Atopic Dermatitis (AD) Disease History With AD Treatment History in a Cohort of AD Patients Treated With Dupilumab From 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 patient and family history of AD, and AD treatments taken before treatment initiation with dupilumab in patients from the PROSE registry**

METHODS

Study design

- PROSE (NCT03428646) is an ongoing (initiated: April 2018), multicenter, longitudinal, prospective, up-to-5-years observational registry in the USA and Canada characterizing dupilumab-treated AD patients in a real-world setting
- Baseline data were recorded at the time of entry into the registry

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

RESULTS

Patients and demographics

- 315 patients were enrolled (**Table 1**)
  - Approximately half of the patients were female, and 60% White
  - Mean age of patients was 42.5 years and the mean duration of AD was 19.7 years

Patient AD history

- 35% of patients had a family history of AD (**Table 2**)
- 54.0% of patients reported one or more type 2 inflammatory comorbidities in the 12 months prior to dupilumab initiation, including allergic rhinitis which was reported in 32.7% of patients (**Table 3**)

Table 1. Baseline demographics and disease characteristics.

	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)
Duration of AD, mean (SD), years	19.7 (17.30)
Age at AD diagnosis, mean (SD), years	23.7 (23.13)
EASI, mean (SD)	16.90 (13.36)
Peak Pruritus NRS, mean (SD)	6.9 (2.30)

[a]Includes American Indian or Alaskan Native and Native Hawaiian or other Pacific Islander. EASI, Eczema Area and Severity Index; N1, number of patients with assessment; NRS, Numerical Rating Scale; SD, standard deviation.

RESULTS (CONT.)

Table 2. Family history of AD.

	N = 315
Patients with family history of AD, n (%)	110 (34.9)
Relationship of family member who had AD, n (%)	
Mother	40 (12.7)
Father	27 (8.6)
Sibling	41 (13.0)
Grandparent	13 (4.1)
Other	32 (10.2)

Table 3. Proportion of patients with type 2 inflammatory comorbidities[a] in the 12 months before dupilumab initiation.

	N = 315
Any type 2 inflammatory comorbidities, n (%)	170 (54.0)
Allergic rhinitis	103 (32.7)
Asthma	81 (25.7)
Allergic conjunctivitis	62 (19.7)
Food allergies	41 (13.0)
Chronic urticaria	17 (5.4)

[a] ≥ 5% of patients.

- The reported history of ocular conditions is shown in **Table 4**
  - Seasonal allergic conjunctivitis was most commonly (19.0%) reported for a mean (SD) of 82.6 (109.84) days in the past year

AD treatment history

- 50.8% of the patients received ≥ 1 topical and 1 systemic medication for AD (**Table 5**)
  - 41.0% used systemic corticosteroids; methotrexate (10.2%) was the most commonly used systemic non-steroidal immunosuppressant

Table 4. Ocular history over the past 12 months.[a]

	N = 315	
	n (%)	No. of days of active condition, mean (SD)
Seasonal allergic conjunctivitis	60 (19.0)	82.6 (109.84)
Dry eye	29 (9.2)	121.3 (149.01)
Perennial allergic conjunctivitis	17 (5.4)	198.4 (160.11)
Ophthalmic herpes simplex	5 (1.6)	3.0 (3.67)
Blepharitis	4 (1.3)	89.0 (141.59)

[a]Conditions reported in > 1% of patients.

Table 5. AD treatment history (life-long recall).

N (%)	N = 315
≥ 1 prior AD medication	315 (100.0)
Previous use of ≥ 1 topical (TCI/TCS/PDE4 inhibitors), and 1 systemic corticosteroid or 1 systemic non-steroidal immunosuppressant	160 (50.8)
Previous use of systemic corticosteroids	129 (41.0)
Previous use of systemic non-steroidal immunosuppressants	53 (16.8)
Methotrexate	32 (10.2)
Cyclosporine	27 (8.6)
Mycophenolate	10 (3.2)
Azathioprine	3 (1.0)

All values are n (%). PDE4, phosphodiesterase-4; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids.

- In the year prior to enrollment, most patients used topical corticosteroids (90.8%), followed by systemic corticosteroids (36.2%) and TCIs (35.9%) (**Table 6**)
  - The average duration of use for these medications was 178.9, 39.6, and 94.6 days, during the past year, respectively

Table 6. AD treatment history (12-month recall).

	N = 315	
	n (%)	Mean number of days
≥ 1 AD medication	294 (93.3)	N/A
TCS	286 (90.8)	178.9
TCI	113 (35.9)	94.6
PDE4 inhibitors	62 (19.7)	66.4
Phototherapy	23 (7.3)	59.7
Systemic corticosteroids	114 (36.2)	39.6
Systemic non-steroidal immunosuppressants	44 (14.0)	150.1
Methotrexate	24 (7.6)	111.6
Cyclosporine	22 (7.0)	160.5
Mycophenolate	6 (1.9)	40.5
Azathioprine	2 (0.6)	75.0

N/A: not applicable.

CONCLUSIONS

- **Family history of AD was common in patients enrolled in this real-world registry**
- **Comorbid ocular diseases were frequently reported, including one-fifth of patients reporting seasonal allergic conjunctivitis**
- **All patients had received other AD treatments before initiating dupilumab, and almost all used ≥ 1 AD medication in the past year**
- **Half of the patients in PROSE also received ≥ 1 topical and ≥ 1 systemic treatment during their life**

References: 1. Macdonald LE, et al. Proc Natl Acad Sci U S A. 2014;111:5147-52. 2. Murphy AJ, et al. Proc Natl Acad Sci U S A. 2014;111:5153-8. 3. Blauvelt A, et al. Lancet. 2017;389:2287-303. 4. de Bruin-Weller M, et al. Br J Dermatol. 2018;178:1083-101. 5. Simpson EL, et al. N Engl J Med. 2016;375:2335-48. 6. Beck LA, et al. Am J Clin Dermatol. 2020;21:567-77.

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