



Use of advanced systemic therapy in adolescent patients with moderate-to-severe atopic dermatitis in the TARGET-DERM Registry

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Introduction

- Moderate-to-severe atopic dermatitis (AD) has a significant negative impact on quality of life in adults and adolescents^{1,2}
- Despite being eligible for advanced systemic therapy (AST) due to uncontrolled moderate or severe AD, many adolescent patients do not progress to AST
- This study characterizes the population of adolescent (age 12-17) patients with moderate-to-severe AD who were AST-treated to those who were not AST-treated (AST-naïve) to better understand progression to AST-usage in these patients.

Methods

- TARGET-DERM AD is an ongoing, longitudinal, observational study of adult and adolescent dermatology patients managed in clinical practice at 32 community (n=15) or academic (n=17) sites in the United States; first patients were enrolled in Jan. 25th, 2019. ³ The data cutoff for this analysis was Aug 11, 2022.
- AST is defined as dupilumab (adolescent indication approved 05/26/2020) and upadacitinib (adolescent indication approved 01/11/22)
- , approved treatments for adolescents with moderate-to-severe AD.
- Patients were classified into two unique AST usage groups: AST-treated (any AST usage at or after enrollment) or AST-naïve (no AST usage at or after enrollment).
- Data was analyzed descriptively. The association between clinical/PROs and AST-usage was estimated by multivariate binary logistic regression controlling for age, race, gender, insurance, and site type.
- All analysis was conducted on enrollment (baseline) data

Patient Population:

- Adolescent (12-17 years)
- Moderate or severe AD defined as a score of 3 or 4 on the validated Investigator Global Assessment - AD (vIGA-AD) at enrollment
- Treatment history: had prior exposure to at least one of the following: topical corticosteroid, systemic corticosteroid, immunomodulator or phototherapy
- Had at least 1 post-enrollment visit
- Excluded were clinical trial patients and any patient treated with an AST prior to enrollment

Variables of Interest:

- 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)
- Total Body Surface Area (BSA) (score 0-100%)
- 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

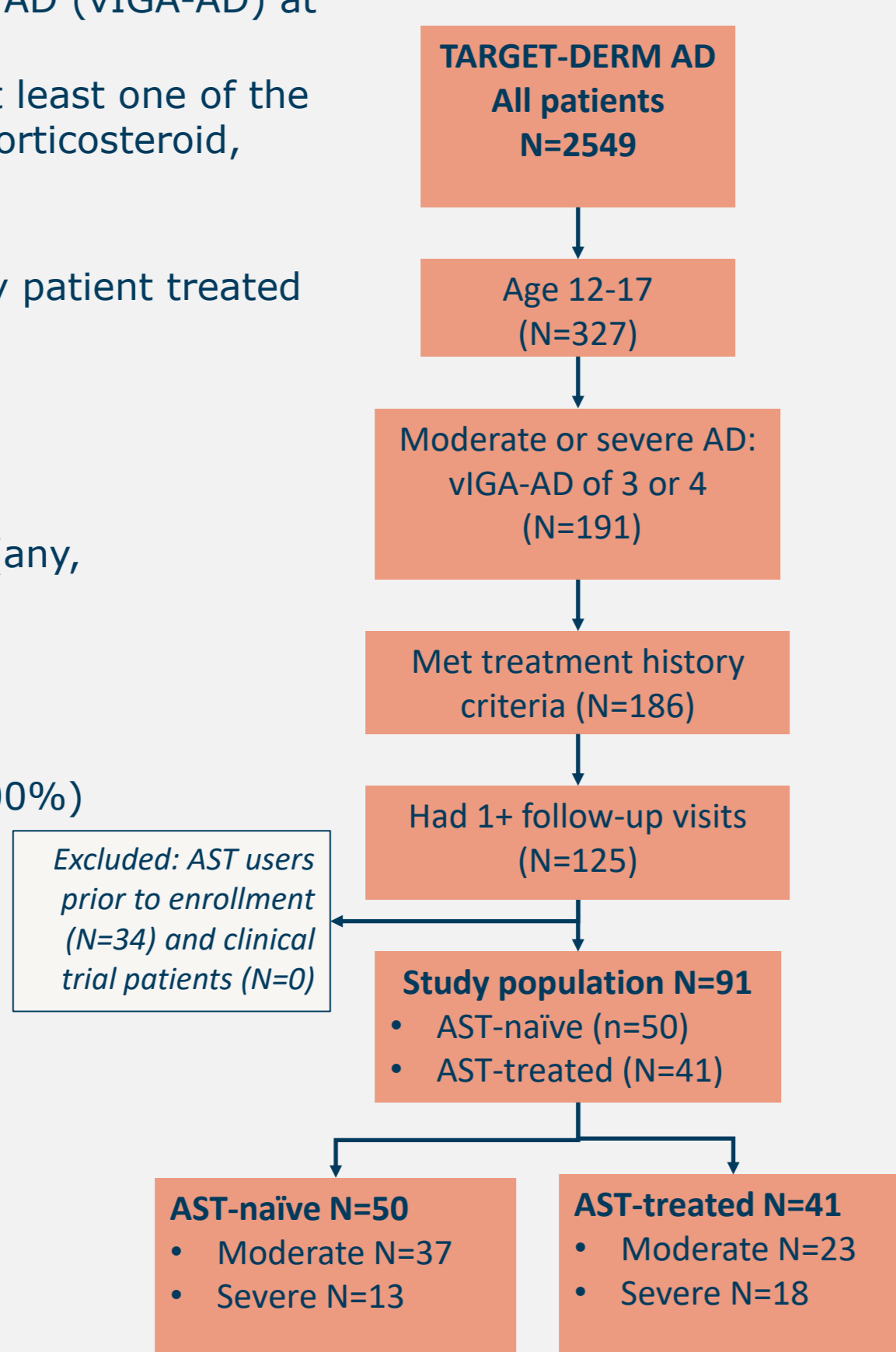


Fig 2a. Patient characteristics by AST-usage

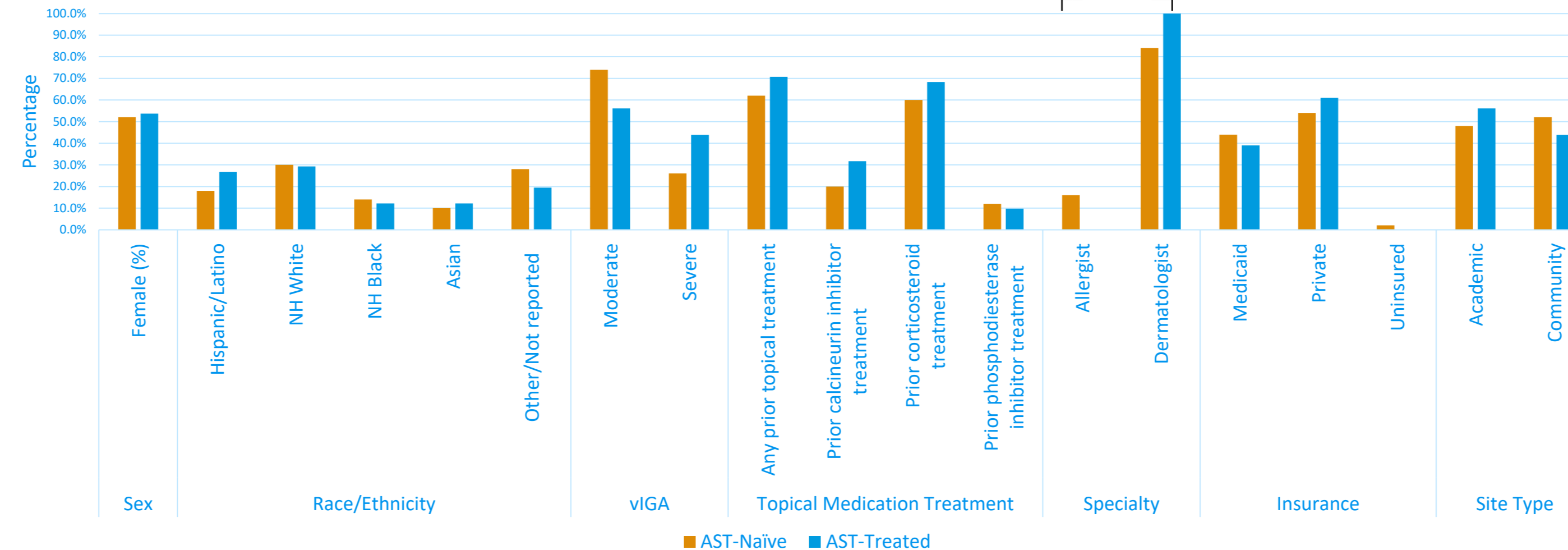
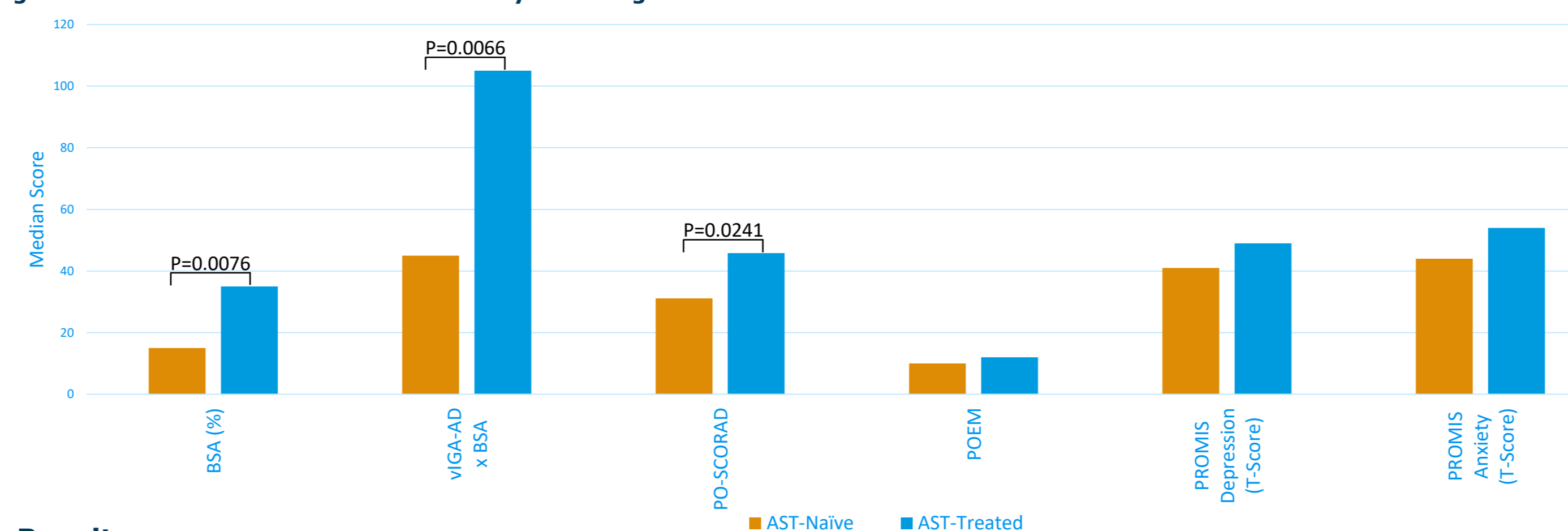


Figure 2b. Median Clinical and PRO Scores by AST-usage



Results

AST-usage

- Less than 50% of patients were treated with an AST among the 91 adolescents who met study criteria: 55% (N=50) were AST-naïve, and 45% (N=41) were AST-treated
- All AST treatment was with dupilumab, no upadacitinib usage reported
- Of 44 physicians, 36 (82%) were dermatologists and 8 (18%) allergists in this analysis. All 41 AST-treated patients (100%) saw a dermatologist, and none saw allergist (0%), of the AST-naïve 42 (84%) saw a dermatologist and 8 (16%) an allergist (p=0.008)

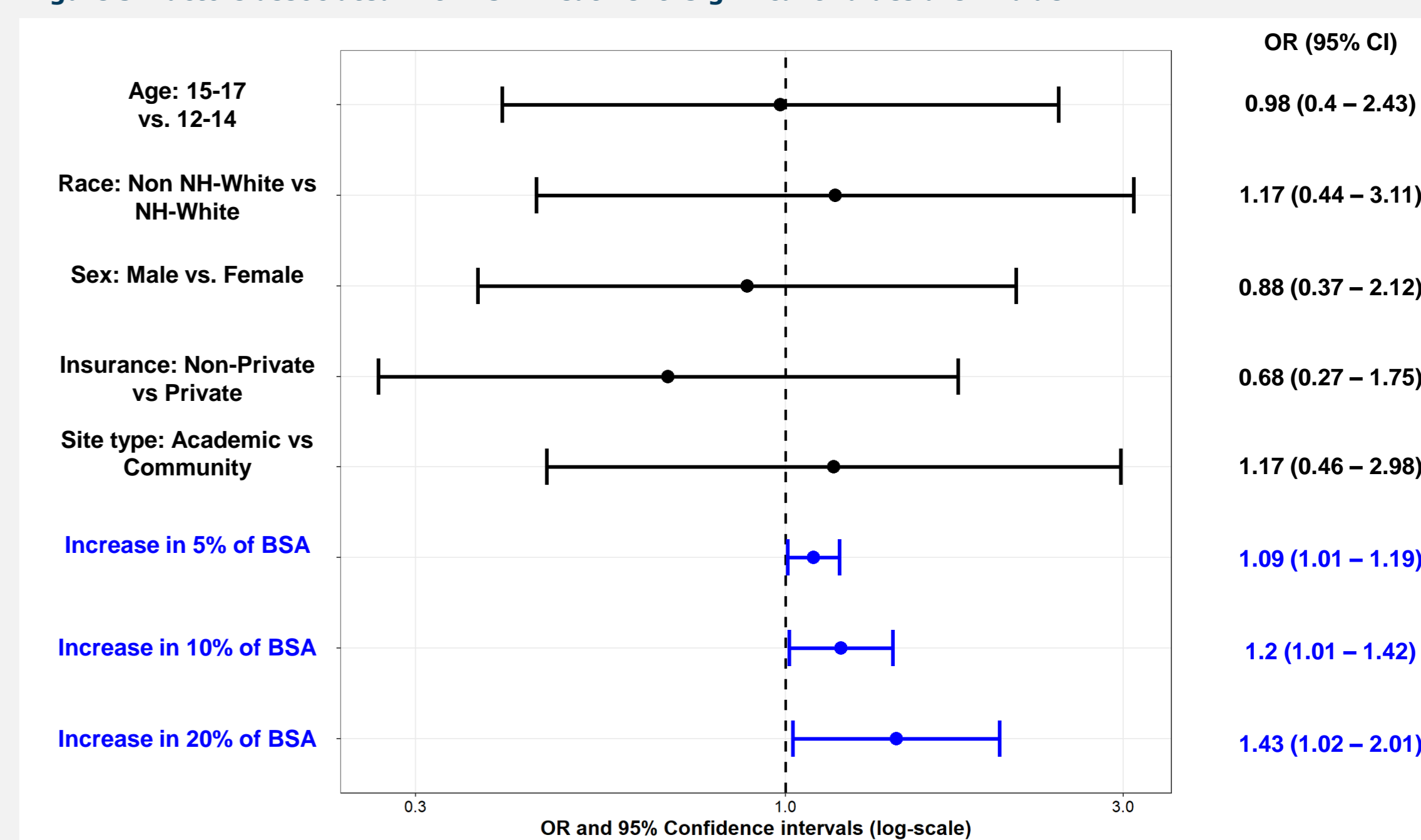
AST-naïve vs. AST-treated descriptive analysis

- No significant differences were observed between AST-usage groups for age, gender, race, insurance type, treatment center, vIGA-AD, CDLQI, POEM, PROMIS Depression, PROMIS Anxiety, or prior use of topical therapies at enrollment
- AST-treated had significantly higher median enrollment severity on two measures of disease severity
 - BSA (35% vs 15%, p=0.0076)
 - vIGA-AD x BSA (105 vs 48, p<0.0066)
- AST-treated had a significantly higher PO-SCORAD at enrollment vs AST-naïve (45.8 vs. 31.1, p<0.03)

AST-naïve vs AST-treated multivariate analysis

- In multivariate analysis controlling for sex, age, insurance, and race, only higher BSA at enrollment was associated with AST-usage
 - BSA of 5% OR=1.09 (1.01-1.19)
 - BSA of 10% OR = 1.2 (1.01-1.42)
 - BSA of 20% OR = 1.43 (1.02-2.01)

Figure 3. Factors associated with AST-Treatment. Significant values are in blue.



In addition to the covariates listed above, other factors were considered, but were not found to be significant; data not shown

Conclusion

- More than half of the patients with considerable disease severity and who experienced negative QOL from moderate-to-severe AD were not prescribed AST
- Compared to AST-naïve patients, descriptive analysis showed that the AST-treated were slightly more severe as indicated by significantly higher baseline BSA, higher vIGA-ADxBSA, and higher PO-SCORAD at enrollment.
- In multivariate analysis to adjust for baseline characteristics, higher BSA at enrollment was significantly associated with use of an AST.
- Longitudinal follow-up is needed to determine the outcomes associated with these treatment patterns to evolve therapeutic interventions and outcomes in these adolescent patients.

References

- Nutten, S., Atopic dermatitis: global epidemiology and risk factors. *Ann Nutr Metab*. 2015. 66 Suppl 1: p. 8-16.
- AD Langan SM, Irvine AD, Weidinger S. *Lancet*. 2020 Aug 1;396(10247):345-360.
- Abuabara, K. International observational atopic dermatitis cohort to follow natural history and treatment course: TARGETDERM AD study design and rationale. *BMJ Open* 2020;10:e0399282020.

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