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Reliability, Validity, and Responsiveness to Change of the Patient Report of Extent of Psoriasis Involvement (PREPI) for Measuring Body Surface Area Affected by Psoriasis

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Abstract

Background—The development of a simple, reliable, valid, and responsive method for measuring the extent of skin involvement in psoriasis is important for use in epidemiologic studies.

Objectives—We sought to investigate the psychometric characteristics of the Patient Report of Extent of Psoriasis Involvement (PREPI), a single-question method for measuring body surface area affected by psoriasis.

Patients/Methods—This was a cross-sectional study of 140 psoriasis patients with an exploratory prospective longitudinal cohort component. Reliability was measured via a test-retest approach and criterion validity was investigated by comparing the patients' PREPI to an assessment of body surface area of involvement by a dermatologist. We additionally compared Skindex-29 scores to the PREPI. To demonstrate responsiveness and establish a minimally important difference in the PREPI, we created receiver operating characteristic curves for the PREPI instrument.

Results—The test-retest reliability of the PREPI was nearly perfect (ICC = 0.99, 95% CI: 0.97, 0.99), and there was substantial agreement between patient and physician assessments (ICC = 0.82, 95% CI: 0.75, 0.87). The PREPI showed significant correlations with all Skindex-29 domains. We found the PREPI to be responsive to change and identified changes in the PREPI score that have good discrimination between patients with and without a minimally important clinical difference.

Conclusion—Our study suggests that the PREPI is a reliable, valid, and responsive measure of body surface area affected by psoriasis that may be useful for future epidemiologic research.

Keywords

Psoriasis; body surface area; epidemiology; validity

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INTRODUCTION

Psoriasis is a common, chronic disease of the skin and joints that has been diagnosed in over 5 million US adults and may remain undiagnosed in at least 600,000 US adults.^{1–3} It is a heterogeneous disease in which the extent of skin involvement can vary widely between patients and within the same patient over time. Severe psoriasis has been associated with excess cardiovascular risk, all-cause mortality, and malignancy.^{4–8} A decreased health-related quality of life has been demonstrated even among those patients with limited disease.^{9–12}

The development of valid and reliable methods for measuring the extent of skin involvement in psoriasis is important for use in large-scale epidemiologic studies. The ideal method would be easy to use, quick (as even a single question added to a large population based survey can be cost-prohibitive), and responsive to change. As clinician assessment is often not economically or logistically feasible for this type of research, patient self-report would be useful as a means of classifying extent of skin involvement with psoriasis. However, to date, there have been no studies validating measures of self-reported psoriasis activity, other than the self-administered Psoriasis Area Severity Index (SAPASI), which can be time-consuming for both the patient and investigator and cannot be used in certain settings such as phone surveys.^{13–15}

The Patient Report of Extent of Psoriasis Involvement (PREPI) is a simple, single-question method in which patients are asked to use the palm of their hand to estimate the body surface area involved with psoriasis. It is a modified version of a question developed by the National Psoriasis Foundation in their population-based study entitled, “Benchmark Survey on Psoriasis and Psoriatic Arthritis.”¹⁶ This same question has additionally been used in the National Health and Nutrition Examination Survey (NHANES).¹⁷ This single question has been previously shown to correlate well with health-related quality of life and is predictive of the probability of having co-morbid psoriatic arthritis.^{18,19} Although these findings suggest that PREPI is useful as a research tool and is clinically meaningful, its psychometric properties have not been formally evaluated. Therefore, the purpose of this study was to investigate the reliability and validity of the PREPI. In addition, during an exploratory longitudinal portion of this study, we sought to assess the responsiveness of the PREPI instrument to changes in surface area of involvement and to estimate the minimum important difference in the PREPI that corresponds to a clinically significant change in psoriasis.

MATERIALS AND METHODS

Patient Population

Institutional Review Board approval was obtained and all patients gave informed consent to participate before any study procedures were performed. The study was conducted in accordance with the Declaration of Helsinki Principles. Participants in this study were patients presenting to the University of Pennsylvania’s Department of Dermatology who had a diagnosis of plaque psoriasis. The population from which we selected our study participants consisted mostly of individuals with health insurance coverage, such that 79.1 percent had commercial health insurance, 9.4 and 10.3 percent had Medicare and Medicaid, respectively, and 1.2 percent were self-pay. New patients and patients in active follow-up for psoriasis in the outpatient setting were included in the study population. Patients were eligible if they were age 18 or older. Patients were excluded if they were unable to provide informed consent.

Study Design

This was a cross-sectional study to evaluate the reliability and validity of the PREPI instrument. We also conducted an exploratory prospective cohort study to evaluate the responsiveness to change of the PREPI. Between October 2004 and October 2008, 140 patients were enrolled and all visits were completed by April 2009. Consecutive patients were enrolled during time periods in which a research coordinator was available. The first 37 consecutive patients were contacted by telephone 2–3 days prior to their scheduled appointment. After obtaining verbal consent from the patient, a trained interviewer administered the PREPI over the telephone. The remaining 103 patients were enrolled during an outpatient office visit. At the first outpatient visit (Visit 1), the PREPI was administered to all newly enrolled patients and re-administered to those patients who were enrolled earlier by telephone. A dermatologist blinded to the patient's response then assessed the patient using the PREPI instrument. Additionally, all patients completed the Skindex-29 questionnaire during the visit. After the first 64 patients, we added a longitudinal component to the study to assess responsiveness to change, during which patients were assessed at a second office visit (Visit 2) (n = 76). Similar to the first office visit, the PREPI was again administered to all patients and a dermatologist who was unaware of the patient's self-reported PREPI score. These patients also completed a Global Rating of Change (GRC) questionnaire (n = 72).

Scales and Measurements

The Patient Report of Extent of Psoriasis Involvement (PREPI) is a single question for measuring body surface area affected by psoriasis in which patients are asked, "If you had to take the palm of your hand and cover up all of the patches of psoriasis on your body today, how many palms of your hand do you think that it would take?" Patients were also given the additional instructions, "One palm of your hand is equal to about 1% of your body surface area (BSA). If your psoriasis is only scattered small dots, try to imagine combining them together into one patch," and "Please remember to include your scalp and back if affected. Do not include areas in which psoriasis has faded, leaving only changes in the color of the skin." The first 15 patients enrolled were asked to select one of the following categorized scores: 1 = Little to no psoriasis visible (<1 palm), 2 = Only a few patches, (1–2 palms), 3 = Scattered patches (3–10 palms), and 4 = Extensive psoriasis covering large areas of the body (>10 palms). These categories were defined based on a question from a population-based survey conducted by the National Psoriasis Foundation^{9,19}. We decided during the course of the study to allow patients to classify their psoriasis as a continuous variable, i.e., the number of palms, rather than as a categorized score. We believed that although previous large surveys, such as NHANES, have had patients self-report their BSA involvement with psoriasis using the aforementioned categories, that it might be more clinically meaningful for patients to report their affected BSA as just the number of palms. For example, if a psoriasis patient had disease involvement of 80% BSA, and another patient had involvement of 10% BSA, they would both have PREPI scores of 4. Alternatively, patients with BSA involvement of 9% and 10% would have PREPI scores of 3 and 4, respectively. Thus, the remaining patients enrolled were asked to report specifically the number of palms, which we then categorized for them. The PREPI score could range from 1 to 4 for the categorized score based on the above definitions and from 0 to 100 (with one palm being approximately equivalent to 1% BSA) for the patient-reported number of palms.

The Skindex-29 questionnaire is a previously validated measure of skin-related quality of life in psoriasis,²⁰ as well as other dermatological disorders.^{20–24} Patients completed the Skindex-29 on their first visit. The Skindex-29 includes 3 domains for emotions, symptoms, and functioning. For each domain, the responses are transformed to a linear scale of 100, varying from 0 (no effect) to 100 (effect experienced all the time). The sum score is the

average of the 3 domain scores.²⁵ During the second visit, patients were asked to complete the single-question Global Rating of Change (GRC) questionnaire, which asks the patient to rate the change in their psoriasis compared to their last visit to the dermatologist. Responses are on a 15 point scale from -7 (a very great deal worse) through 0 (no change) to +7 (a very great deal better).²⁶

Statistical Analysis

Test-Retest Reliability—Reliability estimates the degree to which a measurement is free from error.²⁷ We investigated the reliability of the PREPI by assessing the test-retest reliability for both the patient-reported number of palms and the categorized score. For an instrument to be reliable, measurements should not change significantly when the instrument is reapplied within a brief time period when no clinical change would be expected to occur. The agreement between the patient's two self-assessed PREPI measurements (administered over the telephone and during Visit 1) was calculated using the intra-class correlation coefficient (ICC). The ICC measures the amount of among-subject variability relative to the total within-plus among-subject variability. Values of the ICC range from -1 to +1, with 0 indicating random concordance.²⁸ Concordance can also be measured using a weighted Kappa statistic, which measures the agreement against that which may be expected by chance. The weighting penalizes large disagreements more than small ones. As the ICC is equivalent to quadratic-weighted Kappa, and has been noted to be the most appropriate approach to measuring concordance,^{27,29} only the calculated ICCs are presented. ICC values of 0.80–1.0, 0.60–0.80, and 0.40–0.60 are generally considered to indicate “almost perfect,” “substantial,” or “moderate” agreement, respectively.³⁰ A nonparametric bootstrap method was used to compute the ICC 95% confidence interval (CI).

Criterion Validity—Criterion validity compares an instrument to a well-established or “gold standard” measurement.³¹ We defined the standard of the extent of skin involvement by psoriasis as the dermatologist's assessment using the PREPI instrument. Similarly to the test-retest reliability analysis, we used the ICC to measure the agreement between the dermatologist and the patient. We also measured the agreement between the dermatologist and the patient at the second office visit.

Construct Validity—Construct validity determines how well an instrument measures a theoretical, abstract concept of what the instrument is intended to measure.³¹ We used the Skindex-29 as a measure of the construct validity of the PREPI in order to determine the degree to which PREPI captures information on health-related quality of life. The correlation of the PREPI at Visit 1 with the Skindex-29 domain-specific and composite scores was calculated using the Spearman Correlation coefficient. 95% CIs were calculated using Fisher's z-transformation. Additionally, median Skindex-29 scores were stratified by the PREPI categories and compared statistically using the Kruskal-Wallis test. We also performed a Wilcoxon-type test for trend across the PREPI categories for each of the Skindex-29 domains.

Responsiveness and the Minimum Important Difference (MID)—Responsiveness is the ability of an instrument to detect small but clinically meaningful changes.^{27,32} The MID can be defined as “the smallest difference in score in the domain of interest that patients perceive as important, either beneficial or harmful, and which would lead the clinician to consider a change in the patient's management.”³³ The most widely used analytic strategy to identify a MID is to use a single-anchor approach in which a range is specified on the anchor instrument that corresponds to the MID. This is then used to calculate a corresponding score on the target instrument. We used the Global Rating of Change (GRC) questionnaire as our single anchor, since it has been utilized to define the

MIDs for multiple quality of life instruments across various diseases.^{26,33–37} We sought to find a MID for the change in physician- and patient-reported number of palms and the percent change in number of palms, defined as:

$$\text{Change in \# of palms} = \# \text{ palms at Visit 1} - \# \text{ palms at Visit 2}$$

$$\text{Percent change in \# of palms} = ((\# \text{ of palms reported at Visit 1} - \# \text{ of palms reported at Visit 2}) / \# \text{ of palms reported at Visit 1}) * 100.$$

Our analysis was restricted to the patient- and physician-reported number of palms, as the calculation of an MID for the categorized PREPI would likely not be meaningful. We utilized nonparametric receiver operating characteristic (ROC) curves both to measure the responsiveness of the PREPI instrument and to establish an MID. An ROC curve is a graph of sensitivity (true-positive rate) plotted against one minus specificity (false-positive rate). Thus, the area under the ROC (AUC) describes how well changes in PREPI discriminate between patients with psoriasis that has changed or has not changed. An AUC of 1.0 is considered perfect, whereas an AUC of 0.5 is no better than chance, 0.7 is fair, 0.8 is good, and 0.9 is excellent.³⁸ We constructed ROC curves based on the association of changes in the PREPI score from visit 1 to visit 2 and the patients' judgments of whether change had occurred based on their responses on the Global Rating of Change questionnaire. Previous studies have defined change on the GRC as a score of ≥ 2 (a little better) or ≤ -2 (a little worse).^{35,37} We computed separate ROC curves for different directions of change, as differences may exist in how improvement or worsening is perceived. For the improvement analysis, the GRC was dichotomized by improvement vs. no improvement, with improvement defined as a global rating of ≥ 2 and no improvement defined as a global rating of < 2 . We compared the dichotomized GRC (improvement vs. no improvement) to the change in number of palms and the percent change in number of palms. The worsening analysis was done similarly, with worsening defined as a global rating of ≤ -2 and no worsening defined as a global rating of > -2 . We investigated the change in palms based on both the patient- and physician-assessed PREPI. AUC curves were reported with 95% CIs, computed using the methods of Hanley and McNeil.³⁹ For all assessments with an AUC of > 0.6 , we identified the MID by determining the optimal cut-point at which optimized correct classification. As only 58 of the 70 patients receiving the GRC questionnaire were seen at consecutive visits, we performed separate analyses including all patients and only those patients with consecutive visits.

Estimation of Sample Size—Sample size was determined based on the number of patients necessary to measure the criterion validity of the PREPI with a specified precision (confidence intervals of plus or minus 5%). Our sample size estimate of 140 patients was based on our *a priori* prediction that 90% of patients would correctly classify their extent of skin involvement with psoriasis compared to the dermatologists classification based on PREPI.

All statistical analyses were performed using STATA 10.1 (College Station, TX).

RESULTS

We enrolled 140 psoriasis patients seen during routine dermatologic care. Of 143 patients asked to participate in the study, 3 declined. The characteristics of the study participants are shown in Table 1. Baseline PREPI scores, physician assessment scores, and Skindex-29 domain-specific and composite scores are also presented. A broad range of age, race/ethnicity, and psoriasis severity (based on BSA affected) was represented in study population. The amount of time required to administer the PREPI instrument and instructions to each participant was approximately 2–3 minutes.

Test-Retest Reliability

We assessed the test-retest reliability of the PREPI for both the patient-reported number of palms and the categorized score. The median duration between the PREPI administered over the telephone and the first outpatient visit was 2 days (IQR: 1, 4). We measured the agreement between the PREPI administered by telephone and at the first outpatient visit using intra-class correlation coefficients (ICC) which demonstrated that the test-retest reliability of the PREPI was excellent for both patient-reported number of palms (ICC = 0.99, 95% CI: 0.97, 0.99; n = 22) and the categorized score (ICC = 0.98, 95% CI: 0.96, 0.99; n = 37).

Criterion Validity

Similar to the test-retest reliability analysis, we used ICCs to assess the concordance of the PREPI with a dermatologist's assessment using the PREPI instrument (Table 2). This method allowed us to determine the ability of the PREPI to predict how a dermatologist would classify the extent of psoriasis involvement. The agreement between the PREPI and the physician's assessment at Visit 1 was 0.82 (95% CI: 0.75, 0.87) for patient-reported number of palms and 0.80 (95% CI: 0.73, 0.85) for the categorized score. The agreement was also examined at Visit 2, although with a reduced sample size (n = 76). The agreement ICC at Visit 2 was 0.68 (95% CI 0.54, 0.79) and 0.71 (0.58, 0.80) for the patient-reported number of palms and the categorized score, respectively.

Construct Validity

The PREPI is intended to measure the extent of skin involvement with psoriasis. To determine how PREPI corresponds to a health-related quality of life construct we compared Skindex-29 domain-specific and total scores to the PREPI using Spearman correlation coefficients (see Table 3). For both the physician's and patient's assessments, the correlations were highest with the functioning scale and lowest, but still significant, for the symptoms scale. The correlation between the categorized PREPI and Skindex-29 scores was slightly lower in comparison to the patient-reported number of palms. The patient's self-assessed PREPI correlated more strongly than the physician's assessment with all quality of life measures.

Median Skindex-29 scores were stratified by PREPI categories and compared (see Table 4). This analysis was additionally done for physician's assessment using the PREPI instrument. The median scores on all quality of life scales increased with increasing PREPI scores and skin involvement as assessed by the physician. We found that each patient-reported PREPI category was statistically different when compared with respect to each Skindex-29 domain with the Kruskal-Wallis test (all p-values $p < 0.01$). Similar results were found for the physician's assessment. In addition, test for trends across the PREPI categories were significant for all Skindex-29 domain-specific scores, for both the patient's and physician's assessment (all p-values $p < 0.01$). Thus, more extensive disease on the PREPI was associated with lower skin-related quality of life.

Responsiveness and the Minimum Important Difference (MID)

Overall, the physician-reported change in number of palms and percent change in number of palms discriminated better than the corresponding patient-reported assessments for both the improvement and worsening analyses (see Table 5). Both the physician- and patient-reported assessments discriminated well between those who improved or did not improve and those who worsened or did not worsen.

We further investigated the best cut-points for these measures for the improvement and worsening analyses (for consecutive visits only). The selected cut-points along with their

corresponding sensitivities, specificities, positive and negative likelihood ratios, and correct classifications, are presented in Table 6. An improvement of 6 palms or a 54.6% improvement in the number of palms as assessed by the physician was the cut-point with the greatest correct classification for identifying a clinically significant improvement as reported by the patient on the Global Rating of Change. The corresponding cut-points for the patient's assessment were an improvement of 3.5 palms or an 83.33% improvement. A worsening of 2 palms or a 66.6% worsening in the number of palms as assessed by the physician was the cut-point for identifying a clinically significant degree of worsening. The cut-points for the patient's assessment of worsening were nearly identical.

DISCUSSION

The results of this study suggest that a single-question instrument called the "PREPI" is a psychometrically sound tool for assessing body surface area affected by psoriasis. Test-retest reliability demonstrated that there is minimal error in using the PREPI at two points in time when the extent of psoriasis is not expected to change significantly. Comparison of the patient's assessment of body surface area involved with psoriasis was strongly correlated with the standard (i.e. a dermatologist's assessment) demonstrating that the instrument validly measures what it intends to measure. The PREPI is correlated with health-related quality of life domains indicating its clinical significance.

We also determined that the PREPI is sensitive to clinical change in psoriasis and we have identified changes in the PREPI that correlate with a minimally important clinical difference. Interestingly, we observed that a 54% improvement in the physician's reported change in number of palms is predictive of a minimally important clinical difference as reported by the patient, which is consistent with the suggestion that a 50% reduction in PASI score is a clinically meaningful endpoint.⁴⁰ We determined the MID for the PREPI instrument based on the cut-points that yielded the highest percentage correct classification for each assessment. Alternatively, cut-points could be created that optimize sensitivity or specificity depending on the goals of the investigation.

The results of this study suggest that the PREPI may be a valuable tool for easily, inexpensively, and accurately assessing the body surface area affected by psoriasis in population-based research. Questions similar to the PREPI have been used extensively in psoriasis epidemiological studies performed by the National Psoriasis Foundation and the Centers for Disease Control. Our data confirm the validity of the findings of these studies as they relate to patient report of skin involvement with psoriasis. This study advances the current literature in that, to our knowledge, only one other instrument that uses patient self-report to assess psoriasis activity has been evaluated psychometrically (the SAPASI).^{13,15,41} The SAPASI involves subjects rating the color, induration, and scaliness of their psoriasis on a visual analog scale. In addition, subjects must shade in a diagram of the body to estimate the total involved BSA. This diagram then has to be interpreted and scored by a clinical investigator. The PREPI offers a few important advantages over the SAPASI. The results of this study suggest that PREPI has superior agreement with the physician assessment of BSA and a stronger correlation with skin-related quality of life compared to the SAPASI.^{13,23} In addition, as the PREPI is a simple, single-question instrument that does not have to be interpreted by an investigator, it involves significantly lower patient and administrative burden than does the SAPASI, making it more efficient and simpler to use in a variety of settings.

As with all studies, there are important limitations to consider. First, this study involved patients seen by a single dermatologist at one academic medical center and did not include complete information on the socioeconomic status (e.g. education and income level) of the

participants. Therefore, additional studies in a variety of settings such as general dermatology, general practice, and the general population ideally should be conducted to ensure the generalizability of these results to other populations. Second, the PREPI is a single question that assesses the involved body surface area and therefore it does not fully capture all objective and subjective aspects of psoriasis that may be important to measure. Additionally, as we changed the PREPI score from a categorical to continuous variable during the course of the study, it is possible that we may have overestimated some of the test characteristics of the PREPI. However, this is unlikely as the results for the categorical and continuous variable analyses were very similar. Finally, the standard we used to assess the criterion validity of the PREPI (i.e. the physician's assessment of involved BSA using the PREPI instrument) was an imperfect measure of actual BSA. However, as the PASI score relies on imprecise estimates of BSA, this standard is one which is widely accepted.^{42,43}

In conclusion, the PREPI is a simple, reliable, valid measure of body surface area affected by psoriasis that is clinically meaningful and responsive to change. Because of its promising psychometric qualities and its simplicity, the PREPI is a useful measure of the extent of skin involvement with psoriasis for studies in which physician assessment may not be feasible or is cost-prohibitive, such as large simple trials and epidemiological studies.

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References

1. Gelfand JM, Weinstein R, Porter SB, et al. Prevalence and Treatment of Psoriasis in the United Kingdom: A Population-Based Study. *Arch Dermatol*. 2005; 141:1537–41. [PubMed: 16365254]
2. Kurd SK, Richardson SK, Gelfand JM. Update on the epidemiology and systemic treatment of psoriasis. *Expert Rev Clin Immunol*. 2007; 3:171–85. [PubMed: 20477106]
3. Neimann AN, Porter S, Gelfand JM. Epidemiology of Psoriasis. *Expert Review of Dermatology*. 2006; 1:63–75.
4. Gelfand JM, Shin DB, Neimann AL, Wang X, Margolis DJ, Troxel AB. The Risk of Lymphoma in Patients with Psoriasis. *J Invest Dermatol*. 2006; 126:2194–201. [PubMed: 16741509]
5. Gelfand JM, Neimann AL, Shin DB, Wang X, Margolis DJ, Troxel AB. Risk of Myocardial Infarction in Patients With Psoriasis. *JAMA*. 2006; 296:1735–41. [PubMed: 17032986]
6. Gelfand JM, Troxel AB, Lewis JD, Kurd SK, Shin DB, Wang X, Margolis DJ, Strom BL. The Risk of Mortality in Patients With Psoriasis: Results From a Population-Based Study. *Arch Dermatol*. 2007; 143:1493–9. [PubMed: 18086997]
7. Gelfand JM, Shin DB, Neimann AL, et al. The Risk of Lymphoma in Patients with Psoriasis. *J Invest Dermatol*. 2006; 126:2194–201. [PubMed: 16741509]
8. Gelfand JM, Berlin J, Van Voorhees A, et al. Lymphoma Rates Are Low but Increased in Patients With Psoriasis: Results From a Population-Based Cohort Study in the United Kingdom. *Arch Dermatol*. 2003; 139:1425–9. [PubMed: 14623702]
9. Gelfand JM, Feldman SR, Stern RS, et al. Determinants of quality of life in patients with psoriasis: A study from the US population. *Journal of the American Academy of Dermatology*. 2004; 51:704–8. [PubMed: 15523347]
10. Stern RS, Nijsten T, Feldman SR, Margolis DJ, Rolstad T. Psoriasis is common, carries a substantial burden even when not extensive, and is associated with widespread treatment dissatisfaction. *J Invest Dermatol Symp Proc*. 2004 Mar;9:136.

11. Kimball AB, Jacobson C, Weiss S, Vreeland MG, Wu Y. The psychosocial burden of psoriasis. *Am J Clin Dermatol.* 2005; 6:383–92. [PubMed: 16343026]
12. Wu Y, Mills D, Bala M. Psoriasis: cardiovascular risk factors and other disease comorbidities. *J Drugs Dermatol.* 2008; 2008:4.
13. Feldman SR, Fleischer AB Jr, Reboussin DM, Rapp SR, Exum ML, Clark AR, Nurre L. The self-administered psoriasis area and severity index is valid and reliable. *J Invest Dermatol.* 1996; 106:183–6. [PubMed: 8592072]
14. Fleischer AB Jr, Feldman SR, Rapp SR, Reboussin DM, Exum ML, Clark AR, Rajashekhar V. Disease severity measures in a population of psoriasis patients: the symptoms of psoriasis correlate with self-administered psoriasis area severity index scores. *J Invest Dermatol.* 1996; 107:26–9. [PubMed: 8752834]
15. Fleischer AB Jr, Feldman SR, Dekle CL. The SAPASI is valid and responsive to psoriasis disease severity changes in a multi-center clinical trial. *J Dermatol.* 1999; 1999:4.
16. National Psoriasis Foundation. About psoriasis: statistics. May 12. <http://www.psoriasis.org/about/stats/>; <http://www.psoriasis.org/about/stats/>
17. Kurd SK, Gelfand JM. The prevalence of previously diagnosed and undiagnosed psoriasis in US adults: Results from NHANES 2003–2004. *Journal of the American Academy of Dermatology.* 2009; 60:218–24. [PubMed: 19022533]
18. Gelfand JM, Feldman SR, Stern RS, Thomas J, Rolstad T, Margolis DJ. Determinants of quality of life in patients with psoriasis: A study from the US population. *Journal of the American Academy of Dermatology.* 2004; 51:704–8. [PubMed: 15523347]
19. Gelfand JM, Gladman DD, Mease PJ, et al. Epidemiology of psoriatic arthritis in the population of the United States. *Journal of the American Academy of Dermatology.* 2005; 53:573.e1–e13. [PubMed: 16198775]
20. de Korte J, Mommers FMC, Sprangers MAG, et al. The Suitability of Quality-of-Life Questionnaires for Psoriasis Research: A Systematic Literature Review. *Arch Dermatol.* 2002; 138:1221–7. [PubMed: 12224984]
21. Gisondi P, Sampogna F, Annessi G, Girolomoni G, Abeni D. Severe impairment of quality of life in Hailey-Hailey disease. *Acta Derm Venereol.* 2005; 85:132–5. [PubMed: 15823906]
22. Lasek RJ, Chren M-M. Acne Vulgaris and the Quality of Life of Adult Dermatology Patients. *Arch Dermatol.* 1998; 134:454–8. [PubMed: 9554297]
23. Sampogna F, Sera F, Abeni D. Measures of Clinical Severity, Quality of Life, and Psychological Distress in Patients with Psoriasis: A Cluster Analysis. *J Invest Dermatol.* 2004; 122:602–7. [PubMed: 15086541]
24. Both H, Essink-Bot M-L, Busschbach J, et al. Critical Review of Generic and Dermatology-Specific Health-Related Quality of Life Instruments. *J Invest Dermatol.* 2007; 127:2726–39. [PubMed: 17989733]
25. Chren MM, Lasek RJ, Flocke SA, Zyzanski SJ. Improved discriminative and evaluative capability of a refined version of Skindex, a quality-of-life instrument for patients with skin diseases. *Arch Dermatol.* 1997; 133:1433–40. [PubMed: 9371029]
26. Jaeschke R, Singer J, Guyatt GH. Measurement of health status: Ascertaining the minimal clinically important difference. *Controlled Clinical Trials.* 1989; 10:407–15. [PubMed: 2691207]
27. Diehr P, Deyo R. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. *Controlled Clinical Trials.* 1991; 12:142S–58S. [PubMed: 1663851]
28. Fleiss, J. Statistical methods for rates and proportions. New York: John Wiley and Sons, Ltd; 1981.
29. Farhi D, Falissard B, Dupuy A. Global Assessment of Psoriasis Severity and Change from Photographs: A Valid and Consistent Method. *J Invest Dermatol.* 2008; 128:2198–203. [PubMed: 18418412]
30. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977; 33:159–74. [PubMed: 843571]
31. Streiner, DL.; Norman, GR. Health Measurement Scales: A Practical Guide to Their Development and Use. London: BMJ Books; 1989.
32. Guyatt G, Walter S, Norman G. Measuring change over time: Assessing the usefulness of evaluative instruments. *J Chronic Dis.* 1987;40.

33. Guyatt GH, Osoba D, Wu AW, et al. Methods to Explain the Clinical Significance of Health Status Measures. *Mayo Clinic Proceedings*. 2002; 77:371–83. [PubMed: 11936935]
34. Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. *Journal of Clinical Epidemiology*. 2003; 56:395–407. [PubMed: 12812812]
35. Juniper EF, Guyatt GH, Willan A, et al. Determining a minimal important change in a disease-specific quality of life questionnaire. *Journal of Clinical Epidemiology*. 1994; 47:81–7. [PubMed: 8283197]
36. Schunemann HJ, Puhan M, Goldstein R, et al. Measurement properties and interpretability of the Chronic Respiratory Disease Questionnaire (CRQ). *Journal of COPD*. 2005; 2:81–9.
37. Wiebe S, Matijevic S, Eliasziw M, et al. Clinically important change in quality of life in epilepsy. *J Neurol Neurosurg Psychiatry*. 2002; 73:116–20. [PubMed: 12122166]
38. Hosmer, DW.; Lemeshow, S. *Appl Logistic Regression*. New York: John Wiley and Sons, Inc; 2000.
39. Hanley JA, McNeil BJ. The meaning and use of the area under a receiving operating characteristic (ROC) curve. *Radiology*. 1982; 143:29–36. [PubMed: 7063747]
40. Carlin CS, Feldman SR, Krueger JG, et al. A 50% reduction in the Psoriasis Area and Severity Index (PASI 50) is a clinically significant endpoint in the assessment of psoriasis. *Journal of the American Academy of Dermatology*. 2004; 50:859–66. [PubMed: 15153885]
41. Fleischer AB Jr, Feldman SR, Rapp SR, et al. Disease Severity Measures in a Population of Psoriasis Patients: The Symptoms of Psoriasis Correlate With Self-Administered Psoriasis Area Severity Index Scores. *J Invest Dermatol*. 1996; 107:26–9. [PubMed: 8752834]
42. Yu C-Y, Hsu Y-W, Chen C-Y. Determination of hand surface area as a percentage of body surface area by 3D anthropometry. *Burns*. 2008; 34:1183–9. [PubMed: 18539398]
43. Finlay AY. Current severe psoriasis and the Rule of Tens. *British Journal of Dermatology*. 2005; 152:861–7. [PubMed: 15888138]

Table 1

Baseline characteristics

Characteristics (n = 140) ¹	No. (% of Patients) ²
Sex	
Male	77 (55)
Female	63 (45)
Age, median (25th, 75th percentile), y	45.5 (33.5, 57)
Race	
White	112 (80)
Black	11 (7.9)
Asian	9 (6.4)
Hispanic	5 (3.6)
Other	3 (2.1)
Baseline Extent of Skin Involvement with Psoriasis Assessments	
# of Palms, Median (25 th , 75 th percentile)	
Patient-Estimated	4 (1, 10)
Physician-Estimated	3.5 (1, 10.5)
Patient-Estimated Categorized Score	
1 – Little or no psoriasis visible	25 (17.9)
2 – Only a few patches (1 – 2 palms)	33 (23.6)
3 – Scattered patches (3 – 10 palms)	49 (35.0)
4 – Extensive psoriasis (> 10 palms)	33 (23.6)
Physician-Estimated Categorized Score	
1 – Little or no psoriasis visible	21 (15.0)
2 – Only a few patches (1 – 2 palms)	40 (28.6)
3 – Scattered patches (3 – 10 palms)	44 (31.4)
4 – Extensive psoriasis (> 10 palms)	35 (25.0)
Baseline Quality of Life Assessment Scores, Mean (SD)	
Skinindex-29	
Emotions (n = 131)	47.2 (26.7)
Symptoms (n = 131)	42.3 (21.1)
Functioning (n = 130)	27.6 (24.0)
Sum (n = 130)	39.0 (21.4)

¹ Not all participants completed every assessment. Number of participants for each assessment is noted.

² Values expressed as number (percentage) unless otherwise indicated.

Table 2

Criterion validity of the PREPI at outpatient visit 1 and visit 2: Concordance of patient and physician assessments

Measure	<i>n</i>	Median (25th, 75th percentile)	ICC (95% CI) ^{2I}
Outpatient Visit 1			
Reported # of Palms ²			
Patient-Estimated (PREPI)	127	4 (1, 10)	0.82 (0.75, 0.87)
Physician-Estimated		4 (1, 11)	
Categorized Score			
Patient-Estimated (PREPI)	140	3 (2, 3)	0.80 (0.73, 0.85)
Physician-Estimated		3 (2, 3.5)	
Outpatient Visit 2			
Reported # of Palms			
Patient-Estimated (PREPI)	76	3 (1, 6)	0.68 (0.54, 0.79)
Physician-Estimated		3 (1, 6)	
Categorized Score			
Patient-Estimated (PREPI)	76	3 (1.5, 3)	0.71 (0.58, 0.80)
Physician-Estimated		3 (2, 3)	

¹ ICC = Intra-class correlation coefficient

² There were *n* = 140 pts with data for physician-reported # of palms, but only *n* = 127 pts with data for patient-reported # of palms. Only pts with data for both patient-reported and physician-reported # of palms were included in the criterion validity analyses.

Table 3

Relationship of the PREPI to health-related quality of life

Measure	<i>n</i> ¹	Spearman's rho (95% CI)	P-Value
Patient-Estimated # of Palms (PREPI)			
Skindex29 Emotions	119	0.48 (0.33, 0.61)	<0.0001
Skindex29 Symptoms	119	0.41 (0.25, 0.55)	<0.0001
Skindex29 Functioning	118	0.64 (0.51, 0.73)	<0.0001
Skindex29 Total	118	0.59 (0.45, 0.69)	<0.0001
Patient-Estimated Categorized Score (PREPI)			
Skindex29 Emotions	131	0.41 (0.26, 0.54)	<0.0001
Skindex29 Symptoms	131	0.33 (0.17, 0.47)	0.0001
Skindex29 Functioning	130	0.56 (0.42, 0.66)	<0.0001
Skindex29 Total	130	0.50 (0.53, 0.62)	<0.0001
Physician-Estimated # of Palms			
Skindex29 Emotions	131	0.36 (0.20, 0.50)	<0.0001
Skindex29 Symptoms	131	0.31 (0.14, 0.45)	0.0004
Skindex29 Functioning	130	0.57 (0.44, 0.67)	<0.0001
Skindex29 Total	130	0.48 (0.34, 0.60)	<0.0001
Physician-Estimated Categorized Score			
Skindex29 Emotions	131	0.38 (0.22, 0.51)	<0.0001
Skindex29 Symptoms	131	0.29 (0.12, 0.44)	0.0008
Skindex29 Functioning	130	0.56 (0.43, 0.67)	<0.0001
Skindex29 Total	130	0.48 (0.33, 0.60)	<0.0001

Table 4

SKINDEX-29 scores by PREPI category

Measure	n (%)	Skindex29 Scores ¹ (n = 130) ²			
		Emotions	Symptoms	Functioning	Total
Patient-Estimated Categorized Score (PREPI)					
1: Little or no psoriasis visible	23 (17.7)	26.6 (27.5), 15	31.1 (20.5), 28.6	9.3 (15.9), 2.1	22.0 (18.2), 19.6
2: 1–2 palms	31 (23.8)	38.9 (21.0), 40	36.5 (16.1), 39.3	14.2 (10.1), 14.6	29.9 (12.9), 31.5
3: 3–10 palms	45 (34.6)	56.4 (24.3), 57.5	46.6 (20.9), 39.3	36.9 (23.8), 33.3	46.6 (20.4), 43.6
4: >10 palms	31 (23.8)	57.7 (24.3), 62.5	50.6 (21.6), 53.6	41.1 (24.4), 41.7	49.7 (20.9), 48.9
P Value: ³		0.0001	0.0022	0.0001	0.0001
Physician-Estimated Categorized Score					
1: Little or no psoriasis visible	19 (14.6)	24.9 (24.2), 15	28.7 (17.1), 32.1	9.5 (14.2), 2.1	21.0 (15.9), 14.6
2: 1–2 palms	37 (28.5)	43.4 (26.8), 42.5	40.1 (21.8), 42.9	17.2 (18.9), 12.5	33.5 (19.9), 29.4
3: 3–10 palms	41 (31.5)	52.1 (25.4), 50	43.5 (19.7), 35.7	31.7 (23.4), 27.1	42.5 (19.9), 41
4: >10 palms	33 (25.4)	58.4 (21.8), 57.5	50.8 (20.7), 53.6	44.6 (21.9), 43.8	51.2 (19.2), 52.4
P Value: ³		0.0001	0.006	0.0001	0.0001

¹ Skindex29 scores expressed as mean (SD), median.

² One patient who had a partially complete Skindex-29 questionnaire was omitted from this analysis.

³ P values computed using the Kruskal-Wallis test (without ties) comparing median Skindex-29 domain-specific and composite scores across PREPI categories.

Table 5

Receiver operating characteristic (ROC) curve areas for patient- and physician-reported delta number of palms and percent change number of palms

Measure	All Visits ¹		Consecutive Visits ²	
	AUC	95% CI	AUC	95% CI
Patient's Assessment	(n = 62)		(n = 55)	
Delta # of Palms - Improvement	0.7	(0.58, 0.81)	0.69	(0.55, 0.81)
Percent Change - Improvement	0.7	(0.57, 0.81)	0.69	(0.54, 0.80)
Delta # of Palms - Worsening	0.7	(0.56, 0.80)	0.7	(0.55, 0.81)
Percent Change - Worsening	0.73	(0.59, 0.83)	0.74	(0.60, 0.85)
Physician's Assessment	(n = 72)		(n = 60)	
Delta # of Palms - Improvement	0.78	(0.67, 0.90)	0.76	(0.62, 0.89)
Percent Change - Improvement	0.76	(0.63, 0.88)	0.74	(0.59, 0.89)
Delta # of Palms - Worsening	0.76	(0.64, 0.87)	0.75	(0.62, 0.87)
Percent Change - Worsening	0.81	(0.70, 0.90)	0.79	(0.68, 0.91)

¹The median duration between visit 1 and visit 2 for all visits was 98 days (IQR: 63.5, 181.5).

²The median duration between visit 1 and visit 2 for consecutive visits only was 91 days (IQR: 62, 157.5).

Table 6

Receiver operating characteristic (ROC) curve cut-points with the optimal correct classification

Measure (For consecutive visits only)	Cut-Point	Sensitivity	Specificity	LR ¹	LR ²	Correct Classification
Patient's Assessment						
Delta # of Palms - Improvement	3.5	47.62%	88.24%	4.05	0.59	72.73%
Percent Change - Improvement	83.33%	38.10%	93.94%	6.29	0.66	72.22%
Delta # of Palms - Worsening	-1.5	36.36%	90.91%	4.00	0.70	69.09%
Percent Change - Worsening	-66.67%	38.10%	90.91%	4.19	0.68	70.37%
Physician's Assessment						
Delta # of Palms - Improvement	6	38.10%	100.00%	*** ³	0.62	78.33%
Percent Change - Improvement	54.54%	52.38%	97.37%	19.9	0.49	81.36%
Delta # of Palms - Worsening	-2	45.83%	86.11%	3.3	0.63	70.00%
Percent Change - Worsening	-66.67%	54.17%	88.57%	4.74	0.52	74.58%

¹ Positive likelihood ratio.² Negative likelihood ratio.³ LR is an undefined value for a specificity of 100%.