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Higher rates of skin clearance and efficacy in challenging body areas are associated with better health-related quality of life following ixekizumab maintenance treatment in pediatric patients with plaque psoriasis

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Abstract

Background/Objectives: Information is limited on the relationship between skin clearance, resolution of challenging body areas, and improvement of patient-reported outcomes (PROs) in pediatric psoriasis. Ixekizumab, a high-affinity monoclonal antibody that selectively targets interleukin-17A, is approved for the treatment of moderate-to-severe psoriasis in patients aged 6 to <18 years. This study examines improvement in psoriasis clearance in challenging body areas in pediatric patients relative to health-related quality of life.

Methods: Data from the IXORA-PEDS trial (NCT03073200) were analyzed, and changes from baseline were measured for overall Psoriasis Area and Severity Index (PASI), static Physicians' Global Assessment of psoriasis (sPGA), Psoriasis Scalp Severity Index (PSSI), Palmoplantar Psoriasis Area and Severity Index (PPASI), and Nail Psoriasis Severity Index. Rates of Dermatology Life Quality Index (DLQI), or Children's DLQI (CDLQI), scores of 0 or 1 were evaluated using the Cochran-Armitage trend test.

Results: Higher rates of DLQI/CDLQI (0,1) scores were significantly associated with greater PASI and PSSI responses at both Week 12 and Week 48 ($p < .0001$). A significant association was also observed between DLQI/CDLQI (0,1) and sPGA scores ($p < .0001$). Significantly higher rates of DLQI/CDLQI (0,1) scores were achieved in patients with greater levels of palmoplantar clearance as measured by PPASI at Week 12 ($p = .0139$), but significance was not sustained at Week 48 ($p = .0896$).

Conclusions: Greater skin clearance and scalp resolution are associated with better PROs over a short-term (12-week) and long-term (48-week) period. This demonstrates that greater improvement of skin clearance and scalp resolution may benefit quality of life in pediatric patients with psoriasis.

KEYWORDS
ixekizumab, pediatric, plaque psoriasis, quality of life

1 | INTRODUCTION

Psoriasis is a common, chronic inflammatory disease in children and adults[1] characterized by erythematous, scaly plaques on the skin that can affect sites such as nails, scalp, and palms and soles, with associated comorbid psoriatic arthritis (PsA) in some patients.[1–3] Pediatric psoriasis affects approximately 1% of children and adolescents and impairs quality of life (QoL).[4] Studies have suggested the median age of onset of psoriasis in children is 7–10 years.[1] Psoriatic lesions may differ in distribution and morphology in pediatric patients compared with adults.[5] Additionally, specific localizations of psoriasis may be challenging to treat including the scalp, palms and soles, nails, and genital region, with evidence on therapies for these areas grossly lacking.[3] Despite the often small surface areas involved in these challenging to treat locations, the presence of psoriasis on nails, scalp, and palms can have a significant impact on a patient's social life and QoL, particularly in adolescence,[5] by interfering with self-esteem, family and social relationships, school, and work life.[5,6]

The Dermatology Life Quality Index (DLQI) and Children's Dermatology Life Quality Index (CDLQI) are commonly used dermatology-specific QoL questionnaires used in adults (≥16 years) and children (4 to <16 years), respectively.[7] Both questionnaires are self-administered, have a total score range of 0–30, and consist of 10 questions reflecting the impact of the skin disease on a patient's QoL over the preceding week.[8,9]

Information from adult patients suggests a positive association between improvement in skin clearance and QoL[10,11]; however, there is limited information available on the relationship between skin clearance, challenging body areas, and health-related quality of life (HRQoL) in pediatric psoriasis. Data from randomized clinical trials in adult patients indicate a positive association between achievement of 90% improvement in Psoriasis Area and Severity Index (PASI90) and improvement in QoL compared with lower clinical responses.[10–12] A 2011 study also demonstrated a greater percentage improvement in CDLQI in children who had achieved PASI75.[13] Although multiple systemic treatments are available for psoriasis in adults, only four systemic drugs[14] are approved for use in the pediatric population[4,15]; including the recently approved secukinumab.[16]

Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, is approved for the treatment of moderate-to-severe pediatric (6 to <18 years) psoriasis in addition to previously approved indications for adult patients.[4,17] In pediatric patients treated with IXE in the IXORA-PEDS trial (NCT03073200), CDLQI/DLQI (0,1) responses at Week 12 were significantly greater with IXE than with placebo. Furthermore, sustained or additional improvements were observed for CDLQI/DLQI (0,1) and clearance of nail, scalp, palmoplantar, or genital psoriasis.[4] This summary describes the association between HRQoL and response of skin clearance and efficacy in challenging body areas in a clinical trial.

2 | MATERIALS AND METHODS

2.1 | Study design

IXORA-PEDS (NCT03073200) is a 108-week, multicenter, double-blind, randomized, placebo-controlled, phase III study examining the efficacy and safety of IXE vs. placebo in pediatric

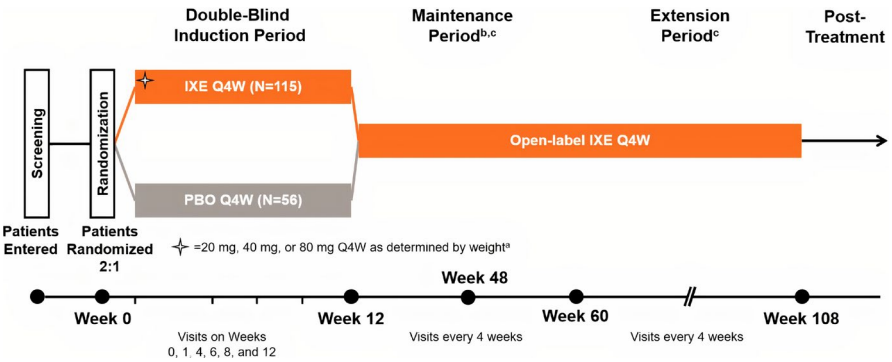

FIGURE 1 Study schema for double-blind induction period. [a]Dosing regimens based on patient weight categories: >50 kg (IXE starting dose of 160 mg [Week 0] and 80 mg Q4W thereafter); ≥25 to ≤50 kg (IXE starting dose of 80 mg [Week 0] and 40 mg Q4W thereafter); <25 kg (IXE starting dose of 40 mg [Week 0] and 20 mg Q4W thereafter). [b]Subjects randomized to IXE during the double-blind induction period received 1 injection of IXE and 1 injection of PBO at Week 12. Subjects randomized to PBO during the double-blind induction period received IXE at doses of 20, 40, or 80 mg (with a starting dose of 40, 80, or 160 mg, respectively) based on weight. All subjects received 2 injections of IXE at Week 12 and 1 injection of IXE Q4W at Week 16 and thereafter. [c]IXE dose was adjusted during the open-label maintenance period and extension periods if a patient changed weight categories. Abbreviations: IXE, ixekizumab; PBO, placebo; Q4W, every 4 weeks

patients with moderate-to-severe plaque psoriasis. The complete study design has been described previously.[4] During a 12-week, double-blind, treatment period, patients were randomized 2:1 to subcutaneous IXE every 4 weeks (Q4W) or placebo, administered according to baseline weight categories (Figure 1). Following Week 12, all patients received IXE in an open-label period for 48 weeks.

2.2 | Participants

Study participants were 6 to <18 years of age and had moderate-to-severe plaque psoriasis, defined as Psoriasis Area and Severity Index (PASI) ≥12, static Physicians' Global Assessment (sPGA) ≥3, and psoriasis-affected body surface area ≥10% at screening and baseline. The subjects were also candidates for phototherapy or systemic therapy, or their psoriasis was not adequately controlled by topical therapies as determined by the investigator. Patient baseline characteristics are detailed in Table 1.

IXORA-PEDS was conducted in accordance with the ethical principles of the Declaration of Helsinki. The study was approved by the ethical review board at each participating site. A parent or legal guardian provided written informed consent, and the patient provided written assent prior to the conduct of study assessments, examinations, or procedures.

2.3 | Outcomes

The major study endpoints have been published previously.[4] In this study, the association between CDLQI (patients aged 6 to <16 years) or DLQI (patients aged ≥16 years) and response of skin clearance and efficacy in challenging body areas: PASI, Psoriasis Scalp Severity Index (PSSI), Palmoplantar Psoriasis Area and Severity Index (PPASI), Nail Psoriasis Severity Index (NAPSI), and sPGA were evaluated at Weeks 12 and 48. Additionally, the association between treatment with IXE and improvement in psoriasis presence on genitalia was examined.

2.4 | Statistical analysis

In this *post hoc* analysis, data from all treatment groups were combined and categorized into 5 groups by percent of PASI, NAPSI, PPASI, and PSSI improvement, and sPGA absolute score categories. The association between CDLQI/DLQI (0,1) and response level of skin clearance and efficacy in challenging body areas (PASI, sPGA, NAPSI, PPASI, PSSI) were evaluated using the Cochran-Armitage trend test. Pairwise comparisons between response levels were conducted using logistic regression model adjusted for region, baseline outcome score, and baseline weight category. Missing values were imputed using last observation carried forward.

TABLE 1 Baseline characteristics and disease characteristics

	Total (*N* = 171)
Age, years, mean ±SD	13.5 (3.0)
Age, years, median (range)	14 (6–17)
Age group, *n* (%)	
<12 years, mean ±SD	43 (25.1)
≥12 years, mean ±SD	128 (74.9)
Male, *n* (%)	72 (42.1)
Female, *n* (%)	99 (57.9)
Weight, kg, median (range)	59 (21.5–135.5)
<25 kg, *n* (%)	3 (1.8)
≥25 to ≤50 kg, *n* (%)	43 (25.1)
>50 kg, *n* (%)	125 (73.1)
Age at psoriasis onset, years, mean ±SD	8.4 (3.9)
Baseline PASI score, *n* (%)	
<20	107 (62.6)
≥20	64 (37.4)
Baseline PASI score (*N* = 171/171), mean ±SD	19.7 (8.0)
Baseline PSSI score >0, *n* (%)	
Yes	152 (88.9)
No	1 (0.6)
N/A	18 (10.5)
Baseline PSSI score (*N* = 153/171), mean ±SD	28.1 (17.1)
Baseline PPASI score >0, *n* (%)	
Yes	26 (15.2)
No	1 (0.6)
N/A	144 (84.2)
Baseline PPASI score (*n* = 27/171), mean ±SD	10.64 (14.1)
Baseline NAPSI score >0, *n* (%)	
Yes	46 (26.9)
No	1 (0.6)
N/A	124 (72.5)
Baseline NAPSI score (*N* = 47/171), mean ±SD	31.30 (27.5)
Baseline sPGA score (*N* = 171/171), mean ±SD	3.5 (0.6)
Baseline sPGA =3, *n* (%)	88 (51.5)
Baseline sPGA =4, *n* (%)	72 (42.1)
Baseline sPGA =5, *n* (%)	11 (6.4)
Baseline CDLQI total score (134/171), mean ±SD	8.1 (5.3)
Baseline CDLQI total score category, *n* (%)	
<5	36 (26.9)
≥5	98 (73.1)
Baseline DLQI total score (*N* = 32/171), mean ±SD	9.4 (4.9)
Baseline DLQI total score category, *n* (%)	
<5	6 (18.8)
≥5	26 (81.3)

Note: Values are reported as observed. Unless otherwise indicated, there were no missing values in the baseline characteristics.

Abbreviations: CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; *n*, number of responders; N/A, non-applicable; NAPSI, Nail Psoriasis Severity Index; PASI, Psoriasis Area and Severity Index; PPASI, Palmoplantar Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index; SD, standard deviation; sPGA, static Physicians' Global Assessment.

3 | RESULTS

3.1 | Baseline characteristics

The main study included 171 patients; overall, 166 patients entered the maintenance period and 91.6% (152 of 166) completed Week 48. Baseline demographics and disease characteristics are presented in Table 1.

3.2 | Association between CDLQI/DLQI (0,1) and PASI, sPGA, PSSI, PPASI, and NAPSI

Significantly higher rates of DLQI/CDLQI (0,1) scores were achieved in patients with greater levels of skin clearance as measured by PASI at Week 12 ($p < .0001$), which was sustained at Week 48 (Table 2). Significantly higher rates of DLQI/CDLQI (0,1) scores were seen in those achieving PASI ≥75 & <90 ($p = .0037$), PASI 90 ($p = .0001$), and PASI 100 ($p < .0001$) at Week 12 compared to those with PASI 50 skin clearance (Figure S1).

Higher rates of DLQI/CDLQI (0,1) scores were achieved in patients with greater levels of skin clearance as measured by sPGA scores (Table 2). Significantly higher rates of DLQI/CDLQI (0,1) scores were achieved in patients with sPGA=3 ($p = .0019$) and sPGA≥4 ($p = .0020$) at Week 12, and sPGA=2 ($p = .0036$), sPGA=3 ($p = .0157$), and sPGA≥4 ($p = .0539$) at Week 48 vs. sPGA=0 (Figure S2).

In patients with baseline scalp involvement, higher rates of DLQI/CDLQI (0,1) scores were achieved in patients with greater levels of scalp clearance as measured by PSSI at Week 12 ($p < .0001$)

TABLE 2 Association between CDLQI/DLQI (0,1) and efficacy measures at Week 12 and Week 48

DLQI/CDLQI (O,1)				
	Week 12		Week 48	
Efficacy measures	Response % (*n*)	*p* value	Response % (*n*)	*p* value
PASI<50	16.3 (7/43)	<.0001	12.5 (1/8)	<.0001
PASI≥50 & <75	33.3 (4/12)		20.0 (1/5)	
PASI≥75 & <90	59.1 (13/22)		57.1 (8/14)	
PASI≥90 & <100	63.9 (23/36)		72.3 (34/47)	
PASI100	69.0 (40/58)		86.6 (84/97)	
PSSI<50	14.7 (5/34)	<.0001	20.0 (2/10)	<.0001
PSSI≥50 & <75	58.3 (7/12)		42.9 (3/7)	
PSSI≥75 & <90	44.4 (4/9)		71.4 (5/7)	
PSSI≥90 & <100	66.7 (10/15)		80.0 (8/10)	
PSSI100	64.6 (53/82)		80.5 (95/118)	
PPASI<50	11.1 (1/9)	.0139	0.0 (0/2)	.0896
PPASI≥50 & <75	50.0 (2/4)		0.0 (0/2)	
PPASI≥75 & <90	0.0 (0/1)		100.0 (3/3)	
PPASI≥90 & <100	0.0 (N/A)		100.0 (1/1)	
PPASI100	70.0 (7/10)		64.7 (11/17)	
NAPSI<50	50.0 (14/28)	.6542	73.3 (11/15)	.9057
NAPSI≥50 & <75	50.0 (4/8)		66.7 (2/3)	
NAPSI≥75 & <90	100.0 (1/1)		66.7 (2/3)	
NAPSI≥90 & <100	0.0 (N/A)		0.0 (N/A)	
NAPSI100	57.1 (4/7)		70.8 (17/24)	
sPGA =5	0.0 (0/1)	<.0001	0.0 (0/1)	<.0001
sPGA =4	7.7 (1/13)		25.0 (1/4)	
sPGA =3	27.0 (10/37)		12.5 (1/8)	
sPGA =2	50.0 (10/20)		58.8 (10/17)	
sPGA =1	61.5 (24/39)		71.4 (30/42)	
sPGA =0	68.9 (42/61)		86.9 (86/99)	

Note: p value from the Cochran-Armitage trend test.

Abbreviations: CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; *n*, number of responders; N/A, non-applicable; NAPSI, Nail Psoriasis Severity Index; PASI, Psoriasis Area and Severity Index; PPASI, Palmoplantar Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index; sPGA, static Physicians' Global Assessment.

which was sustained at Week 48 ($p < .0001$) (Table 2). Significantly higher rates of DLQI/CDLQI (0,1) scores were achieved in those with PSSI ≥50 & <75 ($p = .0310$), PSSI ≥90 & <100 ($p = .0050$), and PSSI 100 ($p < .0001$) at Week 12 compared to those with PSSI 50 scalp clearance (Figure S3).

Significantly higher rates of DLQI/CDLQI (0,1) scores were achieved in patients with greater levels of palmoplantar clearance as measured by PPASI at Week 12 ($p = .0139$); significance was not sustained at Week 48 ($p = .0896$). DLQI/CDLQI (0,1) was achieved by 70% (PPASI 100%) of patients at Week 12 and 64.7% (PPASI 100%) of patients at Week 48. (Table 2). There was no significant association between NAPSI and CDLQI/DLQI (0,1) at either Week 12 ($p = .6542$) or Week 48 ($p = .9057$). DLQI/CDLQI (0,1) was achieved by 57.1% (NAPSI 100%) of patients at Week 12 and 70.8% (NAPSI 100%) of patients at Week 48 (Table 2).

4 | DISCUSSION

Psoriasis has a documented negative impact on HRQoL in both adult and pediatric patients with psoriasis.[6,10] High levels of skin clearance for patients with psoriasis are associated with improvements in several PROs.[18] In this analysis, significant associations were observed between DLQI/CDLQI (0,1) and all PASI and sPGA efficacy measures at Weeks 12 and 48, demonstrating that greater levels of skin and scalp clearance following treatment with IXE were associated with improvement in PROs in pediatric patients with psoriasis over a short-term (12-week) and long-term (48-week) period.

In pediatric patients treated with IXE in the IXORA-PEDS trial, IXE was superior to placebo for primary and gated secondary endpoints (PASI 75, sPGA [0,1], PASI 75, and sPGA [0,1] at Week 4, improvement in itch, and complete skin clearance); IXE also provided significant improvements in QoL and clearance of scalp and genital psoriasis.[4] More recently, Bruins and colleagues[10] reported that the highest improvements in QoL in pediatric patients were associated with ≥90% PASI response and ≥90% reduction in body surface area response. Similar findings have also been reported in adults.[11,12,19] In this analysis, the highest rates of DLQI/CDLQI (0,1) responders were seen in patients achieving PASI100 at Weeks 12 and 48.

Significant progress has been made in recent years with biologic therapies in the treatment of psoriasis; however, certain commonly affected body areas, including the scalp, palms and/or soles, nails, and genital region, remain challenging to treat.[20] In patients with baseline scalp involvement, the highest rates of DLQI/CDLQI (0,1) responders were seen in patients achieving PSSI ≥90 to <100 and PSSI 100 at Week 12 and Week 48. Patients with palmoplantar psoriasis report worse DLQI scores[21] and greater physical discomfort[22] than those without palmoplantar involvement. In this study, significantly higher rates of DLQI/CDLQI (0,1) responders were associated with a significant improvement in overall PPASI score at Week 12, but this was not sustained at Week 48. Nail involvement is also associated with disease severity in pediatric populations with psoriasis[23]; however, this study did not find significantly higher CDLQI/DLQI scores in patients with nail involvement vs. those without.

5 | CONCLUSIONS

This analysis showed that better HRQoL was achieved in pediatric patients with psoriasis with higher levels of skin and scalp clearance over both short- and long-term time points. The burden of disease at baseline in this population was high, and these findings demonstrate that pediatric patients with psoriasis may derive greater benefit from achieving more complete levels of overall skin and scalp clearance. Although the same was not observed for patients with nail and palmoplantar involvement, the study populations were small, and further analysis would be helpful to determine the full effects on HRQoL with clearance in these hard-to-treat areas.

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CONFLICT OF INTEREST

Dr. Hebert reports that the UTHealth McGovern Medical School has received research grants from Pfizer, Arcutis Biotherapeutics, Galderma, Brickell, LEO, Mayne Pharma, Eli Lilly and Company, Novartis, Ortho Dermatologics, GSK, and Bristal Myers Squibb; honoraria have been received from Pfizer, Eli Lilly and Company, Galderma, Novartis, Mayne, Aslan, Vyne, OrthoDermatologics, Arcutis, NoblePharma; DSMBB from Ortho Dermatologics, GSK, Regeneron Sanofi. Dr. Bobonich reports receiving royalties from Wolters Kluwer, consulting fees from Eli Lilly and Company, participating in advisory boards for Bristol Myers Squibb, UBC, Janssen, Dermavant, AbbVie, Eli Lilly and Company, and speaker's bureau for AbbVie and Eli Lilly and Company, and non-financial interests in the Center for Advance Practice Dermatology, LLC. Dr. Becker is an investigator for Celgene Corporation; during the IXORA-PEDS trial, Dr. Becker was affiliated with Texas Dermatology and Laser Specialists, San Antonio, TX, USA. Drs. Rodriguez Capriles, Gallo, Li, Somani, Ridenour, Wang, and Edson-Heredia report being employees and stockholders at Eli Lilly and Company.

DATA AVAILABILITY STATEMENT

Lilly provides access to all individual participant data collected during the trial, after anonymization, except for pharmacokinetic or genetic data. Data are available to request 6 months after the indication studied has been approved in the United States and EU and after primary publication acceptance, whichever is later. No

expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report, blank, or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at www.vivli.org.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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