

Real-World Dupilumab Use in Chinese Infants, Children and Adolescents with Atopic Dermatitis: Patient- and Caregiver-Reported Outcomes in the ADOPED-STAD Study

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Learning objective

To understand the real-world patient- and caregiver-reported outcomes (PROs and CROs) with dupilumab in Chinese paediatric patients with AD

Takeaway message

PROs and CROs showed early and sustained improvements through Week 24 with dupilumab treatment in Chinese paediatric patients with AD across all age groups

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- **Atopic dermatitis (AD) is a chronic inflammatory skin disease, characterized by eczematous dermatitis and severe pruritus, and has a severe impact on patients' quality of life.¹**
- **Patient- and caregiver-reported outcomes (PROs and CROs) are important complements to clinician-based disease measures in paediatric patients with AD and their caregivers.²**
- **Dupilumab is approved for moderate-to-severe AD in patients aged ≥ 6 months (mo) in China.²**
- **However, real-world evidence regarding PROs and CROs following dupilumab treatment in paediatric AD patients remains limited.**

1. Working Group for Atopic Dermatitis, et al. Chinese J Dermatol. 2022;55(6):465-470.

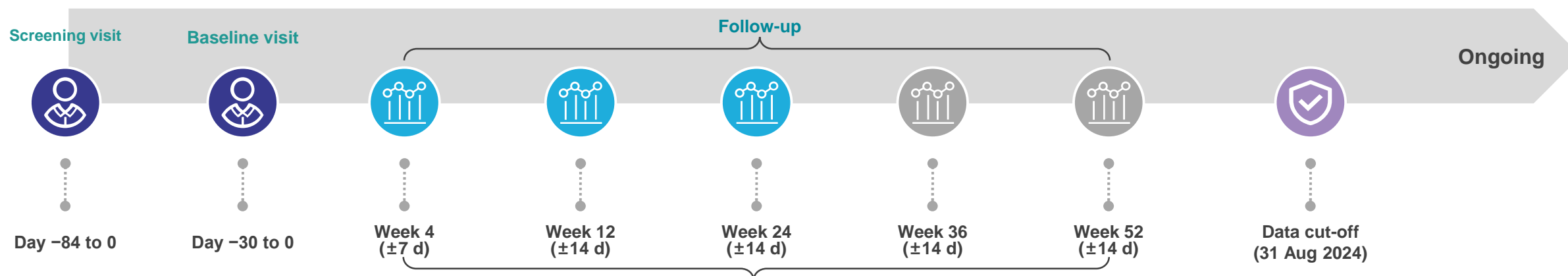
2. Mostafa N, et al. Clin Cosmet Investig Dermatol. 2023;16:2821-2827.



To evaluate real-world **PROs and CROs** with **dupilumab** in **Chinese paediatric patients** with AD

Study design

ADOPEd-STAD is an ongoing, 1-year, national, multicentre, longitudinal, prospective, non-interventional study of paediatric patients (aged ≥ 6 mo to < 18 years [y]) with moderate-to-severe AD who are receiving dupilumab treatment according to the prescribing information in China.



PROs: p-NRS, sd-NRS, IDQOL, CDLQI, DLQI; CROs: CGAD, DFI

Notes: Dupilumab first initiated at Day 1 (from 28 Sep 2022). Data had been collected at baseline and Weeks 4, 12, 24, 36, and 52; this analysis only included baseline and Weeks 4, 12, and 24.

Population

Inclusion Criteria

- ① Age ≥ 6 mo to < 18 y;
- ② Meet dupilumab prescribing criteria in China;
- ③ Gave informed consent.

Exclusion Criteria

- ① Concurrent participation in any clinical trial;
- ② Prior use of dupilumab;
- ③ Any condition that may interfere with patient's ability to participate in the study.

AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index (age ≥ 4 to < 16 years); CGAD, Caregiver Global Assessment of Disease; CROs, caregiver-reported outcomes; d, days; DFI, Dermatitis Family Impact; DLQI, Dermatology Life Quality Index (age ≥ 16 years); IDQOL, Infants' Dermatitis Quality of Life Index (age ≥ 6 mo to < 4 years); mo, months; p-NRS, pruritus-Numerical Rating Scale; PROs, patient-reported outcomes; sd-NRS, sleep disturbance-Numerical Rating Scale.

Baseline demographics and disease characteristics

At data cut-off, 563 patients were enrolled in this study and 531 completed ≥ 1 follow-up assessment.

Characteristic	All patients n=563	≥ 6 mo to < 6 y n=75	≥ 6 to < 12 y n=366	≥ 12 to < 18 y n=122
Age, y	8.5 \pm 3.5	3.1 \pm 1.4	7.9 \pm 1.7	13.5 \pm 1.4
Male sex, n (%)	302 (53.6)	43 (57.3)	192 (52.5)	67 (54.9)
Height, cm	133.7 \pm 22.9	97.0 \pm 14.2	131.3 \pm 12.6	163.3 \pm 9.7
Bodyweight category, n (%)				
<15 kg	35 (6.2)	35 (46.7)	0	0
≥ 15 to < 30 kg	266 (47.2)	39 (52.0)	225 (61.5)	2 (1.6)
≥ 30 to < 60 kg	224 (39.8)	1 (1.3)	137 (37.4)	86 (70.5)
≥ 60 kg	38 (6.7)	0	4 (1.1)	34 (27.9)
Age at AD onset, y	5.8 \pm 3.8	2.2 \pm 1.5	5.4 \pm 2.9	9.3 \pm 4.6
AD disease duration, mo	33.6 \pm 40.2	12.0 \pm 13.9	32.3 \pm 34.9	50.7 \pm 56.1
Baseline PRO/CRO scores				
p-NRS (0–10)	7.0 \pm 2.1	7.5 \pm 1.6	7.0 \pm 2.1	6.5 \pm 2.3
sd-NRS (0–10)	5.5 \pm 2.7	6.4 \pm 1.9	5.6 \pm 2.8	4.7 \pm 2.7
IDQOL ^a (0–32)	13.1 \pm 4.3	13.1 \pm 4.3	–	–
CDLQI ^b (0–30)	12.2 \pm 6.2	14.6 \pm 6.6	12.2 \pm 6.0	11.3 \pm 6.2
DLQI ^c (0–30)	12.3 \pm 7.3	–	–	12.3 \pm 7.3
CGAD (0–4)	2.7 \pm 0.7	2.7 \pm 0.6	2.6 \pm 0.6	2.7 \pm 0.7
DFI (0–30)	13.8 \pm 6.3	16.3 \pm 6.6	13.7 \pm 6.1	12.7 \pm 6.7

Data are presented as mean \pm SD, unless stated otherwise; all data are reported as observed, with missing data excluded.

^aAssessed in patients aged ≥ 6 mo to < 4 y; ^bAssessed in patients aged ≥ 4 to < 16 y; ^cAssessed in patients aged ≥ 16 y.

AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index; CGAD, Caregiver Global Assessment of Disease; CRO, caregiver-reported outcome; DLQI, Dermatology Life Quality Index; DFI, Dermatitis Family Impact; IDQOL, Infants' Dermatitis Quality of Life Index; mo, months; PRO, patient-reported outcome; p-NRS, pruritus-Numerical Rating Scale; SD, standard deviation; sd-NRS, sleep disturbance-Numerical Rating Scale; y, years.

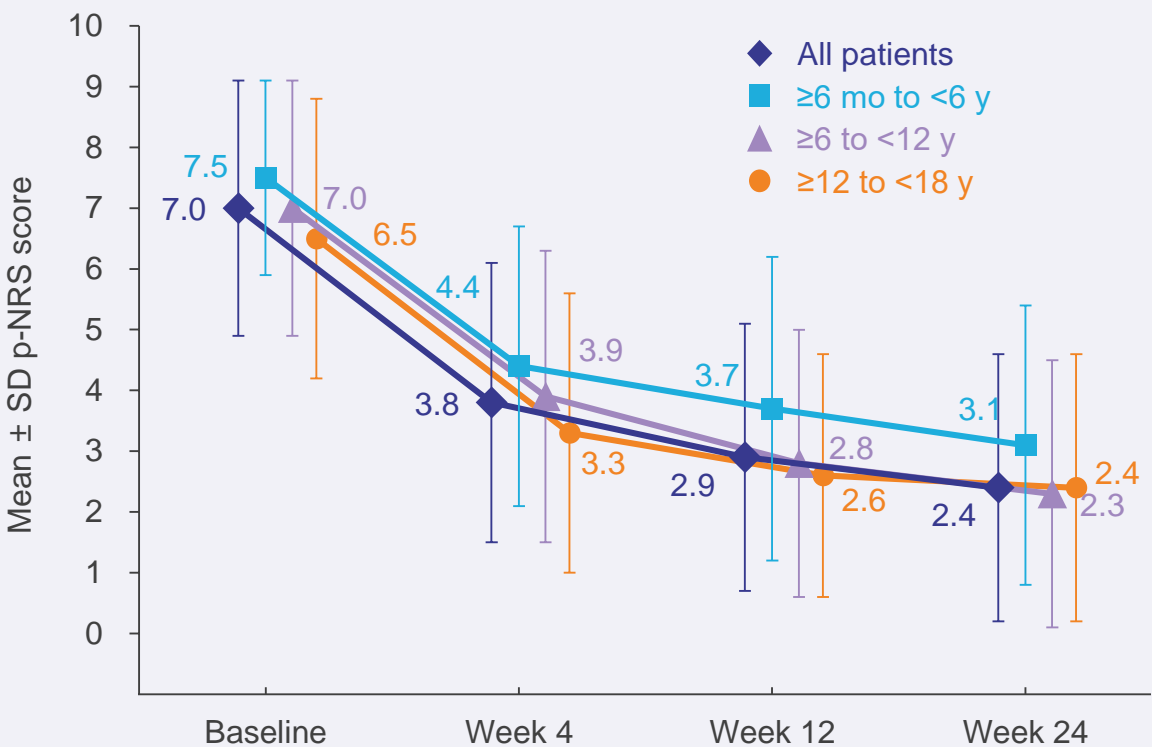
P- and sd-NRS scores decreased with dupilumab across all age groups through Week 24



Results

PROs

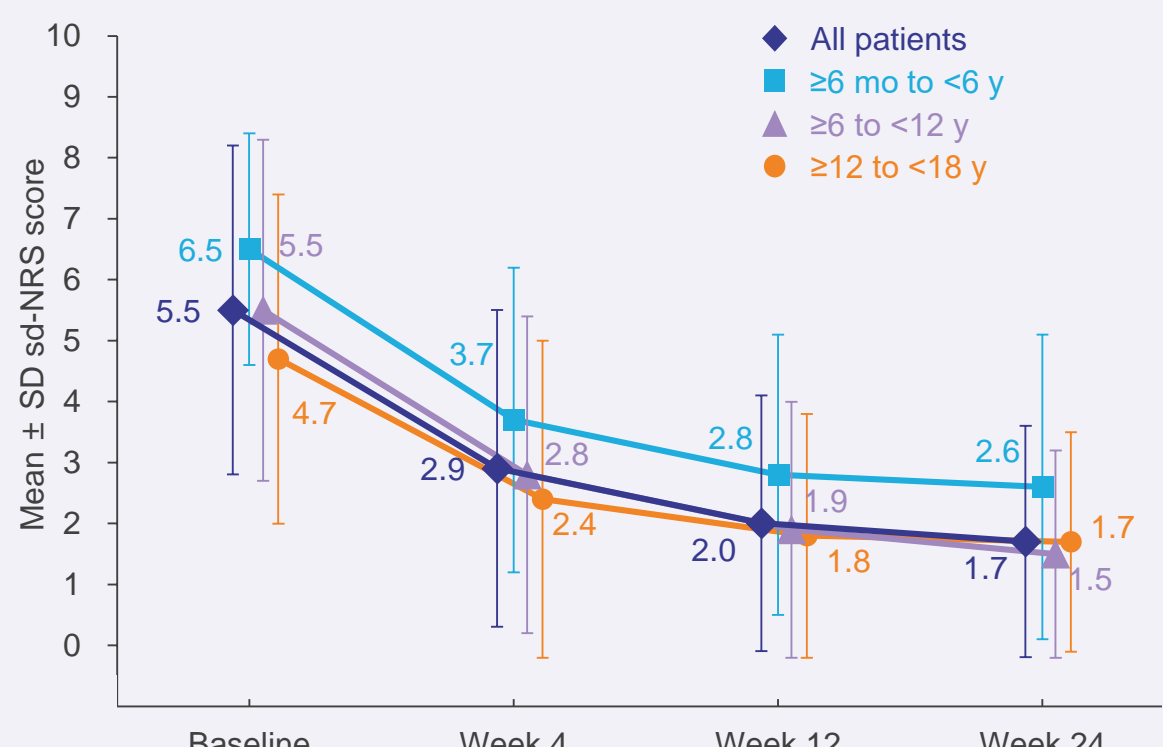
Change in **p-NRS** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients

All patients	531	521	465	346
≥ 6 mo to < 6 y	71	69	68	44
≥ 6 to < 12 y	348	344	308	233
≥ 12 to < 18 y	112	108	89	69

Change in **sd-NRS** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients

All patients	531	521	465	347
≥ 6 mo to < 6 y	71	69	68	45
≥ 6 to < 12 y	348	344	308	233
≥ 12 to < 18 y	112	108	89	69

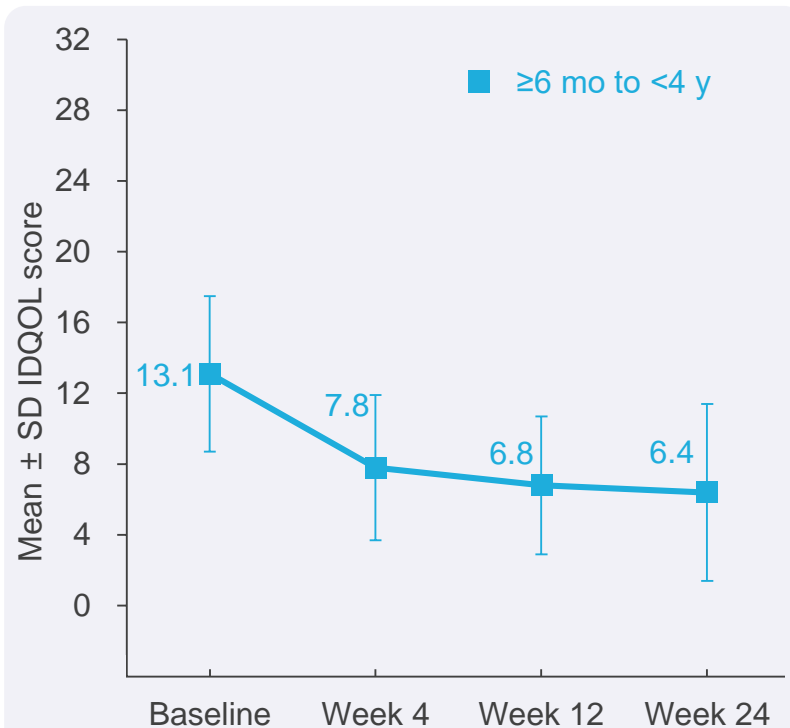
QoL scores improved with dupilumab in each age group through Week 24



Results

PROs

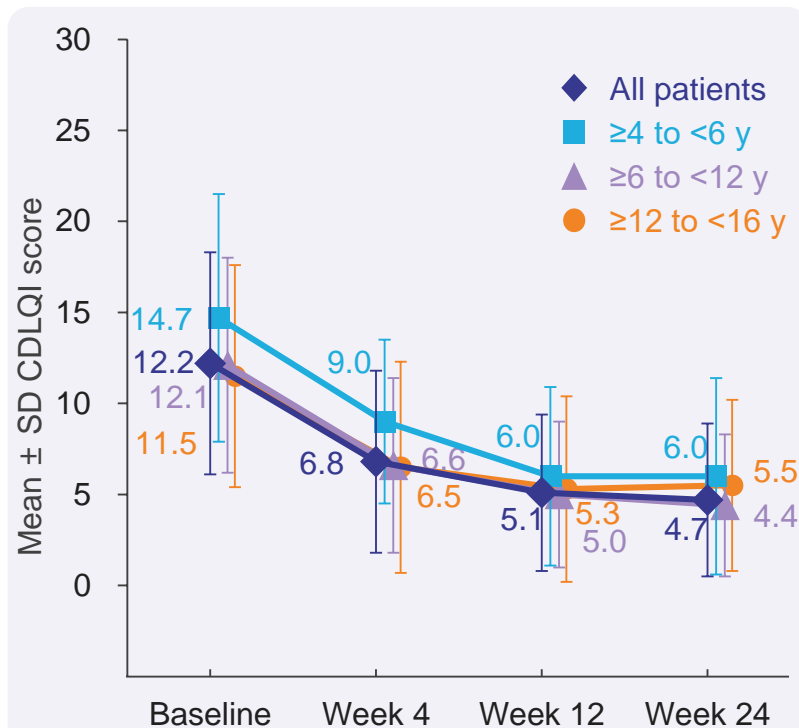
Change in **IDQOL^a** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients

≥ 6 mo to < 4 y	33	31	32	16
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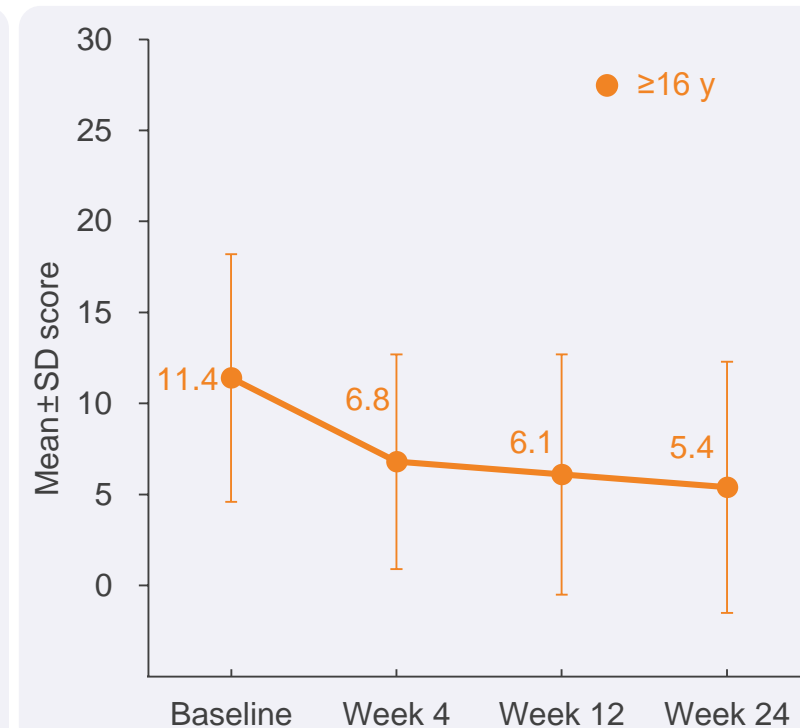
Change in **CDLQI^b** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients

All patients	477	468	409	288
≥ 4 to < 6 y	38	37	35	21
≥ 6 to < 12 y	341	336	298	217
≥ 12 to < 16 y	98	95	76	50

Change in **DLQI^c** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients

≥ 16 y	11	10	10	7
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^aAssessed in patients aged ≥ 6 mo to < 4 y; ^bAssessed in patients aged ≥ 4 to < 16 y; ^cAssessed in patients aged ≥ 16 y.

CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; IDQOL, Infants' Dermatitis Quality of Life Index; mo, month; PROs, patient-reported outcomes; QoL, quality of life; SD, standard deviation; y, year.

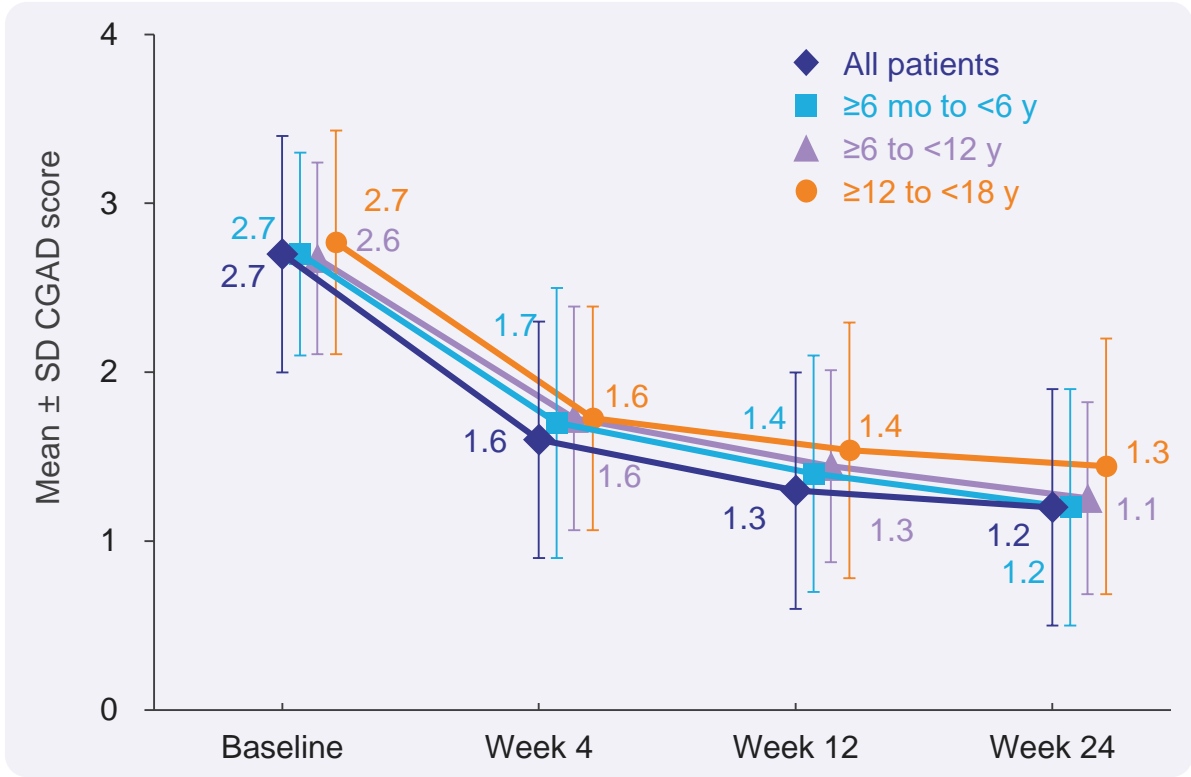
CGAD and DFI scores decreased with dupilumab across all age groups through Week 24



Results

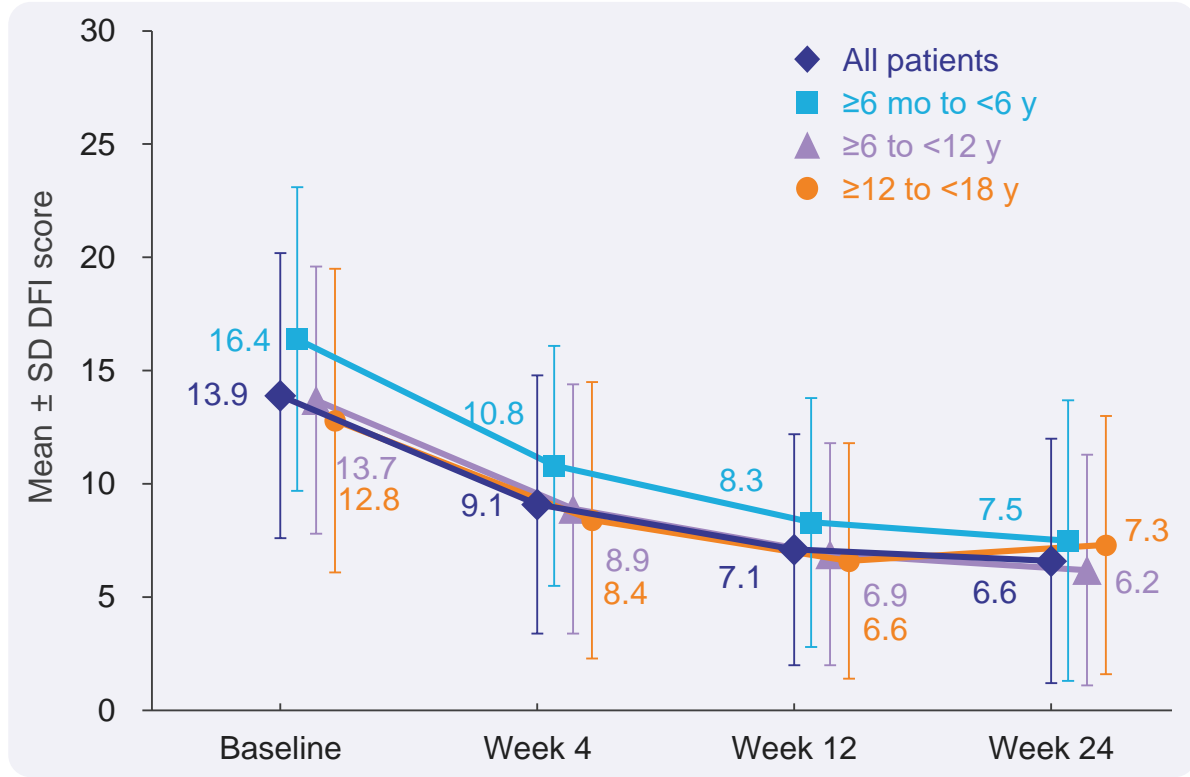
CROs

Change in **CGAD** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients				
All patients	528	516	458	321
≥ 6 mo to < 6 y	71	69	68	41
≥ 6 to < 12 y	345	338	302	217
≥ 12 to < 18 y	112	109	88	63

Change in **DFI** scores from baseline to Week 4, 12, and 24 (mean \pm SD)



Number of patients				
All patients	529	517	458	322
≥ 6 mo to < 6 y	71	69	68	41
≥ 6 to < 12 y	346	339	302	218
≥ 12 to < 18 y	112	109	88	63

CGAD, Caregiver Global Assessment of Disease; CROs, caregiver-reported outcomes; DFI, Dermatitis Family Impact; mo, month; SD, standard deviation; y, year.



PROs and CROs showed **early and sustained improvements** through Week 24 with **dupilumab** treatment in **Chinese paediatric patients** with AD across all age groups