Quality of Life in Psoriasis Vulgaris: Use of the ItchyQoL Questionnaire in a Secukinumab Phase III Trial in Patients with Psoriasis Vulgaris

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Chronic pruritus is a bothersome symptom in psoriasis vulgaris and can profoundly reduce quality of life (QoL). In this exploratory analysis of the PSORITUS study, the impact of pruritus on QoL in 130 subjects with moderate-to-severe psoriasis was assessed using the ItchyQoL questionnaire. The majority of patients ($n = 127$) had to scratch their itchy skin regularly, which led to painful skin and frustration (mean ± standard deviation; SD ItchyQoL scores; 4.50 ± 0.56; 3.80 ± 1.09 and 4.20 ± 0.87, respectively). Changes in either temperature or season led to worsening of itching in most of the patients ($n = 126$; mean ± SD ItchyQoL score; 3.80 ± 1.02). Many patients felt ashamed ($n = 125$) or embarrassed ($n = 127$) due to their itchy skin (mean ± SD ItchyQoL scores; 3.90 ± 1.26 and 3.40 ± 1.19, respectively). The results demonstrated the ItchyQoL questionnaire as a validated tool responsive to treatment for detailed insights into chronic pruritus in patients with psoriasis.

Key words: itch; ItchyQoL questionnaire; pruritus; psoriasis vulgaris; quality of life.

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Psoriasis vulgaris, or plaque-type psoriasis, is the most common clinical presentation of psoriasis, a chronic, disabling, and complex inflammatory disease that primarily affects the skin (1). The estimated worldwide prevalence of psoriasis is 2–3% (2); and approximately 20–44% of patients experience moderate-to-severe forms (3, 4). Pruritus, or itch, is one of the most bothersome symptoms of psoriasis, affecting 60–90% of patients (5–7) and, if lasting for at least 6 weeks, pruritus is defined as chronic by the International Forum for the Study of Itch (IFSI) (8). In Germany, psoriasis was reported in 2.18% of patients in a cross-sectional study, of whom 38.7% had chronic pruritus. Pruritus can considerably compromise the quality of life (QoL) of patients with psoriasis (e.g. through sleep deprivation) and often has serious psychological implications, including depression and suicidal ideation (6, 9, 10).

SIGNIFICANCE

Pruritus is one of the most common and bothersome symptoms of psoriasis and can be of varying intensity, affecting 60–90% of patients with psoriasis. Pruritus has a large impact on patients' quality of life and can significantly alter their psychosocial well-being. For the first time, in this exploratory analysis of the PSORITUS study, the impact of pruritus on quality of life in patients with psoriasis has been described using the ItchyQoL questionnaire. The results provide detailed insights into the aspects of quality of life impacted by pruritus in psoriasis.

Since chronic pruritus affects QoL, specific and validated questionnaires can provide important information on its impact on patients' QoL and also on the efficacy and safety of treatment, thus enabling physicians to refine patient management. In addition to the Dermatology Life Quality Index (DLQI) questionnaire, which is commonly used to assess impairment of QoL, there are several other generic health-related QoL (HRQoL) instruments which are used for patients with dermatoses. However, disease-specific QoL tools provide a deeper understanding of the impact of treatments and disease on QoL than with generic tools (11). The ItchyQoL, as the first pruritus-specific QoL instrument, was developed in 2008 and can be applied to patients with pruritus independent of the underlying disease (12). To date, insufficient data on the use of the ItchyQoL instrument in clinical practice or trials is available for psoriasis. We report here the baseline characteristics from an exploratory analysis of the PSORITUS study performed to assess the impact of treatment on pruritus in patients with psoriasis using the ItchyQoL questionnaire.

METHODS

PSORITUS (Secukinumab study in PSOriasis exploring pruRITUS intensity and lesional biomarkers) was an exploratory, Phase IIIb study conducted at 19 centres in Germany. The study had a 16-week open-label run-in phase, followed by a 16-week randomized, placebo-controlled drug withdrawal phase. Subjects (≥18 years) diagnosed with chronic moderate-to-severe psoriasis (Psoriasis Area and Severity Index (PASI) score >10) of at least 6 months prior to baseline and pruritus intensity ≥30 on a 100-point visual analogue scale (VAS, the worst itch within a recall period of 24 h)

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were included and treated with 300 mg secukinumab (fully human anti-interleukin (IL)-17A monoclonal antibody) per protocol.

Pruritus was assessed using a set of instruments assembled on the PRURITOOLS questionnaire (V1.3, 2017) (13), a 12-item questionnaire tool, which comprised the following: a validated itch numerical rating scale (NRS, 0 = no pruritus to 10 = worst imaginable pruritus); a validated itch visual analogue scale (VAS, 0 = no pruritus to 100 = worst imaginable pruritus); a validated categorical verbal rating scale (VRS, 0 = no pruritus to 4 = very severe pruritus). In addition, the pruritus-specific history was assessed via selected questions of the Neuroderm/AGP (Arbeitsgemeinschaft Pruritusforschung), itch questionnaire in German language (Table SI[1]) (14). The questionnaire consists of 9 questions in 4 categories: (*i*) onset and course of pruritus; (*ii*) localization of pruritus; (*iii*) characteristics of pruritus; (*iv*) worsening of pruritus). Each question offers a number of categorical responses, any of which the subject can select. For questions 1–6, only one response was allowed, while for questions 7–9, multiple responses were allowed. For each question, the number and percentage of subjects with each response was analysed.

The impact of itch-related change in QoL was measured applying the validated ItchyQoL (German version) questionnaire at all visits. The ItchyQoL questionnaire (12) contains 22 items, and each item is rated on a 5-point scale, ranging from 1 = never to 5 = all the time. To demonstrate the responsiveness to treatment with the ItchyQoL questionnaire, we included QoL results from the 16 weeks run-in phase, where every patient received secukinumab, and of the 16-week randomized, placebo-controlled drug-withdrawal phase. The impact of psoriasis on the patients' HRQoL was assessed at baseline and during the study by using the following validated instruments: DLQI (Dermatology Life Quality Index) and the Patient Needs Questionnaire (PNQ) a component of the Patient Benefit Index for Pruritus (PBI-P, **Table I**). The DLQI (11) is a 10-item scale with scores ranging from 0–30; higher scores indicate greater QoL impairment. The PNQ component of the PBI-P (15) contains 27 items, and each item is rated on a scale ranging from 0 = not at all important to 4 = very important.

The study protocol was reviewed by an Independent Ethics Committee or Institutional Review Board for all study centres in Germany and was conducted according to the ethical principles of the Declaration of Helsinki. All patients provided written informed consent prior to study initiation (ClinicalTrials.gov number: NCT02362789).

Analysis

The present correlation analysis comprised an exclusive evaluation of the PSORITUS study baseline data. The baseline characteristics included were the DLQI, ItchyQoL, PASI and pruritus scores, comorbidity, and demographic data. Correlation coefficients between ItchyQoL scores and other individual baseline characteristics were calculated based on Spearman's (r) and Kendall rank (t) correlations. The relationship between the baseline ItchyQoL scores and baseline pruritus duration, as recorded on the AGP questionnaire, was analysed using the gamma rank correlation coefficient, and the correlation coefficient with an associated 95% confidence interval (CI) are presented. A multiple linear regression model was used to assess the effect of exploratory variables correlating with the ItchyQoL score for the achievement of statistical significance ($p < 0.05$).

Missing scores for response variables based on PASI scores were imputed with non-response. If there were 1 or 2 missing items in the ItchyQOL questionnaire, imputation was performed for each subscale (symptom, emotion, function) and the median of the remaining items of the subscale was used. If there were more than 2 items missing within a subscale, then no imputation was performed. PBI-P score was computed only if the patient had provided valid data on importance (PNQ) and benefit (PBQ) for at least 75% of the respective treatment goals. Thus, a treatment goal was regarded as missing if the patient had not responded to the item in the PNQ and/or in the PBI.

RESULTS

Demographics and baseline characteristics

The PSORITUS study included 130 subjects with psoriasis at baseline. The mean ± standard deviation (SD) age of subjects was 46.80 ± 12.3 years; the majority (71.5%) were in the age group 35–64 years and the mean ± SD body mass index (BMI) was 29.9 ± 6.6 kg/m^2. Most subjects (99.2%) were Caucasian, and the majority (64.6%) were male. The mean ± SD time since first diagnosis of psoriasis was 19.5 ± 13.8 years. For subjects with psoriatic arthritis (PsA) (13.8% of subjects), the mean ± SD time since first diagnosis of PsA was 17.2 ± 18.3 years. At baseline, the mean ± SD PASI score was 23.9 ± 10.9; 56.2% of subjects had a score > 20, the DLQI score was 17.8 ± 7.9, and the PNQ score was 84.2 ± 24.2 (**Table II**).

Pruritus assessment

At baseline, mean ± SD visual analogue scale (VAS) scores for "current", "average in the past 24 h", and "worst in the past 24 h" pruritus were 61.9 ± 24.3, 70.5 ± 20.1 and

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Table I. Validated patient-reported outcome (PRO) instruments used at baseline and during the study

PRURITOOLS	A self-administered 12-item questionnaire with a recall period of 24 h including visual analogue scale scale (score 0–100), numerical rating scale scale (score 0–10), categorical verbal rating scale (5-point Likert scale for 3 qualities: pruritus, burning, stinging).
DLQI (Dermatology Life Quality Index)	A 10-item general dermatology disability index designed to assess HRQoL in adult patients with skin diseases, such as eczema, psoriasis, acne, and viral warts (24). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" was also a valid response and was scored as 0. The DLQI total score was the sum of the 10 questions. Scores range from 0 to 30, with higher scores indicating greater QoL impairment.
ItchyQoL (German version)	Consists of 22 items, and each item is scored on a 5-point scale, ranging from 1 (never) to 5 (all the time). Mean scores of the subjects' responses to all 22 items represent the total score.
Arbeitsgemeinschaft Pruritusforschung questionnaire	Each question offers a number of categorical responses, any of which the subject can select. For questions 1–6, only 1 response was allowed, while for questions 7–9, multiple responses were allowed. For each question, the number and percentage of subjects with each response was analysed.
PBI-P (Patient Benefit Index for Pruritus)	The PBI-P is a modified version of the PBI, specifically developed for pruritus. This includes the PNQ, which consists of 27 standardized items on patient treatment needs, such as "to no longer experience itching" and "to have fewer side-effects." The patients need to rate the importance of each need on a Likert scale, ranging from 0="not at all important" to 4="very important." The PBI ranged from 0 (no benefit) to 4 (maximal benefit).

HRQoL: health-related quality of life; ItchyQoL: pruritus-specific QoL; PNQ: Patient Needs Questionnaire; PGA-CP: Patients Global Assessment of Chronic Pruritus.

Table II. Demographic and baseline characteristics

Parameters	Total ($n=130$)
Age, years, mean ± SD	46.8 ± 12.3
Age group, *n* (%)	
18–34 years	28 (21.5)
35–64 years	93 (71.5)
≥ 65 years	9 (6.9)
Sex, male, *n* (%)	84 (64.6)
Race, [a]Caucasian, *n* (%)	129 (99.2)
Body mass index, kg/m^2, mean ± SD	29.9 ± 6.56
Time since first diagnosis of plaque-type psoriasis (year), mean ± SD	19.5 ± 13.8
Subjects with PsA, *n* (%)	18 (13.8)
Time since first diagnosis of PsA (years), mean ± SD	17.2 ± 18.3
Baseline DLQI score, mean ± SD, (median)	17.8 ± 7.9 (18.5)
Baseline PASI score, mean ± SD, (median)	23.9 ± 10.9, (20.9)
Baseline PASI score category, *n* (%)	
>10–20	57 (43.8)
>20	73 (56.2)
Visual analogue scale[b] component score, mean ± SD	
Current	61.9 ± 24.3
Worst in the past 24 h	77.1 ± 18.0
Mean in the past 24 h	70.5 ± 20.1
Numerical rating scale[b] component score, mean ± SD	
Current	6.2 ± 2.3
Worst in the past 24 h	8.1 ± 1.63
Mean in the past 24 h	7.1 ± 1.86
Patient Needs Questionnaire score, mean ± SD	84.2 ± 24.2
ItchyQoL score, mean ± SD	78.7 ± 17.4
For PASI score >10–20	78.5 ± 17.55
For PASI score >20	78.9 ± 17.43

[a]One patient was black. [b]The itching component as part of the Patients Global Assessment of Chronic Pruritus.
For Patient Needs Questionnaire score, $n=126$, for ItchyQoL score, $n=129$.
All patient demographics were collected at screening and summarized within the population completed screening phase. Age (years)=screening year – year of birth.
DLQI: Dermatology Life Quality Index; *n*: number of subjects meeting the criterion (for categorical variables), number of subjects with non-missing assessment (for continuous variables); PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; SD: standard deviation.

77.1 ± 18.0, respectively; and the corresponding numerical rating scale (NRS) scores were 6.2 ± 2.3, 7.1 ± 1.9 and 8.1 ± 1.6, respectively (Table II). Overall, subjects with pruritus at its "worst in the past 24 h" accounted for the majority of subjects with severe or very severe pruritus (≥7 NRS, **Fig. 1**).

Baseline characteristics of itch and impact on quality of life

At baseline, the mean duration of pruritus was >10 years in 46.9% of subjects; the frequency of pruritus was at least once daily in 83.1% of subjects. The occurrence of pruritus was "continuously" in 36.9%, but more frequent "in sudden attacks" in 56.2% of subjects. The current localization of pruritus was in multiple regions of the body in 67.7% of subjects, or the entire body in 26.2% of patients. Pruritus was mainly localized at the site of the psoriasis plaque in 78.5% of subjects, although in 21.5% of subjects itch also emerged elsewhere (Table SII[1]). The most common characteristics of pruritus were burning (53.8%), prickling (27.7%) and warm (22.3%) sensation, often reported along with pain (33.8%). Factors increasing pruritus intensity were scratching or rubbing the skin (72.3%) and sweating (46.9%), but stress (46.2%) also intensified the itch. In >50% of subjects, cold water or cold compresses were

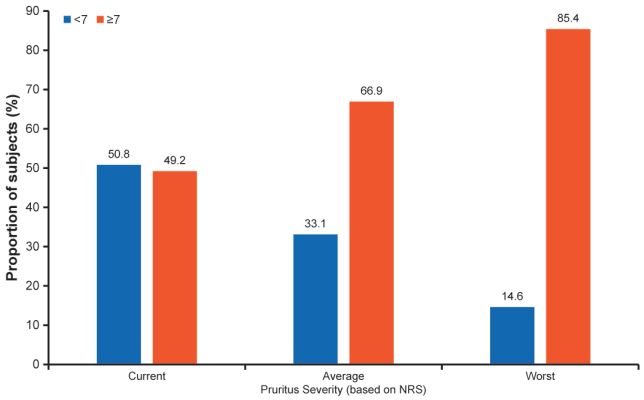

Fig. 1. Pruritus severity at baseline (numeric rating scale; NRS). Note: Pruritus severity <7 was defined as moderate pruritus and ≥7 as severe pruritus.

reported to relieve itching, but also hot water/showers were reported to give relief (30.8%) (Table SII[1]).

The mean ± SD ItchyQoL score, with a score range from 33 to 110, was 78.7 ± 17.4 (Table II) and the mean ± SD DLQI total score was 17.8 ± 7.9 at baseline. Regardless of higher or lower PASI score categories >10–20 ($n=57$) and >20 ($n=72$), the mean ItchyQoL score was equally high, at 78.5 ± 17.55 and 78.9 ± 17.43, respectively.

Furthermore, the ItchyQoL scores demonstrated responsiveness to anti-IL-17 treatment. All patients received secukinumab in the run-in phase of the trial ($n=130$) resulting in a profound any change from baseline at week 16 of –56.8%. After randomization, change from baseline was maintained during the withdrawal phase in the secukinumab arm (–58.4%), although not to this extent in the placebo group (–39%). Overall, the ItchyQol score corresponded well compared with the NRS, DLQI and PASI (**Table III**).

The majority of patients ($n=127$) scratched their itchy skin or felt the urge to scratch, which resulted in chronic pain in the skin and frustration (mean ± SD) ItchyQoL scores; 4.50 ± 0.56; 3.80 ± 1.09 and 4.20 ± 0.87, respectively). Changes in the temperature or season led to a

Table III. ItchyQol change from baseline according to treatment in the run-in and randomized withdrawal phases

Parameters	Mean ± SD	Δ (% change from baseline)
Run-in phase: Secukinumab all patients (week 16)		
PASI ($n=128$)	1.9 ± 4.4	–92.2
NRS ($n=113$)	1.35 ± 2.0	–86.2
DLQI ($n=112$)	2.1 ± 4.0	–88.1
ItchyQoL ($n=112$)	34 ± 17.5	–56.2
Withdrawal phase: Secukinumab ($n=33$) or Placebo ($n=25$) randomized patients (week 32)		
PASI Secukinumab	0.9 ± 1.7	–96.2
PASI Placebo	3.8 ± 4.1	–84.2
NRS Secukinumab	1.4 ± 2.3	–82.4
NRS Placebo	3.0 ± 3.34	–65.7
DLQI Secukinumab	2.1 ± 5.2	–87.3
DLQI Placebo	6.8 ± 9.2	–65.7
ItchyQol Secukinumab	32.7 ± 18.1	–54.5
ItchyQol Placebo	47.8 ± 29.0	–43.69

DLQI: Dermatology Life Quality Index; ItchyQoL: pruritus-specific QoL; NRS: numerical rating scale; PASI: Psoriasis Area and Severity Index.

Table IV. ItchyQoL scores at baseline for the 22 components of the ItchyQoL questionnaire

	Total ($n = 130$)	
Pruritus characteristics	n	Mean ± SD
My itching skin bleeds	127	3.40 ± 0.97
Itching causes skin to become painful	127	3.80 ± 1.09
My itching skin burns or stings	127	3.70 ± 1.11
The itching leads to scars on the skin	126	2.70 ± 1.29
I have to scratch my itching skin	127	4.50 ± 0.56
Changes in temperature/seasons itching worse	126	3.80 ± 1.02
Spent a lot of money on treatment	127	3.10 ± 1.13
Itching hinders me in working	127	3.60 ± 1.10
Itching influences my interaction	127	3.70 ± 1.19
Itching influences how well I sleep	127	3.70 ± 1.23
Itching find difficult to concentrate	126	3.20 ± 1.11
Itching limits my choice of clothing	127	3.80 ± 1.25
Itching makes me to buy special soaps	127	3.90 ± 1.35
Itching frustrates me	126	4.20 ± 0.87
Ashamed because of my itching skin	125	3.90 ± 1.26
Itching is driving me crazy/mad	127	3.90 ± 1.01
Itching makes infuriated or irritable	127	3.30 ± 1.28
Itching makes me depressive or sad	127	3.10 ± 1.27
Worried about what other people think	126	3.50 ± 1.31
Worried that itching will never stop	127	3.70 ± 1.10
Itching makes embarrassed or uncertain	127	3.40 ± 1.19
Itching has changed my personality	127	3.00 ± 1.39

worsening of the itching in most of the patients ($n = 126$; mean ± SD ItchyQoL score; 3.80 ± 1.02). Many patients felt ashamed ($n = 125$) and were embarrassed or uncertain ($n = 127$) due to their itchy skin (mean ± SD ItchyQoL scores; 3.90 ± 1.26 and 3.40 ± 1.19, respectively). In addition, in many patients, itchy skin limited the choice of clothing and necessitated the purchase of special skincare products ($n = 127$; mean ± SD ItchyQoL scores; 3.80 ± 1.25 and 3.90 ± 1.35, respectively). Due to frequent episodes of itch, many patients were worried that their itching might never stop and also felt depressive or sad ($n = 127$; mean ± SD ItchyQoL scores; 3.70 ± 1.10 and 3.10 ± 1.27, respectively) (**Table IV**).

When categorizing ItchyQol scores by observed baseline characteristics, the observed differences between subgroups were relatively small, although mean ± SD scores were slightly higher in female subjects (85.8 ± 15.9), higher BMI categories >25–30 kg/m^2 (81.0 ± 14.1), and in current smokers (81.3 ± 18.6) (**Fig. 2**A). The ItchyQoL score was not affected by the presence of certain comorbidities, such as cardiovascular, gastrointestinal, or other disorders, as shown in Fig. 2B.

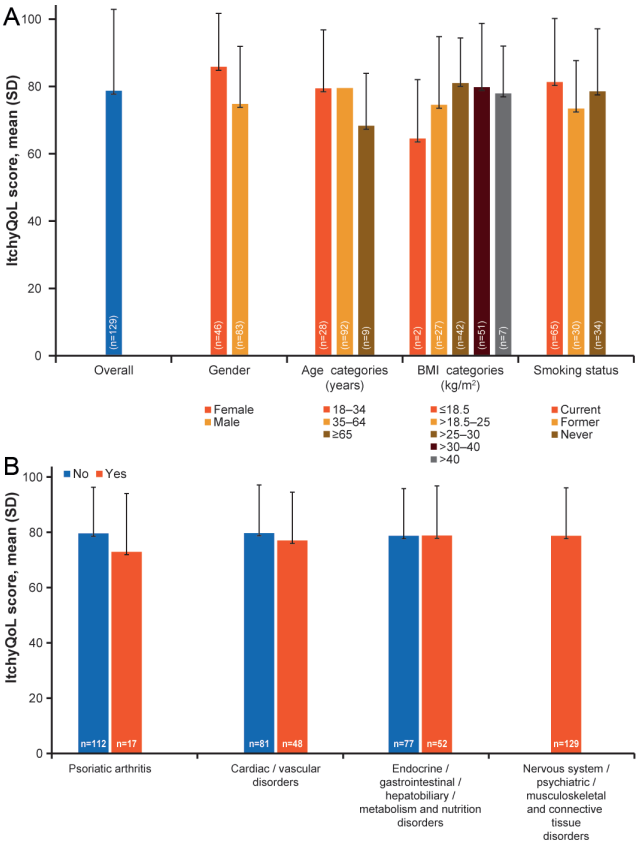

Fig. 2. (A) Baseline ItchyQoL score by demographic characteristics and (B) Clinical characteristics. BMI: body mass index; PASI: Psoriasis Activity Severity Index; QoL: quality of life; SD: standard deviation.

Correlations between baseline ItchyQoL scores and baseline characteristics

A Spearman's and Kendall rank correlation analysis demonstrated a moderate correlation between the baseline ItchyQoL scores and baseline VAS and NRS scores for "average in the past 24 h" (r: 0.542 (95% CI: 0.41, 0.65)

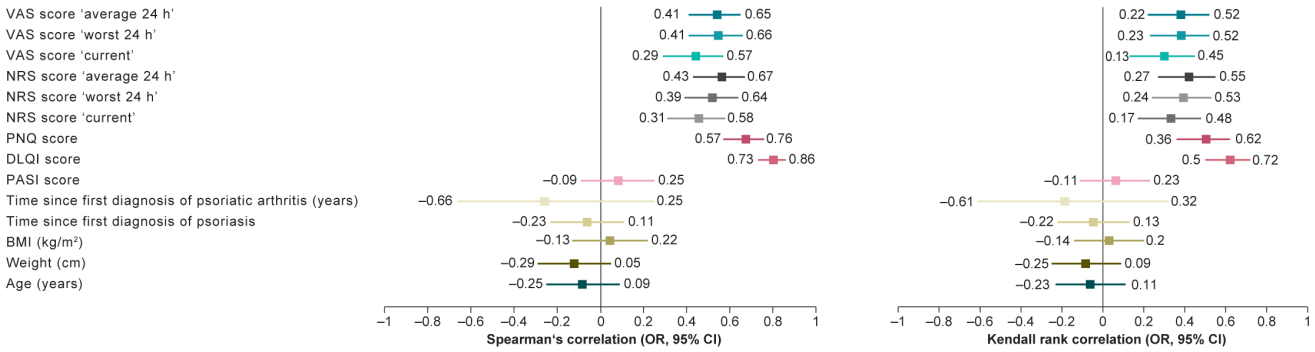

Fig. 3. Correlations between ItchyQoL questionnaire score at baseline and baseline characteristics. Correlation coefficient was done for the subjects with baseline ItchyQoL score and was calculated based on Spearman's rank correlation and Kendall rank correlation between corresponding parameter and ItchyQoL. BMI: body mass index; CI: confidence interval; DLQI: Dermatology Life Quality Index; NRS: numerical rating scale; PASI: Psoriasis Area and Severity Index; PNQ: Patient Needs Questionnaire; QoL: quality of life; VAS: visual analogue scale.

t: 0.381 (0.22, 0.52)), "worst in the past 24 h" (r: 0.547 (0.41, 0.66); t: 0.383, (0.23, 0.52)) and "current" pruritus (r: 0.803 (0.73, 0.86); t: 0.622 (0.50, 0.72)), and a higher correlation for DLQI and PNQ scores. There was a weak correlation between the baseline ItchyQoL score and baseline BMI, age, PASI scores, or the time since the first diagnosis (**Fig. 3**).

The gamma correlation analysis demonstrated a lack of correlation between baseline ItchyQoL scores and pruritus duration (–0.027 (95% CI –0.21, 0.15)). The analysis also demonstrated a weak correlation between baseline ItchyQoL scores and most baseline pruritus characteristics, except for the characteristics of "cold" (0.641 (95% CI: 0.48, 0.81)) and "electric shocks" (0.782 (95% CI 0.60, 0.96)), for which a high correlation was observed (**Table V**).

Table VI. Effect of baseline characteristics on ItchyQoL score

Baseline parameters	*n*	Estimate (SE)	Correlation coefficient (*t* value)	*p*-value
Time since first diagnosis of psoriasis, years	129	−0.14 (0.059)	−2.42	0.0168
VAS score (mean in the past 24 h)	129	0.18 (0.043)	4.11	<0.0001
NRS score (mean in the past 24 h)	129	1.90 (0.482)	3.95	0.0000
PNQ score	126	0.13 (0.043)	2.94	0.0027
DLQI score	129	1.34 (0.142)	9.44	<0.0001
Sex (female vs male)	129	5.51 (1.724)	3.19	0.0018
Pruritus characteristics				
Burning (no vs yes)	70	2.07 (1.706)	1.21	0.2279
Stinging (no vs yes)	25	−0.01 (2.140)	−0.004	0.9971

A multiple linear regression model was performed to assess the effect of exploratory variables. DLQI: Dermatology Life Quality Index; NRS: numerical rating scale; PNQ: Patient Needs Questionnaire; QoL: quality of life; SE: standard error; VAS: visual analogue scale.

Effects of baseline characteristics on mean ItchyQoL questionnaire scores

The multiple linear regression analysis showed that baseline characteristics, such as the time since the first diagnosis of psoriasis, VAS score "mean in the past 24 h", NRS score " mean in the past 24 h", health-related patient needs as measured by PNQ score, DLQI score and female sex had a significant effect on baseline ItchyQoL scores; pruritus qualities of burning and stinging did not have a significant effect (**Table VI**).

DISCUSSION

Pruritus is one of the most embarrassing and distressing symptoms for patients with psoriasis, and has profound effects on HRQoL (16–19). This can be emphasized by the fact that nearly all patients with psoriasis experience pruritus (5, 17, 20). This exploratory analysis of baseline characteristics from the PSORITUS study has described the impairment of QoL in psoriasis and, for the first time using the ItchyQoL questionnaire, in a larger psoriasis patient population.

Table V. Correlations between ItchyQoL questionnaires score at baseline and baseline pruritus characteristics

	Total (*n* = 128)	
Pruritus characteristics	*n*	Gamma rank correlation (95% CI)
Itchy	124	−0.254 (−0.92, 0.41)
Stinging	25	0.252 (0.02, 0.49)
Prickly	36	0.193 (−0.02, 0.40)
Localized deep inside	17	−0.027 (−0.36, 0.30)
Pinpricking	17	0.226 (−0.09, 0.54)
Burning	70	0.103 (−0.10, 0.31)
Sharp	11	0.142 (−0.23, 0.52)
Painful	44	0.248 (0.03, 0.47)
Pointed	2	0.244 (−0.29, 0.78)
Superficially localized	24	−0.159 (−0.40, 0.08)
Tingling	36	0.193 (−0.02, 0.40)
Warm	29	0.206 (−0.05, 0.47)
Cold	5	0.641 (0.48, 0.81)
Biting	18	0.222 (−0.01, 0.46)
Piercing	3	0.210 (−0.26, 0.68)
Electric shocks	3	0.782 (0.60, 0.96)

CI: confidence interval; *n*: number of patients ticking characteristic (more than one pruritus characteristic possible).

The current analysis demonstrated the impact of chronic pruritus on QoL in subjects with psoriasis vulgaris. Nearly 50% of patients had pruritus for longer than 10 years. The majority of subjects were affected daily by pruritus, which occurred "in sudden attacks" rather than continuously, and was localized mainly at the site of psoriasis. Itch and burning were the most common pruritus-associated characteristics, and factors such as scratching and rubbing the skin or sweating increased its intensity.

The mean ItchyQoL scores at baseline were high, and were unaffected by baseline PASI score categories or by associated comorbidities. When categorized by observed baseline characteristics, the differences in ItchyQoL scores between subgroups were relatively small, scores were slightly higher in female subjects, in subjects with a higher BMI, and in current smokers. The baseline characteristics that had a significant effect on the ItchyQoL scores, based on a regression analysis, were years since first diagnosis of psoriasis, VAS score "average in the past 24 h", NRS score "average in the past 24 h", PNQ score, DLQI score, and female sex.

Furthermore, the ItchyQoL scores showed moderate correlations with VAS and NRS (the "worst" and "average" itch within a recall period of 24 h) and strong correlations with DLQI and PNQ scores. DLQI and the ItchyQoL scores showed a strong correlation (r = 0.803), suggesting that the "embarrassed" and "self-conscious" components mainly contributed to the emotional impact in patients with pruritus. Both questionnaires have their advantages, but in patients where itch is the most bothersome symptom, the ItchyQol questionnaire might be the better option to monitor itch-related changes in QoL. The 22-item questionnaire allows a detailed read-out on QoL components, e.g. sleep and pain related to scratching, that are important to monitor during the course of psoriasis therapy. A variety of systemic treatments are available for psoriasis. In previous studies, anti-IL-17 and JAK inhibitors, adalimumab, and apremilast have been shown to be effective in reducing

pruritus in psoriasis (21). Here we show that the ItchyQol score was responsive to anti-IL-17 secukinumab treatment during the run-in and the randomized withdrawal phases of the study, and corresponded well to changes in DLQI, NRS and PASI scores. Furthermore, the assessment of a patient-relevant treatment benefit by using the PBI is an novel approach in the treatment of pruritus in particular, and dermatology in general (22). A recent study showed that QoL impairment measured with the DLQI influences the patient needs assessment. According to our results, the ItchyQoL also strongly correlates with the PNQ score (23).

A limitation of the current study is the exploratory nature of the analysis, focusing mainly on the baseline trial results.

In conclusion, this exploratory analysis using the ItchyQoL questionnaire confirms the link between the impact of itch as a leading symptom in psoriasis and HRQoL. To our knowledge, this is the first report from a large patient cohort with psoriasis, which demonstrates that the ItchyQoL questionnaire can be used as a valuable tool to determine the impact of pruritus, the most bothersome symptom in patients with psoriasis. The ItchyQol questionnaire showed responsiveness to treatment, delivered insights on the individual patient characteristics and psychological impact of itch, and therefore enables clinicians to enhance patient management in psoriasis.

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Conflicts of interest: SS has received personal fees from Menlo Therapeutics, Almirall, Beiersdorf, Celgene, Galderma, Kneipp, Nerre, Novartis, Pierre Fabre, Sienna, and Ziarco, has participated in advisory boards for Almirall, Astellas, Beiersdorf, Celgene, Galderma, Kneipp, Maruho, Nerre, Novartis, Pierre Fabre, Sienna, and Ziarco; and has been an investigator for Menlo Therapeutics, Dermasence, Trevi, Novartis, Galderma, Kiniksa,and Vanda. DB and CS are employees of Novartis Pharma GmbH, Germany. The other authors have no conflicts of interest to declare.

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