

Burden of Atopic Dermatitis in Infants/Preschoolers From EPI-CARE: An International Survey

Stephan Weidinger¹, Eric L Simpson², Jonathan I Silverberg³, Sebastien Barbarot⁴, Ana B Rossi⁵, Lysel Brignoli⁶, Laurent Eckert⁷, Ryan Thomas⁸, Gaëlle Bego-Le-Bagousse⁷, Ashish Bansal⁸, Jianyi Lee⁵, Chien-Chia Chuang⁵

¹Christian-Albrechts-University Kiel, University Hospital Schleswig-Holstein, Kiel, Germany; ²Oregon Health & Science University, Portland, OR, USA; ³George Washington University School of Medicine and Health Sciences, Washington, DC, USA;

⁴University of Nantes, Nantes, France; ⁵Sanofi, Cambridge, MA, USA; ⁶Kantar Health, Paris, France; ⁷Sanofi, Chilly-Mazarin, France; ⁸Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

INTRODUCTION

- Atopic dermatitis (AD) is a chronic inflammatory skin condition that is often observed in early childhood between 1 and 5 years of age.¹
- Little is known about the global AD-related burden in infants/preschoolers.
- Improved knowledge of the AD-related burden may help reinforce the medical need in the pediatric population, and contribute to better and earlier adequate management of the disease.
- Here, we report on AD severity and outcomes in infants/preschoolers aged 6 months to <6 years in 18 countries from 5 regions (North America, Latin America, Europe, the Middle East/Eurasia, and East Asia) from the Epidemiology of Children with Atopic Dermatitis Reporting on their Experience (EPI-CARE) study.^{2,3}

METHODS

- Designed to be representative of general pediatric populations (aged 6 months to <18 years), EPI-CARE is a cross-sectional, web-based survey conducted between September 2018 and December 2019.
- Eligible infants/preschoolers were identified as having “diagnosed AD” based on meeting all items of the International Study of Asthma and Allergies in Childhood (ISAAC) criteria and self-report or parent/guardian report of ever being told by a physician that they/their child had eczema.
 - In addition, infants/preschoolers aged <6 years were required to meet 2 additional criteria: itchy rash affecting, at any time, the face (cheeks, forehead) *and* affecting, at any time, elbow to wrist or knee to ankle.
- Parents/guardians answered all questions for infants/preschoolers aged <4 years.
- Preschoolers aged 4 to <6 years were asked to answer questions related to the impact of AD on their health-related quality of life (HRQoL), if the parents/guardians agreed to pass control to them; parents/guardians answered questions related to disease severity and outcomes.
- AD severity was assessed using Patient Global Assessment (PtGA), where parents/guardians described their child’s eczema severity over the past week as mild, moderate, or severe.
- Outcomes were stratified by geographic region and AD severity and included the following: atopic comorbidities; worst itch, worst skin pain, and overall sleep disturbance over the past 24 hours (numeric rating scale; 0–10, higher scores indicate worse severity); eczema-related hospitalization in the previous 12 months; frequency and average duration of flares over the past month; HRQoL (Children’s Dermatitis Life Quality Index [CDLQI] or Infants’ Dermatology Quality of Life Index [IDQOL]; range, 0–30 [worst HRQoL]); and missed school days in the past 4 weeks (for preschoolers aged 4 to <6 years).

RESULTS

Patient Characteristics

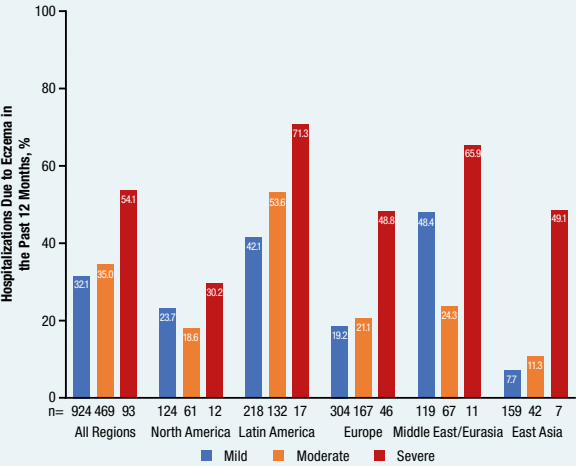
- Of 1489 infants/preschoolers aged <6 years with diagnosed AD, the mean (SD) age was 3.0 (1.6) years.
- According to PtGA-based AD severity, the majority (61.6%) of infants/preschoolers had mild AD, while severe AD was 5.6% across all regions, ranging from 3.3% in East Asia to 8.7% in Europe.

- In the overall population, ≥1 atopic comorbidity was reported in 88.3%, 92.1%, and 95.8% of infants/preschoolers with mild, moderate, and severe AD, respectively.
 - The most common atopic comorbidities in the overall population, regardless of AD severity, were hay fever, asthma, and seasonal allergies.
 - Incidence of atopic comorbidities increased with increasing AD disease severity.

Impact of Disease on Infants/Preschoolers With AD

- Infants/preschoolers with moderate or severe AD had worse itch, skin pain, and sleep disturbances over the past 24 hours, compared with those with mild AD across regions (**Table 1**).
- More than half of infants/preschoolers with severe AD had >2 flares in the past month (50.6%), compared with smaller proportions of infants/preschoolers with moderate (18.1%) and mild AD (6.3%) (**Table 1**).
- More than half of infants/preschoolers with severe AD also had an average flare duration of ≥2 weeks (50.7%), compared with smaller proportions of infants/preschoolers with moderate (20.8%) and mild AD (10.0%) (**Table 1**).
- The majority of infants/preschoolers with severe AD (54.1%) reported being hospitalized in the past 12 months (ranging from 30.2% to 71.3% across regions), as were large proportions of patients with moderate (35.0%) and mild AD (32.1%) (**Figure 1**).

Figure 1. Percentage of Hospitalizations by Region and Severity



- Generally higher scores on the IDQOL or CDLQI (reflecting lower HRQoL) were observed with increasing AD severity across geographic regions (**Figure 2A and 2B**).
- The majority (78.3%) of preschoolers aged 4 to <6 years missed ≥1 school day in the past 4 weeks, with a mean (SD) of 5.1 (5.7) days lost with mild AD, 7.3 (7.1) days with moderate AD, and 12.1 (7.8) days with severe AD.

Table 1. Impact of Disease on Infants/Preschoolers With AD by Region and Severity

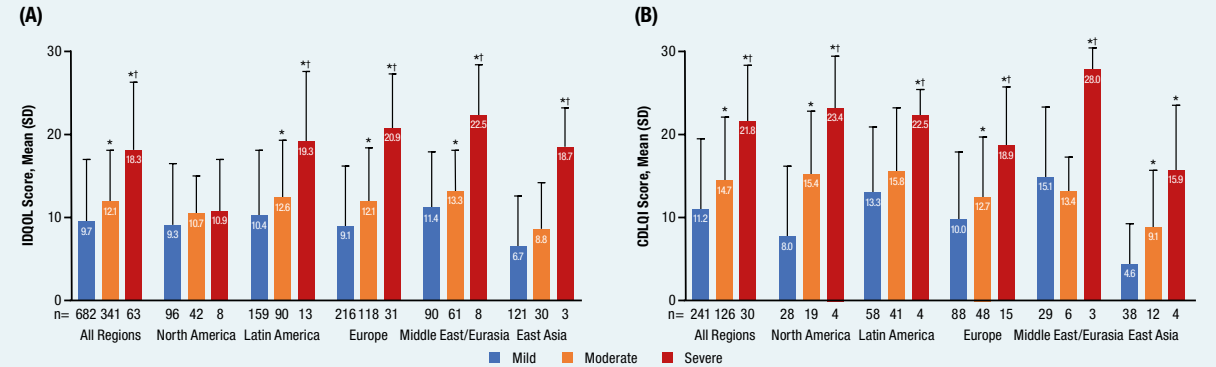
PtGA-based AD severity	All Regions (N=1489)			North America (n=198)			Latin America (n=368)			Europe (n=518)			Middle East/Eurasia (n=197)			East Asia (n=208)		
	Mild	Mod.	Severe	Mild	Mod.	Severe	Mild	Mod.	Severe	Mild	Mod.	Severe	Mild	Mod.	Severe	Mild	Mod.	Severe
Base, n	924	469	93	124	61	12	218	132	17	304	167	46	119	67	11	159	42	7
Itch ^a , mean (SD)	3.9 (2.9)	5.6 (2.4)	7.8 (2.0)	3.2 (2.7)	4.8 (2.6)	7.7 (2.4)	4.4 (3.0)	6.1 (2.4)	8.0 (1.6)	3.6 (2.7)	5.4 (2.4)	7.6 (1.9)	4.3 (2.8)	5.5 (2.2)	8.5 (1.8)	2.9 (2.5)	5.7 (1.9)	6.7 (1.2)
Skin pain ^a , mean (SD)	3.8 (3.0)	5.3 (2.6)	7.5 (2.1)	2.9 (2.6)	4.1 (2.6)	6.2 (2.4)	4.5 (3.0)	5.9 (2.4)	8.4 (1.5)	3.4 (2.7)	5.3 (2.4)	7.2 (2.0)	4.3 (3.1)	5.4 (2.4)	8.5 (1.8)	2.5 (2.5)	4.2 (2.8)	6.8 (1.4)
Sleep disturbance ^a , mean (SD)	3.9 (3.0)	5.2 (2.6)	7.3 (2.4)	3.0 (2.7)	4.6 (2.6)	6.2 (2.3)	4.6 (3.1)	5.6 (2.6)	7.8 (1.9)	3.5 (2.7)	4.8 (2.5)	7.0 (2.6)	4.5 (2.9)	5.3 (2.1)	8.9 (2.0)	2.6 (2.7)	4.2 (2.6)	6.0 (2.4)
>2 flares in the past month, %	6.3	18.1	50.6	18.1	30.6	62.5	2.6	9.5	43.2	4.9	22.3	46.9	2.5	16.6	64.9	6.2	38.2	33.0
Flare duration ≥2 weeks ^a , %	10.0	20.8	50.7	14.3	20.0	54.4	7.3	20.5	48.2	9.0	24.5	49.2	8.0	16.6	52.7	17.5	26.2	49.5

AD=atopic dermatitis; Mod.=moderate; PtGA=Patient Global Assessment. Bases are unweighted.

^aWorst instance as assessed by numeric rating scale; 0–10, higher scores indicate worse severity.

^bAverage duration of flares in the past month.

Figure 2. Mean (SD) IDQOL (A) and CDLQI (B) by Region and Severity



CDLQI=Children’s Dermatology Life Quality Index; IDQOL=Infants’ Dermatitis Quality of Life Index.

*P<0.05 vs. mild; †P<0.05 vs. moderate.

(A) IDQOL was administered to parents/guardians of infants/preschoolers aged <4 years old and those aged 4 to <6 years old for whom parents/guardians did not agree to pass control. (B) CDLQI was administered in preschoolers aged 4 to <6 years if parents/guardians agreed to pass control to their child. Higher scores on both the IDQOL and CDLQI indicate poorer quality of life (range, 0–30).

CONCLUSIONS

- Infants/preschoolers with AD experience a substantial disease burden across multiple domains, including atopic comorbidities, pruritus, sleep loss, hospitalizations, frequent prolonged flares, missed school days, and HRQoL. Overall, burden increased with AD severity.
- Daily and cumulative burden should be considered when assessing AD severity and therapeutic management plans for infants/preschoolers, with the goal of improving their HRQoL and reducing impact in later life.

References: 1. Irvine AD, Mina-Osorio P. *Br J Dermatol* 2019;181:895–906. 2. Silverberg JJ, et al. *Ann Allergy Asthma Immunol* 2021;126:417–28.e2. 3. Weidinger SSE, et al. *EADV* 2019, Poster.

Acknowledgements: This study was funded by Regeneron Pharmaceuticals, Inc., and Sanofi. Medical writing/editorial assistance was provided by Joshua Fink, PhD, of Curo, a division of Envision Pharma Group, and funded by Regeneron Pharmaceuticals, Inc., and Sanofi.

Disclosures: SW: Co-principal investigator of the German Atopic Dermatitis Registry TREATGermany, institutional research grants (LEO, L’Oreal, Novartis, and Pfizer), consultant fees (Incyte, LEO, Novartis, Regeneron, and Sanofi Genzyme), lecturer at educational events (AbbVie, Galderma, LEO, Regeneron, and Sanofi Genzyme), and performs clinical trials with many pharmaceutical industries that manufacture drugs used for the treatment of psoriasis and atopic eczema. **ELS:** Grants/research support (Amgen, Celgene, Chugai, Eli Lilly, Galderma, Genentech, MedImmune, Sanofi/Regeneron, TioGa, and Vanda) and consultant fees (Anacor, Celgene, Galderma, Genentech, Merck, and Sanofi/Regeneron). **JIS:** Consultant fees and/or grants/honoraria (AbbVie, AnaptysBio, Asana Biosciences, Eli Lilly, Galderma, GlaxoSmithKline, Glenmark Generics, Kiniksa, LEO, MedImmune, Menlo Therapeutics, Pfizer, PuriCore, Regeneron, and Sanofi). **SB:** Research grants (Pierre Fabre Laboratory and Fondation pour la dermatite atopique), personal fees (Bioderma, Ferring, Laboratoire La Roche-Posay, Novartis, and Sanofi Genzyme), and non-financial support (AbbVie, Janssen, Novartis). **ABR, LE, GB-L-B, JL, and C-CC:** Employees of, and stockholders in, Sanofi. **LB:** Employee of Kantar Health, Paris, France, a company which received research funds from Sanofi/Regeneron Pharmaceuticals, Inc., during the conduct of the study. **RT and AB:** employees of, and stockholders in, Regeneron Pharmaceuticals, Inc.