed in the present study. Dr. Merola has served as a consultant/investigator/advisory board for Merck, AbbVie Eli Lilly, Incyte, Janssen, UCB, Almirall, Pfizer, Sun Pharma, Novartis, and Burrage Capital Mgmt. In addition, he received grants from Aclaris, Novartis, Leo, Celgene, and Dermavent. Dr. Armstrong serves as a consultant/advisor/investigator for Leo Pharma, Novartis, Delmira, UCB, Abbvie, Janssen, Eli Lilly, Regeneron and Sanofi,

Science 37, Modernizing Medicine, Merck, Parexel, Celgene, Ortho Dermatologics, and Pfizer. Drs. Perez-Chada, Salame, and Ford have no conflicts of interest that are directly relevant to the content of this article.

Supplementary material

40257_2019_496_MOESM1_ESM.pdf (632 kb)
Supplementary file1 (PDF 632 kb)

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