Real-world effectiveness of 12 months tralokinumab in 495 adult atopic dermatitis patients with hand and feet involvement: Final data from the prospective, non-interventional, international TRACE study

TRACE

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Conclusions

- In this real-world study, the majority of patients with hands and/or feet (H&F) involvement experienced rapid clearance over 12 months with tralokinumab, with early and significant improvements in overall disease severity and PROs
- In this sub-population with atopic dermatitis (AD) in difficult-to-treat areas, improvements were comparable to those in the overall TRACE study population

Objectives

- To examine the real-world effectiveness of up to 12 months of tralokinumab treatment in patients with AD and H&F involvement in the TRACE study

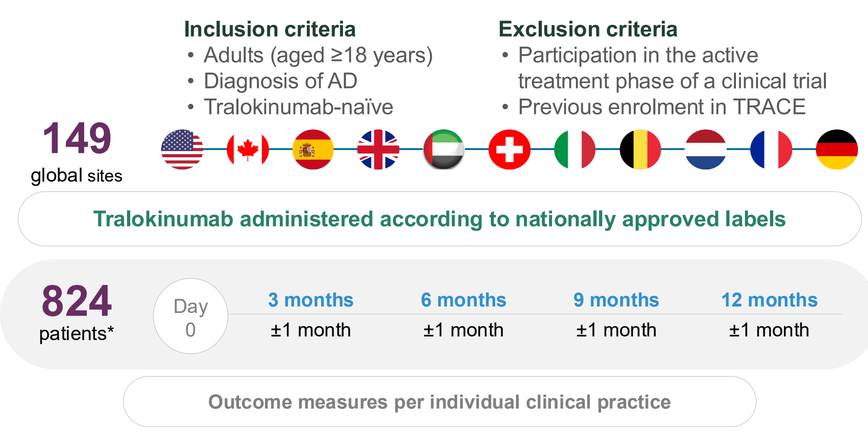
Background

- AD is a chronic, inflammatory disease that commonly affects high-burden and difficult-to-treat areas such as the H&F[1-3]
  - However, few studies have assessed the effectiveness of tralokinumab in patients with AD and H&F involvement
- TRACE was a prospective, non-interventional, international study of adults with AD who were prescribed tralokinumab according to the nationally approved label at the treating physician's discretion (**Figure 1**)

Methods

- This analysis was performed in a subset of patients from the TRACE study with AD on H&F at baseline
- Outcome measures were assessed per individual clinical practice
- ClinROs: IGA, EASI, and SCORAD
- PROs: DLQI, PP-NRS, and Sleep-NRS
- Data are presented as observed

Figure 1 TRACE study design



*835 patients were enrolled, of whom 824 were included in the full analysis set.

Results

Baseline characteristics

- At baseline, 60% (495/824) of the total TRACE population had H&F involvement; 52.3% were male, mean age was 43.1 years, and mean AD duration was 20.5 years (**Table 1**)
- Baseline patient characteristics were similar between AD patients with H&F involvement and the overall TRACE population

Table 1 Baseline patient characteristics

	Full analysis set (N = 824)	Patients with H&F involvement at baseline (N = 495)
Mean age, years (SD)	44.1 (17.9)	43.1 (17.3)
Sex, n (%)		
Female	392 (47.6)	236 (47.7)
Male	432 (52.4)	259 (52.3)
Race, n (%)		
White	624 (75.7)	384 (77.6)
Asian	44 (5.3)	30 (6.1)
Black or African American	37 (4.5)	15 (3.0)
Other/Multiple/Unknown/Not Reported	119 (14.4)	66 (13.3)
Mean baseline BMI, kg/m² (SD)	26.9 (5.8); N = 722	27.2 (5.7); N = 441
Mean duration of AD, years (SD)	18.8 (17.7); N = 814	20.5 (17.8); N = 490
IGA, n (%)		
0/1 (clear/almost clear skin)	16 (1.9)	4 (0.8)
2 (mild)	69 (8.4)	40 (8.1)
3 (moderate)	414 (50.3)	236 (47.7)
4 (severe)	281 (34.1)	189 (38.2)
Not assessed	43 (5.2)	26 (5.3)
Mean EASI (SD)	20.1 (11.1); N = 640	21.3 (11.8); N = 393
Mean DLQI (SD)	12.8 (7.5); N = 452	13.8 (7.5); N = 272
Mean SCORAD (SD)	47.1 (21.0); N = 435	48.2 (21.7); N = 282
Mean Sleep-NRS (SD)	5.1 (3.2); N = 377	5.3 (3.0); N = 222
Mean PP-NRS (SD)	6.4 (2.5); N = 490	6.5 (2.5); N = 283

N values in individual rows are shown when different from respective total number of patients in group. n, number of patients with indicated metric.

H&F involvement resolved in the majority of patients by Month 12 of treatment with tralokinumab

- Among patients with baseline H&F involvement, 57.4% had no AD on H&F by Month 12 of treatment with tralokinumab (**Figure 2**)

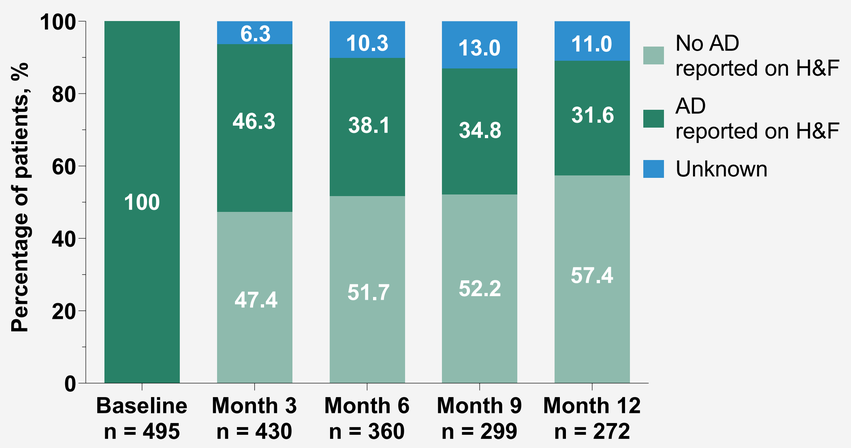
Improvements in overall AD severity among patients with H&F involvement were consistent with the full analysis set

- The percentage of patients who achieved composite response (IGA 0/1, EASI ≤7, or SCORAD <10) increased over 12 months (**Figure 3**)
- The percentage of patients with IGA 0/1 increased over 12 months (**Figure 4**)
- Rapid and continuous improvements in IGA, EASI, and SCORAD were observed over 12 months with tralokinumab, consistent with the full analysis set (**Figure 5**)

Improvements in PROs among patients with H&F involvement treated with tralokinumab

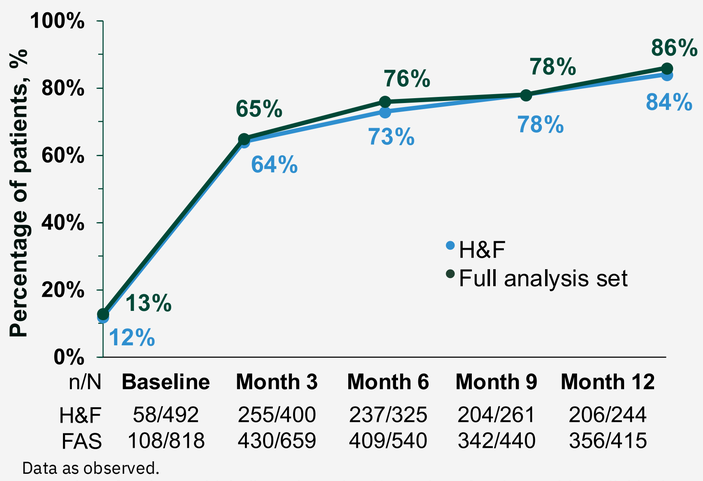
- Rapid and sustained improvements in mean DLQI, PP-NRS, and Sleep-NRS were observed over 12 months of tralokinumab treatment (**Figure 6**)

Figure 2 Percentage of patients with AD on H&F over 12 months



Data as observed.
n, number of patients with available data.

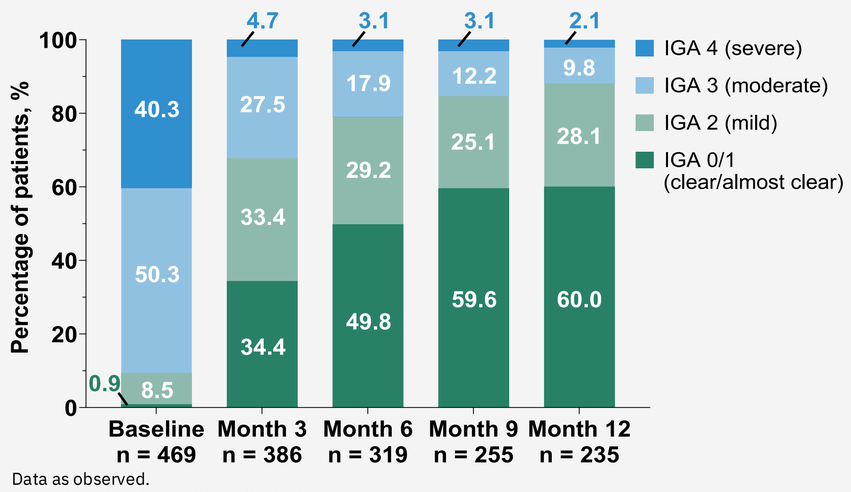
Figure 3 Percentage of patients achieved composite response (IGA 0/1, EASI ≤7, or SCORAD <10)



n/N	Baseline	Month 3	Month 6	Month 9	Month 12
H&F	58/492	255/400	237/325	204/261	206/244
FAS	108/818	430/659	409/540	342/440	356/415

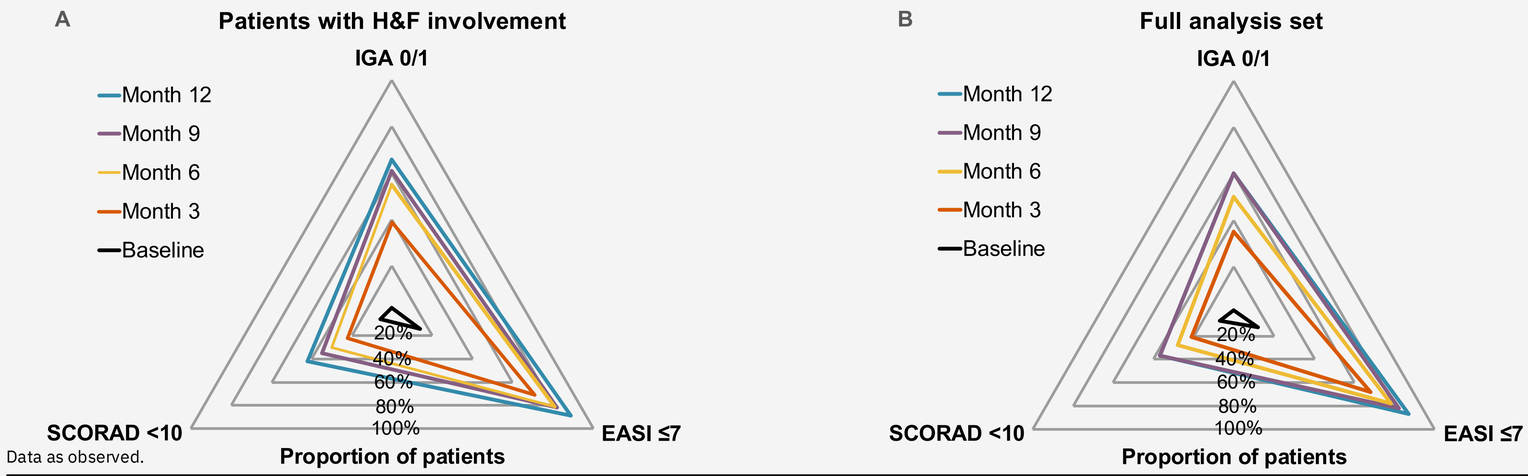
Data as observed.
n, number of patients with indicated metrics; N, number of patients with available data.

Figure 4 Percentage of patients with IGA 0/1 over 12 months



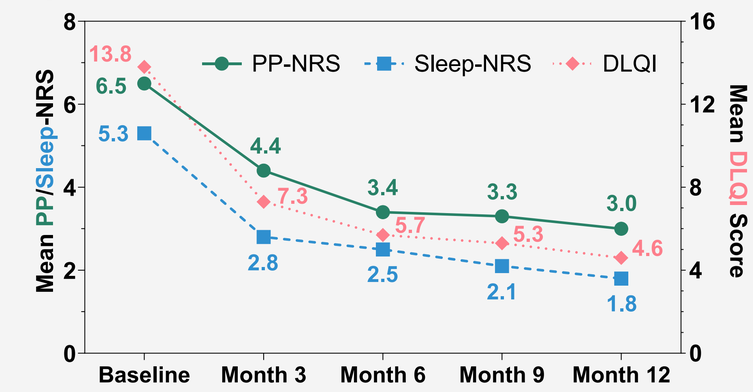
Data as observed.
n, number of patients with available data.

Figure 5 Improvements in IGA, EASI, and SCORAD over 12 months with tralokinumab



Data as observed.

Figure 6 Improvements in PROs over 12 months



Sample size (n)					
PP-NRS:	283	164	135	102	104
Sleep-NRS:	222	127	95	80	81
DLQI:	272	159	129	103	107

Data as observed.

Abbreviations AD: atopic dermatitis; BMI: body mass index; ClinRO: clinician-reported outcome; DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; H&F: hands and/or feet; IGA: Investigator's Global Assessment; NRS: numeric rating scale; PP: peak pruritus; PRO: patient-reported outcome; SCORAD: SCORing Atopic Dermatitis; TRACE: Tralokinumab ReAl world Clinical usE.

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References **1.** Lio PA, et al. *J Drugs Dermatol*. 2020;19(10):943-48. **2.** Silverberg JI, et al. *J Eur Acad Dermatol Venereol*. 2019;33(7):1341-48. **3.** Silverberg JI, et al. *J Am Acad Dermatol*. 2023;89(3):519-28.

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