Baseline Characteristics of Atopic Dermatitis (AD) and AD Treatments in a Cohort of Adult AD Patients Initiating Dupilumab in a Real-World Registry (PROSE)

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BACKGROUND

- Dupilumab is a fully human monoclonal antibody[1,2] that blocks the shared receptor component for interleukin-4 and interleukin-13 and has a demonstrated safety profile and sustained efficacy in adult and pediatric patients (aged ≥ 6 years) with moderate-to-severe atopic dermatitis (AD)[3–6]
- There is currently a paucity of information on patients who receive dupilumab in a real-world setting
- We present baseline data from a real-world registry of adult AD patients, initiating commercial dupilumab treatment for AD per approved prescribing information

OBJECTIVE

- **To report baseline disease severity and treatment burden of AD in patients initiating dupilumab using data from the PROSE registry**

METHODS

Study design

- PROSE (NCT03428646) is a multicenter, longitudinal, prospective, up-to-5-years observational registry in the USA and Canada characterizing patients receiving dupilumab treatment for AD in a real-world setting
- Standard AD investigator assessments as well as patient-reported outcomes were utilized
- The investigator-led Overall Disease Severity (ODS) instrument was introduced on an exploratory basis
  - ODS is a 5-point categorical tool that takes all important aspects characterizing AD severity into account at a given timepoint
- Baseline data were recorded on the date at which dupilumab treatment was initiated

Analysis

- Data presented here are from the first interim analysis set of adult patients receiving dupilumab (data cutoff: July 2019)
- All analyses are descriptive, without imputation for missing values

Table 1. Baseline demographics.

	N = 315
Age, mean (SD), years	42.5 (16.99)
Female sex, n (%)	174 (55.2)
Race, n (%)	
White	187 (59.4)
Black or African American	56 (17.8)
Asian	51 (16.2)
Other[a]	7 (2.2)
Not reported	14 (4.4)
Height, mean (SD), cm	168.03 (10.27)
Weight, mean (SD), kg	79.72 (20.60)
BMI, mean (SD), kg/m^2	28.24 (7.23)

[a]Includes American Indian or Alaskan Native and Native Hawaiian or Other Pacific Islander.
BMI, body mass index; SD, standard deviation.

RESULTS

Table 2. Summary of current medication.

Therapeutic class / Chemical class	N = 315
≥ 1 current medication	182 (57.8)
Corticosteroids, dermatological preparations	81 (25.7)
Moderately potent (group II)	43 (13.7)
Potent (group III)	24 (7.6)
Very potent (group IV)	26 (8.3)
Moderately potent in combination with antibiotics	1 (0.3)
Corticosteroids for systemic use	39 (12.4)
Glucocorticoids	37 (11.7)
Anticorticosteroids	2 (0.6)
Other dermatological preparations	63 (20.0)
Agents for dermatitis, excluding corticosteroids	61 (19.4)
Antihidrotics	2 (0.6)
Other	2 (0.6)

Current medication is defined as the medication(s) that the patients were taking at baseline visit. All data are reported as number of patients (%). Classification is based on the World Health Organization Drug Dictionary, March 2019 B3 format.

Table 3. Baseline disease characteristics.

	N = 315
AD duration, mean (SD), years	19.7 (17.30)
EASI, mean (SD), N1	16.90 (13.36), 314
ODS, n (%)	
No disease (scale = 0)	2 (0.6)
Minimal disease (scale = 1)	4 (1.3)
Mild disease (scale = 2)	26 (8.3)
Moderate disease (scale = 3)	176 (55.9)
Severe disease (scale = 4)	105 (33.3)
Missing	2 (0.6)
BSA affected by AD, mean (SD), %, N1	26.76 (23.670), 313
Peak Pruritus NRS, mean (SD), N1	6.9 (2.30), 227
Peak Pruritus NRS ≥ 3, n/N1 (%)	215 (68.3)
Skin pain/soreness NRS, mean (SD), N1	5.3 (2.99), 227
Skin pain/soreness NRS ≥ 3, n (%)	177 (56.2)
Skin feeling hot NRS, mean (SD), N1	4.6 (3.09), 226
Skin feeling hot NRS ≥ 3, n (%)	157 (49.8)
Skin sensitivity NRS, mean (SD), N1	5.1 (3.17), 227
Skin sensitivity NRS ≥ 3, n (%)	166 (52.7)
Sleep disturbance NRS, mean (SD), N1	5.4 (3.26), 224
Sleep disturbance NRS ≥ 3, n (%)	171 (54.3)
POEM, mean (SD), N1	18.5 (6.65), 233
DLQI, mean (SD), N1	19.0 (7.71), 227
PGAD, n (%)	
Poor (Scale = 1)	5 (1.6)
Fair (Scale = 2)	22 (7.0)
Good (Scale = 3)	77 (24.4)
Very good (Scale = 4)	69 (21.9)
Excellent (Scale = 5)	53 (16.8)
Missing	89 (28.3)

BSA, body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; N1, number of patients with measurement; NRS, Numerical Rating Scale; ODS, Overall Disease Severity; PGAD, Patient Global Assessment of AD; POEM, Patient-Oriented Eczema Measure.

Baseline demographics and current treatment use

- 315 patients were enrolled in the PROSE cohort at data cutoff
- Patient demographics are shown in **Table 1**
  - The mean age was 42.5 years; 55.2% of patients were female; and 59.4% White
- At baseline, 57.8% of patients were using ≥ 1 medication, including topical corticosteroids that were used by 25.7% of patients (**Table 2**)
  - 12.4% of patients used systemic corticosteroids (**Table 2**)

Disease characterization

- The mean duration of AD was 19.7 years, with mean EASI of 16.9 (**Table 3**)
- Mean POEM score was 18.5 (on a scale of 0 to 28) and mean DLQI was 19.0 (on a scale of 0 to 30), consistent with moderate-to-severe AD (**Table 3**)
- Most patients reported significant skin and sleep disturbance symptoms; 68.3% of patients had Peak Pruritus NRS scores of 3 or more (**Table 3**)
  - The proportions of patients with scores ≥ 3 in Skin pain/soreness NRS, Skin feeling hot NRS, Skin sensitivity to touch NRS and Sleep disturbance NRS were 56.2%, 49.8%, 52.7%, and 54.3%, respectively (**Table 3**)
  - One-quarter of patients assessed their disease status as “Good” at baseline (**Table 3**)
- There was a tendency for baseline EASI, POEM scores, and DLQI to increase with severity assessed according to ODS (**Table 4**)

Table 4. Disease characteristic analysis by baseline ODS.

	Baseline ODS						
	No disease (n = 2)	Minimal disease (n = 4)	Mild disease (n = 26)	Moderate disease (n = 176)	Severe disease (n = 105)	Missing (n = 2)	Total (N = 315)
Baseline EASI total score	0	3.18 (2.49)	3.93 (2.60)	13.41 (8.58)	26.66 (15.45)	30.00 (N/A)	16.90 (13.36)
Baseline POEM total score	7.0 (N/A)	2.0 (0)	16.9 (5.82)	17.8 (6.77)	20.6 (5.72)	N/A (N/A)	18.5 (6.65)
Baseline DLQI total score	1.0 (N/A)	1.5 (2.12)	10.4 (7.19)	11.5 (7.22)	15.5 (7.19)	N/A (N/A)	12.7 (7.52)

All values are mean (SD). N/A, not available.

CONCLUSIONS

- **Patients initiating dupilumab in routine clinical practice had significant burden of disease as determined by both patient- and clinician-assessed outcomes of AD lesions and quality of life**
- **AD symptomology extended beyond itch and included skin sensitivity to touch and disturbances to sleep**
- **More than half of the patients in PROSE were on ≥ 1 medication at study baseline, that included TCS and systemic AD treatments, signifying a high treatment burden**

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