# Family Impact of Moderate-to-Severe Atopic Dermatitis in Children Aged < 12 years: Results From 732 Patients in the PEDIatric STudy in Atopic Dermatitis (PEDISTAD) Observational Study

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## **BACKGROUND**

 Primary caregivers of children with moderate-to-severe AD experience a significant burden on normal family life<sup>1-3</sup>

#### **OBJECTIVE**

To describe real-world impact of AD on family in children aged < 12 years with moderate-to-severe AD enrolled in **PEDISTAD** 

# **METHODS**

- PEDISTAD (NCT03687359)<sup>4</sup> is an ongoing, global, 5-year, observational registry describing the disease characteristics, atopic comorbidities, and treatment patterns in pediatric patients (aged < 12 years) with moderate-to-severe AD
- Study population: children aged < 12 years at baseline, with investigator-assessed moderate-to-severe AD
- Currently receiving systemic treatment (including phototherapy) or
- Currently on topical treatment, but otherwise candidates for systemic treatment
- All summaries presented are from patients enrolled between September 2018 and July 2020 (N = 732)
- Family burden/caregiver assessment of symptom severity was measured using the DFI and the CGAD questionnaires
  - DFI questionnaire evaluates the impact of AD on QoL of the caregiver(s)/family; it consists of 10 questions (each scored 0 [not at all] to 3 [very much]; range: 0–30); examines domains of family life that may be impacted by AD
  - CGAD questionnaire reports the caregiver's assessment of their child's AD symptoms (no symptoms, mild, moderate, severe, or very severe)

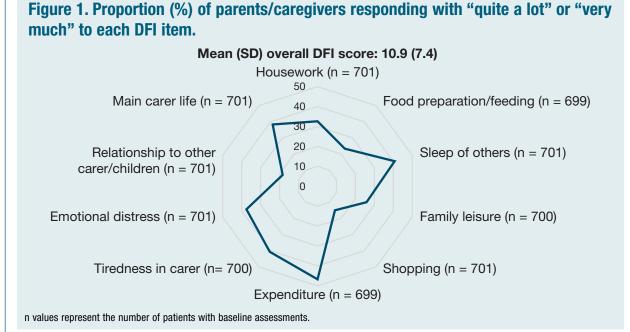
# **RESULTS**

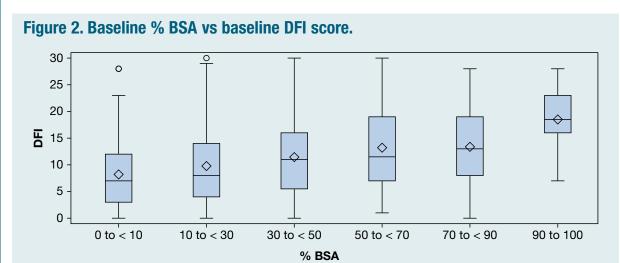
Table. Baseline demographics and assessment of patient burden.

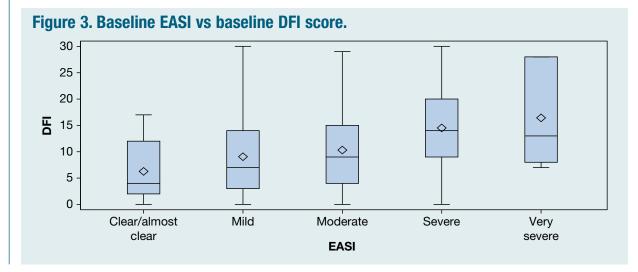
	0 to < 2 years (n = 77)	2 to < 6 years (n = 224)	6 to < 12 years (n = 431)	AII (N = 732)
Age, mean (SD), years	1.1 (0.5)	3.6 (1.1)	8.5 (1.7)	6.2 (3.2)
Male, n (%)	49 (63.6)	125 (55.8)	208 (48.3)	382 (52.2)
Race, <sup>a</sup> n (%)				
White	56 (72.7)	139 (65.0)	264 (63.9)	459 (65.2)
Asian	6 (7.8)	27 (12.6)	59 (14.3)	92 (13.1)
Black or African American	8 (10.4)	24 (11.2)	58 (14.0)	90 (12.8)
Other/multiple	7 (9.1)	24 (11.2)	32 (7.7)	63 (8.9)
Age at AD onset, <sup>b</sup> median (IQR), years	0.3 (0.2–0.5)	0.5 (0.3–1.0)	1.0 (0.3–4.0)	0.7 (0.3–2.0)
Any concomitant AD comorbidity, n (%)	24 (31.2)	131 (58.5)	293 (68.0)	448 (61.2)
Type 2 inflammatory comorbidity <sup>c</sup>	24 (31.2)	130 (58.0)	278 (64.5)	432 (59.0)
Anxiety	0	5 (2.2)	32 (7.4)	37 (5.1)
ADD/ADHD	0	1 (0.4)	30 (7.0)	31 (4.2)
Clinical and patient/caregiver assessments, mean (SD)				
EASI <sup>d,e</sup> (range: 0-72)	15.1 (10.3)	13.2 (9.3)	15.0 (11.3)	14.4 (10.7)
% BSA affected by AD <sup>f</sup>	36.4 (20.6)	31.7 (20.8)	33.6 (21.1)	33.3 (21.0)
POEM score <sup>g,h</sup> (range: 0–28)	15.7 (6.6)	16.1 (7.5)	15.3 (7.2)	15.6 (7.2)
Worst scratching during the previous 24 hours <sup>i,j</sup> (range: 0–10)	6.0 (2.6)	5.9 (2.8)	-	-
Worst itching during the previous night <sup>j,k</sup> (range: 0–10)	_	-	4.9 (2.9)	-
Worst itching during the current dayj, <sup>k</sup> (range: 0–10)	_	_	3.8 (2.7)	-
DFI (range 0-30)	11.1	12.0	10.3	10.9
aN1 = 77, 214, 413, and 704. N1 = 77, 222, 427, and 726. Includes: asthma, allergic conjunctivitis, allergic rhinitis, eosinophilic esophagitis, food				

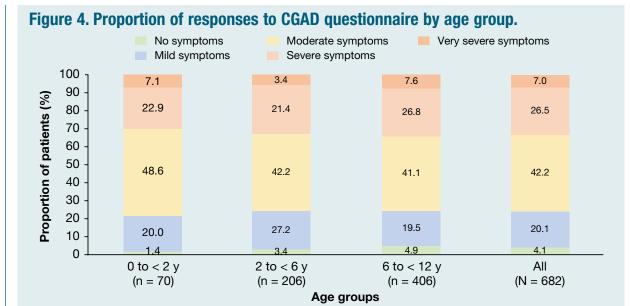
allergy, and nasal polyposis.  $^dN1=75$ , 220, 422, and 717.  $^eEASI$ : 0 to  $\leq 1$  = clear/almost clear; > 1 to  $\leq 7$  = mild; > 7 to  $\leq 21$  = moderate; > 21 to ≤ 50 = severe; > 50 to ≤ 72 = very severe. <sup>1</sup>N1 = 72, 214, 410, and 696. <sup>9</sup>N1 = 72, 209, 417, and 698. <sup>h</sup>POEM score: 0–2 = clear/almost clear; 3-7 = mild; 8-16 = moderate; 17-24 = severe; 25-28 = very severe. N1 = 63 and 185. Scored from 0 "no itch" to 10 "worst imaginable itch"

ADD, attention-deficit disorder; ADHD, attention-deficit hyperactivity disorder; BSA, body surface area; EASI, Eczema Area and Severity Index; IQR, interquartile range; N1, number of patients with reported data; POEM, Patient-Oriented Eczema Measure; SD, standard deviation









- Caregivers of children aged < 12 years with moderate-tosevere AD in PEDISTAD reported a multidimensional impact on caregiver/family life
- Across age groups, the majority of caregivers reported moderate-to-severe symptoms of AD (CGAD)
- According to the DFI questionnaire, areas of family life most impacted by AD include expenditure, tiredness, family sleep and caregiver QoL due to AD treatment.
- When comparing DFI with disease severity measures (EASI, BSA), a trend toward increased DFI was observed with increases in disease severity
- AD burden in children aged < 12 years with moderate-tosevere AD extends to their family/caregivers, demonstrating an additional impact of inadequate disease control
- The adverse effects on QoL in families of children aged < 12 years with moderate-to-severe AD reflect an unmet need for effective and safe therapies

References: 1. Al Shobaili HA, Pediatr Dermatol, 2010;27:618-23, 2. Al Robaee AA, Shahzad M, Acta Dermatovenerol Croat, 2010;18:243-7, 3. Lawson V, et al. Br J Dermatol, 1998;138;107-13, 4. Paller AS, et al. BMJ Open 2020;10:e033507,

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### **CONCLUSIONS**