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ORIGINAL ARTICLE

Secukinumab demonstrates greater sustained improvements in daily activities and personal relationships than ustekinumab in patients with moderate-to-severe plaque psoriasis: 52-week results from the CLEAR study

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Abstract

Background Psoriasis can greatly impact patients' lives by influencing clothing worn as well as by impairing sexual functioning. Secukinumab, a human monoclonal antibody selectively neutralizing interleukin-17A, has demonstrated good efficacy and safety in the treatment of moderate-to-severe psoriasis and psoriatic arthritis with a rapid onset of action and sustained response.

Objective This analysis using the CLEAR study, a phase 3b double-blind study comparing the efficacy and safety of secukinumab vs. ustekinumab in adults with moderate-to-severe plaque psoriasis, evaluated the treatment effects on patient's daily activities and personal relationships.

Methods Impact on daily activities (interference with home/shopping/garden, and influence on clothes worn) and impact on personal relationships (problems with partner/others, and sexual difficulties) as well as their corresponding subscales were selected from the Dermatology Life Quality Index scale and evaluated for patients treated with secukinumab vs. ustekinumab from the CLEAR study. Treatment differences in mean scores and proportions of responders (score = 0, indicating no impact) were evaluated through 52 weeks. Time to response was evaluated through Week 16.

Results Significant differences between secukinumab and ustekinumab were observed for daily activities and personal relationships at Week 16 and sustained through Week 52 (Week 52 response rates for daily activities: 82.9% vs. 73.5%, including interference with home/shopping/garden: 88.5% vs. 78.2%, and influence on clothes worn: 85.6% vs. 74.4%; personal relationships: 86.1% vs. 73.7%, including problems with partner/others: 86.6% vs. 74.8%, and sexual difficulties: 88.5% vs. 74.3%; all $P < 0.01$). The median time to response was 4 weeks for secukinumab vs. 8 weeks for ustekinumab for daily activities and personal relationships (both $P < 0.05$).

Conclusion Secukinumab treatment helps patients with moderate-to-severe plaque psoriasis have a more normal life faster when compared to ustekinumab, by providing greater and sustained improvement in clothing choice and sexual functioning.

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Conflicts of interest

Dr. Blauvelt has served as a scientific adviser and clinical study investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Genentech, GlaxoSmithKline, Janssen, Eli Lilly, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Sandoz, Sanofi Genzyme, Sun Pharma, UCB and Valeant, and as a paid speaker for Lilly, Regeneron and Sanofi Genzyme. Dr. Reich has served as a consultant and/or paid speaker for and/or participated in clinical trials sponsored by companies that manufacture drugs used for the treatment of psoriasis

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including AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly, Forward Pharma, GSK, Janssen-Cilag, Leo Pharma, Medac, MSD, Novartis, Pfizer, Vertex, Takeda and Xenoport.

Dr. Mehlis has served as a consultant and has been a principal investigator for several psoriasis studies including this study for Novartis.

Dr. Vanaclocha has served as a principal investigator in clinical studies sponsored by Celgene, Janssen, Merck and Novartis.

Dr. Abramovits has served on advisory boards, as a speaker, as a consultant, and has been an investigator for AbbVie, Allergan, Amgen, Anacor Pharm, Aqua Pharma, Celgene, Centocor, Conversant, Eli Lilly, Exeltis, Galderma, Genentech, Glenmark, GSK, Innocutis, Janssen Biotech, Leo Pharma, MediMetrics, Merck, Novartis, Novan, Otsuka, PharmaDerm, Perrigo, Pfizer, Promius, Prothena, PuraCap, Quinova, Ranbaxy, Regeneron, Sanofi, Serono, Taro, Teva, Tioga, Tolmar, Valeant, and Xenoport.

Dr. Sofen has been an investigator and consultant for Novartis, Amgen, Lilly, Merck, Pfizer and Celgene.

Dr. Zhao was a full-time employee of Novartis Pharmaceuticals Corporation at the time of this research.

Dr. Gilloteau is a full-time employee of Novartis Pharma AG.

Mr. Davenport is a full-time employee of RTI Health Solutions.

Mrs. Williams is a full-time employee of RTI Health Solutions.

Dr. Guana is a full-time employee of Novartis Pharmaceuticals Corporation.

Dr. Tying has performed clinical research sponsored by Novartis.

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Introduction

Psoriasis is a chronic, immune-mediated, systemic inflammatory disease that affects more than 125 million people in the United States (US), Europe and Japan.¹ Patients exhibit a wide spectrum of symptoms, including itching, pain and scaling of varying severity.^{2,3} The impact of psoriasis can be substantial on health-related quality of life (HRQOL) and is typically lifelong unless the patient receives highly effective therapy.⁴ Indeed, treatments that can help patients, especially those with moderate-to-severe disease, attain a normal everyday life, are desired.⁵

Psoriasis impacts activities of daily living, especially affecting clothing choice, the need to bathe more frequently and the need to change/wash clothes more frequently.⁶ More than 40% of patients with moderate-to-severe psoriasis in one European survey reported that psoriasis affected their clothing choice either 'very much' or 'a lot'.⁶ Not only are clothing choices used by patients to potentially mask their disease (i.e. wearing long sleeves in the warm summer months), but improper selection of clothing can exacerbate symptoms (e.g. clothes may stick to open areas and traumatize lesions),⁷ which can lead to further impairment in HRQOL. Psoriasis also impacts emotional and sexual functioning, which disrupts social interactions and intimate relationships.^{8–14} Sensitive issues, however, such as sexual relationships, typically are not assessed by clinicians.¹² Richards *et al.*¹⁵ propose that the psychologic burden associated with psoriasis is a stronger component of psoriasis burden than physical aspects of the disease, such as disease severity, location or duration. On a promising note, patient complaints of psoriasis-related social and sexual difficulties have significantly decreased

since the advent of highly efficacious biologic therapeutics for the treatment of psoriasis.^{16–18}

Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin-17A, has been shown to have significant efficacy in the treatment of moderate-to-severe psoriasis and psoriatic arthritis, demonstrating a rapid onset of action and sustained responses with a favourable safety profile^{19–23} and has been approved for use in these indications.^{24,25} In the pivotal phase 3 trials, secukinumab achieved significantly greater improvements on skin-related quality of life as measured by the Dermatology Life Quality Index (DLQI), including aspects related to sexual difficulty and clothing worn, when compared to both placebo and etanercept.^{22,26} The impact of secukinumab vs. ustekinumab on daily activities and personal relationships has not been investigated. Therefore, for this post hoc analysis, long-term (52-week) data from a randomized clinical trial^{27,28} are used to compare the efficacy of secukinumab vs. ustekinumab on enabling patients to have more normal lives, especially related to daily activities and personal relationships. Daily activities were assessed using items related to interference with going shopping or looking after home/garden, and influence on clothes worn. Personal relationship impacts were assessed using items related to interactions with partners/close friends/relatives and sexual difficulties.

Methods

Study design

As previously reported, CLEAR was a multicentre, randomized, double-blind, head-to-head, parallel-group superiority trial.^{27,28}

Eligible patients were randomized 1 : 1 to subcutaneous injection of secukinumab 300 mg (dosing per label) or ustekinumab (dosing per label: 45 mg for patients ≤ 100 kg at baseline; 90 mg for patients >100 kg at baseline). Randomization was stratified by body weight at baseline (≤ 100 kg and >100 kg). Patients assigned to secukinumab received a 300 mg dose at baseline and Weeks 1, 2 and 3, and then every 4 weeks from Week 4 onwards. Ustekinumab dosage (45 or 90 mg based on weight) was dosed at baseline and Week 4, then every 12 weeks from Week 16 onwards. To maintain blinding, placebo injections matching the secukinumab regimen were given to patients in the ustekinumab group. After the Week 52 database lock, secukinumab patients entered an extended treatment phase (up to Week 104). The focus of the current evaluation is on patient-reported outcomes through Week 52.

The Declaration of Helsinki, the International Conference on Harmonisation's Harmonised Tripartite Guideline for Good Clinical Practice and applicable local regulations (including European Directive 2001/20/EC; US Code of Federal Regulations Title 21; and Japanese Ministry of Health, Labor and Welfare) guided the design, implementation and reporting of this clinical trial. All patients signed consent prior to study entry.

Study patients

The CLEAR study randomized 676 adults with moderate-to-severe chronic plaque psoriasis. Study inclusion criteria were as follows: (i) diagnosis of psoriasis at least 6 months before randomization; (ii) Psoriasis Area and Severity Index (PASI) of 12 or greater, Investigator's Global Assessment (IGA mod 2011) score of 3 (moderate) or greater [5-point scale: 0 (clear)–4 (severe)], and at least 10% of body surface area involvement; and (iii) be a candidate for systemic therapy (chronic plaque psoriasis inadequately controlled by topical treatment, and/or phototherapy, and/or previous systemic therapy). Key exclusion criteria were as follows: other forms of psoriasis, drug-induced psoriasis, ongoing use of psoriasis treatments, previous exposure to secukinumab or other IL-17 pathway inhibitors, and previous exposure to ustekinumab or other any therapies targeting IL-12 or IL-23. Use of an adequate method of birth control was required by women of childbearing potential.

Impact on daily activities and personal relationships

Specific questions related to daily activities and personal relationships were captured in the Dermatology Life Quality Index (DLQI)^{29–31} which was administered in CLEAR at baseline and Weeks 4, 8, 12, 16, 28, 48 and 52. The daily activities items focused on interference with going shopping or looking after one's home or garden and influence on clothes worn. The personal relationships items focused on impact on relationships with partner, close friends or relatives and sexual difficulties. Each question asks patients to consider the impact over the last week and includes four response categories for how much the

skin problem had affected each aspect: not at all (score = 0), a little (score = 1), a lot (score = 2) and very much (score = 3). In addition to evaluating the individual item scores, the item scores are summed to form two subscale scores (daily activities and personal relationships). Responder was defined as a post-baseline score of 0 for the daily activities and personal relationships subscales as well as for each of the individual items examined, indicating an achievement of no effect of skin problems on HRQOL.

Analytic methods

The daily activities and personal relationships scores as well as the individual item scores were evaluated from baseline to Week 52 for patients with a baseline score and at least one postbaseline score. Analyses were exploratory, therefore not adjusted for multiple comparisons. Mean changes from baseline at Week 16 and Week 52 were summarized using analysis of covariance (ANCOVA); the ANCOVA model included treatment, analysis visit and body weight stratum as covariates and the baseline score as a continuous variable. The proportions of responders at Week 16 and Week 52 were summarized by treatment using the Fisher's exact test. In addition, time to response (defined as the period from the randomization to the week when the first score of 0 had occurred among patients with baseline score >0 , indicating no impact) was summarized using Kaplan–Meier method up to Week 16. Within the time to response analyses, Cox proportional hazards regression model was used to assess treatment effect after adjustment for body weight and baseline score as covariates.

Table 1 Demographics and baseline characteristics

	Secukinumab (N = 336)	Ustekinumab (N = 339)
Male, %	68.0	74.3
Age, mean (SD)	45.2 (13.96)	44.6 (13.67)
Weight, mean (SD)	87.4 (19.95)	87.2 (22.11)
BSA score, mean (SD)	32.6 (17.78)	32.0 (16.80)
PASI score, mean (SD)	21.7 (8.50)	21.5 (8.07)
IGA, n (%)		
Moderate (level = 3)	205 (60.8)	214 (63.1)
Severe (level = 4)	130 (38.6)	125 (36.9)
Daily activities, mean (SD)		
Skin interferes with going shopping or looking after home/garden	1.1 (1.01)	1.1 (1.01)
Skin influenced clothes worn	1.7 (1.11)	1.8 (1.14)
Personal relationships, mean (SD)		
Skin created problems with partner or close friends or relatives	1.1 (1.02)	1.0 (1.00)
Skin caused any sexual difficulties	0.9 (1.10)	0.9 (1.08)

BSA, body surface area; IGA, Investigator's global assessment; PASI, Psoriasis area and severity index; SD, standard deviation.

Results

Patient characteristics

Baseline demographic and clinical characteristics were similar across treatment groups (Table 1). The mean age of patients ranged from 44.6 years (ustekinumab) to 45.2 years (secukinumab). Baseline mean PASI scores were 21.7 for secukinumab and 21.5 for ustekinumab.

Daily activities

Mean (standard deviation) baseline daily activities scores were similar for both treatment arms (secukinumab = 2.9 (1.88); ustekinumab = 2.8 (1.83), Table 1). The mean reduction in the daily activities was significantly higher for secukinumab than for ustekinumab at Week 16 (−2.63 vs. −2.43, $P < 0.001$, Fig. 1) and was maintained through Week 52 (−2.60 vs. −2.33, $P < 0.001$). At the item level, mean reductions for interference with shopping or looking after home/garden (Week 16: −0.99 vs. −0.91, $P < 0.05$; Week 52: −0.98 vs. −0.88, $P < 0.01$) and influence on clothes worn (Week 16: −1.63 vs. −1.50, $P < 0.01$; Week 52: −1.60 vs. −1.42, $P < 0.0001$) were significantly higher

for secukinumab than for ustekinumab at Week 16 and were sustained through 52 weeks.

The response rates (% patients reporting no impact) were also significantly higher for secukinumab than for ustekinumab for the daily activities at Week 16 and were sustained over 52 weeks (Fig. 2; Week 16: 83.6% vs. 73.1%, $P < 0.01$; Week 52: 82.9% vs. 73.5%, $P < 0.01$). At the item level, the response rates were significantly higher for secukinumab than for ustekinumab for interference with going shopping or looking after home/garden (Week 16: 88.5% vs. 79.6%, $P < 0.05$; Week 52: 88.5% vs. 78.2%; $P < 0.01$) and influence on clothes worn (Week 16: 86.7% vs. 77.9%, $P < 0.01$; Week 52: 85.6% vs. 74.4%, $P < 0.01$).

The proportion of patients reporting their first daily activities response through Week 16 was significantly higher for secukinumab than for ustekinumab (91.4% vs. 85.5%, $P < 0.01$) (Table 2). The median time to daily activities response was 4 weeks for secukinumab vs. 8 weeks for ustekinumab; with a statistically significant difference after adjusting for body weight and baseline score in the regression model (Hazard Ratio, 1.29; 95% Confidence Interval, 1.08–1.54; $P < 0.01$) (Table 2). Specifically, the model showed that secukinumab-treated patients were

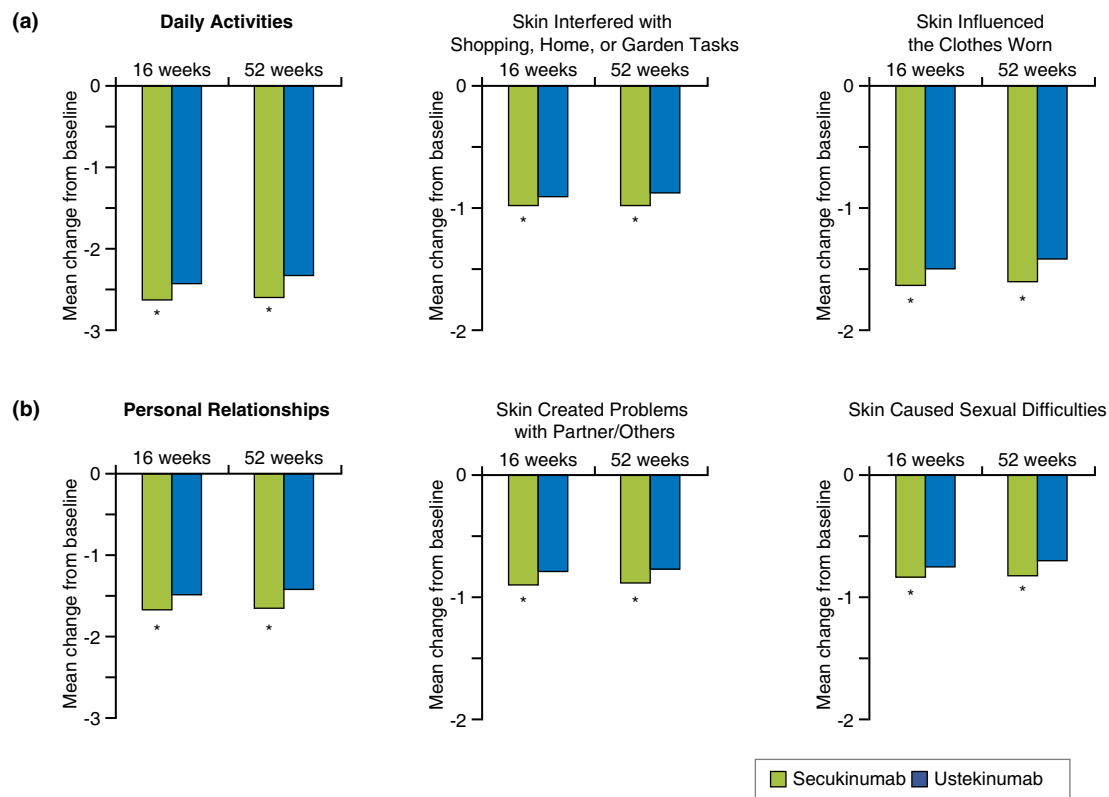


Figure 1 Mean change from baseline for daily activities and personal relationships and related items. (a) Daily activities includes the items 'skin interfered with shopping, home or garden tasks' and 'skin influenced the clothes worn'. (b) Personal relationships includes the items 'skin created problems with partner/others' and 'skin caused sexual difficulties'. * $P < 0.05$.

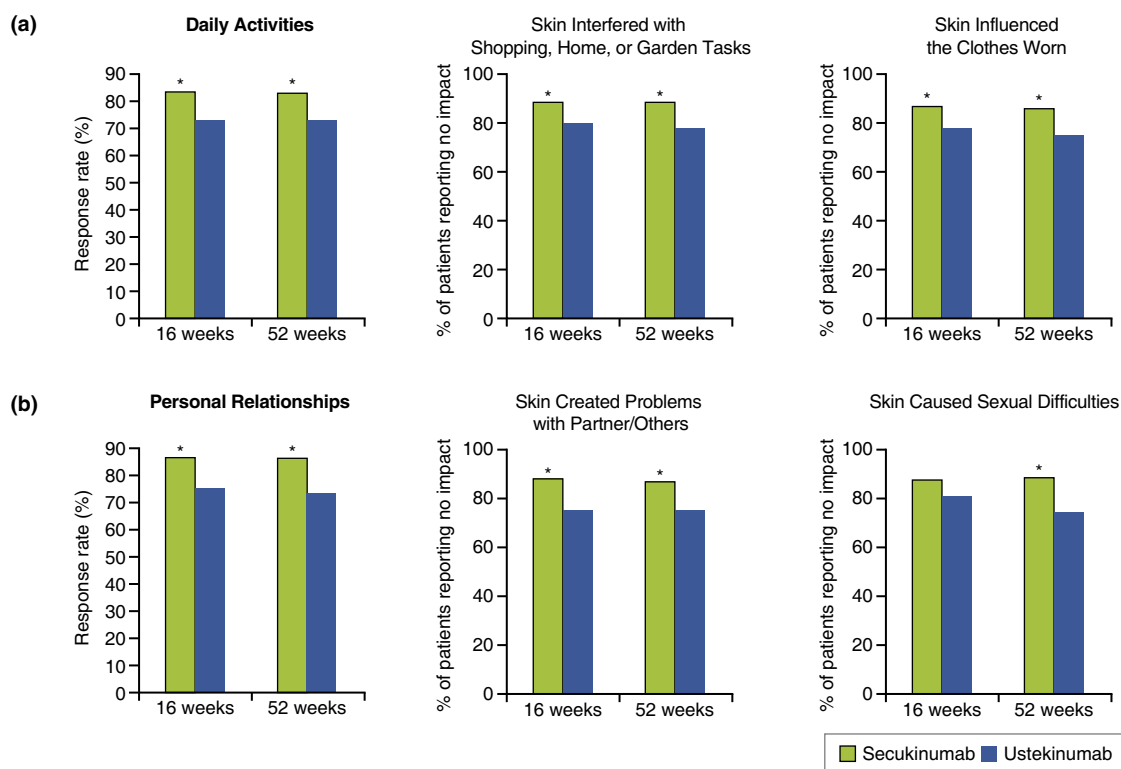


Figure 2 Response rates for daily activities and personal relationships and related items. (a) Daily activities includes the items 'skin interfered with shopping, home or garden tasks' and 'skin influenced the clothes worn'. (b) Personal relationships includes the items 'skin created problems with partner/others' and 'skin caused sexual difficulties'. * $P < 0.05$; Data presented using LOCF.

1.29 times more likely to achieve daily activities response (no impact) than ustekinumab-treated patients.

Personal relationships

Mean (SD) baseline personal relationships scores were similar for both treatment arms [secukinumab = 1.8 (1.90); ustekinumab = 1.9 (1.94), Table 1]. Patients on secukinumab achieved significantly greater mean improvement in personal relationships than patients on ustekinumab at Week 16 (Week 16: -1.67 vs. -1.49 , $P < 0.01$, Fig. 1) and sustained through Week 52 (Week 52: -1.65 vs. -1.42 , $P < 0.01$). At the item level, mean reductions for the impact of relationships with partners/close friends/relatives (Week 16: -0.90 vs. -0.79 , $P < 0.001$; Week 52: -0.88 vs. -0.77 , $P < 0.01$) and caused sexual difficulties (Week 16: -0.83 vs. -0.75 , $P < 0.05$; Week 52: -0.82 vs. -0.70 , $P < 0.01$) were significantly higher for secukinumab than for ustekinumab at Week 16 and were sustained through Week 52.

The response rates were also higher for secukinumab than for ustekinumab for personal relationships (Fig. 2; Week 16: 86.5% vs. 75.4%, $P < 0.01$; Week 52: 86.1% vs. 73.7%, $P < 0.01$) and its individual items on relationships with partners/close friends/

Table 2 Time to daily activities and personal relationships response up to Week 16

	Secukinumab (N = 336)	Ustekinumab (N = 339)
Daily activities		
n	280	283
Number of responders through Week 16 (%)	256 (91.4%)	242 (85.5%)
Median time to response, weeks	4.0	8.0
P value vs. ustekinumab	0.001	
Hazard ratio (95% CI)	1.29 (1.08–1.54)	
P value vs. ustekinumab	0.005	
Personal relationships		
n	208	224
Number of responders through Week 16 (%)	190 (91.3%)	190 (84.8%)
Median time to response, weeks	4.0	8.0
P value vs. ustekinumab	0.004	
Hazard ratio (95% CI)	1.27 (1.03–1.55)	
P value vs. ustekinumab	0.022	

CI, confidence interval; *n*, number of patients with baseline score >0.

relatives (Week 16: 87.6% vs. 75.2, $P < 0.01$; Week 52: 86.6% vs. 74.8%, $P < 0.01$) and sexual difficulties (Week 16: 87.3% vs. 80.8%, ns; Week 52: 88.5% vs. 74.3%, $P < 0.01$).

The proportion of patients reporting their first personal relationships response through Week 16 was significantly higher for secukinumab than for ustekinumab (91.3% vs. 84.8%, $P < 0.01$, Table 2). The median time to personal relationships response was 4 weeks for secukinumab vs. 8 weeks for ustekinumab; with a statistically significant difference after adjusting for body weight and baseline score in the regression model (Hazard Ratio, 1.27; 95% Confidence Interval, 1.03–1.55; $P < 0.05$) (Table 2). Specifically, the model showed that secukinumab-treated patients were 1.27 times more likely to achieve personal relationships response (no impact) than ustekinumab-treated patients.

Discussion

Psoriasis can disrupt many aspects of daily living for individuals, including influencing the clothes they wear to negatively impacting their personal relationships with friends, sexual partners and other family members. In the present analysis, we compared the effect of secukinumab treatment to ustekinumab treatment on aspects of daily living and personal relationships. For each measure, patients on secukinumab experienced greater improvements than patients on ustekinumab at Week 16 and Week 52. Further, secukinumab enabled patients to return to normal lives, defined by the daily activities and personal relationships aspects, approximately 4 weeks faster than ustekinumab.

Secukinumab targets IL-17A, a key pro-inflammatory mediator of psoriatic inflammation, and leads to rapid and sustained clinical responses with a favourable safety profile.^{22,28} While the impact of secukinumab treatment has been shown on overall skin-related quality of life, little is known about specific aspects and even less is known in comparison to ustekinumab. In this analysis, patients treated with secukinumab for 52 weeks experienced greater improvements in daily activities and personal relationships as well as the related individual items, when directly compared with patients treated with ustekinumab. These results indicate that secukinumab's efficacy translates into meaningful patient-reported benefits, including fast improvements in clothing choice and personal interactions. As the negative effects of psoriasis on HRQOL can often outweigh physical aspects of the disease,¹⁵ data reported here showing improvements in many aspects of skin-related quality of life may be as important (especially for patients) as data highlighting efficacy.²² Another key feature of our findings is that the results provide critical head-to-head information for clinicians when considering long-term treatment options for their psoriasis patients. Similar to efficacy data already reported,^{27,28} secukinumab provided faster, greater and sustained improvements in patient-reported daily activities and personal relationships when compared to ustekinumab.

Future studies should be considered to confirm these clinical trial results using a real-world setting in patients initiating or switching to secukinumab.

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