Unmet Needs of Adolescents with Moderate to Severe Atopic Dermatitis in the TARGET-DERM Registry

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Introduction

- Atopic dermatitis (AD) is a chronic, heterogeneous, relapsing-remitting disease characterized by intense itch and eczematous lesions.
- Two advanced systemic therapies are approved in adolescents with moderate-to-severe AD.
- This study describes demographic characteristics, clinical and patient-reported outcomes in adolescents with moderate-to-severe AD in the TARGET-DERM AD registry stratified by advanced systemic therapy (AST) treatment status.

Methods

- TARGET-DERM AD, launched in 2019, is an ongoing, longitudinal, observational study of patients managed in clinical practice at 48 community (n=23) or academic (n=25) sites in the United States; first enrolled patients Jan. 25th, 2019, and the data herein spans the registry start date to November 11, 2022.
- Enrollment demographic, site, and clinical characteristics are analyzed descriptively
- Categorical variables are presented as numbers and percentages. Continuous variables are shown as means with standard deviation, medians, minimum and maximum
- ASTs considered in this study: dupilumab and upadacitinib
- Outcomes are only reported at each timepoint (enrollment, 12, 24, 36 and 52 weeks) if there were at least 14 patients with data on any given measure, at each timepoint

Inclusion/Exclusion Criteria

- Adolescent (12-17 years) at enrollment
- Moderate/severe AD defined by a score of 3 or 4 on validated Investigator Global Assessment (vIGA-AD)
- At least one follow-up visit post-enrollment
- Clinical trial patients excluded

AST-treatment groups

- AST-naïve (never AST-treated)
- AST-treated:
  - Retrospective (initiated AST prior to enrolling in TARGET-DERM AD)
  - Prospective (initiated AST after enrolling in TARGET-DERM AD)
  - Failed, stopped an AST and had either: a vIGA-AD increase or an AST-related adverse event

Demographic/concomitant treatment variables

- Patient demographics
- Site and physician type
- Prior and concomitant topical AD therapy (any, calcineurin inhibitor, corticosteroid, phosphodiesterase)

Disease severity measures:

- vIGA-AD (scores 0-4)
- Body Surface Area (BSA) (score %)
- vIGA-AD x BSA (score 0-400)

Patient reported outcomes:

- CDLQI: Children's Dermatology Life Quality Index (scores 0-30)
- POEM: Patient-Oriented Eczema Measure (scores 0-28)
- PO-SCORAD: Patient-Oriented Scoring Atopic Dermatitis (scores 0-103)
- Patient-Reported Outcomes Measurement Information System (PROMIS) Depression (scores 41.0-79.4) and PROMIS Anxiety (scores 40.9-85.2)

Figure 1. Patient Disposition

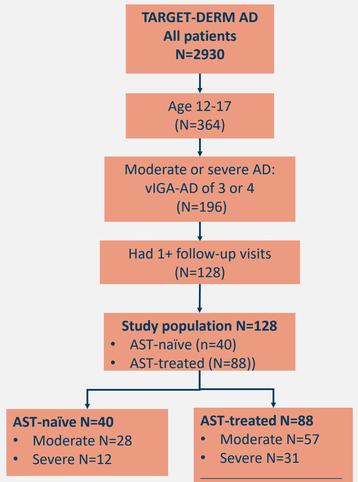


Table 1. Change Over Time Definitions

Scale	Unchanged*	Worsening*
vIGA-AD	no change	increase to 4
BSA	±9%	10%+ increase
vIGA-ADxBSA	±58.2	>=58.3
CDLQI	±3	4+ increase
PO-SCORAD	±8.6	>=8.7
POEM	±3.3	>=3.4
All PROMIS	±9	>9

*Versus most recent value

Results

AST-usage

- Of 128 adolescents who met study criteria, 40 (31.3%) were AST-naïve, 34 (26.6%) were retrospectively-treated, 50 (39.1%) were prospectively-treated, and 4 (3.1%) were AST-failed
- All AST treatment was dupilumab, no upadacitinib usage reported. Median days of dupilumab treatment was 500, 613, and 141 (retrospective, prospective and failed; p=0.01)
- Of 35 physicians, 25 (71%) were dermatologists and 7 (29%) allergists in this analysis. A dermatologist was the treating physician for AST-naïve (85%), AST-retrospective (94.1%), AST-prospective (96.0%) and AST-failed (100%). The remainder were treated by an allergist. Differences were not significant (p=0.14)

Enrollment outcomes

- At enrollment, there were no significant differences among treatment groups on demographic variables, physician specialty/site, vIGA-AD, and all PROs.
- Significant enrollment differences were observed for median BSA (15% naïve, 18% retrospective, 40% prospective, 36% failed; p<0.01) and median vIGA-AD x BSA (45 naïve, 49 retrospective, 113 prospective, 124 failed; p<0.01)

Figure 2. Patient Characteristics at Enrollment by AST-status

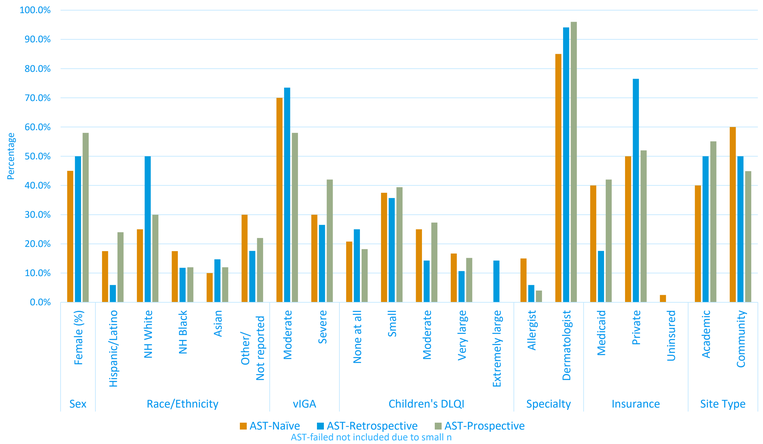


Figure 3. Disease Severity and Patient-Reported Outcomes at Enrollment

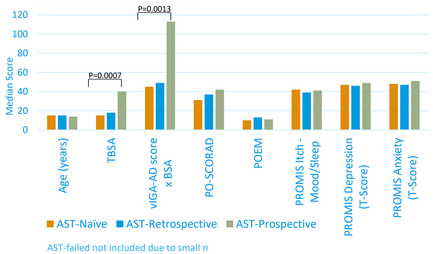
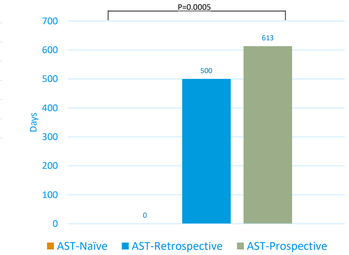


Figure 4. Duration of Dupilumab Therapy

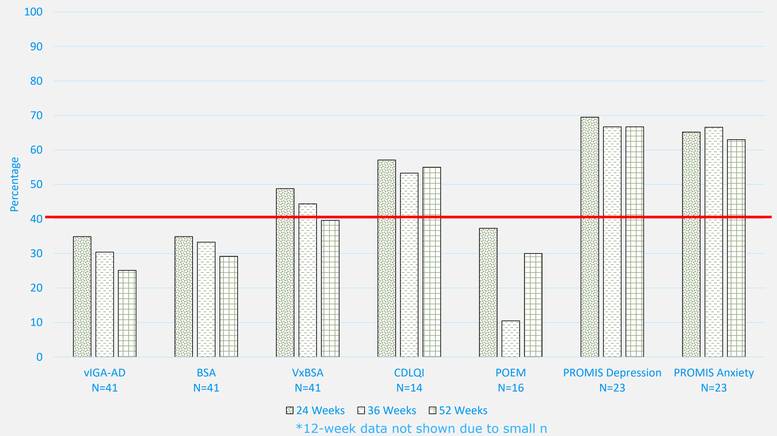


Longitudinal outcomes

Compared to enrollment, prospectively AST-treated patients were unimproved or worsened at 12 weeks on outcomes with n>=14, except where noted:
- Disease severity measures: vIGA-AD (43.9%), BSA (43.9%), vIGA x BSA (53.6%)
- PROs: PROMIS depression (66.7%) and PROMIS anxiety (60.0%)

Several PRO measures persisted as unimproved or worse vs enrollment to 24, 36, 52 weeks, respectively
- CDLQI (57.1%, 63.3%, and 55.0%)
- PROMIS Depression (69.5%, 66.7%, and 66.7%)
- PROMIS Anxiety (65.2, 66.6, and 63.0%)

Figure 5. Percentage of Prospectively AST-treated Unchanged or Worsening at 24, 36, 52 Weeks* with n>=14



*12-week data not shown due to small n

Conclusions

- In adolescents with moderate-to-severe AD, nearly one-third did not progress to AST despite being eligible based on clinical and disease characteristics.
- Evaluation of prospective AST-treated showed more than 40% were not improved or had worsened at 12 weeks, on measures with n>=14.
- Although physician-reported outcomes with n>=14 were largely improved by 52 weeks, patient-reported quality of life (CDLQI), depression, and anxiety were unchanged or worsened in ≥50% of prospectively treated AST.
- These real-world data suggest there is an unmet need to understand the reasons behind treatment inadequacies and potentially advancing more adolescents with moderate-to-severe AD who meet criteria to AST, and that more treatment options are needed for this population.

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