Understanding Flares in Pediatric and Adolescent Patients with Moderate or Severe Atopic Dermatitis: A Real-world Study in the United States and Europe

Lawrence F Eichenfield[1], Vivian Y Shi[2], JiaDe Yu[3,4], Evangeline J Pierce[5], Amber Reck Atwater[5], Jenny Austin[6], Phoebe Salmon[6], James Piercy[6], Peter Anderson[6], Amy S Paller[7]

1. Departments of Dermatology and Pediatrics, University of California San Diego School of Medicine and Rady Children's Hospital San Diego; 2. Department of Dermatology, University of Arkansas for Medical Sciences; 3. Department of Dermatology Massachusetts General Hospital; 4. Harvard Medical School; 5. Eli Lilly and Company, Indianapolis, USA ; 6. Adelphi Real World, Bollington, UK; 7. Department of Dermatology, Northwestern University Feinberg School of Medicine, Chicago, USA

BACKGROUND / SYNOPSIS

- Atopic dermatitis (AD) is a chronic heterogeneous inflammatory skin disorder characterised by pruritus and eczematous lesions
- AD has a fluctuating disease pattern with many patients experiencing acute exacerbations often referred to as 'flares'[1,2]
- Currently, real-world data on pediatric and adolescent (≤17 years) AD are limited, with the impact of the reported disease burden, including flares, largely unquantified

OBJECTIVE

- The objective of this study is to better understand flaring in patients ≤17 years old with moderate or severe AD

KEY RESULTS

Figure 1. Physician-reported flares among moderate and severe patients

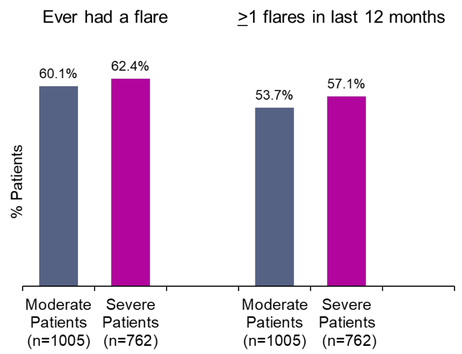
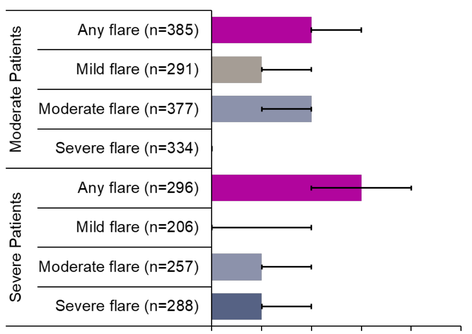
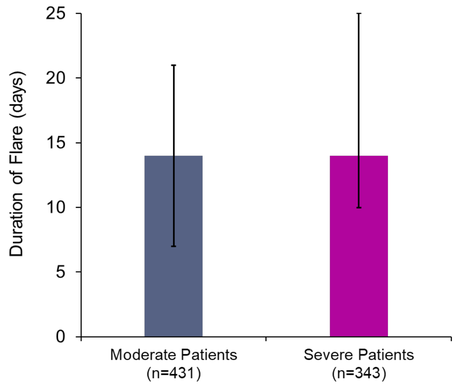


Figure 2. Physician-reported median [IQR] number of flares over the last 12 months



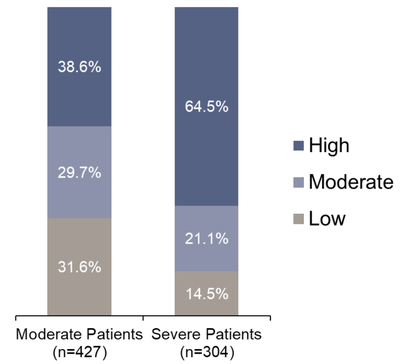
IQR: Interquartile range

Figure 3. Physician-reported median [IQR] duration of flares (days) over the last 12 months



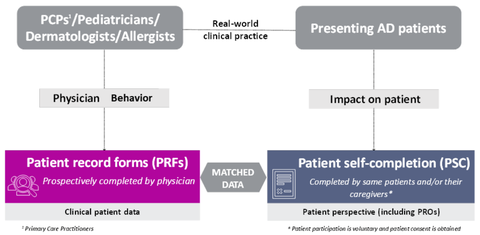
IQR: Interquartile range

Figure 4. Patient-reported degree of bother during times when their skin gets much worse



METHODS

Study Design



Key Eligibility Criteria

Physician inclusion criteria:

- Primary Care Practitioners / Pediatricians / Dermatologists / Allergists
- Actively involved in drug management of patients ≤17 years old with AD
- Minimum monthly workload of
  - *For PCPs / Pediatricians:*
    - ≥4 AD patients, aged ≤17 years (≥1 ever mild, ≥1 mild with history of moderate/severe AD, ≥1 moderate)
  - *For Dermatologist / Allergists / Immunologists:*
    - ≥6 AD patients, aged ≤17 years (≥1 mild with history of moderate/severe AD, ≥3 moderate, ≥1 severe).

Patient inclusion criteria (for this analysis):

- ≤17 years old
- Physician diagnosis of AD
- Currently assessed to have moderate or severe AD
- Not currently involved in a clinical trial.

Additional Methods

- Data were drawn from the Adelphi Pediatric AD Disease Specific Programme[3], a retrospective cross-sectional real-world study conducted in the United States, France, Germany, Italy, Spain and the United Kingdom between February and June 2019
- Physicians provided information on clinical characteristics including current overall disease severity (physician determination of mild, moderate, or severe AD) as well as severity, number, and duration of flares
- Flares were defined in the physician completed patient record forms as "acute episodes = flares, temporary worsening of symptoms"
- Patients, or their parent/guardian, were invited to complete a patient self-completion questionnaire (PSC) reporting the degree of bother for "times when your skin gets much worse'" (extremely, very, moderately, a little, or not at all bothered by flares)
- For this analysis "very/extremely" were defined as a high degree of bother and "a little/not at all" as low degree of bother

RESULTS

- A total of 390 physicians (49 PCPs; 90 Pediatricians; 210 Dermatologists; 41 Allergists) provided records for 2570 patients of whom 1005 were considered currently moderate and 762 currently severe (Table 1). 803 currently mild patients were excluded
- 427 moderate and 304 severe patients or their parent/guardian completed a PSC
- For 60.1% of moderate patients and 62.4% of severe patients, the physician reported the patient had suffered acute episodes (flares) as part of their disease pattern; 53.7% of moderate and 57.1% of severe patients experienced 1 or more flares during the last 12 months (Fig 1)
- Of those with flares in the last 12 months, moderate patients suffered a median [interquartile range] of 2[2-3] flares and severe patients suffered a median of 3[2-4] (Fig 2)
- Moderate patients were more likely to have mild or moderate flares (determined by physicians) while severe patients had more moderate and severe flares (Fig 2)
- The median duration of a typical flare for both moderate and severe patients was 14 days (Fig 3)
- 64.5% of severe patients self-reported the degree of bother of flares as high, 21.1% reported moderate bother and 14.5% reported low bother. For moderate patients, 38.6% reported a high degree of bother, 29.7% moderate bother and 31.6% low bother (Fig 4)

Table 1. Patient Demographics and Clinical Characteristics

	Moderate Patients (n=1005)	Severe Patients (n=762)
Demographics		
Mean Age, Years (SD)	9.9 (5.0)	11.2 (5.0)
Male Gender, %	50.5	55.2
Mean BMI (SD), kg/m^2	19.8 (6.3)	20.7 (8.6)
Race: White, %	76.7	76.9
Clinical Characteristics		
Time Since Diagnosis, Years (SD)	3.4 (3.6)	4.3 (4.3)
Those with Type II Comorbidity, %	46.8	60.2
BSA Currently, %	18.6	32.2
EASI *(range 0-72)*	9.2	20

Type II Comorbidity: Allergic Contact Dermatitis, Allergic Rhinitis, Alopecia Areata, Angioedema, Atopic Keratoconjunctivitis, Asthma, Nasal Polyps, Other Allergic Conditions, Urticaria, Vitiligo

REFERENCES

1. Girolomoni G and Busà VM. *Ther Adv Chronic Dis.* 2022; 13:1-19
2. Sidbury R et al. *J Am Acad Dermatol.* 2014; 71(6): 1218–1233.
3. Anderson P et al. *Curr Med Res Opin.* 2008;24(11):3063-7

CONCLUSIONS

- Just over 60% of moderate and severe patients with AD, aged ≤17 years, experience flares, the large majority having experienced multiple flares during the past year. A typical flare for moderate or severe patients lasted two weeks
- AD flares cause a moderate to high degree of bother in both moderate and severe patients although greater in patients with severe AD
- These findings suggest that controlling flares could lead to a lower burden of disease

DISCLOSURES

- LE, VS, and AP are in receipt of consultancy payments with Eli Lilly and Company
- EP and ARA are employees of Eli Lilly and Company
- JA, PS, JP and PA are employees of Adelphi Real World
- The DSP is a wholly owned Adelphi Real World multi-subscriber product. Eli Lilly and Company is one of a number subscribers to the DSP.
- This study is previously presented at Fall Clinical Dermatology Conference (Fall CDC 2022); Hybrid / Las Vegas, USA; 20-23 October 2022

Scan or click the QR code or use this URL (https://lillyscience.lilly.com/congress/wcdc2023) for a list of all Lilly content presented at the congress.

Study was sponsored by Eli Lilly and Company