Real-world evidence demonstrating tralokinumab onset of action and efficacy in two skin of color patients with moderate-to-severe atopic dermatitis

Daniel Tinker, MD, SSM[1]; Duane Dilworth, MD, FAAD[2]

[1]Saint Louis University Department of Dermatology, St Louis, MO; [2]Deluxe Dermatology, St Louis, MO

Introduction

- Atopic dermatitis (AD) is a chronic, inflammatory skin disease that has higher prevalence, persistence, and severity, as well as different response to treatment, in skin of color (SOC) patients[1]
- This underscores the importance of clinical trial diversity and real-world case reports to help reduce health inequity, improve clinical understanding, and enhance treatment access for all patient populations
- Tralokinumab is the first and only FDA-approved biologic that specifically targets interleukin-13, and the onset, efficacy, and safety outcomes from the initial clinical trials revealed striking therapeutic potential[2]

Objective

To provide examples of rapid tralokinumab onset of action in SOC patients, including improvement of the difficult-to-treat head and neck subtype and of hyperpigmentation on the hands.

Methods

Patients and data collection

- The authors describe the clinical outcomes of two SOC patients:
  - An 18-year-old Asian male [patient 1] and
  - A 37-year-old African-American male [patient 2]
- Data collected during routine clinical practice related to tralokinumab treatment included duration of treatment, dose, investigator's global assessment (IGA), body surface area (BSA), and adverse events (AEs)

Results

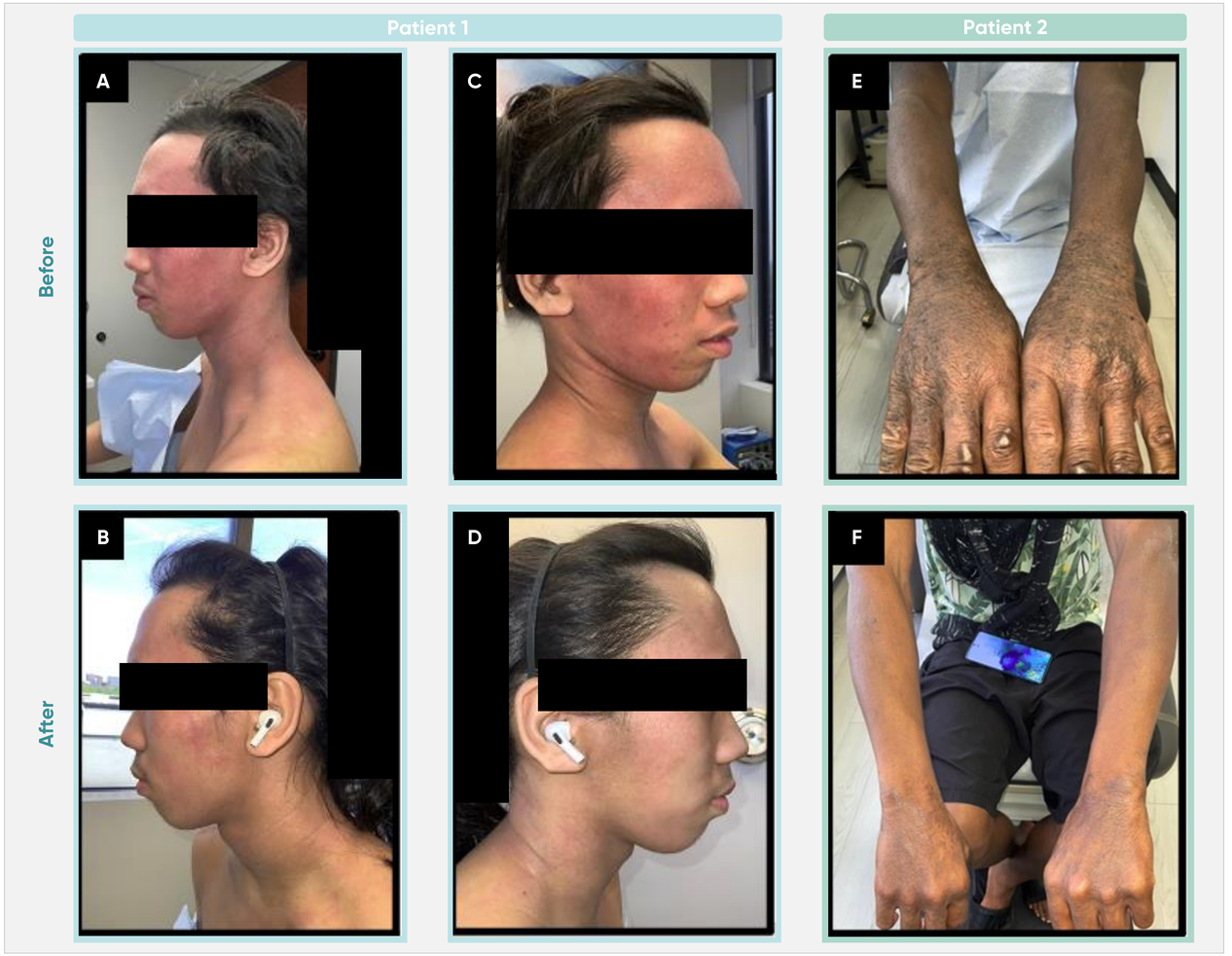
Baseline Characteristics

- Baseline characteristics of the 2 patients included in the case series are shown in **Table 1A**
- Both patients were diagnosed with AD in infancy and have continued to suffer from AD
- At baseline, each had clearly perceptible erythema, induration, and lichenification and were assigned IGA scores of 3
- Patient 1 had a BSA of 22%, managed with clobetasol 0.05% ointment for the body and ruxolitonib 1.5% cream for the face
  - Patient 1 had never received systemic treatment
- Patient 2 had previous medical history of mild asthma and BSA of 29%. His AD was managed with clobetasol 0.05% ointment
  - Over the prior two decades, Patient 2 had been managed with myriad topical corticosteroids, prednisone tapers, as well as methotrexate

Table 1. (A) Baseline characteristics and **(B)** outcomes on tralokinumab of patients 1 and 2.

	(A) Baseline characteristics at time of tralokinumab initiation						(B) Outcomes on tralokinumab				
Patient #	Sex	Age (years)	Ethnicity	IGA	BSA (%)	Duration of AD	Duration on tralokinumab (weeks)	Tralokinumab dose	IGA	BSA (%)	AEs
1	M	18	Asian	3	22	Since infancy	10	300 mg Q2W	1	7	None
2	M	37	African-American	3	29	Since infancy	6	300 mg Q2W	1	6	None

Figure 1. Photographs[a] of Patient 1 and 2 before (**A, C, E**) and after (**B, D, F**) initiating tralokinumab.



[a]Patients provided consent for use of photographs.

Outcomes on tralokinumab

- Due to insurance barriers, there were challenges obtaining tralokinumab immediately for both patients
  - The lapse in time was less than 6 weeks in each case
  - Not surprisingly, IGA 3 was assigned at both time of initial presentation and at time of tralokinumab initiation
- Both patients were prescribed an initial dose of 600 mg (four 150 mg subcutaneous injections) followed by 300 mg (two 150 mg subcutaneous injections) administered every other week (**Table 1B**)
- After 10 weeks, patient 1 experienced a decrease in IGA from 3 to 1; his BSA decreased from 22% to 7% (**Figure 1**)
- After only 6 weeks, patient 2 also exhibited a decrease in IGA from 3 to 1; his BSA decreased from 29% to 6% (**Figure 1**)
- The improvement was sustained throughout a 6-month follow-up period in both patients
- The authors observed significant improvement in the quality of life for both patients, subjectively and objectively
- To date, no patient-reported or investigator-recognized adverse outcomes have occurred

Conclusions

- **The patients' onset of improvement, in conjunction with improvement in erythema, hyperpigmentation, and lichenification, arguably surpasses the findings in the original tralokinumab clinical trials**
  - **The authors postulate this may be due to unique health disparities in allergic and immunologic underserved populations' living conditions, among other factors**
- **In conclusion, tralokinumab 300 mg, every other week, showed a rapid onset of action, with superior efficacy to the original clinical trials in two SOC patients with moderate-to-severe AD**
- **With no patient- or physician- adverse events reported to date, this observational study underscores the importance of future real-world reports to potentially corroborate our findings**

Abbreviations

AD, atopic dermatitis; AE, adverse event; BSA, body surface area; IGA, Investigator's Global Assessment; M, male; Q2W, every 2 weeks, SOC, skin of color.

References

1. Davis CM, et al. *J Allergy Clin Immunol Pract*. 2023 May;11(5):1376-1383. **2.** Duggan S. Tralokinumab: First Approval. *Drugs*. 2021;81(14):1657-1663.

Acknowledgements

The authors thank the patients for granting permission to publish this information. Medical writing and editorial support from Alphabet Health by Juliel Espinosa, PhD, was funded by LEO Pharma Inc., Madison, NJ, USA according to Good Publication Practice guidelines (https://www.ismpp.org/gpp-2022).

Disclosures

Daniel Tinker has no potential conflicts of interest to disclose. **Duane Dilworth** has the following disclosures: Galderma (Speaker), Lilly (Speaker), Pfizer (Speaker), Sanofi (Consultant), Bristol Meyers Squibb (Advisor).