

Burden of Disease is Positively Associated with Disease Severity in Atopic Dermatitis

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Introduction:

- Previous work showed that clinician-reported severity measures are correlated with patient-reported outcomes and quality of life in atopic dermatitis (AD)
- Research examining associations between clinician-reported validated Investigator Global Assessment for AD (vIGA-AD) and patient-reported burden of disease is sparse

Methods:

- The TARGET-DERM AD cohort is an ongoing longitudinal, observational study launched in 2019 capturing adult, adolescent and pediatric AD patients in 44 community or academic sites in the United States
- Clinical AD severity was measured using the validated Investigator's Global Assessment for AD (vIGA-ADTM)
- Symptom severity and quality of life were assessed by the Patient-Oriented Eczema Measure (POEM) and Dermatology Life Quality Index (DLQI) or children's DLQI (CDLQI), respectively
- Patient characteristics and outcomes were assessed overall and by vIGA-AD category using descriptive statistics
- Associations with vIGA-AD were evaluated using unadjusted and adjusted ordinal logistic regression and linear regression models

Results:

- vIGA-AD severity was associated with greater symptom severity and poorer quality of life, with greater POEM and CDLQI/DLQI scores observed at greater vIGA-AD severity levels ($p < 0.0001$). AD severity was also associated with age category, race/ethnicity, site type, treatment class, and allergic disorder (**Table 1**).
- Compared to patients with clear/almost clear AD, patients with mild (odds ratio [OR] = 3.16) and moderate/severe AD (OR = 6.88) were more likely to be in a more severe POEM category (**Figure 1**) and more likely to be in a more severe DLQI/CDLQI category (OR = 2.37 and 4.93, respectively) (**Figure 2**).
- Adjusted linear regression analyses of DLQI in adults showed statistically significant differences by vIGA-AD level, with mild AD and moderate/severe AD associated with a 2.11-point and 5.15-point greater DLQI relative to clear/almost clear AD (**Figure 3**).

Figure 1. Ordinal multivariable logistic regression for POEM score category by risk factor (N=1,230)

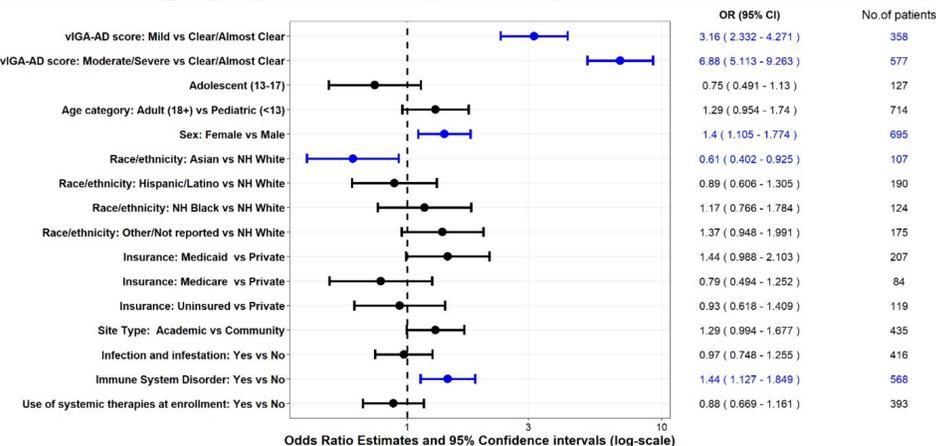


Table 1. Demographics, characteristics, current treatments and Patient Reported Outcome Measures by disease severity at enrollment

	vIGA-AD ¹ score at enrollment			Total (N=1888)	p-value ⁸
	Clear or Almost Clear (N=421)	Mild (N=558)	Moderate or Severe (N=909)		
Summary					
Demographics, insurance and site characteristics					
Age at study entry ² (years)					
Median (n)	22 (421)	23 (558)	21 (909)	22 (1888)	0.9911
Min - Max	0 - 83	0 - 89	0 - 90	0 - 90	
Age Category, n (%)					0.0429
Pediatric (<13)	154 (36.6%)	183 (32.8%)	279 (30.7%)	616 (32.6%)	
Adolescent (13-17)	35 (8.3%)	52 (9.3%)	115 (12.7%)	202 (10.7%)	
Adult (18+)	232 (55.1%)	323 (57.9%)	515 (56.7%)	1070 (56.7%)	
Gender, n (%)					0.2765
Female	248 (58.9%)	301 (53.9%)	501 (55.1%)	1050 (55.6%)	
Male	173 (41.1%)	257 (46.1%)	408 (44.9%)	838 (44.4%)	
Race-Ethnicity, n (%)					0.0003
NH White	226 (53.7%)	260 (46.6%)	416 (45.8%)	902 (47.8%)	
NH Black	44 (10.5%)	64 (11.5%)	117 (12.9%)	225 (11.9%)	
Hispanic/Latino	81 (19.2%)	98 (17.6%)	132 (14.5%)	311 (16.5%)	
Asian	20 (4.8%)	46 (8.2%)	107 (11.8%)	173 (9.2%)	
Other/Not reported	50 (11.9%)	90 (16.1%)	137 (15.1%)	277 (14.7%)	
Insurance ^{3,4} , n (%)					0.5011
Medicaid	90 (21.4%)	108 (19.4%)	180 (19.8%)	378 (20.0%)	
Medicare	27 (6.4%)	38 (6.8%)	54 (5.9%)	119 (6.3%)	
Private	253 (60.1%)	350 (62.7%)	593 (65.2%)	1196 (63.3%)	
Uninsured	51 (12.1%)	62 (11.1%)	82 (9.0%)	195 (10.3%)	
Site Type, n (%)					0.0011
Academic	191 (45.4%)	197 (35.3%)	323 (35.5%)	711 (37.7%)	
Community	230 (54.6%)	361 (64.7%)	586 (64.5%)	1177 (62.3%)	
Treatment Class at Enrollment, n (%)					
Systemics ⁵	138 (32.8%)	135 (24.2%)	308 (33.9%)	581 (30.8%)	0.0003
Topical therapies ⁶	332 (78.9%)	496 (88.9%)	784 (86.2%)	1612 (85.4%)	<.0001
Medical History, n (%)					
Allergic/immunologic disorders	205 (48.7%)	220 (39.4%)	391 (43.0%)	816 (43.2%)	0.0148
Infections	152 (36.1%)	178 (31.9%)	297 (32.7%)	627 (33.2%)	0.3432
Patient Reported Outcomes					
Dermatology Life Quality Index (DLQI/CDLQI)					
Median (n)	2 (283)	4 (342)	6 (555)	4 (1180)	<.0001
Min - Max	0 - 26	0 - 25	0 - 30	0 - 30	
DLQI/CDLQI Score Category, n (%)⁷					
n	283	342	555	1180	<.0001
No effect at all on patient's life	131 (46.3%)	86 (25.1%)	92 (16.6%)	309 (26.2%)	
Small effect on patient's life	90 (31.8%)	137 (40.1%)	177 (31.9%)	404 (34.2%)	
Moderate effect on patient's life	42 (14.8%)	81 (23.7%)	137 (24.7%)	260 (22.0%)	
Very large effect on patient's life	17 (6.0%)	33 (9.6%)	108 (19.5%)	158 (13.4%)	
Extremely large effect on patient's life	3 (1.1%)	5 (1.5%)	41 (7.4%)	49 (4.2%)	
Patient-Oriented Eczema Measure (POEM) Score					
Median (n)	4 (295)	9 (358)	13 (577)	9 (1230)	<.0001
Min - Max	0 - 27	0 - 27	0 - 28	0 - 28	
POEM Score Category, n (%)					
n	295	358	577	1230	<.0001
Clear or almost clear (0-2)	96 (32.5%)	65 (18.2%)	41 (7.1%)	202 (16.4%)	
Mild eczema (3-7)	110 (37.3%)	82 (22.9%)	110 (19.1%)	302 (24.6%)	
Moderate, Severe or Very Severe eczema (8-28)	89 (30.2%)	211 (58.9%)	426 (73.8%)	726 (59.0%)	

¹Validated Investigator Global Assessment scale for Atopic Dermatitis
²Age calculated based on year of consent minus birth year
³The private insurance category includes participants with private insurance and those with "other" insurance. The majority of participants with "other" insurance have Tricare (a military and veteran insurance).
⁴The uninsured insurance category includes participants with no known insurance.
⁵Systemic treatments include systemic Corticosteroids, Methotrexate, Cyclosporine, Dupilumab, Phototherapy at enrollment.
⁶Topical treatments include topical Corticosteroids, Calcineurin Inhibitors, Phosphodiesterase Inhibitors at enrollment.
⁷CDLQI score categories are defined as 0-1 no effect, 2-6 small effect, 7-12 moderate effect, 13-18 very large effect, and 19-30 extremely large effect. DLQI score categories are defined as 0-1 no effect, 2-5 small effect, 6-10 moderate effect, 11-20 very large effect, and 21-30 extremely large effect.
⁸Chi-square test for categorical variables or Kruskal-Wallis test for continuous variables are reported.

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 ClinicalTrials.gov (NCT03661866).

Figure 2. Ordinal multivariable logistic regression for DLQI score category by risk factor (N=1,180)

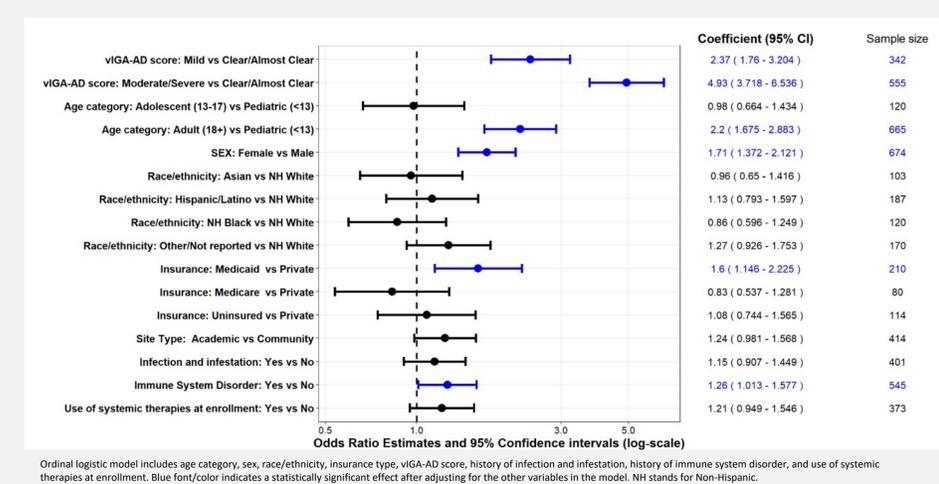
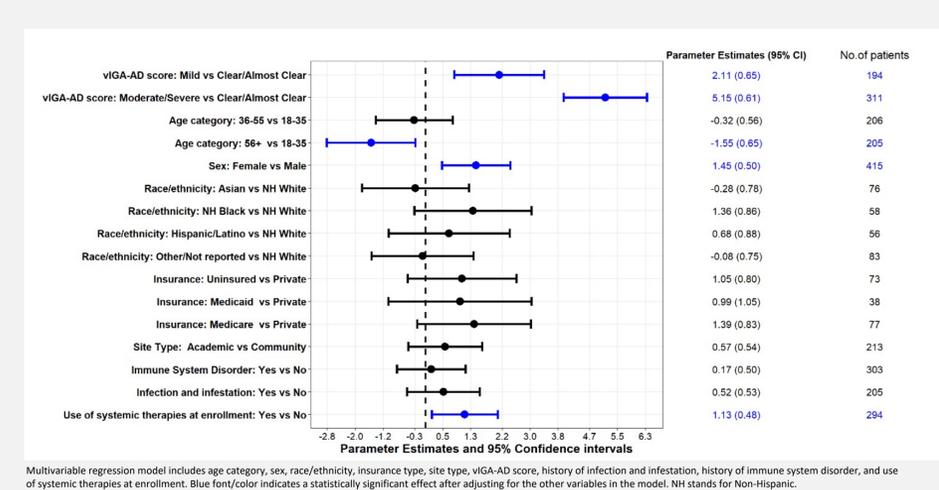


Figure 3. Multivariable linear regression for DLQI score in adult AD patients (N=665)



Conclusion:

- In this real-world study of patients with AD, greater disease severity is significantly associated with higher symptom severity and lower quality of life
- Future analyses will explore associations between AD severity as measured by vIGA-AD and other PROs, such as WPAI and relevant PROMIS measures, as well as differences by age group