Why Do Optimal Targets for Itch and Skin Clearance Matter in Atopic Dermatitis Treatment? Insights from the TARGET-DERM AD Registry

Jonathan I. Silverberg, MD, PhD, MPH[1], Christopher G. Bunick MD[2], Brian Calimlim DrPH[3], Ayman Grada, MD, MS[3], Keith D. Knapp PhD[4], Breda Munoz PhD[4], Julie M. Crawford MD[4], Chibuzo Obi PharmD[3], Amy S. Paller MD[5], on behalf of the TARGET-DERM AD Investigators.

[1]George Washington University School of Medicine and Health Sciences. Washington D.C., USA; [2]Department of Dermatology and Program in Translational Biomedicine, Yale University School of Medicine, New Haven, CT, USA; [3]AbbVie Inc. North Chicago, Illinois, USA; [4] Target RWE. Durham, North Carolina, USA; [5] Northwestern Feinberg School of Medicine. Chicago, Illinois, USA.

TARGET RWE
BETTER EVIDENCE • BETTER HEALTH

Introduction

- Atopic dermatitis (AD) patients undergoing treatment may only experience partial improvement in itch and skin lesions, often leading to suboptimal outcomes.
- The Aiming High in Eczema/Atopic Dermatitis (AHEAD)[1] treat-to-target recommendations emphasize the importance of achieving optimal treatment targets, such as complete or near-complete itch relief and skin clearance.
- However, there is limited evidence on the impact of achieving these higher efficacy targets on patient-reported outcomes (PROs) and quality of life in AD.

Objective

- To evaluate the independent and combined effects of achieving optimal treatment targets for itch and skin clearance on PROs in AD, based on the AHEAD treat-to-target recommendations.

Methods

- A cross-sectional analysis was conducted on adult participants in TARGET-DERM AD, a longitudinal study with over 4,000 participants across 52 U.S. and Canadian clinical-practice sites (2019-2024 ongoing).
- Skin and itch outcomes were measured using:
  - The validated Investigator Global Assessment (vIGA-AD), where 0/1 represents clear or almost clear skin (optimal target).
  - The PROMIS Itch-Severity question (NRS-Itch, 0–10 scale), with scores of 0/1 indicating no or minimal itch (optimal target).
- Patient-reported outcomes were assessed using optimal targets of:
  - POEM 0–2 (clear/almost-clear disease)
  - DLQI 0/1 (minimal/no impact on quality of life)
  - NRS-Sleep 0/1, and
  - NRS-Pain 0/1.
- Logistic regression models examined the main and interaction effects of itch and skin severity.

Results

- Among 1,920 patients, 58.6% were female, 54.5% Non-Hispanic White, 93.8% from US clinical site, and had a mean age 45 years.
- Optimal DLQI, POEM, NRS-Sleep, and NRS-Pain were most frequent among those achieving the optimal treatment targets for skin clearance (vIGA-AD 0/1; 44.7%, 44.3%, 44.7%, and 74.3%, respectively, figure 2).
- Optimal DLQI, POEM, NRS-Sleep, and NRS-Pain were most frequent among those achieving the optimal treatment targets for itch (WI-NRS 0/1; 52.1%, 53.7%, 57.3%, and 83.1%, respectively, figure 3)
- For patients reporting no/minimal itch, optimal DLQI, POEM, NRS-Sleep, and NRS-Pain were also most frequent among those achieving the optimal treatment targets for skin clearance (vIGA-AD 0/1; 68.9%, 78.4%, 67.6%, and 92.0%, respectively, figure 4)

Figure 1. Patient disposition

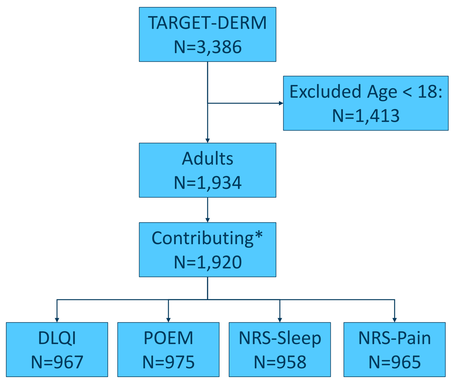


Table 1b. Patient characteristics at enrollment

Patient characteristic	Cohort (N=1920)
Age at enrollment	
Mean (SD)	44.5 (18.6)
Median (n)	43.0 (1920)
Q1–Q3 (IQR)	27.0 - 60.0 (33.0)
Sex, n (%)	
Female	1126 (58.6%)
Male	794 (41.4%)
Race-Ethnicity, n (%)	
NH White	1047 (54.5%)
NH Black	195 (10.2%)
NH Asian	199(10.4%)
Hispanic/Latino	166 (8.6%)
Other/Not Reported	313 (16.3%)
Insurance type, n (%)	
Commercial/Private	1334 (69.5%)
Medicaid	152 (7.9%)
Medicare	209 (10.9%)
Uninsured	225 (11.7%)

Patient characteristic	Cohort (N=1920)
vIGA-AD	
Mean (SD)	2.3 (1.1)
Median (n)	3.0 (1913)
Worst itch	
Mean (SD)	6.0 (3.1)
Median (n)	8.0 (1042)
DLQI	
Mean (SD)	6.5 (6.2)
Median (n)	5.0 (967)
POEM	
Mean (SD)	9.5 (7.3)
Median (n)	8.0 (974)
NRS-Sleep	
Mean (SD)	3.4 (2.8)
Median (n)	3.0 (958)
NRS-Pain	
Mean (SD)	2.1 (2.4)
Median (n)	1.0 (965)

Figure 2. Among respondents reporting an optimal outcome in each PRO category, distribution by vIGA-AD category

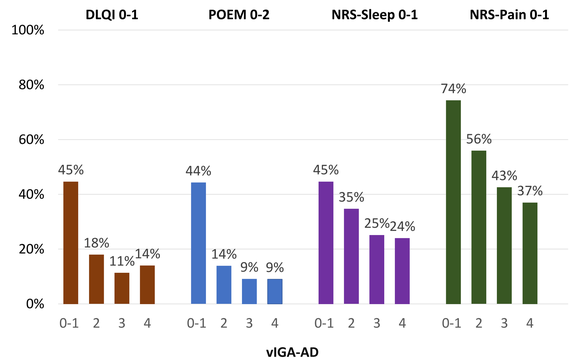


Figure 3. Among respondents reporting an optimal outcome in each PRO category, distribution by WI-NRS category

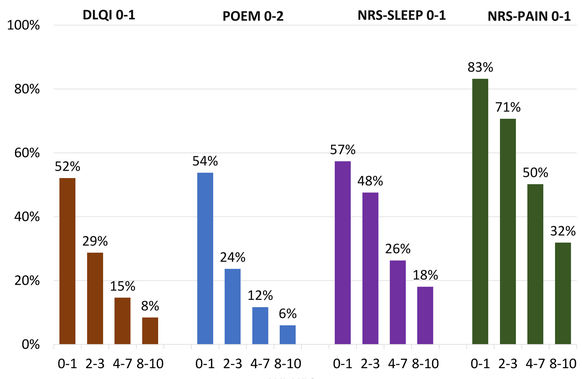


Figure 4. Among respondents reporting no/minimal itch (WI-NRS 0/1), percent of patients within each PRO category reporting an optimal outcome by vIGA-AD category

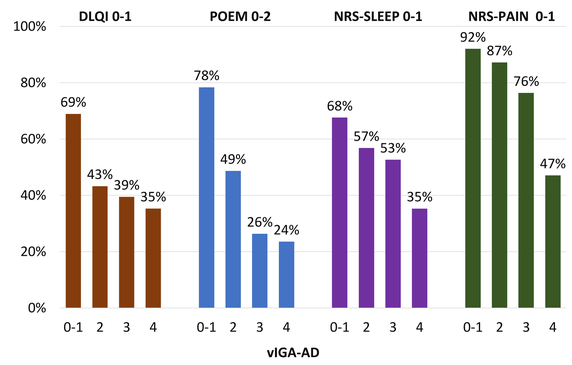
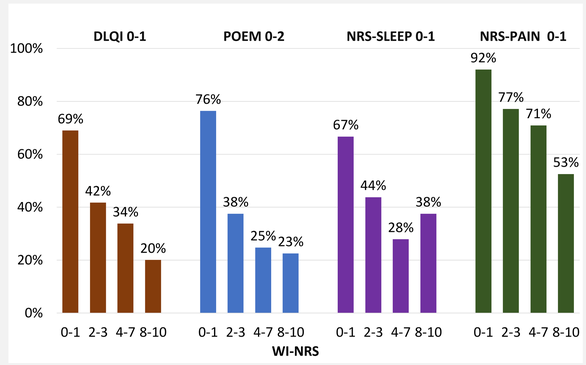


Figure 5. Among respondents with clinician-reported clear skin (vIGA-AD 0/1), percentage of patients within each PRO category reporting an optimal outcome by WI-NRS category



- Of the patients having clear/almost clear skin (vIGA-AD 0/1) and reporting itch relief (WI-NRS 0/1), greater than 67% report an optimal outcome.

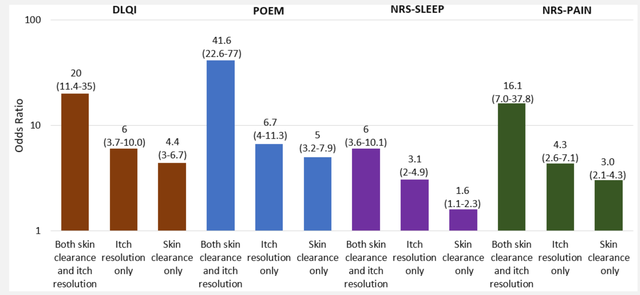
Table 2. The log odds for each model parameter statistically associated with ideal state for patient-reported outcomes.

	DLQI 0-1			POEM 0-2			NRS-Sleep 0-1			NRS-Pain 0-1		
Effects description	Coefficient	SE	P-value	Coefficient	SE	P-value	Coefficient	SE	P-value	Coefficient	SE	P-value
WI-NRS 0/1	1.8	0.25	<0.01	1.9	0.27	<0.01	1.12	0.23	<0.01	1.47	0.25	<0.01
vIGA-AD 0/1	1.49	0.21	<0.01	1.61	0.23	<0.01	0.47	0.19	0.01	1.1	0.19	<0.01
Interaction	-0.29	0.39	0.46	0.23	0.42	0.59	0.2	0.37	0.59	0.21	0.52	0.69

SE=Standard Error; P-value=Probability Value; Clear/Almost Clear Skin * No/Minimal Itch = the interaction of both terms

- Itch relief and skin clearance are each significantly associated with improved quality of life (DLQI), patient-reported disease severity (POEM), sleep and pain outcomes.

FIGURE 6. The adjusted odds ratios (95% confidence interval) of achieving improved PROs based on skin clearance and itch resolution status compared to patients with neither.



Skin clearance (clear/almost clear skin); itch resolution (no/minimal itch); Data in parentheses represent the 95% confidence interval

- Compared to partial improvement, the adjusted odds ratios (aOR) of optimal PROs were greatest for participants with complete or near-complete resolution of both itch and skin lesions (DLQI 0/1: 20.0; POEM 0-2: 41.7; Sleep-NRS: 16.1; Pain-NRS: 6.0, Figure 6).

Conclusion:

- Achieving optimal treatment targets for both itch and skin lesions markedly enhances patient-reported outcomes in AD.
- The results of this real-world study support treat-to-optimal targets to assess therapeutic effectiveness and optimize patient outcomes.

References

1. Liu, L. Y., et al. (2016). "Health-related quality of life (HRQoL) among patients with alopecia areata (AA): A systematic review." J Am Acad Dermatol 75(4): 806-812.e803.
2. Lloyd, A., et al. (2024). "Psychometric Properties of the EQ-5D-5L in Patients with Alopecia Areata." PharmacoEconomics - Open 8(5): 715-725.

Acknowledgements and Disclosures: TARGET-DERM is a study sponsored by Target RWE. Target RWE is a health evidence solutions company headquartered in Durham, NC. The authors would like to thank all the investigators, participants, and research staff associated with TARGET-DERM. *TARGET-DERM Investigators are the participating investigators who provided and cared for study patients; they are authors and non-author contributors. For the complete list, please see ClinicalTrails.gov (NCT03661866).

JIS received honoraria as a consultant and/or advisory board member for Abbvie, Afyx, Aobiome, Arena, Asana, BioMX, Bluefin, Bodewell, Boehringer-Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly, Galderma, GlaxoSmithKline, Incyte, Kiniksa, Leo Pharma, Luna, Menlo, Novartis, Pfizer, RAPT, Regeneron, Sanofi-Genzyme; speaker for Abbvie, Eli Lilly, Leo Pharma, Pfizer, Regeneron, Sanofi-Genzyme; institution received grants from Galderma, Pfizer. **CGB** has served as an investigator for AbbVie, Almirall, Daiichi Sankyo, LEO Pharma, Ortho Dermatologics, Sun Pharma, Timber, and Palvella; a consultant for AbbVie, Almirall, Apogee, Arcutis, Eli Lilly, EPI Health/Novan, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; and a speaker for and received honoraria from Allergan, Almirall, LEO Pharma, and UCB. **KK, BM, and JMC** are employees of Target RWE and may hold stock options. **BC, AG**, and **CO** are employees of AbbVie Inc. may hold stock options. **AP** is an investigator with: AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, KrystalBio, Regeneron, UCB; Consultant with honorarium – Abbvie, Abeona, Alcimed, Almirall, Amagma, Anaptysbio, Arena, Azitra, BiomX, Boehringer Ingeheim, Castle Biosciences, Catawba, Dermira, Eli Lilly, Exicure, Forte, Kamari, Leo, Lifemax, NAOS, Novartis, Pfizer, Phoenix, Pierre Fabre, Regeneron, Sanofi/Genzyme, Seanergy, Trifecta, UCB; Data Safety Monitoring Board – AbbVie, Bausch, Galderma, Novan