Disease and Family Burden of Moderate-to-Severe Atopic Dermatitis in Children aged <12 years from the PEDIatric STudy in Atopic Dermatitis (PEDISTAD) Observational Study

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OBJECTIVE

- To describe the real-world disease burden of moderate-to-severe AD and the impact on family members in patients aged <12 years enrolled in the PEDISTAD study

METHODS

- PEDISTAD is an ongoing, international, multicenter, 5-year, non-interventional study in patients <12 years old with moderate-to-severe AD either receiving systemic therapy or inadequately controlled with topical therapies or for whom those therapies are not advisable (NCT03687359)[1]
- All summaries presented are from baseline data of all patients enrolled in the study prior to dupilumab use (N = 1,329)
- Disease burden is assessed by clinical and patient-reported outcomes of EASI, BSA, and CDLQI/IDLQI, POEM and peak pruritus NRS
- Family burden was assessed using the Dermatitis Family Impact (DFI) questionnaire which measures how much having a child with AD affects the quality of life of other (adult) members of the family
  - 10 questions covering various domains of family life with a recall period of one week.
  - Each question is scored from 0 (not at all) to 3 (very much)
  - The minimum DFI score is 0 (no impact on life of family) and maximum score 30 (maximum impact on life of family)
- Descriptive analyses were used for summarizing outcomes; only observed data were summarized

CONCLUSION

- Baseline characteristics of children enrolled in PEDISTAD reflect a multidimensional AD disease burden and family impact. The high disease burden observed in this real-world dataset suggests a major unmet need for therapies in moderate-to-severe AD in children aged <12 years

RESULTS

Table 1. Baseline demographics, atopic comorbidities and AD treatment

	0 to <2 years (n = 153)	2 to <6 years (n = 445)	6 to <12 years (n = 731)	Total (N = 1329)
Age, years, mean (SD)	1.09 (0.50)	3.58 (1.10)	8.46 (1.72)	5.98 (3.18)
Sex, male, n (%)	93 (61.6)	249 (56.2)	360 (49.5)	702 (53.1)
Race, n/N1 (%)				
American Indian or Alaska Native	1/148 (0.7)	6/429 (1.4)	9/689 (1.3)	16/1266 (1.3)
Asian	35/148 (23.6)	105/429 (24.5)	161/618 (23.4)	301/1116 (23.8)
Black or African American	10/148 (6.8)	37/429 (8.6)	79/618 (11.5)	126/1116 (10.0)
White	92/148 (62.2)	254/429 (59.2)	405/618 (58.8)	751/1116 (59.3)
Multiple	4/148 (2.7)	13/429 (3.0)	16/618 (2.3)	33/1116 (2.6)
Other	6/148 (4.1)	14/429 (3.3)	19/618 (2.8)	39/1116 (3.1)
Any concomitant AD comorbidity, n (%)	50 (32.7)	260 (58.4)	494 (67.6)	804 (60.5)
Allergic Conjunctivitis	0	32 (7.2)	117 (16.0)	149 (11.2)
Allergic Rhinitis	5 (3.3)	117 (26.3)	326 (44.6)	448 (33.7)
Asthma	4 (2.6)	76 (17.1)	223 (30.5)	303 (22.8)
Eosinophilic Oesophagitis	0	1 (0.2)	7 (1.0)	8 (0.6)
Food Allergy	49 (32.0)	259 (58.2)	472 (64.6)	780 (58.7)
Nasal Polyposis	0	0	7 (1.0)	7 (0.5)
ADD/ADHD	0	2 (0.4)	45 (6.2)	47 (3.5)
Anxiety	0	6 (1.3)	45 (6.2)	51 (3.8)
Systemic medications for AD, n (%)	19 (12.4)	116 (26.1)	285 (39.0)	420 (31.6)
Cyclosporine	2 (1.3)	33 (7.4)	89 (12.2)	124 (9.3)
Methotrexate	1 (0.7)	35 (7.9)	80 (10.9)	116 (8.7)
Dupilumab[a]	0	32 (7.2)	128 (17.5)	160 (12.0)
Azathioprine	1 (0.7)	4 (0.9)	10 (1.4)	15 (1.1)
Mycophenolate	0	10 (2.2)	5 (0.7)	15 (1.1)
Systemic corticosteroids	19 (12.4)	49 (11.0)	68 (9.3)	136 (10.2)
Non-systemic medications for AD, n (%)	130 (85.0)	388 (87.2)	651 (89.1)	1169 (88.0)
TCS	108 (70.6)	340 (76.4)	556 (76.1)	1004 (75.5)
TCI	38 (24.8)	169 (38.0)	272 (37.2)	479 (36.0)
Crisaborole	3 (2.0)	24 (5.4)	26 (3.6)	53 (4.0)
Phototherapy	3 (2.0)	11 (2.5)	31 (4.2)	45 (3.4)

[a]Dupilumab was not available in all countries at the time of enrollment.
N1, number of patients with available data; SD, standard deviation. AD, atopic dermatitis; ADD, attention deficit-disorder; ADHD, attention-deficit hyperactivity disorder; TCI, topical calcineurin inhibitor; TCS, topical corticosteroids

Table 2. Baseline disease characteristics

	0 to < 2 years (n = 153)	2 to < 6 years (n = 445)	6 to < 12 years (n = 731)	Total (N = 1,329)
Age at AD onset, median	0.30	0.50	1.00	0.60
Clinical and patient/caregiver assessments[†]				
EASI, (range: 0–72)	15.04 (10.36)	14.21 (10.97)	14.71 (11.12)	14.58 (10.98)
BSA % affected by AD	35.8 (21.81)	32.2 (20.85)	33.0 (20.85)	33.1 (20.98)
POEM, (range: 0–28)	14.9 (6.77)	16.3 (7.40)	15.1 (7.33)	15.5 (7.31)
CDLQI/IDQOL, (range: 0-30)[‡]	10.5 (5.5)	11.1 (6.5)	10.9 (6.9)	10.9 (6.6)
Worst scratching during the previous 24 hours[†], NRS*	5.6 (2.70)	5.9 (2.74)	N/A	N/A
Worst itching during the previous night[†], peak pruritus NRS*	N/A	N/A	4.9 (2.87)	N/A
Worst itching during the current day[†], peak pruritus NRS*	N/A	N/A	3.8 (2.77)	N/A
DFI[†], (range: 0–30)	11.9 (7.27)	12.4 (7.73)	10.2 (7.14)	11.1 (7.42)

[†]Data represents mean (SD). *Range 0-10, 0 being 'no itch', 10 being 'worst itch'. [‡]Includes non missing data.
BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Index; EASI, Eczema Area and Severity Index; IDQOL, Infants' Dermatitis Quality of Life Index; NRS, Numerical Rating Scale; POEM, Patient-Oriented Eczema Measure.

Figure 1. Example of a patient enrolled in PEDISTAD[a]

Patient aged 5 years, duration of AD 5 years, EASI baseline score of 45.6 [severe].

[a]Photos courtesy of Dr. Vania Oliveira de Carvalho. All patients/caregivers provided authorization for use of photos with covered eyes in publication

Figure 2. Proportions of patients with individual response in the POEM domains of (A) itching skin, (B) disturbed sleep, by age group.
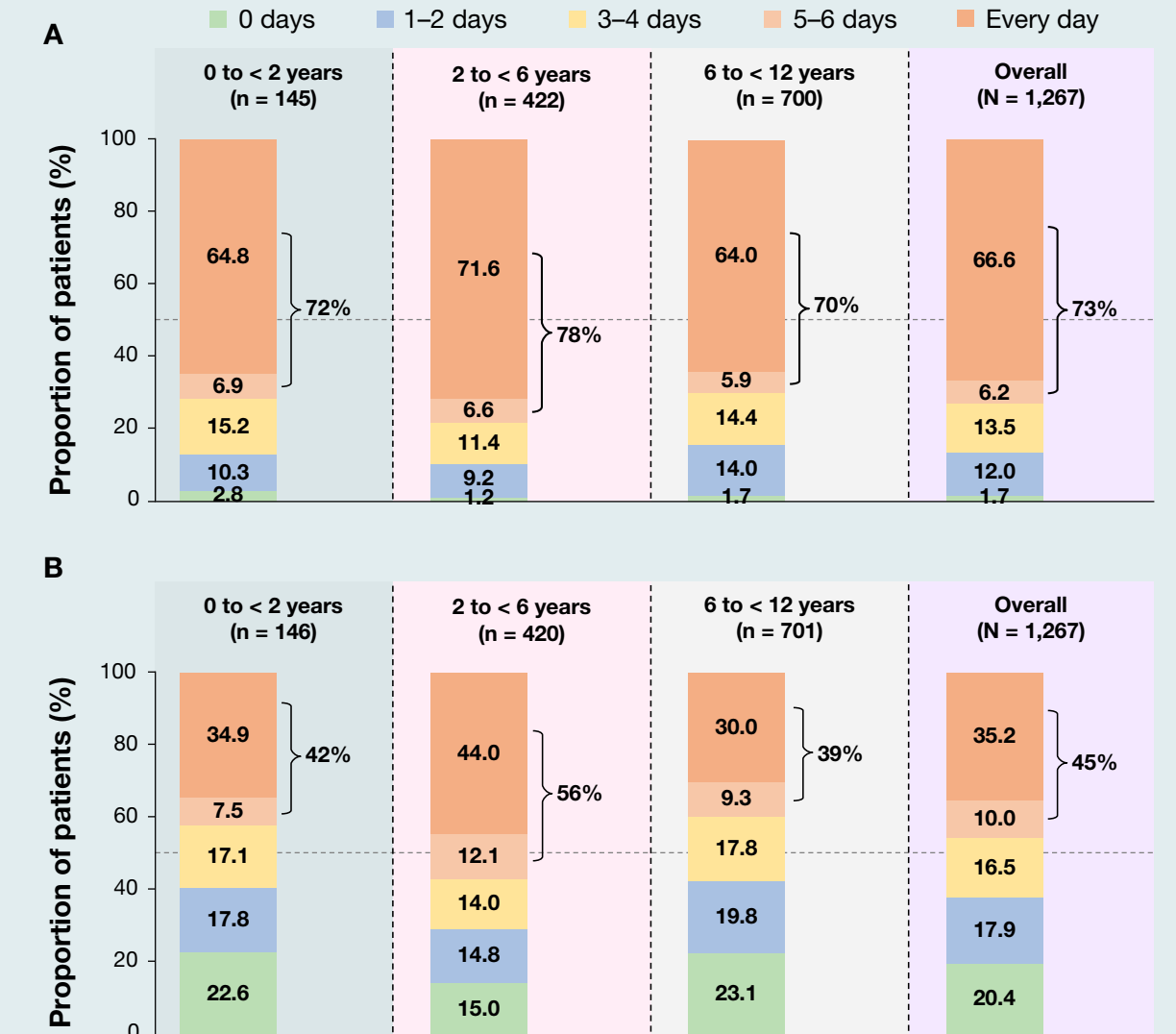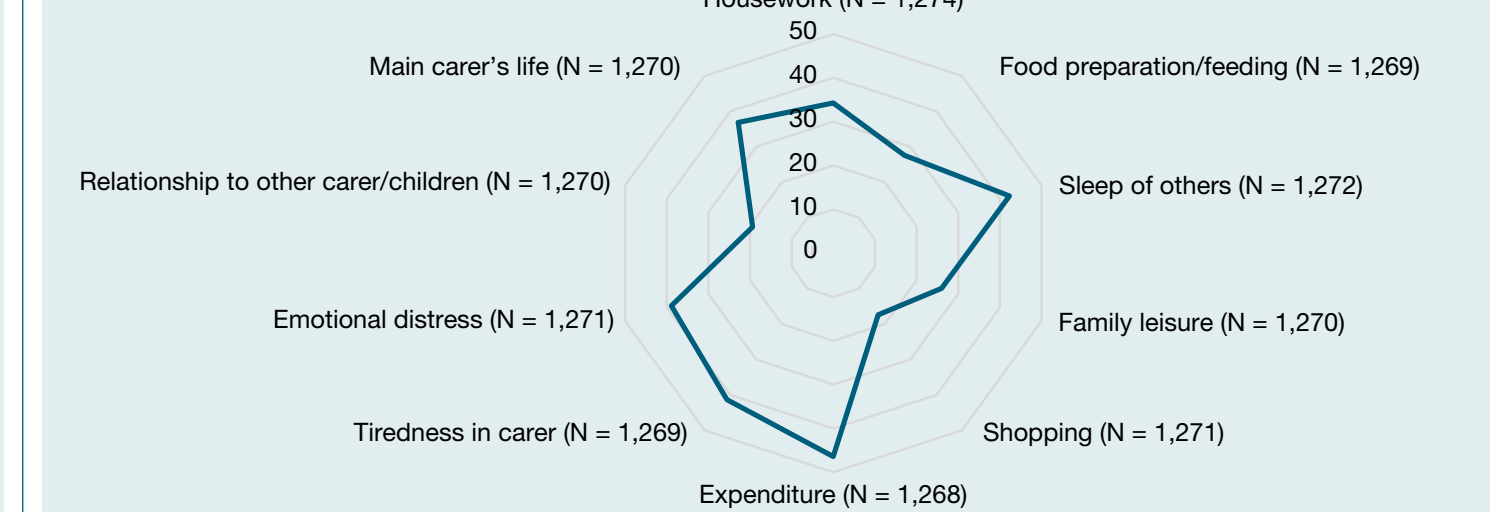

Figure 3. Proportion (%) of parents/caregivers responding with "quite a lot" or ''very much'' to each DFI item.

References: 1. Paller AS, et al. BMJ Open 2020;10:e033507.

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