Early Insights into the Characteristics of Tralokinumab Patients in a Real-World Setting in the United States

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Introduction

- **Tralokinumab-ldrm (Adbry™) was approved in the United States (US) in December 2021 for the treatment of moderate-to-severe atopic dermatitis (AD) in adult patients**
- **Real-world characteristics of patients prescribed tralokinumab are not yet understood**

Objective

The objective of this study was to understand the demographic, medical history, and clinical baseline characteristics of adult patients who were prescribed tralokinumab for the treatment of AD in a real-world setting.

Materials and Methods

- This retrospective, observational, descriptive study used electronic health record (EHR) data from the OMNY Health platform
- The OMNY Health platform is comprised of approximately 1,500 dermatologists and clinicians from integrated delivery networks and ambulatory dermatology practices in the US
- Patients who met both of the following criteria were included:
  - Ever had a prescription for tralokinumab from February 2022 to September 2022
  - 18 years or older at the date of first the tralokinumab prescription
- Patients were further divided into two groups for comparative analysis: biologic-naïve and biologic-experienced. The biologic-experienced group was composed of patients who had a history of dupilumab prescription in their medical history, as it was the only US-approved biologic for AD prior to tralokinumab
- Deidentified EHR data was summarized to report descriptive statistics of the patient characteristics
- The study index date was the date of the first tralokinumab prescription
- Baseline clinical characteristics, demographic, and prescription data were collected from the index date and the time period preceding the index date
- All variables were derived from EHRs that were populated during patient encounters in the real-world healthcare setting:
  - Patient demographics (age, gender, race, and weight)
  - Treatment characteristics (dose and prescriber)
  - Disease activity metrics (body surface area [BSA], investigator's global assessment [IGA], itch numerical rating scale [NRS] score)
  - Comorbidities
  - Treatment history and concomitant medications

Results

Patient Population

- As of September 2022, 195 adult patients met the criteria for this analysis **(Table 1)**
- Of the 195, 105 (54%) had a previous prescription of dupilumab (biologic-experienced)

Table 1. Patient Criteria

Criteria	N
Ever had a prescription for tralokinumab	198
AND Age 18 years or older at time of first tralokinumab prescription	195
Biologic Naïve	90
Biologic Experienced	105

Table 2. Baseline demographic characteristics at Index Tralokinumab Prescription

	Study Population N = 195	Biologic Naive N = 90	Biologic Experienced N = 105
Gender, n (%)	n = 195	n = 90	n = 105
Female	107 (54.9%)	55 (61.1%)	52 (49.5%)
Male	88 (45.1%)	35 (38.9%)	53 (50.5%)
Age (years)	n = 195	n = 90	n = 105
Mean (SD)	50.9 (18.2)	54.1 (18.7)	48.2 (17.5)
Median (Q1, Q3)	53.0 (36.5, 62.5)	57.5 (40.2, 66.0)	50.0 (34.0, 60.0)
Min, Max	18, 90	20, 90	18, 90
Race, n (%)	n = 112	n = 47	n = 65
White	87 (77.7%)	34 (72.3%)	53 (81.5%)
Black or African American	18 (16.1%)	10 (21.3%)	8 (12.3%)
American Indian or Alaska Native	1 (0.9%)	1 (2.1%)	0 (0.0%)
Asian	3 (2.7%)	1 (2.1%)	2 (3.1%)
Other	3 (2.7%)	1 (2.1%)	2 (3.1%)
Ethnicity, n (%)	n = 81	n = 39	n = 42
Hispanic or Latino	7 (8.6%)	2 (5.1%)	5 (11.9%)
Not Hispanic or Latino	74 (91.4%)	37 (94.9%)	37 (88.1%)
Region, n (%)*	n = 193	n = 89	n = 104
Northeast	28 (14.5%)	12 (13.5%)	16 (15.4%)
Southeast	83 (43.0%)	41 (46.1%)	42 (40.4%)
Southwest	43 (22.3%)	22 (24.7%)	21 (20.2%)
Midwest	37 (19.2%)	13 (14.6%)	24 (23.1%)
West	2 (1.0%)	1 (1.1%)	1 (1.0%)

*Geographic region was defined based on observed values as follows: Northeast (MD, PA), Southeast (FL, GA, NC, SC, TN, VA, WV), Southwest (AZ, TX), Midwest (IL, IN, KS, MI, MN, MO, OH), and West (CO).

Patient Demographics

- Majority of patients were female, ≥50 years old, and self-identified as White race **(Table 2)**
- Biologic-naïve patients, on average, had a higher proportion of females and were older than biologic-experienced patients

Figure 1. Medical History and Comorbidities at Index Tralokinumab Prescription

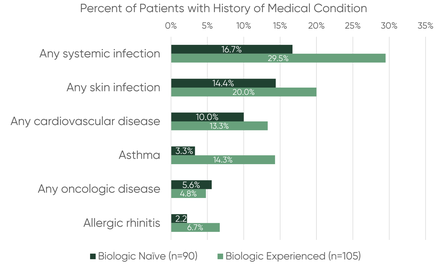

Table 3. Treatment History at Index Tralokinumab Prescription

	Study Population N = 195	Biologic Naive N = 90	Biologic Experienced N = 105
Topical corticosteroids	157 (80.5%)	69 (76.7%)	88 (83.8%)
Topical calcineurin inhibitors	74 (37.9%)	28 (31.1%)	46 (43.8%)
Systemic corticosteroids	68 (34.9%)	30 (33.3%)	38 (36.2%)
Ruxolitinib cream	44 (22.6%)	14 (15.6%)	30 (28.6%)
Crisaborole	34 (17.4%)	10 (11.1%)	24 (22.9%)
Systemic immunosuppressants	18 (9.2%)	7 (7.8%)	11 (10.5%)
Phototherapy	12 (6.2%)	3 (3.3%)	9 (8.6%)
Janus kinase inhibitors	3 (1.5%)	0 (0.0%)	3 (2.9%)
Other biologic*	3 (1.5%)	2 (2.2%)	1 (1.0%)
Apremilast	2 (1.0%)	1 (1.1%)	1 (1.0%)
Antidepressants	2 (1.0%)	0 (0.0%)	2 (1.9%)
Tapinarof cream	0 (0.0%)	0 (0.0%)	0 (0.0%)
Roflumilast cream	0 (0.0%)	0 (0.0%)	0 (0.0%)

*Other biologics include the following: certolizumab pegol, secukinumab, etanercept, adalimumab, tildrakizumab-asmn, infliximab, brodalumab, golimumab, risankizumab-rzaa, ustekinumab, ixekizumab, and/or guselkumab

Comorbidities and Treatment History

- In the entire cohort, the most documented comorbidities were systemic infection and skin infection **(Figure 1)**
  - A higher proportion of biologic-experienced patients had systemic infection (29.5%) and skin infection (20.0%) compared to the biologic-naïve patients (16.7% and 14.4%, respectively; **Figure 1**)
- History of asthma was recorded in less than 20% of the entire cohort, and it was more prevalent in biologic-experienced patients (14.3% vs 3.3%; **Figure 1**)
- Overall, the most common previously used AD treatments were topical corticosteroids, topical calcineurin inhibitors, and systemic corticosteroids. All these treatments were more prevalent among the biologic-experienced vs biologic-naïve patients **(Table 3)**

Clinical Characteristics at Baseline

- Dermatologists were more likely to prescribe tralokinumab to biologic-naïve patients than biologic-experienced patients (43.2% vs 30.4%); the opposite trend was observed for nurse practitioners (5.7% for biologic-naïve patients; 14.7% for biologic-experienced patients) **(Table 4)**
- Among patients with available disease activity data, approximately 79% had moderate or severe AD per their recorded index IGA score
- The mean AD-affected BSA at index was 22.0% and the mean itch NRS score was 5.7 (range: 0 to 10)
- More biologic-experienced patients had severe AD compared to their biologic-naïve counterparts, while the opposite trend was observed with moderate AD
- A larger proportion of biologic-experienced patients had documented AD involvement of the face and hands compared to the biologic-naïve patients

Study Limitations

- The OMNY Health platform did not include all EHRs across the entire US, which may limit generalizability
- As with all EHRs, clinicians may not have documented disease activity measures consistently within the structured data, resulting in missing data
- Other treatments, diagnoses, and health events occurring outside of these settings or outside of this time period may not have been captured in this data source; thus, only data that the provider chose to record in the structured EHR fields were available for analysis

Table 4. Clinical Characteristics at Index Tralokinumab Prescription

	Study Population N = 195	Biologic Naive N = 90	Biologic Experienced N = 105
Clinician taxonomy, n (%)	n = 190	n = 88	n = 102
Dermatology	69 (36.3%)	38 (43.2%)	31 (30.4%)
Physician assistant	86 (45.3%)	39 (44.3%)	47 (46.1%)
Nurse practitioner	20 (10.5%)	5 (5.7%)	15 (14.7%)
Internal medicine	1 (0.5%)	1 (1.1%)	1 (1.0%)
Other	1 (0.5%)	5 (5.7%)	8 (7.8%)
AD-affected body surface area percent	n = 83	n = 40	n = 43
Mean (SD)	22.0 (19.9)	21.0 (17.2)	22.9 (22.2)
Median (Q1, Q3)	15.0 (9.5, 28.0)	20.0 (10.0, 26.0)	15.0 (8.0, 30.0)
Min, Max	0, 100	1, 70	0, 100
Investigator's global assessment, n (%)	n = 56	n = 26	n = 30
Clear	3 (5.4%)	0 (0.0%)	3 (10.0%)
Almost Clear	2 (3.6%)	2 (7.7%)	0 (0.0%)
Mild	7 (12.5%)	3 (11.5%)	4 (13.3%)
Moderate	32 (57.1%)	16 (61.5%)	16 (53.3%)
Severe	12 (21.4%)	5 (19.2%)	7 (23.3%)
Itch numerical rating scale (0 to 10 scale)	n = 35	n = 19	n = 16
n	35	19	16
Mean (SD)	5.7 (2.6)	6.1 (2.6)	5.2 (2.7)
Median (Q1, Q3)	6.0 (4.0, 8.0)	6.0 (4.5, 8.0)	5.0 (3.8, 7.2)
Min, Max	1, 10	1, 10	1, 10
AD current/previous face involvement, n (%)	n = 26	n = 14	n = 12
Yes	4 (15.4%)	2 (14.3%)	2 (16.7%)
No	22 (84.6%)	12 (85.7%)	10 (83.3%)
AD current/previous hand involvement, n (%)	n = 26	n = 14	n = 12
Yes	11 (42.3%)	5 (35.7%)	6 (50.0%)
No	15 (57.7%)	9 (64.3%)	6 (50.0%)

Conclusions

- This study provides early insights into the baseline characteristics of tralokinumab patients in a real-world setting in the US
- While many characteristics were similar between biologic-naïve and biologic-experienced patients, a higher proportion of biologic-experienced patients had a greater degree of documented disease severity
- Understanding the types of patients who were being prescribed tralokinumab may help identify other patients who may benefit from tralokinumab to manage their moderate-to-severe AD
- Additional real-world studies are required to observe the changes in clinical outcomes after the initiation of tralokinumab over a longer period of time

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Disclosures

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