
Patient-reported outcomes for psoriasis patients with clear versus almost clear skin in the clinical setting

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Background: There is little evidence to guide the establishment of treatment goals for moderate to severe psoriasis in the clinical setting.

Objective: We sought to compare Dermatology Life Quality Index scores and prescription topical medication use between patients with clear versus almost clear skin.

Methods: This was a multicenter cross-sectional study of 97 patients with clear skin and 441 patients with almost clear skin receiving current systemic therapy or phototherapy for a primary indication of plaque psoriasis evaluated at 1 of 10 US outpatient dermatology sites participating in the Dermatology Clinical Effectiveness Research Network.

Results: In adjusted analyses, patients with clear versus almost clear skin were more likely to report no impact of psoriasis on quality of life (relative risk 1.60; 95% confidence interval 1.37-1.86). Patients with clear versus almost clear skin were also more likely to report no prescription topical medication use in the preceding week (relative risk 2.08; 95% confidence interval 1.73-2.49).

Limitations: Cross-sectional design prohibits longitudinal assessment of outcomes.

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Novartis Corp, and Pfizer Inc; and received payment for continuing medical education work related to psoriasis. Dr Krueger served as a consultant for Abbvie, Amgen Inc, and Janssen Biologics; had grants or has pending grants from Abbvie and Amgen Inc; and received payment for lectures and travel-related expenses from Abbvie, Amgen Inc, and Janssen Biologics. Dr Robertson is employed by the National Psoriasis Foundation, which receives unrestricted financial support from companies that make products used to treat psoriasis and psoriatic arthritis, including Abbvie, Amgen Inc, Celgene, Eli Lilly and Co, Galderma Laboratories LP, Janssen Biotech Inc, Leo Pharma Inc, Novartis, Pfizer Inc, and Stiefel, a GSK Company. Dr Robertson has also served as an uncompensated member of advisory boards at Abbvie and Merck. Dr Takeshita has received payment for continuing medical education work related to psoriasis. Dr Van Voorhees served on advisory boards for Amgen Inc, Abbvie, Genentech Inc, Warner Chilcott, Leo, and Janssen Biologics; served as an investigator for Amgen Inc and Abbvie, receiving grants; and served as a consultant for Amgen Inc. Mr Shin and Dr Troxel have no conflicts of interest to declare.

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Conclusions: Clinically important differences in quality of life and prescription topical medication use exist between patients with clear versus almost clear skin. Collectively, our results indicate that achievement of clear skin may be an important clinical distinction among patients with moderate to severe psoriasis. (J Am Acad Dermatol 2014;71:633-41.)

Key words: Dermatology Life Quality Index; patient-reported outcome; Physician Global Assessment; psoriasis; Psoriasis Area and Severity Index; quality of life.

Psoriasis is a common chronic inflammatory disease of the skin that affects 2% to 4% of the population.¹ Particularly when more severe, psoriasis is increasingly recognized as having important physical and psychosocial effects that extend beyond the skin.^{2,3} Despite the rapid expansion of treatment options for moderate to severe psoriasis over the last decade, therapies often fail to achieve or maintain skin clearance in patients, and patients are frequently dissatisfied with their treatments.⁴ In an effort to improve treatment outcomes and satisfaction, guidelines for appropriate psoriasis treatment largely based on expert consensus have been created in Canada, Europe, the United Kingdom, and Australia.⁵⁻⁹ Recognizing the evidence that suggests that typical physician-reported measures of psoriasis severity (eg, body surface area [BSA] affected, Psoriasis Area and Severity Index [PASI], and Physician Global Assessment [PGA]) may not adequately capture psoriasis severity from the patient's perspective,^{10,11} patient-reported outcomes, which are metrics that assess a patient's health status or quality of life (QoL) from the patient perspective, are increasingly being used to guide clinical care. In fact, recommendations for treatment goals in many of the aforementioned psoriasis treatment guidelines incorporate both physician- and patient-reported outcomes (eg, the Dermatology Life Quality Index [DLQI], a validated and widely used dermatology-specific health-related QoL [HRQoL] measure)^{12,13} as measures of treatment response. Yet, a gold-standard definition for adequate treatment response and universally accepted treatment target remain to be established.

At least 75% improvement in PASI score is the mostly widely used measure of clinical efficacy and is a suggested treatment goal in most guidelines.⁶⁻⁹ Improvements in PASI score of at least 50%¹⁴ and 90%^{15,16} have also been suggested to represent important clinical end points by some. The use of

CAPSULE SUMMARY

- Universally accepted treatments goals for moderate to severe psoriasis do not exist.
- Achieving clear skin over almost clear skin is associated with clinically important differences in health-related quality of life.
- Longitudinal and cost-effectiveness studies are needed to further clarify the importance of skin clearance as a treatment goal.

PASI-based outcome measures in the real-world clinical setting remains unclear, however, as the PASI score is not commonly used outside the clinical trial setting, and it has little use as a single score.

PGA is increasingly being used to define treatment efficacy in clinical trials and has been suggested to be a reasonable and more feasible alternative to the PASI score as a measure of psoriasis severity in the clinical setting.¹⁷ Several versions of the PGA exist, and, in

clinical trials, treatment efficacy is often defined by the proportion of patients having clear or almost clear skin corresponding to a PGA score less than or equal to 1.¹⁷ PGA-defined clear or almost clear skin is an alternative treatment goal to at least 75% improvement in PASI score or the patient-reported outcome measure, DLQI score less than or equal to 1, according to the European S3 Guidelines.⁶ It remains unknown, however, if complete skin clearance itself should be a treatment goal, particularly from the patient perspective. Thus, the primary aim of this study was to determine if physician-reported differences in patients with clear versus almost clear skin as defined by PGA are associated with significant differences in patient-reported HRQoL as measured by the DLQI in the routine clinical practice setting. We hypothesized that patients with clear skin would be more likely to report lower DLQI scores corresponding to lesser impact of their skin disease on QoL compared with patients with almost clear skin. Secondarily, especially because topical medication use has been associated with poor treatment satisfaction,¹⁸⁻²⁰ we also aimed to assess the differences in prescription topical medication use in patients with clear versus almost clear skin.

METHODS

Study design and participant protection

We conducted a cross-sectional study to compare patient-reported outcomes among patients with

Abbreviations used:

BSA:	body surface area
CI:	confidence interval
DLQI:	Dermatology Life Quality Index
HRQoL:	health-related quality of life
IQR:	interquartile range
NNT:	number needed to treat
PASI:	Psoriasis Area and Severity Index
PGA:	Physician Global Assessment
QoL:	quality of life
RR:	relative risk

minimal psoriasis activity (ie, clear or almost clear skin). The study was approved by the University of Pennsylvania and University of Utah institutional review boards, and verbal informed consent was obtained from all patients. The study was conducted in accordance with the Declaration of Helsinki and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.²¹

Setting

Data were collected by 12 clinicians (10 dermatologists and 2 physician assistants) who were members of the Dermatology Clinical Effectiveness Research Network. The Dermatology Clinical Effectiveness Research Network includes 2 academic medical centers (University of Pennsylvania and University of Utah, each with a hospital-based site and a separate community-based site) and 6 private practices in Georgia, Pennsylvania, New York, and Colorado (see www.dermcern.org for details). Patient data were collected prospectively at a single, regularly scheduled clinic appointment from February 2010 through June 2011.

Participants

As previously described in detail,²² broad inclusion criteria were used to enroll consecutive patients seen by their dermatology provider in Dermatology Clinical Effectiveness Research Network practices for a routine follow-up appointment in order to minimize selection bias. Eligible participants included patients who met at least one of the following criteria to define moderate to severe psoriasis: were currently receiving or had previously received systemic therapy or phototherapy prescribed by a dermatology provider for treatment of psoriasis, or were candidates for systemic therapy with a documented history of at least 5% BSA involvement. In the analyses presented, patients were included if they were currently receiving any systemic therapy or phototherapy for

a primary indication of plaque psoriasis and if they had clear or almost clear skin (PGA score <1.5) as defined by a 6-point PGA scale of psoriasis lesions (scored separately for erythema [0, no evidence of erythema, hyperpigmentation may be present; 1, faint erythema; 2, light red coloration; 3, moderate red coloration; 4, bright red coloration; 5, dusky to deep red coloration], induration [0, no evidence of plaque elevation; 1, minimal plaque elevation, 0.25 mm; 2, mild plaque elevation, 0.5 mm; 3, moderate plaque elevation, 0.75 mm; 4, marked plaque elevation, 1 mm; 5, severe plaque elevation, ≥ 1.25 mm], and scaling [0, no evidence of scaling; 1, minimal, occasional fine scale over <5% of the lesion; 2, mild, fine scale dominates; 3, moderate, coarse scale predominates; 4, marked, thick, nontenacious scale predominates; 5, severe, very thick tenacious scale predominates] and then averaged to produce a single static score [0, clear; 1, minimal; 2, mild; 3, moderate; 4, marked; and 5, severe; note: averaged scores should be rounded to the nearest whole number]).^{23,24} This 6-point PGA scale was chosen based on its use in at least 2 large psoriasis clinical trials^{23,24} and national expert consensus including representation from the National Psoriasis Foundation.

Variables

Detailed patient- and provider-level data including medical history, current and past psoriasis treatments, sociodemographic factors, psoriasis characteristics, height, weight, and alcohol and tobacco use history were collected by trained study coordinators using standardized case report forms and via patient self-report with confirmation by the patient's dermatology clinic record and assessments by the clinician investigators.²² The main exposure was PGA score dichotomized as clear (PGA score = 0) or almost clear ($0 < \text{PGA} < 1.5$) skin. As a secondary exposure, PASI was used to define clear (PASI = 0) and almost clear ($0 < \text{PASI} < 3$) skin (PASI score cut-off was based on a receiver operating characteristic analysis comparing PASI scores with PGA scores). The primary outcome measure was DLQI, a skin-specific HRQoL measure that is widely used in clinical trials and has been shown to be valid and reliable in the clinical setting.^{12,25,26} The DLQI outcome was dichotomized as no effect (0-1) or small to extremely large effect (2-30) on QoL.²⁷ The secondary outcome was prescription topical medication use in the preceding week, which was dichotomized as no versus any use. All other variables served as potential confounders.

Table I. Baseline characteristics of patients with clear or almost clear skin

Characteristic	Clear (PGA = 0) N = 97	Almost clear (0 < PGA < 1.5) N = 441	P value*
Age, y			
Mean (SD)	52.6 (13.5)	47.3 (15.5)	.002 [†]
Median (IQR)	52 (43-63)	47 (35-59)	.002 [‡]
Female sex, N (%)	52 (53.6)	224 (50.8)	.65
Caucasian race, N (%)	83 (85.6)	394 (89.3)	.29
Practice setting of dermatologist, N (%)			.26
Academic	54 (55.7)	216 (49.0)	
Private	43 (44.3)	225 (51.0)	
Smoking status, N (%)			.80
Current	15 (15.5)	71 (16.1)	
Past	30 (30.9)	150 (34.0)	
Never	52 (53.6)	220 (49.9)	
Current drinking status, N (%)			.001
Heavy [§]	6 (6.2)	21 (4.8)	
Moderate	47 (48.4)	299 (67.8)	
None in last year	44 (45.4)	121 (27.4)	
BMI, median (IQR)	28.8 (24.4-32.2)	28.1 (24.7-32.8)	.97 [‡]
Total No. of comorbidities, median (IQR)	3 (1-5)	2 (1-4)	.05 [‡]

BMI, Body mass index; IQR, interquartile range; PGA, Physician Global Assessment; SD, standard deviation.

*Fisher exact test.

[†]Student *t* test.

[‡]Wilcoxon rank sum test.

[§]>2 Drinks per day for men and >1 drink per day for women.

Current treatment and prescription topical medication use (in the primary analysis only) were considered potential effect modifiers.

Study size

Target enrollment was established for the primary comparative effectiveness study,²² within which the current study was nested. This study was descriptive in nature, thus the sample size was not determined a priori. The maximum number of eligible subjects was included, and all effect measures are reported with 95% confidence intervals (CI).

Statistical analysis

First, univariate analyses were conducted using unpaired, 2-tailed *t* tests and Wilcoxon rank sum tests for comparisons of continuous data, and Fisher exact test for categorical data. We performed modified Poisson regression with robust error variance²⁸ to determine which factors were independently associated with the primary and secondary outcomes. Being almost clear of psoriasis served as the reference for all analyses. To build our multivariable model, we used a purposeful selection approach in which age, sex, and any covariates (ie, race, ethnicity, marital status, education, income, health insurance type, dermatologist's practice

setting, smoking history, drinking history, body mass index, total number of comorbid diseases, age of psoriasis onset, psoriasis severity at its worst, family history of psoriasis, presence of psoriatic arthritis, and Fitzpatrick skin type) with significance at *P* less than or equal to .20 in univariate analyses were included in the multivariable model as potential confounding variables.^{29,30} No variables were found to be collinear. Current treatment and prescription topical medication use were considered part of the causal pathway between exposure and primary outcome and, thus, were not considered potential confounders. Nonsignificant covariates (*P* > .10) were eliminated from the multivariable model if their removal did not change the risk ratio estimates of the exposure variable by more than 10%. Effect modification by current treatment (both treatment type and number of treatments) and by prescription topical medication use were each assessed and included in the multivariable model if the interaction terms were significant (*P* < .10). Model fit was assessed using goodness-of-fit tests based on deviance and Pearson statistics. The modified Poisson modeling approach was used to yield the clinically relevant statistic of relative response rate (ie, relative risk [RR]), which was then used to calculate the relative response difference and the number needed to treat (NNT).

Table II. Psoriasis characteristics of patients with clear or almost clear skin

Characteristic	Clear (PGA = 0) N = 97	Almost clear (0 < PGA < 1.5) N = 441	P value*
Age of psoriasis onset, median (IQR), y	30 (18-41)	23 (15-38)	.02 [†]
Psoriasis duration, median (IQR), y	20 (9-33)	19 (8-29)	.33 [†]
Family history of psoriasis, [‡] N (%)	33 (34.0)	182 (41.4)	.71
Psoriasis extent at its worst, N (%)			.01
Mild	5 (5.2)	53 (12.0)	
Moderate	23 (23.7)	144 (32.7)	
Severe	69 (71.1)	244 (55.3)	
Psoriatic arthritis diagnosed by a physician, N (%)	28 (28.9)	112 (25.4)	.52
Prescription topical medication use in the last week, median (IQR), d	0 (0-0)	3 (0-7)	<.001 [†]
Any prescription topical medication use in the last week, N (%)	22 (22.7)	289 (65.5)	<.001
Current therapy, [§] N (%)			
Single therapy	66 (68.0)	341 (77.3)	.07
Biologic	48 (72.7)	185 (54.2)	.006
Oral systemic	14 (21.2)	81 (23.8)	.75
Light	4 (6.1)	75 (22.0)	.002
Combination therapy	31 (32.0)	100 (22.7)	.07
Biologic, oral systemic	24 (77.4)	46 (46.0)	.003
Biologic, light	3 (9.7)	15 (15.0)	.56
Oral systemic, light	2 (6.4)	22 (22.0)	.06
Other	2 (6.4)	17 (17.0)	.24
No. of current therapies, N (%)			.09
1	66 (68.1)	341 (77.3)	
2	30 (30.9)	92 (20.9)	
≥ 3	1 (1.0)	8 (1.8)	

IQR, Interquartile range; PGA, Physician Global Assessment.

*Fisher exact test.

[†]Wilcoxon rank sum test.

[‡]17.1% and 7.1% of patients with clear and almost clear skin, respectively, answered "do not know."

[§]Percentages of biologic, oral systemic, and light therapies are calculated among those on single therapy only. Percentages of biologic and oral systemic, biologic and light, oral systemic and light, and other combination therapies are calculated among those on combination therapies only.

^{||}Current therapy count includes any biologic, oral systemic, or light therapies only.

We performed sensitivity analyses including using an alternative outcome definition of DLQI score less than or equal to 5 (no to small effect on QoL), stricter definition of almost clear defined by PGA score greater than 0 and less than or equal to 1, limiting the study population to patients with current psoriasis extent of BSA less than 3%, excluding patients who reported their psoriasis to be mild at its worst state, and excluding patients with psoriatic arthritis. Missing data did not exceed 1% for any of the variables analyzed, and patients with missing data were excluded from analyses.

RESULTS

The baseline characteristics of 97 patients with clear and 441 patients with almost clear skin on current psoriasis therapy are summarized in Table I. Patients with clear skin were older than patients with

almost clear skin with mean (SD) ages of 52.6 (13.5) and 47.3 (15.5) years, respectively ($P = .002$). Men and women were nearly equally represented in both groups, and the majority of patients were Caucasian. There were no significant differences in median body mass index or smoking status between groups. Drinking status was significantly different with more patients with clear (45.4%) versus almost clear (27.4%) skin reporting no alcoholic drinks in the past year ($P = .001$). Median number of comorbidities was greater among patients with clear (3; interquartile range [IQR] 1-5) versus almost clear (2; IQR 1-4; $P = .05$) skin.

The psoriasis characteristics of patients with clear and almost clear skin are summarized in Table II. Median age of psoriasis onset was higher among patients with clear (30 years; IQR 18-41) versus almost clear (23 years; IQR 15-38; $P = .02$) skin.

Table III. Dermatology Life Quality Index among patients with clear or almost clear skin

	Clear (PGA = 0) N = 97	Almost clear (0 < PGA < 1.5) N = 441	P value*
DLQI, median (IQR)	0 (0-1)	2 (0-5)	<.001 [†]
DLQI bands, N (%)			<.001
0-1 No effect	74 (76.3)	194 (44.2)	
2-5 Small effect	21 (21.7)	160 (36.4)	
6-10 Moderate effect	1 (1.0)	56 (12.8)	
11-20 Very large effect	1 (1.0)	22 (5.0)	
21-30 Extremely large effect	0 (0)	7 (1.6)	
DLQI 0-5 No-small effect, N (%)	95 (97.9)	354 (80.6)	<.001

DLQI, Dermatology Life Quality Index; IQR, Interquartile range; PGA, Physician Global Assessment.

*Fisher exact test.

[†]Wilcoxon rank sum test.

Median psoriasis duration and proportions of patients with family history of psoriasis and with physician-diagnosed psoriatic arthritis were similar in the 2 groups. More patients with clear (71.1%) versus almost clear (55.3%) skin reported their psoriasis to be severe in its worst state ($P = .01$). Total number of current therapies was similar between the 2 groups, and there were no significant differences in the proportions of patients on single or combination therapies. However, among patients on single therapy, patients with clear skin were more likely to be on biologic monotherapy (clear 72.7%; almost clear 54.2%; $P = .006$) and less likely to be receiving phototherapy (clear 6.1%; almost clear 22.0%; $P = .002$) than patients with almost clear skin. Treatment with single oral systemic therapy was similar in both groups. Among those on combination therapy, patients with clear skin were more likely to be on combined biologic and oral systemic therapy than those with almost clear skin (clear 77.4%; almost clear 46.0%; $P = .003$). Fewer patients with clear (22.7%) versus almost clear (65.5%) skin reported any prescription topical medication use in the last week ($P < .001$).

In univariate analyses, DLQI scores of patients with clear versus almost clear skin were significantly different (Table III). The median DLQI score for patients with clear skin was 0 (IQR 0-1), corresponding to having no effect on QoL whereas that for patients with almost clear skin was 2 (IQR 0-5), corresponding to having small effect on QoL ($P < .001$). Similarly, a higher proportion of patients with clear (76.3%) versus almost clear (44.2%)

skin had DLQI scores less than or equal to 1, corresponding to having no effect on QoL ($P < .001$).²⁷ Importantly, based on European guidelines that identify a DLQI score greater than 5 to be an indication of treatment failure and thus a criterion for therapy change,⁷ only 2.1% of patients with clear skin versus 19.4% of patients with almost clear skin exhibited inadequate treatment response ($P < .001$).

In multivariable analyses using DLQI score less than or equal to 1 (no effect on QoL) as the outcome and PGA score to define clear and almost clear skin, patients with clear skin were more likely to report that psoriasis had no effect on their QoL than patients with almost clear skin (RR 1.60; 95% CI 1.37-1.86) after adjusting for confounding factors (Table IV). No significant effect modification by current treatment (neither treatment type nor number of treatments) or by prescription topical medication use was identified. The risk difference between patients with clear and almost clear skin was significant at .25 (95% CI 0.16-0.38; data not shown), corresponding to an NNT of 3.8 (95% CI 2.8-6.4). The clinical significance of NNT in this scenario is that 4 patients (rounded up from 3.8 per convention) with almost clear skin would need to achieve skin clearance for 1 additional patient to reach the DLQI response of no effect on QoL over what would be expected if those same patients persisted with almost clear skin. In secondary multivariable analyses of prescription topical medication use, patients with clear skin were twice as likely to report no prescription topical medication use in the preceding week compared with patients with almost clear skin (RR 2.08; 95% CI 1.73-2.49), resulting in an NNT of 2.7 (95% CI 2.2-3.8) (data not shown).

In sensitivity analyses, we redefined our primary outcome as DLQI score less than or equal to 5 (no to small effect on QoL). We found an attenuated but still significantly increased response rate among patients with clear skin compared with patients with almost clear skin (RR 1.19; 95% CI 1.12-1.27), resulting in a slight increase in NNT over our primary analysis to 6.4 (95% CI 5.0-11.5). Our findings were also robust to the following: stricter definition of almost clear defined by PGA score greater than 0 and less than or equal to 1, use of PASI score to define clear and almost clear skin, limiting our study population to patients with BSA less than 3% to further ensure that included patients truly had limited disease activity, exclusion of patients who reported their psoriasis to be mild at its worst state, and exclusion of patients with psoriatic arthritis (Table IV).

Table IV. Relative risk of Dermatology Life Quality Index outcome* and number needed to treat for clear versus almost clear skin

Analysis	Unadjusted RR (95% CI)	Adjusted RR [†] (95% CI)	NNT [‡] (95% CI)
Primary analysis [‡]			
Clear vs almost clear defined by PGA	1.73 (1.48-2.01)	1.60 (1.37-1.86)	3.8 (2.8-6.4)
Sensitivity analyses			
Clear vs almost clear defined by PGA = 0 vs 0 < PGA ≤ 1	1.60 (1.36-1.89)	1.49 (1.27-1.74)	4.3 (3.0-8.5)
Outcome redefined by DLQI ≤ 5	1.21 (1.15-1.28)	1.19 (1.12-1.27)	6.4 (5.0-11.5)
Clear vs almost clear defined by PASI [§]	1.64 (1.42-1.89)	1.53 (1.32-1.77) ^{//}	4.0 (2.9-6.9) ^{//}
Limited to BSA < 3	1.53 (1.31-1.79)	1.48 (1.26-1.73)	4.2 (3.0-7.9)
Exclude patients with mild psoriasis at worst	1.72 (1.46-2.02)	1.60 (1.36-1.89)	3.7 (2.8-6.4)
Exclude patients with PsA	1.72 (1.42-2.09)	1.57 (1.30-1.89)	4.2 (2.8-9.2)

BSA, Body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index; NNT, number needed to treat; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; PsA, psoriatic arthritis; RR, relative risk.

*DLQI ≤ 1 unless otherwise noted.

[†]Adjusted for age, sex, practice site, marital status.

[‡]PGA 0 vs (0, 1.5).

[§]PASI 0 vs (0, 3).

^{//}Adjusted for age, sex, practice site, race, marital status, psoriasis severity at its worst.

DISCUSSION

In this study we compared a validated and widely used patient-reported outcome measure, the DLQI, between patients with clear and almost clear skin as defined by PGA and PASI scores determined during routine dermatologic care in academic and private practices across the United States. In univariate analyses, we found DLQI scores to be lower among patients with clear versus almost clear skin. Importantly, nearly 20% of patients with almost clear skin compared with only 2% of patients with clear skin reported DLQI scores indicative of treatment failure according to European guidelines.⁷ In fully adjusted analyses, patients with clear skin were 50% to 60% more likely to report no effect on QoL than patients with almost clear skin. Our results were independent of the measure used to define clear and almost clear skin and were robust to exclusion of patients with current BSA greater than or equal to 3, indicating that our findings were representative of patients with truly limited psoriasis. In addition, using an alternative outcome of no to small effect on QoL resulted in an attenuated but still significantly increased response rate among patients with clear versus almost clear skin.

To our knowledge, our study is the first to specifically compare HRQoL between patients with clear and almost clear skin evaluated during routine clinical follow-up. Our findings are novel in suggesting that clearance of psoriasis abrogates the negative impact that active psoriasis has on a patient's QoL and that clinically important improvements in QoL accompany the transition from almost clear to clear skin. Furthermore, we demonstrate that inadequate treatment response is more prevalent

among patients with almost clear versus clear skin. Thus, overall, our results suggest that achieving skin clearance may be an important independent treatment end point especially from the patient perspective.

We also found clear skin to be associated with less prescription topical medication use compared with almost clear skin. Topical therapies for psoriasis are generally associated with poor treatment satisfaction, poor adherence because of low efficacy, treatment inconvenience, unsatisfactory cosmetic appearance of the medications, and undesired side effects with long-term use.^{18-20,31-33} Thus our data suggest that a decrease in prescription topical medication use may contribute to improvements in QoL associated with skin clearance.

Strengths of our study include its broad inclusion criteria, patient population drawn from multiple clinical practices across the United States, and use of multivariable statistical models to account for potential confounding factors. Limitations include the cross-sectional design, which does not allow for longitudinal assessment of the outcomes of interest. In addition, patients included in our study were those currently receiving phototherapy or systemic treatment, and thus our findings may not be generalizable to those on topical treatment only. Although our analyses did not reveal any differences among therapies, our study may not have been adequately powered to detect therapy effects. Finally, our study does not address specific issues related to health-related decision-making, thus any differences in DLQI scores related to clear versus almost clear skin must be interpreted carefully with respect to treatment and other

costs and benefits associated with achieving skin clearance.

In summary, this multicenter study of patient-reported outcomes among patients with moderate to severe psoriasis and clear versus almost clear skin provides new insight into the impact of achieving skin clearance on HRQoL as measured by DLQI in the real-world clinical setting. Our findings collectively suggest an end point of skin clearance to be an important treatment goal. Future longitudinal studies and cost-effectiveness analyses are needed to further our understanding of the clinical impact of HRQoL differences that accompany the transition from almost clear to clear skin.

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