Real-World Effectiveness of Upadacitinib in Moderate-to-Severe Atopic Dermatitis (AD): Results From Longitudinal Analyses of the CorEvitas AD Registry

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OBJECTIVE

To describe the longitudinal real-world outcomes of upadacitinib-treated adults with atopic dermatitis enrolled in the CorEvitas Atopic Dermatitis Registry

CONCLUSIONS

- In the real-world setting, the majority of adults with moderate-to-severe atopic dermatitis receiving treatment with upadacitinib for 6 months achieved clinically meaningful improvements in skin lesions, itch, pain, quality of life, and disease burden
- Many participants achieved complete skin clearance, little-to-no itch, little-to-no pain, no impact of atopic dermatitis on their quality of life, no or almost clear symptoms, and well-controlled disease at the 6-month follow-up visit
- Findings from this real-world study are consistent with clinical trial results and show the potential of upadacitinib to offer multidimensional relief to people with atopic dermatitis in routine clinical practice

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The authors would like to thank all the investigators, their clinical staff, and patients who participate in the CorEvitas Atopic Dermatitis Registry. The design, study conduct, and financial support for the study was provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the poster. This study is sponsored by CorEvitas, LLC. CorEvitas has been supported through contracted subscriptions in the last 2 years by AbbVie, Amgen, Inc., Arena, Boehringer Ingelheim, Bristol Myers Squibb, Chugai, Eli Lilly and Company, Genentech, GSK, Janssen Pharmaceuticals, Inc., LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Sun Pharmaceutical Industries Ltd., and UCB S.A. Data are available from CorEvitas, LLC through a commercial subscription agreement and are not publicly available. No additional data are available from the authors.

All authors had access to relevant data and participated in the drafting, review, and approval of this poster. No honoraria or payments were made for authorship. Medical writing support was provided by Alicia Salinero, PhD, ISMPP CMPP, of JB Ashtin, and funded by AbbVie.

J.I. Silverberg has served as an advisor, speaker, researcher, or consultant for AbbVie, Asana Biosciences, Dermavant, Galderma, GSK, Glenmark, Kiniksa, LEO, Lilly, Menlo, Novartis, Pfizer, Realm, and Sanofi/Regeneron. M. Gooderham has served as an advisor, investigator, speaker, or consultant for AbbVie, Acelyrin, Amgen, AnaptysBio, Apogee, Arcutis, Aristea, ASLAN, Bausch Health, BI, BMS, Cara, Dermavant, Dermira, Galderma, GSK, Incyte, Jamp, Janssen, LEO, Lilly, L'Oreal, Meiji Seika, MoonLake, Nimbus, Novartis, Pfizer, Regeneron, Reistone, Sanofi-Genzyme, Sun, Takeda, Tarsus, UCB, Union, Ventyx, and Vyne. C.G. Bunick has served as an investigator, consultant, speaker for, and/or received honoraria from AbbVie, Allergan, Almirall, Apogee, Arcutis, Daiichi-Sankyo, EPI Health/Novan, LEO, Lilly, Novartis, Ortho Dermatologics, Palvella, Pfizer, Sanofi-Regeneron, Sun, Timber, and UCB. B. Calimlim and A. Grada are full-time employees of AbbVie, and may hold AbbVie stock and/or stock options. Y. Muñoz Maldonado, A. Li, and N. Fergestrom are employees of CorEvitas, LLC (formerly Corrona, LLC). CorEvitas is supported through contracted subscriptions with multiple pharmaceutical companies. The poster was a collaborative effort between CorEvitas and AbbVie with financial support provided by AbbVie. E. Simpson has served as an advisor, consultant, investigator, speaker for, and/or received grants from AbbVie, Actelion, Amgen, AnaptysBio, Aralez, Arcutis, Arena, Aspen, Bausch Health, BioScript Solutions, BI, BMS, Canadian Psoriasis Network, Celgene, Cipher, Concert, Eczema Society of Canada, Galderma, GSK, Homeocan, Incyte, Janssen, LEO, Lilly, Medexus, Nimbus Lakshmi, Novartis, Pediapharm, Pfizer, Regeneron, Reistone, Sanofi-Genzyme, Sun, Tribute, UCB, and Valeant.

Presented at the 44th Anniversary Fall Clinical Dermatology Conference (Fall CDC), October 24–27, 2024, Las Vegas, NV, USA [Ref# DV 012708]

BACKGROUND

- Atopic dermatitis (AD) is an inflammatory skin condition characterized by eczematous lesions and intense itch[1,2]
- AD is chronic and relapsing,[2] and patients often require long-term treatment and may need systemic therapy for refractory AD[3]
- Upadacitinib (UPA) is an oral selective Janus kinase inhibitor approved to treat moderate-to-severe AD in adults and adolescents[4,5]
- While phase 3 studies of UPA in AD (Measure Up 1, Measure Up 2, and AD Up) demonstrated rapid and sustained improvement in skin clearance and itch endpoints through 140 weeks,[6] the long-term, real-world outcomes of patients with AD treated with UPA are less understood

METHODS

Study Design and Treatment

- The CorEvitas AD Registry is a prospective, non-interventional registry for adults with AD in the United States and Canada receiving care from a dermatologist or qualified physician
- Participants were enrolled in the registry if they were aged 18 years or older, had a diagnosis of AD from a dermatologist, and began receiving treatment with an eligible medication (including biologics, small molecules, nonbiologic systemics, or systemic corticosteroids) at or within 12 months of the enrollment visit
- Participants were not included if they were enrolled in or planned to enroll in a double-blind, randomized trial for a systemic AD medication
- The registry comprises 4169 participants across 81 study sites as of June 30, 2024

METHODS CONTINUED

- Longitudinal data were collected from participants and their dermatology providers during routine clinic visits using a structured and standardized data collection method with follow-up visits occurring approximately every 6 months (±3 months)

Inclusion Criteria and Outcome Assessments

- This analysis included participants in the CorEvitas AD registry who were treated with UPA 15 mg or UPA 30 mg continuously for ≥6 months and had an enrollment date from January 14, 2022 (date of UPA approval by the United States Food and Drug Administration) or October 1, 2021 (for participants in Canada) through April 30, 2024
- For inclusion in this analysis, participants had to have available data before UPA exposure and at the 6-month follow-up visit
- The baseline visit was designated as the first UPA prescription date or, if applicable, the clinic visit within 6 weeks before this date, provided no other biologic or small-molecule treatments were used in the interim
- The proportion of patients achieving clinically relevant outcomes, including simultaneous achievement of optimal skin and itch targets corresponding to minimal disease activity as outlined by the Aiming High in Eczema/Atopic Dermatitis (AHEAD) recommendations,[7] were assessed at the 6-month follow-up visit **(Figure 1)**
- Safety was not assessed in this analysis

Statistical Analysis

- Change from baseline was calculated as the difference between the follow-up visit and baseline values
- Data were analyzed as observed with no imputation
- As study objectives were descriptive in nature, no formal hypothesis testing was performed

Figure 1. AD Outcomes Assessed

Skin Clearance	• vIGA-AD score 0 or 1 (**vIGA-AD 0/1**) among participants with a baseline vIGA-AD score >1 • EASI score improvement ≥75%/≥90%/100% from baseline (**EASI 75/90/100**)
Worst Itch	• **No/minimal itch (PP-NRS 0/1):** PP-NRS score 0 or 1 among participants with a baseline PP-NRS score >1 • **Clinically meaningful improvement (ΔPP-NRS ≥4):** PP-NRS score improvement ≥4 from baseline among participants with a baseline PP-NRS score ≥4
Skin Pain	• **No/minimal skin pain (SP-NRS 0/1):** SP-NRS score 0 or 1 among participants with a baseline SP-NRS score >1 • **Clinically meaningful improvement (ΔSP-NRS ≥4):** SP-NRS score improvement ≥4 from baseline among participants with a baseline SP-NRS score ≥4
QoL	• **No/minimal impact on QoL (DLQI 0/1):** DLQI score 0 or 1 among participants with a baseline DLQI score >1 • **Clinically meaningful improvement (ΔDLQI ≥4):** DLQI score improvement ≥4 from baseline among participants with a baseline DLQI score ≥4
Patient-Reported Disease Burden	• **No/almost clear symptoms (POEM ≤2):** POEM score ≤2 among participants with a baseline POEM score >2 • **Clinically meaningful improvement (ΔPOEM ≥4):** POEM score improvement ≥4 from baseline among participants with a baseline POEM score ≥4
Disease Control	• **Well-controlled disease (ADCT <7):** ADCT score <7 among participants with a baseline ADCT score ≥7
Simultaneous Skin and Itch Improvement	• **Complete or almost complete skin clearance and itch relief (EASI 90 and PP-NRS 0/1):** EASI score improvement ≥90% from baseline and PP-NRS score 0 or 1 among participants with a baseline PP-NRS score >1

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; POEM, Patient-Oriented Eczema Measure; PP-NRS, Peak Pruritus Numeric Rating Scale; QoL, quality of life; SP-NRS, Skin Pain Numeric Rating Scale; vIGA-AD, validated Investigators Global Assessment Scale for Atopic Dermatitis.

RESULTS

Table 1. Baseline Demographics and Clinical Characteristics

Characteristics	Total (n = 192)
Age at registry enrollment, years, mean (SD)	46.2 (16.6)
Age at AD onset, years, mean (SD)	27.6 (23.0)
Sex	
Male	81 (42.2)
Female	111 (57.8)
Race	
White	134 (69.8)
Black	12 (6.2)
Asian	24 (12.5)
Other[a]	22 (11.5)
Country	
United States	121 (63.0)
Canada	71 (37.0)
Bio-experienced[b]	84 (43.8)
vIGA-AD	
0: Clear	13 (6.8)
1: Almost clear	10 (5.2)
2: Mild	34 (17.7)
3: Moderate	96 (50.0)
4: Severe	39 (20.3)
EASI, mean (SD)	10.6 (10.3)
DLQI, mean (SD)	10.9 (7.4)
PP-NRS, mean (SD)	6.0 (3.0)
SP-NRS, mean (SD)	5.1 (3.3)
POEM, mean (SD)	16.5 (7.8)
ADCT, mean (SD)	12.9 (6.5)

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool (score range: 0–24); DLQI, Dermatology Life Quality Index (score range: 0–30); EASI, Eczema Area and Severity Index (score range: 0–72); POEM, Patient-Oriented Eczema Measure (score range: 0–28); PP-NRS, Peak Pruritus Numeric Rating Scale (score range: 0–10); SP-NRS, Skin Pain Numeric Rating Scale (score range: 0–10); vIGA-AD, validated Investigators Global Assessment Scale for Atopic Dermatitis.
Data are presented as n (%) unless otherwise specified.
[a]Includes participants who selected multiple races, American Indian or Alaskan Native, Native Hawaiian or Other Pacific Islander, or "other race."
[b]Defined as participants who have been previously exposed to biologics indicated for the treatment of AD (dupilumab and tralokinumab).

Table 2. Medications at Baseline and at the 6-Month Follow-Up

Treatment Characteristics	Baseline (n = 192)	6-Month Follow-Up (n = 192)
Time treated with UPA, months, mean (SD)	—	6.0 (1.1)
UPA dose, n (%)[a]		
15 mg	139 (72.8)	123 (64.4)
30 mg	52 (27.2)	68 (35.6)
Treatment change from baseline, n/N (%)[b]		
Dose increase	—	18/139 (12.9)
Dose decrease	—	2/52 (3.8)

UPA, upadacitinib.
[a]n = 191 at baseline and follow-up. [b]Not mutually exclusive; includes treatment in use at the time of the visit.

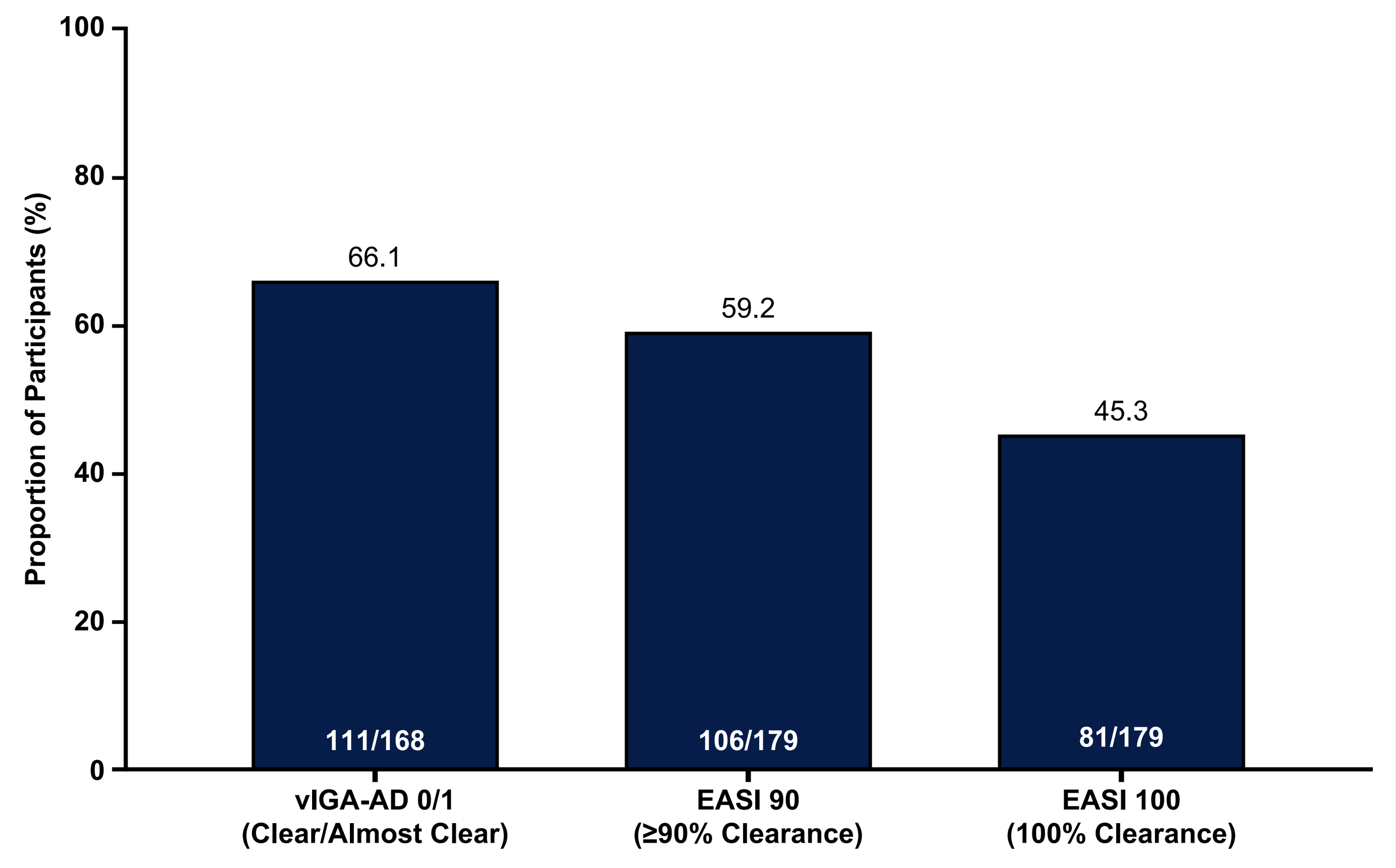
Participants

- Among 467 participants treated with UPA who had a valid baseline visit and who were not treated with another biologic or small molecule between the prior visit and UPA initiation, 233 (49.9%) had a 6-month follow-up visit, and 192 (41.1%) were persistent on UPA therapy at the 6-month visit
- Of the 192 participants included in this analysis **(Table 1)**, the majority were White, were from the United States, and had moderate-to-severe AD, as assessed by the vIGA-AD; nearly half were bio-experienced (prior treatment with biologics for AD [dupilumab and tralokinumab])
- The mean (SD) duration of UPA treatment was 6.0 (1.1) months; the majority of participants were treated with UPA 15 mg at baseline and at the 6-month follow-up **(Table 2)**

Achievement of Improvement at 6-Month Follow-Up

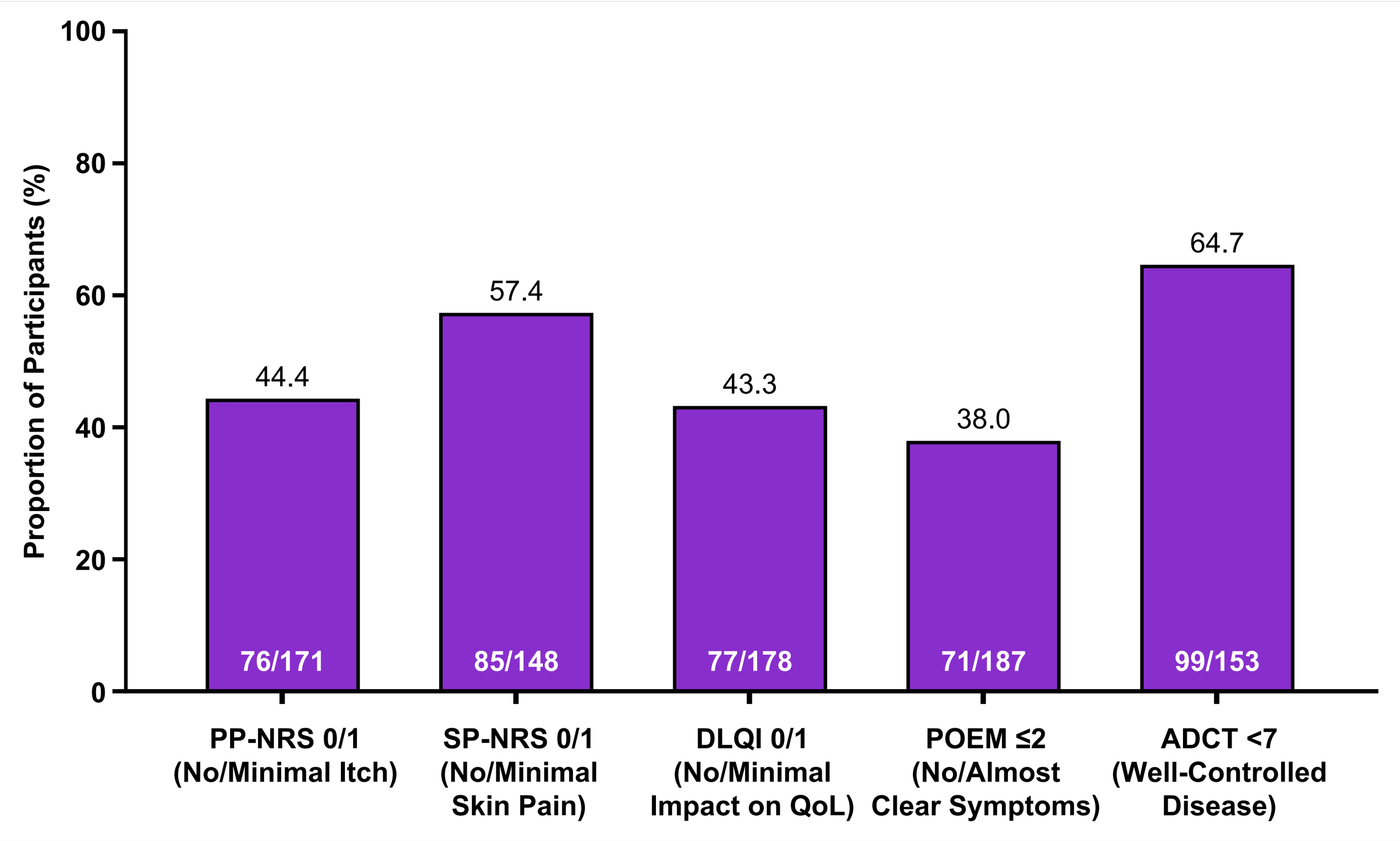
- After 6 months of treatment with UPA, more than half of participants (66.1%) achieved clear/almost clear skin (vIGA-AD 0/1), 59.2% achieved ≥90% skin clearance (EASI 90), and 45.3% achieved complete skin clearance (EASI 100) **(Figure 2)**; 69.3% achieved ≥75% skin clearance (EASI 75)
- Nearly half of participants (44.4%) reported little-to-no itch (PP-NRS 0/1) **(Figure 3)**; more than half (58.6%) reported meaningful improvement in itch (ΔPP-NRS ≥4)
- More than half of participants (57.4%) achieved minimal or no skin pain (SP-NRS 0/1) **(Figure 3)**; over two-thirds (67.2%) reported clinically meaningful improvements in skin pain (ΔSP-NRS ≥4)
- Nearly half of participants (43.3%) reported no impact of AD on quality of life (DLQI 0/1) **(Figure 3)**; a majority (76.0%) reported meaningful improvements in quality of life (ΔDLQI ≥4)
- Over one-third of participants (38.0%) achieved little-to-no disease burden (POEM ≤2) **(Figure 3)**; most (77.1%) achieved clinically meaningful improvement in disease burden (ΔPOEM ≥4)
- Overall, 64.7% of participants achieved disease control (ADCT score <7) **(Figure 3)**
- At 6 months, 46.6% of participants achieved simultaneous attainment of EASI 90 and PP-NRS 0/1 **(Figure 4)**

Figure 2. Achievement of Clinician-Reported Outcomes at the 6-Month Follow-Up



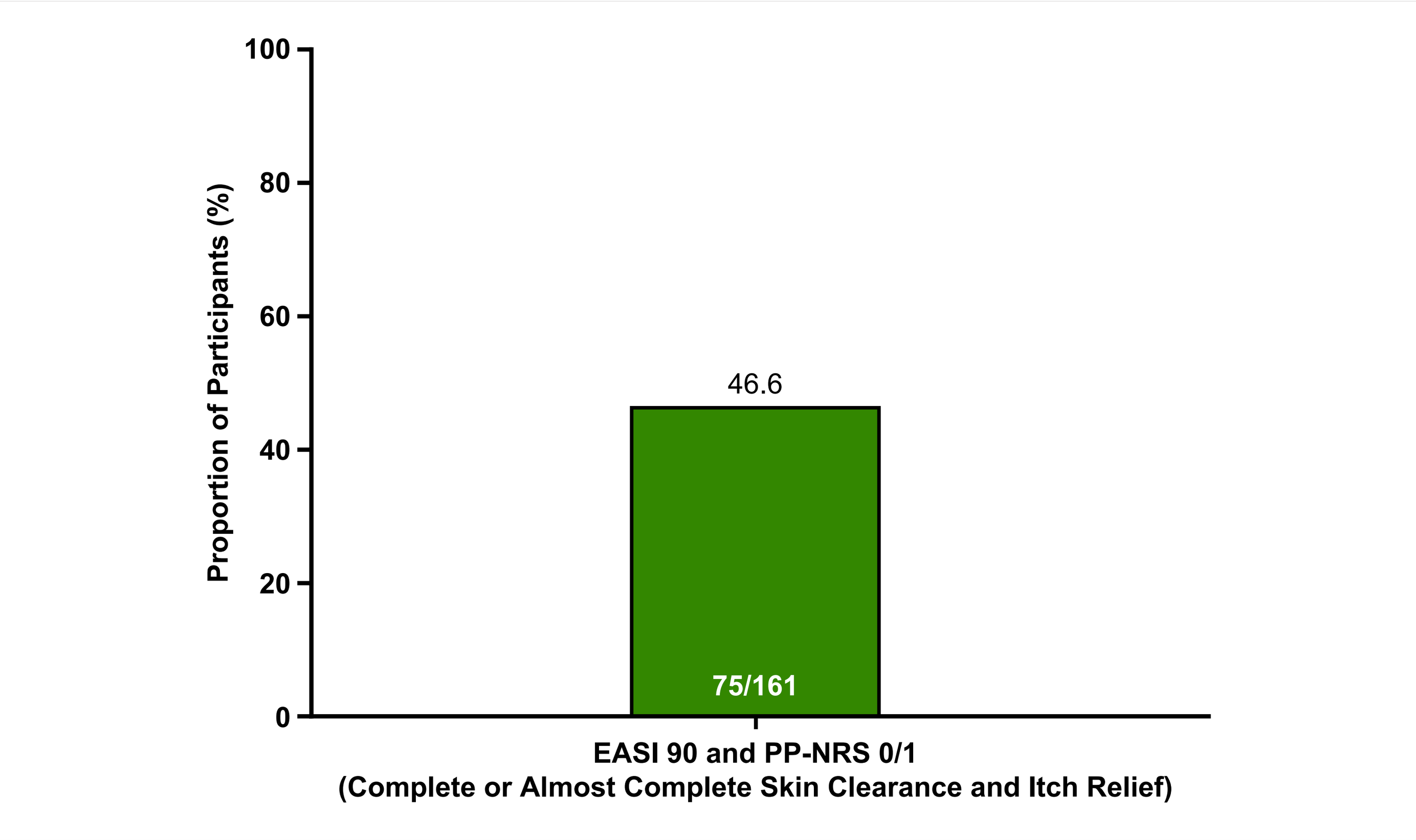
EASI, Eczema Area and Severity Index; vIGA-AD, validated Investigators Global Assessment Scale for Atopic Dermatitis.

Figure 3. Achievement of Patient-Reported Outcomes at the 6-Month Follow-Up


Proportion of Participants (%)
100
80
60
40
20
0
44.4
76/171
57.4
85/148
43.3
77/178
38.0
71/187
64.7
99/153
PP-NRS 0/1
(No/Minimal Itch)
SP-NRS 0/1
(No/Minimal Skin Pain)
DLQI 0/1
(No/Minimal Impact on QoL)
POEM ≤2
(No/Almost Clear Symptoms)
ADCT <7
(Well-Controlled Disease)

ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; POEM, Patient-Oriented Eczema Measure; PP-NRS, Peak Pruritus Numeric Rating Scale; QoL, quality of life; SP-NRS, Skin Pain Numeric Rating Scale.

Figure 4. Simultaneous Achievement of EASI 90 and PP-NRS 0/1 at the 6-Month Follow-Up



EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numeric Rating Scale.