

## ORIGINAL ARTICLE

# Patient-reported outcomes of adalimumab, phototherapy, and placebo in the Vascular Inflammation in Psoriasis Trial: A randomized controlled study

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**Background:** There are limited data about the impact of narrowband ultraviolet B phototherapy on patient-reported measures of health-related quality of life.

**Objective:** To evaluate the impact of adalimumab and phototherapy on health-related quality of life.

**Methods:** We examined patient-reported outcomes from a multicenter, randomized, placebo-controlled trial ([ClinicalTrials.gov](https://clinicaltrials.gov) no. NCT01553058). The Dermatology Life Quality Index and EQ-5D-3L were evaluated every 4 weeks.

**Results:** We enrolled 97 patients: 30.9% were female, mean age was 43.5 years (standard deviation, 14.0), and median Psoriasis Area and Severity Index score was 16.7 (interquartile range, 13.9-21.6). At week 12, patients being treated with adalimumab (odds ratio [OR], 2.88; 95% confidence interval [CI], 1.02-8.17) and phototherapy (OR, 8.83; 95% CI, 2.47-31.57) were more likely to achieve the minimal clinically important difference in the Dermatology Life Quality Index compared with those receiving placebo. There were higher odds of achieving the minimal clinically important difference for the EQ-5D-3L Index score when comparing phototherapy versus placebo (OR, 9.78; 95% CI, 2.99-31.95) and phototherapy versus adalimumab (OR, 4.07; 95% CI, 1.42-11.70).

**Limitations:** Small sample size, secondary analysis, generalizability.

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Funding sources: Supported in part by a grant from the National Institutes of Health 5P30AR069589-03 and National Institutes of

Health/National Heart, Lung, and Blood Institute R01-HL111293 (Dr Gelfand), a grant from AbbVie for Vascular Inflammation in Psoriasis (Dr Gelfand), National Institute of Arthritis and Musculoskeletal and Skin Diseases K23-AR073932 (Dr Noe), and a medical dermatology fellowship from the National Psoriasis Foundation (Dr Wan).

Disclosure: Dr Armstrong has served as a research investigator or consultant to AbbVie, Janssen, Lilly, Leo, Novartis, UCB, Ortho Dermatologics, Dermira, Sanofi Genzyme, Regeneron, BMS, Dermavant, Science 37, and Modernizing Medicine. Dr Callis Duffin has served as a research investigator or consultant to Amgen, AbbVie, Celgene, Janssen, Lilly, Novartis, UCB, Ortho Dermatologic, Regeneron, BMS, Pfizer, and Stiefel. Dr Gelfand served as a consultant for BMS, Boehringer Ingelheim, GSK, Janssen Biologics, Novartis Corp, UCB (DSMB), Sanofi, and Pfizer, receiving honoraria; receives research grants (to the Trustees of the University of Pennsylvania) from AbbVie, Janssen, Novartis Corp, Celgene, Ortho Dermatologics, and Pfizer; received payment for continuing medical education work related to psoriasis

**Conclusion:** Phototherapy and adalimumab both improve skin-related quality of life and overall health-related quality of life compared with placebo in patients with psoriasis; however, patients treated with phototherapy achieved more improvement in overall health-related quality of life compared with patients treated with adalimumab. (J Am Acad Dermatol <https://doi.org/10.1016/j.jaad.2019.05.080>.)

**Key words:** adalimumab; DLQI; EQ5D; patient-reported outcomes; phototherapy; psoriasis; randomized controlled trials.

The treatment of psoriasis has been revolutionized by the development of biologic antibodies that target cytokines central to the pathophysiology of psoriasis. Despite these advances, narrowband ultraviolet B (nbUVB) phototherapy, which has been used since the 1980s, remains a treatment preferred by both dermatologists and patients.<sup>1,2</sup> Multiple placebo-controlled studies involving thousands of patients have shown that novel biologics improve both physician-reported and

### CAPSULE SUMMARY

- There are limited multicenter, head-to-head trials with phototherapy monotherapy evaluating patient-reported outcomes.
- Phototherapy and adalimumab both improve skin-related and overall health-related quality of life in patients with psoriasis. Patients treated with phototherapy achieved more improvement in overall health-related quality of life compared with patients treated with adalimumab.

patient-reported outcomes (PROs),<sup>3-5</sup> but the effects of nbUVB phototherapy are less well established in rigorous clinical trials.

A meta-analysis combining data from 9 randomized controlled trials, with a total of 293 patients, concluded that the mean percentage of patients achieving a 75% reduction in Psoriasis Area and Severity Index (PASI) score (PASI 75) with nbUVB monotherapy was 62% (95% confidence interval [CI], 45-79).<sup>6</sup> However, the trials included in this analysis

that was supported indirectly by Lilly, Ortho Dermatologic, and Novartis; is a co-patent holder of resiquimod for treatment of cutaneous T-cell lymphoma; and is a deputy editor for the *Journal of Investigative Dermatology*, receiving honoraria from the Society for Investigative Dermatology. Dr Kalb has received grants/research funding from AbbVie, Amgen, Boehringer Ingelheim, Janssen-Ortho, Merck & Co, and Novartis Pharmaceuticals Corp over the last 24 months; during this time frame, he has also served as a consultant and received honoraria for Dermira, Janssen-Ortho, and Sun Pharmaceutical Industries Ltd and a DSMB member honoraria for Eli Lilly and Co. Dr Mehta is a full-time US government employee and receives research grants to the National Heart, Lung, and Blood Institute from AbbVie, Janssen, Celgene, and Novartis and serves on the medical board of the National Psoriasis Foundation and is associate editor of the *Journal of Translational Medicine*. Dr Menter in the last 24 months has served on the advisory board for AbbVie, Allergan, Amgen, Boehringer Ingelheim, Eli Lilly, Janssen Biotech, and LEO Pharma; has worked as a consultant for AbbVie, Allergan, Amgen, Eli Lilly, Galderma, Janssen Biotech, LEO Pharma, Novartis, Pfizer, Vitae, and Xenoport; has acted as an investigator for AbbVie, Allergan, Amgen, Anacor, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, Janssen Biotech, LEO Pharma, Merck, Neothetics, Novartis, Pfizer, Regeneron, Symbio/Maruho, and Xenoport; serves as a speaker for AbbVie, Amgen, Janssen Biotech, and LEO Pharma; has received compensation in the form of grants from AbbVie, Allergan, Amgen, Anacor, Boehringer Ingelheim, Celgene, Dermira, Janssen Biotech, LEO Pharma, Merck, Neothetics, Novartis, Pfizer, Regeneron, Symbio/Maruho, and Xenoport; and has received honoraria from AbbVie, Allergan, Amgen, Boehringer Ingelheim, Eli Lilly, Galderma, Janssen Biotech, LEO Pharma, Novartis, Pfizer, Vitae, and Xenoport. Dr Simpson has served as a consultant for AbbVie, Anacor, Celgene, Dermira, Genentech,

Leo, GlaxoSmithKline, Pfizer, Regeneron, Sanofi-Genzyme, Menlo, and Eli Lilly in the last 24 months and has acted as the primary investigator for the following sponsored trials: Anacor, Celgene, Chugai, Dermira, Eli Lilly, Genentech, MedImmune, Merck, Novartis, Regeneron, Roivant, Tioga, and Vanda. Dr Takeshita receives a research grant from Pfizer (to the Trustees of the University of Pennsylvania) and has received payment for continuing medical education work related to psoriasis that was supported indirectly by Eli Lilly. Dr Tying conducts clinical studies sponsored by the following companies: AbbVie/BI, Celgene, Coherus, Dermira, Eli Lilly, Janssen, Leo, Merck, Novartis, Pfizer, Regeneron/Sanofi, and Valeant and is a speaker for AbbVie, Eli Lilly, Janssen, Leo, Novartis, Pfizer, Regeneron/Sanofi, and Valeant. Dr Van Voorhees has served on the advisory board of Celgene, Dermira, Allergan, Merck, Pfizer, Aqua, AstraZeneca, Janssen, Amgen, Leo, Allergan, and Lilly; acts as a consultant and serves on the board for Novartis and AbbVie; and has received a portion of ex-spouse pension from Merck. Drs Chiesa Fuxench, Noe, Shin, and Wan have no conflicts of interest to declare.

Accepted for publication May 30, 2019.

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Published online August 9, 2019.

0190-9622/\$36.00

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<https://doi.org/10.1016/j.jaad.2019.05.080>

*Abbreviations used:*

CI:	confidence interval
DLQI:	Dermatology Life Quality Index
EQ-VAS:	EQ-5D-3L visual analog scale
HRQoL:	health-related quality of life
MCID:	minimal clinically important difference
nbUVB:	narrowband ultraviolet B
OR:	odds ratio
PASI 75:	a 75% reduction in the Psoriasis Area and Severity Index score
PRO:	patient-reported outcome

were small ( $n = 10$ -55), each was performed at a single center, and the data on PROs were limited. Additionally, there are minimal data comparing phototherapy, as monotherapy, to other active comparators. There are also relatively limited data about the impact of nbUVB on patient-reported measures of health-related quality of life (HRQoL) in patients with psoriasis and, to our knowledge, no controlled trials comparing phototherapy alone versus modern biologic treatments.<sup>7</sup> We recently published the results of the Vascular Inflammation in Psoriasis trial, which showed that the rate of achieving PASI 75 at week 12 was nearly identical for patients receiving adalimumab and those receiving phototherapy.<sup>8</sup> Therefore, the purpose of this study was to evaluate the impact of adalimumab and phototherapy on commonly used measures of HRQoL when compared with each other and compared with placebo injections.

## METHODS

### Patients and study design

This was a multicenter, 3-arm, randomized, placebo-controlled, 12-week trial designed to enroll 97 patients with a 1:1:1 allocation at baseline to adalimumab injections, placebo injections, or nbUVB phototherapy ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01553058) no. NCT01553058), as previously described.<sup>8</sup> All participants were 18 years or older, had an affected body surface area of 10% or greater, had a PASI score of 12 or greater, and were not receiving any concurrent prescription psoriasis treatment. Patients were also excluded if they had a previous adverse event from or lack of response to a tumor necrosis factor- $\alpha$  antagonist and/or ultraviolet phototherapy that led to discontinuation of either of those therapies. Adalimumab therapy (or corresponding placebo injections) was administered in a double-blind manner as subcutaneous injections with an initial 80-mg dose at baseline followed by maintenance doses of 40 mg every other week throughout the study.

nbUVB phototherapy was administered 3 times weekly. Blinding of phototherapy (i.e., such as the

use of sham treatment) was not performed. Dosing was based on an estimated minimal erythema dose and Fitzpatrick skin type using a modified protocol published by Zanolli and Feldman.<sup>9</sup> Participants with skin types 1/2, 3/4, and 5/6 received 300, 500, and 800 mJ/cm<sup>2</sup>, respectively, as initial doses. After that, dosing was adjusted at each treatment visit, allowing for increases as a percentage of minimal erythema dose based on patient reaction to the previous treatment. Patients presenting with 1) transient erythema lasting for less than 24 hours after treatment had a 20% dose increase; 2) persistent erythema for 24 to 48 hours had the same dose held until the erythema lasted for less than 24 hours; and 3) persistent erythema for longer than 48 hours resulted in no treatment on that day and a return to the last lower dose that did not cause persistent erythema. The primary outcomes were aortic vascular inflammation measured by 18-fludeoxyglucose positron emission tomography/computed tomography and blood-based cardiovascular biomarkers. Sample size calculations were based on the primary outcome. Details of the power analyses, randomization, and blinding methods were reported in a previous article.<sup>8</sup> Here, we report secondary outcomes measuring HRQoL.

The institutional review board at the University of Pennsylvania or the respective local institutional review board, when indicated, approved the study, and the study was conducted in accordance with the principles of the Declaration of Helsinki, good clinical practice, and the Belmont Report. All study participants provided written informed consent. The randomized, placebo-controlled trial was overseen by an independent data-monitoring committee.

### PROs

The Dermatology Life Quality Index (DLQI) is a dermatology-specific quality-of-life questionnaire that has been used extensively in psoriasis clinical trials.<sup>10</sup> The 10 DLQI questions are scored on a 4-point scale (range, 0-3). The total DLQI score ranges from 0 to 30. Higher score indicates more impaired HRQoL.<sup>11</sup>

The EQ-5D-3L is a widely used measure of generic health status.<sup>12</sup> The first part of the tool involves rating the extent of having difficulties in 5 dimensions: mobility, self-care, usual activities, pain, and anxiety. Each dimension is ranked according to 3 levels as follows: *having no problems*, *having some or moderate problems*, or *being unable to do/having extreme problems*. These domains can be converted to an EQ-5D Index utility score in which 0 corresponds to death and 1 corresponds to perfect health.<sup>13,14</sup> The second part of the EQ-5D-3L is a

**Table I.** Baseline characteristics of the study population

Characteristics	Placebo (n = 31)	Adalimumab (n = 33)	Phototherapy (n = 33)
Age in years, mean (SD)	44.3 (14.5)	44.2 (14.0)	42.0 (14.0)
Male, n (%)	20 (60.5)	24 (72.7)	23 (69.7)
Body mass index in kg/m <sup>2</sup> , mean (SD)	32.0 (7.7)	30.9 (7.4)	32.6 (8.7)
Alcohol, standardized units/week, mean (SD)	2.53 (3.54)	3.30 (4.50)	2.59 (3.79)
Current smoker, n (%)	9 (29.03)	10 (30.30)	5 (15.15)
Psoriasis duration in years, mean (SD)	19.3 (13.6)	15.0 (14.7)	15.9 (13.6)
Psoriatic arthritis, n (%)	2 (6.5)	4 (12.1)	3 (9.1)
History of biologic treatment, n (%)	11 (35.5)	10 (30.3)	8 (24.2)
History of phototherapy, n (%)	11 (35.5)	5 (15.2)	13 (39.4)
Psoriasis assessment, baseline			
% BSA, mean (SD)	25.7 (15.0)	23.4 (14.5)	23.0 (13.4)
PASI, median (IQR)	15 (13.3-20.6)	17.4 (15.4-22)	16.8 (14.5-21)
PGA, mean (SD)	3.2 (0.6)	3.4 (0.6)	3.3 (0.7)
Health-related quality of life, baseline			
DLQI, mean (SD)	12.13 (6.75)	13.67 (5.90)	12.79 (7.10)
EQ-5D-3L Index, mean (SD)	0.80 (0.13)	0.78 (0.14)	0.72 (0.21)
EQ VAS, mean (SD)	67.58 (23.78)	53.38 (31.07)	54.86 (34.55)

BSA, Body surface area; DLQI, Dermatology Life Quality Index; IQR, interquartile range; PASI, Psoriasis Area and Severity Index; PGA, physician global assessment; SD, standard deviation; VAS, visual analogue scale.

visual analogue scale (EQ-VAS) on which the patient marks his or her health status on a 10-cm vertical scale that ranges from 0 to 100, with a higher score corresponding to a better HRQoL.

### Statistical analyses

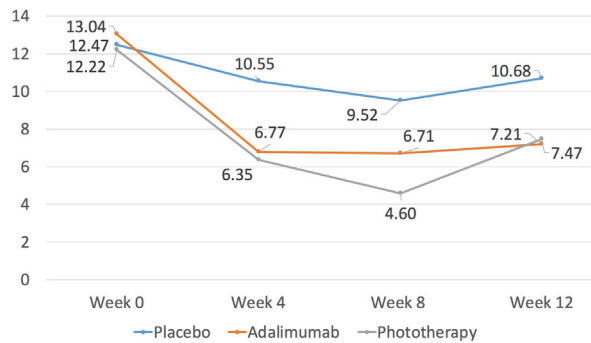
All data were summarized by using descriptive statistics and graphical techniques. The mean EQ-5D VAS and mean DLQI responses were plotted longitudinally over weeks 0, 4, 8, and 12. Multiple imputation with bootstrapping was used to account for missing data that was greater than 10% at week 4 on the EQ-5D VAS and DLQI. A change score for each PRO was calculated as the difference between the week 12 and baseline values. Between-group comparisons were conducted using 1-way analysis of variance, with Tukey correction used for multiple comparisons. The continuous DLQI and EQ-5D-3L overall and subcomponent scores were converted into 2 different dichotomous variables to identify individuals who reported that their skin disease had *no effect* on their quality of life and to identify individuals who achieved the previously established minimal clinically important difference (MCID) for the PRO.<sup>15</sup> For the DLQI, a score of less than 2 at 12 weeks signified that symptoms had *no effect* on quality of life. (A score of greater than 2 suggests *any effect*.) Achievement of the MCID is defined as a 4-point decrease in DLQI score at week 12.<sup>16</sup> For the EQ-5D-3L, scores less than or equal to 1 represented *no problem/effect on quality of life*, and scores greater than 1 suggested *any problem*.<sup>12</sup>

Achievement of the MCID was considered at a 0.05-point increase in score at week 12.<sup>17</sup> Using these dichotomized outcomes, logistic regression was used to compare the odds of achieving *no effect on quality of life* or the MCID for each treatment as compared with placebo and with each other. Various sensitivity analyses were conducted: imputing patients who dropped out as treatment failures, excluding patients with a history of phototherapy, history of biologic drug use, and those with psoriatic arthritis (data not shown). We also performed a multivariable logistic regression model to adjust for comorbidities that effect HRQoL as a sensitivity analysis to ensure that any potential unbalanced covariates that can occur during randomization of trials with smaller sample sizes did not affect the results (data not shown). Stata, version 15.1 (StataCorp LLC, College Station, TX), was used for analysis.

### RESULTS

After screening 179 patients for eligibility, 97 were randomized to the treatment groups. The baseline characteristics were similar for the 3 treatment groups (Table I and previously described).<sup>8</sup> Study participants were a mean of 43.5 years old, were 69.1% male, and had a median PASI of 16.7. At baseline, the mean DLQI scores were 12.13, 13.67, and 12.79 in the placebo, adalimumab, and phototherapy groups, respectively. The mean EQ-5D Index scores were 0.80, 0.78, and 0.72 in the placebo, adalimumab, and phototherapy groups,





**Fig 1.** Mean Dermatology Life Quality Index score over time by treatment group.

respectively. The mean EQ-VAS scores were 67.58, 53.38, and 54.86 in the placebo, adalimumab, and phototherapy groups, respectively.

After 12 weeks, patients in all 3 treatment groups achieved statistically significant improvements in skin-related HRQoL compared with baseline, as measured by the DLQI (Fig 1 and Table II). However, the difference in the mean change score was higher when comparing the change in the adalimumab group versus the change in the placebo group ( $-3.80$ ; 95% CI,  $-7.64$  to  $0.04$ ) and the change in the phototherapy group versus the change in the placebo group ( $-4.80$ ; 95% CI,  $-8.67$  to  $-0.93$ ) (Table II). There was no difference in the change score when comparing the phototherapy group with the adalimumab group ( $-1.0$ ; 95% CI,  $-4.81$  to  $2.81$ ). When using dichotomous outcomes, patients were more likely to report *no effect* versus *any effect* as determined by the DLQI in the adalimumab and phototherapy groups compared with the placebo group and in the phototherapy group compared with the adalimumab group. However, statistical significance for *no effect* was observed only in the comparison of phototherapy versus placebo (odds ratio [OR], 7.41; 95% CI, 1.85-29.66). Participants in both active treatment groups were more likely to reach a clinically meaningful improvement in DLQI than those in the placebo group (adalimumab vs placebo: OR, 2.88; 95% CI, 1.02-8.17; phototherapy vs placebo: OR, 8.83; 95% CI, 2.47-31.57). When comparing phototherapy to adalimumab, patients receiving phototherapy were more likely to achieve the MICD, but this result was not statistically significant (OR, 3.07; 95% CI, 0.85-11.13) (Table III).

The phototherapy and adalimumab groups also had improved generic HRQoL change scores at week 12 compared with baseline, as measured by the EQ-5D Index and EQ-VAS (Fig 2). Both active treatment groups performed better than the placebo group, as determined by the EQ-5D Index and EQ-VAS change scores. Only the change score in the phototherapy

group versus the placebo group was statistically significant ( $P = .004$ ; adalimumab vs placebo,  $P = .36$ ) (Table II). There was no difference in the mean change score between phototherapy vs adalimumab using the EQ-5D Index (0.80; 95% CI,  $-0.02$  to  $0.18$ ) or EQ VAS ( $-1.66$ ; 95% CI,  $-20.53$  to  $17.21$ ). In general, patients treated with both adalimumab and phototherapy scored higher in the individual EQ-5D-3L domains than those who received placebo, but only phototherapy compared with placebo achieved statistical significance in the pain domain (OR of having *no problems* vs *any problems*, 5.97; 95% CI, 1.95-18.33) (Table III). There were higher odds of achieving the MCID for the EQ-5D Index score when comparing phototherapy versus placebo (OR, 9.78; 95% CI, 2.99-31.95) and phototherapy versus adalimumab (OR, 4.07; 95% CI, 1.42-11.70). Statistical significance of achieving the MCID for the EQ-5D Index score was not observed in the adalimumab versus placebo groups (OR, 2.40; 95% CI, 0.76-7.55). The results were robust across a variety of sensitivity analyses (data not shown), with the exception that significance in the EQ-5D pain domain was not seen in phototherapy versus placebo when patients with a history of phototherapy were excluded.

## DISCUSSION

Both adalimumab and phototherapy are well-established treatments for psoriasis, and the results from this randomized controlled trial confirm that both adalimumab and phototherapy treatments are also associated with a statistically significant improvement in PROs, compared with placebo, after 12 weeks of treatment. Additionally, patients treated with phototherapy for 12 weeks were more likely to report that psoriasis had no effect on QoL than patients in the placebo group, as measured by the DLQI (OR, 7.41; 95% CI, 1.85-29.66). They were also more likely to report *no problem* with pain, as measured by the EQ-5D-3L (OR, 5.97; 95% CI, 1.95-18.33). The results of this study are important in that they allow for a direct comparison of the patient-reported benefits of these first-line treatments in a rigorous randomized controlled study.

Although extensive data are available on the impact of adalimumab on DLQI and EQ-5D-3L scores, similar data are limited for phototherapy.<sup>19-21</sup> Our study shows that phototherapy alone not only improves skin-related quality of life (based on the DLQI) in psoriasis patients but also improves general HRQoL (based on the EQ-5D-3L). Of special interest, our results show that patients treated with phototherapy were more likely to report *no problem* with pain than those treated with placebo (OR, 5.97; 95% CI, 1.95-

**Table II.** Change between week 12 and baseline scores of each PRO, by treatment group

Instrument	Change score, by group (week 12 – baseline)			Difference of mean change score (95% CI)*		
	Placebo, mean (SD), P value†	Adalimumab, mean (SD), P value†	Phototherapy, mean (SD), P value†	Adalimumab vs placebo	Phototherapy vs placebo	Phototherapy vs adalimumab
DLQI‡	<b>-3.26 (5.38), .002</b>	<b>-7.06 (7.71), &lt;.001</b>	<b>-8.06 (5.58), &lt;.001</b>	-3.80 (-7.64 to 0.04)	<b>-4.80 (-8.67 to -0.93)</b>	-1.00 (-4.81 to 2.81)
EQ-5D Index§	-0.002 (0.17), .95	<b>0.07 (0.14), .01</b>	<b>0.15 (0.21), &lt;.001</b>	0.07 (-0.04 to 0.18)	<b>0.15 (0.04 to 0.26)</b>	0.80 (-0.02 to 0.18)
EQ VAS	-7.26 (23.97), .11	<b>11.73 (31.94), .046</b>	10.06 (36.76), 0.14	18.99 (-0.04 to 38.01)	17.32 (-1.85 to 36.50)	-1.66 (-20.53 to 17.21)

Bold values are statistically significant.

CI, Confidence interval; DLQI, Dermatology Life Quality Index; SD, standard deviation; VAS, visual analogue scale.

\*95% CI based on the post hoc group comparisons with Tukey adjustment.

†P value based on paired t test.

‡The DLQI is scored from 0 to 30, where a higher score signifies more impaired health-related quality of life (HRQoL). A negative change score is associated with improvement in HRQoL over time. A change score of  $\pm 4$  is associated with a clinically meaningful change in HRQoL.

§The EQ-5D Index score is a measure of utility, where 0 corresponds to death and 1 corresponds to perfect health. A positive change score is associated with improvement in HRQoL over time. A change of 0.05 represents a clinically meaningful improvement in HRQoL for patients.

||The EQ-VAS is a visual analogue scale ranging from 0 to 100, where a higher score corresponds to improved HRQoL. A positive change score is associated with improvement in HRQoL over time. The minimally important difference has been estimated to be between 7 and 8, depending on the disease being examined.<sup>17,18</sup>

18.33). Patients treated with adalimumab also were more likely to report *no problem* with pain than those treated with placebo; however, this finding was not statistically significant (OR, 2.90; 95% CI, 0.97-8.66). The instruments ask questions about overall pain and do not differentiate between skin pain and joint pain, which may explain the improvement seen after treatment with phototherapy. An exact mechanism for how phototherapy improves overall pain is not well understood; however, previous studies suggest that the skin generates opioid  $\beta$ -endorphins in response to ultraviolet radiation, which ameliorates pain signals.<sup>22</sup>

Patients treated with phototherapy were more likely to achieve a clinically significant improvement in the EQ-5D Index (OR, 4.07; 95% CI, 1.42-11.70) compared with patients treated with adalimumab. Patients treated with phototherapy were more than twice as likely as patients treated with adalimumab to achieve *no impairment* on the DLQI (OR, 2.47; 95% CI, 0.85-7.19) and *no pain* on the EQ-5D-3L (OR, 2.06; 95% CI, 0.75-5.67); however, these findings were not statistically significant. These results suggest that phototherapy may outperform or at least achieve similar results to adalimumab on PROs in patients with psoriasis. Previously, in a multicenter routine clinical practice study, we showed that patients with psoriasis treated with phototherapy had an HRQoL based on the DLQ1 similar to that of patients treated with biologics, including adalimumab and ustekinumab.<sup>20</sup>

Our study has certain limitations. First, the relatively small sample size resulted in imprecise estimates of our measurements of HRQoL. Similarly, HRQoL was a secondary outcome for our trial, and the study was not specifically designed to test the hypothesis of superiority or noninferiority of adalimumab compared with phototherapy on measures of HRQoL. Of special importance, the trial was designed such that after the placebo-controlled period, all patients crossed over to start or continue adalimumab for 52 weeks. As a result, patients who may not have been ideal candidates for phototherapy (e.g., those with extensive scalp or genital disease) may have enrolled because they would eventually be treated with an approved biologic, and, thus, we may have underestimated the benefit of phototherapy in patients who are better candidates for this treatment approach. Additionally, there was no sham treatment for phototherapy, so we are unable to ascertain the degree to which the improvements observed are related to the efficacy of phototherapy as opposed to the benefits of being seen regularly by phototherapy staff. Finally, our study found lower response rates, as determined by PASI

**Table III.** The odds of reporting standard improvements in patient-reported outcomes, by treatment group

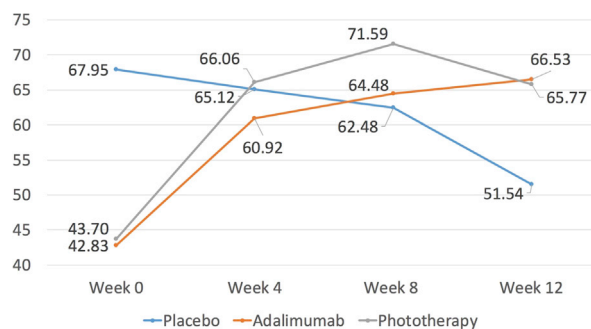
Instrument	Placebo, n (%)	Adalimumab, n (%)	Phototherapy, n (%)	Adalimumab vs placebo, OR (95% CI)	Phototherapy vs placebo, OR (95% CI)	Phototherapy vs adalimumab, OR (95% CI)
No impairment in Quality of Life*						
DLQI*	3 (10.0)	8 (25.0)	14 (45.16)	3.00 (0.71-12.62)	<b>7.41 (1.85-29.66)</b>	2.47 (0.85-7.19)
EQ-5D-3L†						
Mobility dimension	25 (83.33)	26 (81.25)	26 (83.87)	0.87 (0.23-3.20)	1.04 (0.27-4.03)	1.20 (0.33-4.43)
Self-care dimension	27 (90.0)	31 (96.88)	29 (93.55)	3.44 (0.34-35.09)	1.61 (0.25-10.39)	0.47 (0.04-5.42)
Activity dimension	21 (70.0)	25 (78.12)	27 (87.10)	1.53 (0.49-4.81)	2.89 (0.78-10.71)	1.89 (0.49-7.24)
Pain dimension	7 (23.33)	15 (46.88)	20 (64.52)	2.90 (0.97-8.66)	<b>5.97 (1.95-18.33)</b>	2.06 (0.75-5.67)
Anxiety dimension	17 (56.67)	20 (62.50)	23 (74.19)	1.27 (0.46-3.52)	2.20 (0.75-6.48)	1.73 (0.59-5.06)
Achievement of the Minimal Clinically Important Difference†						
DLQI	13 (43.33)	22 (68.75)	27 (87.1)	<b>2.88 (1.02-8.17)</b>	<b>8.83 (2.47-31.57)</b>	3.07 (0.85-11.13)
EQ-5D index	6 (20.00)	12 (37.50)	22 (70.97)	2.40 (0.76-7.55)	<b>9.78 (2.99-31.95)</b>	<b>4.07 (1.42-11.70)</b>

Bold values are statistically significant.

DLQI, Dermatology Life Quality Index; OR, odds ratio.

\*Univariable logistic regression comparing the odds of reporting *no effect* on quality of life (<2) versus *any effect* (≥2) for the DLQI and *no problem* (≤1) vs *any problem* (>1) for each of the EQ-5D dimensions.

†Univariable logistic regression comparing the odds of achieving MCID for the DLQI (4-point decrease in DLQI score at week 12) and EQ-5D index (0.05-point increase in EQ-5D index value at week 1).

**Fig 2.** Mean EQ-5D-3L visual analog scale scores over time by treatment group.

75, than what is typically expected to adalimumab (46.88%<sup>8</sup> vs >71%)<sup>5,23</sup> and nbUVB (46.67%<sup>8</sup> vs 62%)<sup>6</sup>.

In summary, the results of this multicenter, randomized, placebo-controlled trial suggest that nbUVB phototherapy treatment of psoriasis achieves similar improvements in HRQoL to adalimumab, with higher improvements in specific measures. Surprisingly, phototherapy also significantly improved symptoms of pain in patients with psoriasis, a new finding for a treatment that has been used for decades. Unfortunately, phototherapy is limited by both its availability (90% of counties in the United States have no physicians who offer phototherapy) and its inconvenience, given the difficulties for patients who do not live near a physician offering phototherapy to travel to the office for regular

treatments.<sup>24</sup> Therefore, we are conducting a large-scale pragmatic trial of home- vs office-based narrowband phototherapy for the treatment of psoriasis (the LITE study, [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03726489) no. NCT03726489) to further advance our knowledge of how to use this treatment in a safe, effective, and patient-centered manner.

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