USE OF SYSTEMIC THERAPY IN ADULTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS: ANALYSIS FROM THE COREVITAS ATOPIC DERMATITIS REGISTRY

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INTRODUCTION AND OBJECTIVE

- Despite recent advances in systemic treatment of atopic dermatitis (AD), many patients eligible for systemic therapy remain only on topical treatments, often with inadequate disease control.
- The degree to which under- or inadequate use of systemic treatment in AD (i.e., lack of treatment according to disease severity and patient profile) exists is currently poorly understood, and we set out to address this knowledge gap with the current study.

Study objective

To identify differences in patient and clinical characteristics between systemic-eligible patients by use of systemic therapy for AD at registry enrollment.

METHODS

Study Population

- The CorEvitas Atopic Dermatitis Registry is a prospective, non-interventional, research study launched in July 2020 for patients with atopic dermatitis (AD) under the care of a licensed dermatologist or qualified dermatology practitioner.
- Patients are enrolled into the registry if they satisfy all inclusion criteria listed below.
 - Diagnosed with AD by a dermatologist or qualified dermatology practitioner
 - At least 18 years of age or older
 - Willing to provide Personal Information
 - Meets ONE of the following conditions at the time of enrollment
 - Has started taking a new Eligible Medication^a within the 12 months prior to the Enrollment visit
 - Is prescribed a new Eligible Medication^a at the Enrollment visit
 - Is NOT being treated with an Eligible Medication^a at the time of enrollment, but has an Eczema Area and Severity Index (EASI) score ≥12 and a vIGA-AD[™] score ≥3 at enrollment
- This was a cross-sectional, descriptive study of all patients at enrollment in the registry from July 2020 (registry launch) through October 2021.

Statistical analyses

- Patient characteristics at enrollment were summarized descriptively, for all enrollees overall and by current use of systemic therapy.
 - Current use of systemic therapy was defined by eligibility criterion met at enrollment
- Cohen's f (effect size for difference in means for continuous variables; 0.10=small. 0.25=moderate, 0.40=large effect) and Cohen's phi (effect size for difference in proportions for categorical variables, 0.10=small, 0.30=moderate, 0.50=large effect) were used to compare demographic and disease characteristics between systemic therapy groups. Statistical analyses were performed in Stata version 16

^aEligible biologics (Dupixent and other biologics prescribed off-label for AD [Cosentyx, Stelara, Skyrizi, Taltz, Xolair]); eligible small molecules prescribed off-label for AD (Olumiant, Otezla, Rinvoq, Xeljanz); and eligible non-biologic systemics prescribed off-label for AD (azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid, tacrolimus).

RESULTS



| Characteristics | [1] Started systemic therapy ≤12 months before enrollment | [2] Started/ prescribed systemic therapy at enrollment | [3] No systemic therapy use at enrollment | Effect size ^a : | | |
|----------------------------------|---|--|---|----------------------------|---------------|---------------|
| | | | | [1] vs [2] | [1] vs [3] | [2] vs [3] |
| | N = 659 | N = 655 | N = 158 | | | |
| Age (years) | N = 659 | N = 655 | N = 154 | 0.03 | 0.04 | 0.07 |
| Mean (SD) | 48.9 (17.8) | 50.2 (18.9) | 46.9 (19.0) | | | |
| Sex at birth, n (%) | N = 659 | N = 655 | N = 154 | 0.02 | 0.05 | 0.06 |
| Female | 389 (59%) | 399 (61%) | 82 (53%) | | | |
| Race, n (%) | N = 659 | N = 652 | N = 154 | 0.06 | 0.14 | 0.17 |
| White | 437 (66%) | 436 (67%) | 91 (59%) | | | |
| Black | 89 (14%) | 102 (16%) | 11 (7%) | | | |
| Asian | 81 (12%) | 59 (9%) | 28 (18%) | | | |
| Other ^b | 52 (8%) | 55 (8%) | 24 (16%) | | | |
| Hispanic ethnicity, n (%) | N = 655 | N = 653 | N = 154 | 0.01 | 0.09 | 0.08 |
| Hispanic or Latino | 41 (6%) | 44 (7%) | 19 (12%) | | | |
| Nork status, n (%) | N = 659 | N = 655 | N = 154 | 0.10 | 0.20 | 0.18 |
| Full time | 341 (52%) | 286 (44%) | 50 (32%) | | | |
| Part time | 57 (9%) | 51 (8%) | 18 (12%) | | | |
| Student | 31 (5%) | 42 (6%) | 12 (8%) | | | |
| Disabled | 57 (9%) | 66 (10%) | 14 (9%) | | | |
| Retired | 109 (17%) | 145 (22%) | 33 (21%) | | | |
| Stay-at-home parent/spouse | 23 (3%) | 26 (4%) | 2 (1%) | | | |
| Unemployed | 41 (6%) | 39 (6%) | 25 (16%) | | | |
| Geographic region of site, n (%) | N = 659 | N = 655 | N = 158 | 0.14 | 0.26 | 0.31 |
| Northeast | 121 (18%) | 94 (14%) | 11 (7%) | | | |
| Midwest | 183 (28%) | 233 (36%) | 56 (35%) | | | |
| South | 212 (32%) | 232 (35%) | 22 (14%) | | | |
| West | 108 (16%) | 85 (13%) | 58 (37%) | | | |
| Canada | 35 (5%) | 11 (2%) | 11 (7%) | | | |

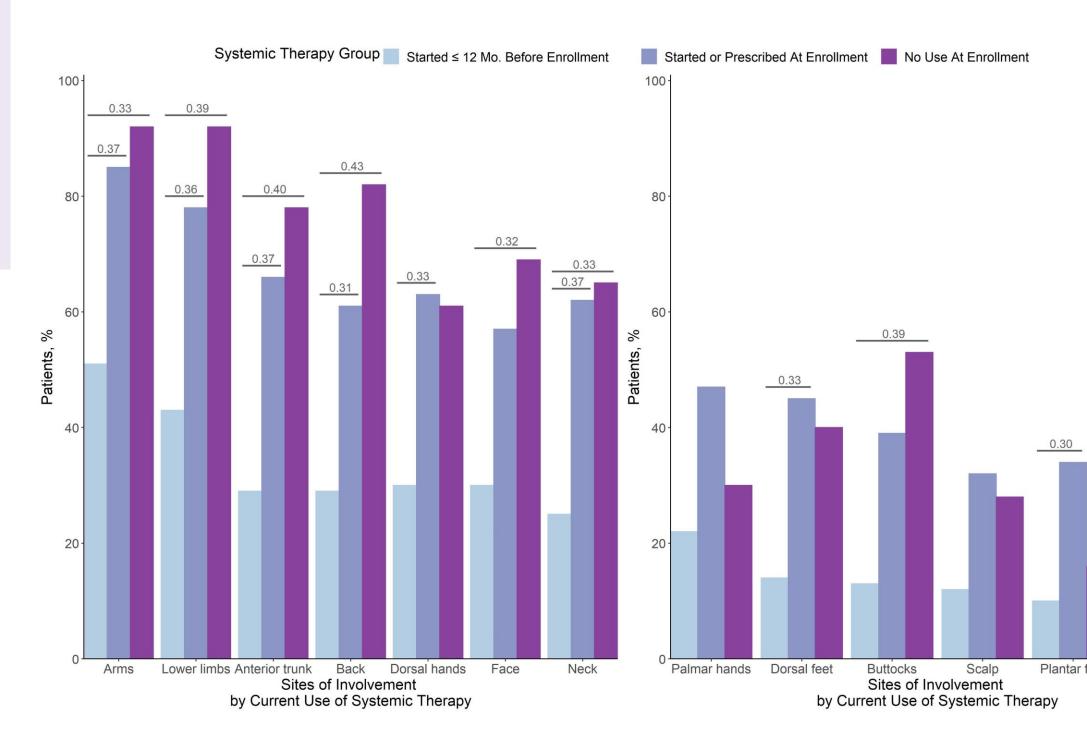
At enrollment, 89% of patients were either using (45%) or newly prescribed (44%) a systemic therapy, while 11% of patients were not treated with systemic therapy.

Among sociodemographic characteristics (Table 1), the largest between group differences observed were by geographic location of the clinic

 The proportion of patients in use or newly prescribed systemic therapy ranged from a low of 77% (West), to 81% (Canada) and 88% (Midwest), and to a high of 95% (both Northeast and South) (Cohen's phi: 0.22).

As expected, mean EASI scores were lower, and the percentage of patients with "controlled" AD according to the ADCT was higher, among patients already using a systemic therapy compared to patients newly prescribed or not prescribed at systemic therapy (see Table 2). Similar patterns were observed for AD sites of involvement (see Figure 1).

Table 1. Sociodemographic characteristics at enrollment in the CorEvitas AD registry, stratified by current use of systemic therapy.



| Characteristics | [1] Started systemic therapy ≤12 months before enrollment | [2] Started/ prescribed systemic therapy at enrollment | [3] No systemic therapy use at enrollment | Effect size ^a | | |
|---|---|---|---|--------------------------|---------------|---------------|
| | | | | [1] vs [2] | [1] vs [3] | [2] vs [3] |
| | N = 659 | N = 655 | N = 158 | | | |
| EASI (range: 0-72) ^b , mean (SD) | 5.3 (8.4) | 16.4 (12.7) | 19.8 (9.0) | 0.52 | 0.67 | 0.11 |
| vIGA-AD, n (%) | N = 659 | N = 655 | N = 158 | 0.60 | 0.55 | 0.17 |
| 0: Clear | 143 (22%) | 6 (1%) | 0 (0%) | | | |
| 1: Almost clear | 157 (24%) | 13 (2%) | 0 (0%) | | | |
| 2: Mild | 140 (21%) | 58 (9%) | 0 (0%) | | | |
| 3: Moderate | 161 (24%) | 301 (46%) | 91 (58%) | | | |
| 4: Severe | 58 (9%) | 277 (42%) | 67 (42%) | | | |
| ADCT "controlled" (<7) ^b , n (%) | 405 (62%) | 99 (15%) | 38 (25%) | 0.48 | 0.29 | 0.10 |
| DLQI 'effect on life', n (%) | N = 658 | N = 652 | N = 154 | 0.42 | 0.25 | 0.10 |
| 0 to 1 (no effect) | 208 (32%) | 30 (5%) | 14 (9%) | | | |
| 2 to 5 (small effect) | 210 (32%) | 149 (23%) | 44 (29%) | | | |
| 6 to 10 (moderate effect) | 121 (18%) | 195 (30%) | 39 (25%) | | | |
| 11 to 20 (very large effect) | 98 (15%) | 210 (32%) | 40 (26%) | | | |

^aPairwise effect sizes are presented to measure global balance in characteristics between systemic therapy use groups. ^bNon-response for these items was <3% within all groups

Figure 1. AD sites of involvement at enrollment in the CorEvitas AD Registry, overall and stratified by current use of systemic therapy. Pairwise effect sizes are presented for sites with at least moderate imbalance observed between systemic therapy use groups.

Table 2. Disease severity measures and patient reported measures at enrollment in the CorEvitas AD registry, stratified by current use of systemic therapy.

STRENGTHS AND LIMITATIONS

Strengths

Limitations

- limited.



 The CorEvitas AD Registry is a longitudinal prospective registry collecting data on AD treatment through physician- and patient-reported disease outcomes

The registry provides opportunities for in-depth analyses of patient historical treatment data, disease locations and phenotypes, and responses to therapies using a combination of patient and expert clinician-reported disease characteristics longitudinally.

 Findings of this observational study are limited to physicians and patients who voluntarily enrolled in the CorEvitas AD Registry and generalizability may be

This is not a population-based study.

CONCLUSIONS

Demographics, disease characteristics and comorbidity were generally similar between adult patients who newly initiated systemic therapy compared to systemiceligible patients not treated with systemic therapy.

The most prominent differences, albeit small, were observed across geographic regions of North America, with less prominent differences for several patient characteristics.

Geographic differences could speak to seasonality / seasonal effects in AD regional differences in physician training, region-specific or health system-wide differences.

Further research is needed to identify why systemic treatment initiation may differ by geography.