

Real-world Efficacy and Safety of Stapokibart in Children and Adolescents with Moderate-to-severe Atopic Dermatitis: A Retrospective Study

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Paediatric real-world evidence for stapokibart in moderate-to-severe atopic dermatitis (AD) is scarce. We retrospectively analysed 55 patients aged 6–17 years treated at a single centre for 16 weeks using weight-tiered dosing (<30 kg: 600 mg loading, then 300 mg every 4 weeks; ≥30 kg: 600 mg loading, then 300 mg every 2 weeks). Eczema Area and Severity Index (EASI), Scoring Atopic Dermatitis (SCORAD), body surface area (BSA), Investigator's Global Assessment (IGA), Children's Dermatology Life Quality Index (CDLQI) and Pruritus Numerical Rating Scale (P-NRS) were assessed at baseline and weeks 4, 8, 12 and 16. At week 16, median EASI fell from 10.0 to 1.95 and SCORAD from 46.2 to 13.3; P-NRS from 8.0 to 1.0 and CDLQI from 14.0 to 4.0. Week 16 response rates were 92.7% (EASI-50), 70.9% (EASI-75), 38.2% (EASI-90), 52.7% (IGA 0/1) and 67.3% (P-NRS≤2). Mild adverse events occurred in 9.1%. Stapokibart was associated with rapid improvements in disease severity, itch and quality of life and was well tolerated in routine paediatric care.

Key words: atopic dermatitis; children; adolescent; treatment outcome; safety; stapokibart.

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Atopic dermatitis (AD) is one of the most common chronic, relapsing inflammatory skin diseases in children and adolescents, characterized by refractory pruritus, sleep disturbance and markedly impaired quality of life (1, 2). Patients with moderate-to-severe disease often respond inadequately to conventional topical therapies, phototherapy or systemic agents, underscoring the unmet need for treatments that are both rapidly effective and suitable for long-term disease control (3, 4).

SIGNIFICANCE

We reviewed the first 16 weeks of stapokibart treatment in 55 children and teenagers (6–17 years) with moderate-to-severe eczema. Skin symptoms, itching and day-to-day quality of life improved quickly, and most patients had a large drop in disease severity by week 16. Children following the weight-based dosing schedule had similar outcomes regardless of body weight. Side-effects were uncommon and mild. These real-world results support stapokibart as a practical treatment option for paediatric eczema and help guide dosing in routine care.

Stapokibart has recently been introduced as a systemic treatment option for moderate-to-severe AD and, in both real-world practice and clinical studies, has shown robust and sustained efficacy in adults (5, 6). In addition to improving skin lesions, pruritus and health-related quality of life, stapokibart has been reported to allow extension of dosing intervals in responders, supporting flexible, response-driven maintenance strategies (5, 6). More recently, a multicentre, open-label phase 1b/2 a trial in children aged 6–11 years suggested short-term efficacy and tolerability of stapokibart and further provided pharmacokinetic (PK)/pharmacodynamic and immunogenicity data under a weight-tiered regimen (7); however, evidence remains limited in adolescents and in real-world settings, particularly regarding longer-term outcomes and weight-stratified dosing strategies.

The present study focuses on children and adolescents aged 6–17 years and aims to address this evidence gap to better inform individualized treatment and long-term management in paediatric AD. We retrospectively analysed paediatric patients with moderate-to-severe AD treated with stapokibart at our institution, with a follow-up period of 16 weeks. We evaluated the efficacy and safety of stapokibart, characterized the improvement of lesions across different anatomical sites and explored the feasibility of weight-based dosing in this age group, with the goal of providing clinically relevant data to guide evidence-based and personalized use of stapokibart in paediatric patients with AD.

MATERIALS AND METHODS

Study design and data collection

This was a single-centre, retrospective observational study of children and adolescents with moderate-to-severe AD treated with stapokibart at a tertiary dermatology centre in China between October 2024 and August 2025. The patient inclusion criteria were as follows: age ≥ 6 to <18 years; AD diagnosis established by a dermatologist according to the Hanifin and Rajka criteria; a score of 3 (moderate) or 4 (severe) on the Investigator Global Assessment (IGA) scale; previous failure to respond to conventional therapy (including topical treatments, phototherapy, or systemic immunosuppressive or corticosteroid therapy); and at least 16 weeks of stapokibart treatment. Key exclusion criteria were as follows: (1) use of systemic immunosuppressants, systemic corticosteroids or Janus kinase inhibitors within 4 weeks prior to baseline; (2) treatment with dupilumab within 16 weeks prior to baseline; (3) known contraindications to stapokibart (e.g. hypersensitivity to the drug or its excipients, active tuberculosis, severe hepatic or renal impairment); and (4) conditions conferring high risk with biologic therapy (e.g. congenital immunodeficiency, malignancy within the previous 6 months).

Stapokibart was administered according to body weight. Patients weighing <30 kg received a subcutaneous loading dose of 600 mg at baseline, followed by 300 mg every 4 weeks. Patients weighing ≥ 30 kg received a subcutaneous loading dose of 600 mg at baseline, followed by 300 mg every 2 weeks. Stapokibart was supplied as a 300 mg prefilled syringe (Kangyueda; Chengdu Kangnoxing Biopharmaceutical Co., Ltd., Chengdu, China). During the 16 week observation period, concomitant use of topical therapies was allowed, including topical corticosteroids, topical calcineurin inhibitors, topical phosphodiesterase-4 inhibitors and emollients. Oral H1- or H2-antihistamines were permitted as needed for symptomatic relief of pruritus.

Clinical data were collected from medical records at baseline and at follow-up visits approximately every 4 weeks (weeks 4, 8, 12 and 16), including disease severity scores, patient-reported outcomes and adverse events.

This study was approved by the relevant medical ethics committee [KY2025-R372]. Signed informed consent forms were obtained from the patients' parents or legal guardians.

Outcome measures

Patients were evaluated at baseline and at weeks 4, 8, 12 and 16 after initiation of stapokibart. At each visit, clinicians recorded the Eczema Area and Severity

Index (EASI), Scoring Atopic Dermatitis (SCORAD), body surface area (BSA) and Investigator's Global Assessment (IGA). Patients and/or caregivers completed the Children's Dermatology Life Quality Index (CDLQI) and a pruritus numerical rating scale (P-NRS). Adverse events (AEs), defined as any adverse medical condition occurring during the treatment period, were systematically documented. The treatment period was defined from the first stapokibart injection, and week 16 (W16) was prespecified as the primary efficacy time point.

EASI (0–72) assessed eczema extent and severity across four regions (head and neck, upper limbs, trunk and lower limbs) by scoring erythema, oedema/infiltration/papulation, excoriation and lichenification, weighted by regional BSA; EASI-50/75/90 were defined as $\geq 50\%$ / $\geq 75\%$ / $\geq 90\%$ improvement from baseline. SCORAD (0–103) combined extent and intensity of skin signs (erythema, oedema/papulation, oozing/crusts, excoriation, lichenification and dryness) with pruritus and sleep disturbance (0–10 visual analogue scale). BSA was estimated using the patient's palm (including fingers) as approximately 1% of BSA. IGA was rated on a 0–4 scale (0 clear to four severe), with IGA 0/1 indicating clear or almost clear disease. CDLQI (0–30) measured paediatric dermatology-specific quality of life impairment. Pruritus was assessed using an 11-point P-NRS (0–10), with P-NRS ≤ 2 prespecified as a threshold for adequate itch control.

Statistical analyses

Statistical analyses were performed using IBM SPSS Statistics 26 and GraphPad Prism 9. Patient demographic and clinical characteristics were summarized using descriptive statistics: categorical variables as counts and percentages, and continuous variables as mean $\pm$ standard deviation (SD) or median (interquartile range, IQR), as appropriate. Between-group comparisons were performed using the independent-samples *t* test or Mann–Whitney *U* test, and paired comparisons using the Wilcoxon signed-rank test. Comparisons among more than two independent groups were performed using the Kruskal–Wallis test. Categorical variables were compared using the χ^2 test or Fisher exact test, as appropriate. All tests were two-sided, and $p < 0.05$ was considered statistically significant.

RESULTS

Demographics

A total of 55 children and adolescents aged 6–17 years with moderate-to-severe AD were included. The clinical and demographic information of all included patients is presented in **Table I**. All 55 patients completed at

Table I. Baseline characteristics of 55 patients aged 6–17 years with moderate-to-severe atopic dermatitis (AD)

Characteristic	Value
Sex, male, <i>n</i> (%)	31 (56.36)
Age, years, median (IQR)	14 (9.5, 17)
Duration of AD, years, mean (SD),	4 (2.04)
Weight, kg, median (IQR)	50 (30.25, 58.50)
<30, <i>n</i> (%)	14 (25.45)
≥30, <i>n</i> (%)	41 (74.55)
Body mass index, mean (SD)	18.4 (2.27)
Family atopic history, <i>n</i> (%)	27 (49.09)
Patients with ≥1 concurrent allergic condition, <i>n</i> (%)	36 (65.45)
Allergic rhinitis	21 (38.18)
Asthma	5 (9.09)
Food allergies	15 (27.27)
Allergic conjunctivitis	3 (5.45)
Previous treatments, <i>n</i> (%)	
Antihistamine	38 (69.09)
Immunosuppressive drugs: cyclosporine A	2 (3.64)
Oral JAK inhibitors	2 (3.64)
Dupilumab	8 (14.55)
Topical corticosteroids	34 (61.82)
Topical calcineurin inhibitors	22 (40.00)
Clinical scores (baseline)	
IGA score of 3, <i>n</i> (%)	50 (90.91)
IGA score of 4, <i>n</i> (%)	5 (9.09)
EASI score, median (IQR)	10 (7.75, 14.10)
SCORAD, median (IQR)	46.2 (40.75, 55.25)
P-NRS, median (IQR)	8 (7, 8.5)
BSA, median (IQR)	24 (19.00, 36.50)
CDLQI, median (IQR)	14 (13, 15)
Frequency of subcutaneous injection of stapokibart, median (IQR)	7.50 (5.00, 8.00)

BSA: body surface area; CDLQI: Children's Dermatology Life Quality Index; EASI: eczema area and severity index; IGA: Investigator Global Assessment; IQR: interquartile range; P-NRS: pruritus numerical rating score; SCORAD: SCORing Atopic Dermatitis; SD: standard deviation.

least 8 weeks of stapokibart treatment and 16 weeks of follow-up. During this period, 13 patients discontinued treatment due to disease stability or financial reasons. A small number of patients had adjustments in their maintenance dosing frequency: 1 patient originally scheduled for every-4-week dosing was switched to every-3-week dosing at week 8 (W8) due to suboptimal disease control. Additionally, 5 patients originally planned for every-2-week dosing were switched to every-3-week or every-4-week dosing after W8 due to disease stability or financial reasons.

Efficacy of treatment

At week 4 (W4), a rapid improvement in disease activity was observed across all key outcomes compared with baseline. Median EASI decreased from 10.0 (IQR, 7.75–14.10) at baseline to 5.0 (2.85–8.63), SCORAD from 46.20 (40.75–55.25) to 28.30 (21.35–31.65), P-NRS from 8.0 (7.0–8.5) to 4.0 (2.0–5.0), CDLQI from 14.0 (13.0–15.0) to 9.0 (7.0–10.0) and BSA involvement from 24.0% (19.0–36.5) to 16.0% (11.25–26.5). Wilcoxon signed-rank tests showed that all changes from baseline at W4 were statistically significant (all $p < 0.001$) (Fig. 1, Table II). By W4, more than half of patients had achieved an EASI-50 response, and approximately 31% had P-NRS ≤ 2 (Fig.

2), indicating early relief of pruritus and improvement in health-related quality of life.

With continued treatment to W16, efficacy further deepened. Median EASI, SCORAD, P-NRS, CDLQI and BSA decreased to 1.95 (0.95–3.93), 13.30 (10.20–18.10), 1.0 (1.0–3.0), 4.0 (3.0–5.0) and 8.5% (5.0–15.0), respectively (Fig. 1, Table II). At W16, EASI-50, EASI-75 and EASI-90 response rates were 92.73%, 70.91% and 38.18%, respectively; 52.73% of patients achieved IGA 0/1, and 67.26% had P-NRS ≤ 2 (Fig. 2). Overall, the majority of patients attained at least an EASI-50 response by W16, more than half reached IGA 0/1, and pruritus was markedly reduced.

Regional improvement across anatomical sites

During treatment, EASI scores for the head and neck, upper limbs, trunk and lower limbs all showed a sustained decline from baseline, mirroring the trajectory of the total EASI. By W16, the median percentage improvement in regional EASI scores from baseline [median (IQR), %] was 79.39 (75.00–90.08) for the head and neck, 80.23 (72.50–89.90) for the upper limbs, 81.94 (76.06–92.62) for the trunk and 78.13 (68.53–89.47) for the lower limbs. Kruskal-Wallis analysis indicated no statistically significant differences in percentage reduction among the four regions ($p > 0.05$) (Fig. 3), suggesting that stapokibart produced broadly comparable efficacy across different anatomical sites.

Weight-stratified subgroup analysis

Among the 55 patients, 14 were assigned to the <30 kg group and 41 to the ≥30 kg group according to the weight-based dosing regimen. Baseline characteristics are summarized in Table III. As expected, age, disease duration, body weight and BMI differed significantly between the two subgroups (all $p < 0.001$). In contrast, there were no significant between-group differences in atopic background, prior treatment history, or baseline disease severity measures, indicating that the two subgroups were broadly comparable with respect to key clinical variables.

Following initiation of stapokibart, both weight groups showed progressive improvement over time (Fig. 4). And the ≥30 kg group demonstrated a greater reduction in EASI at W4 compared with the <30 kg group ($p < 0.05$), whereas no significant between-group differences were observed at later time points. For SCORAD, P-NRS and BSA, between-group differences were not statistically significant at any visit, although both subgroups exhibited sustained within-group reductions relative to baseline.

With respect to responder outcomes, numerically higher EASI-50 and EASI-75 response rates were generally observed in the ≥30 kg group compared with the <30 kg group (Fig. 4). However, the Fisher exact

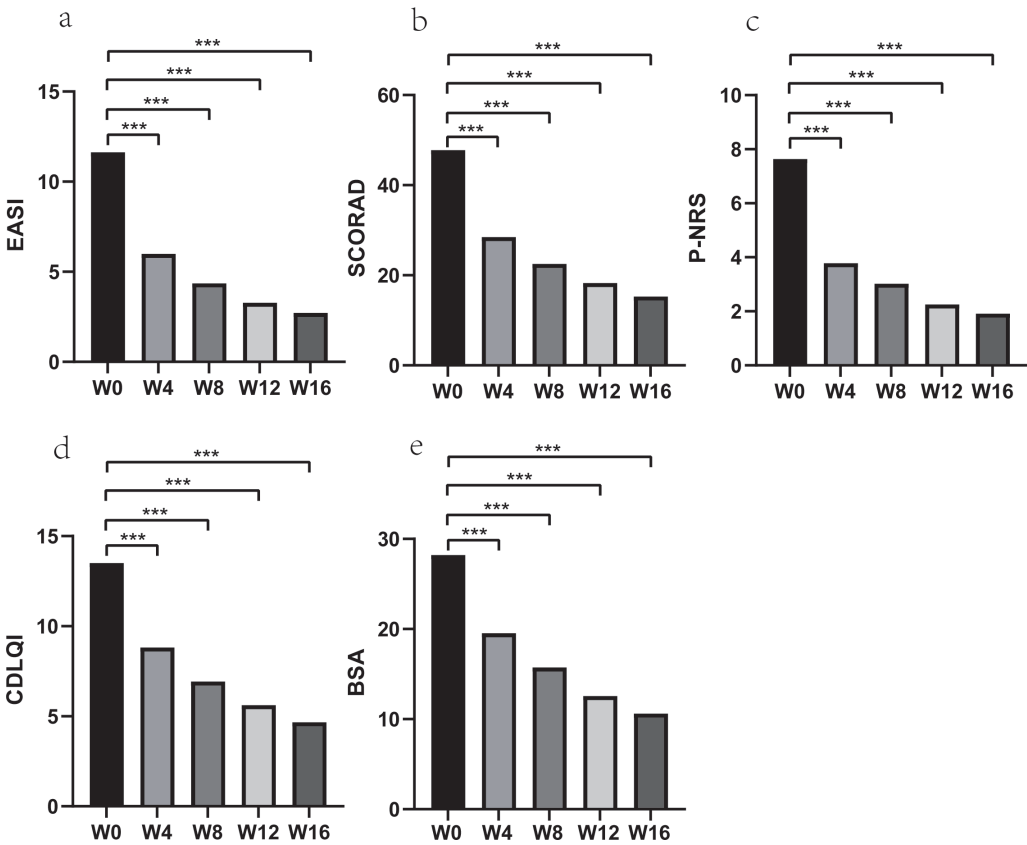


Fig. 1. Clinical efficacy of stapokibart in 55 patients (6–17 years) with moderate-to-severe AD. Scores of (A) EASI, (B) SCORAD, (C) P-NRS, (D) CDLQI, (E) BSA at baseline (W0), W4, W8, W12 and W16 after first stapokibart administration are shown. Statistical significance was assessed by Wilcoxon signed-rank test: *** $p < 0.001$. AD, atopic dermatitis; EASI, eczema area and severity index; SCORAD, SCORing Atopic Dermatitis; P-NRS, pruritus numerical rating score; CDLQI, Children's Dermatology Life Quality Index; BSA, body surface area.

test showed a statistically significant between-group difference only for EASI-75 at W4 ($p < 0.05$); all other comparisons of EASI-50 and EASI-75 at subsequent time points were not significant. Proportions of patients achieving P-NRS ≤ 2 and IGA 0/1 increased over time in both subgroups, reaching high levels by W16, with no significant between-group differences. Overall, aside from modest early advantages in some endpoints in the ≥ 30 kg group at W4, the efficacy of stapokibart over the 16-week period was largely comparable between the two weight-based dosing groups.

Safety

Over the 16-week treatment period, stapokibart was generally well tolerated. Reported AEs were mild to

moderate in severity and were effectively managed with routine measures. The most common treatment-related reactions were injection-site erythema and pruritus, occurring in 3 patients (5.45%), all of which resolved spontaneously. In addition, 2 patients (3.64%) developed conjunctivitis within 2 weeks after injection, presenting with ocular pruritus; these events improved with topical ophthalmic therapy.

DISCUSSION

The present study indicates that stapokibart provides a relatively rapid onset of action, stable efficacy and broadly balanced improvement across anatomical sites in paediatric patients aged 6–17 years with moderate-to-

Table II. Changes in clinical outcome scores before and after stapokibart treatment in 55 patients aged 6–17 years with moderate-to-severe AD

Characteristic	W0	W4	W8	W12	W16
EASI	10.00 (7.75, 14.10)	5.00 (2.85, 8.63)	3.30 (1.83, 6.43)	2.40 (1.15, 4.65)	1.95 (0.95, 3.93)
SCORAD	46.20 (40.75, 55.25)	28.30 (21.35, 31.65)	21.10 (15.95, 25.30)	16.00 (12.90, 21.90)	13.30 (10.20, 18.10)
P-NRS	8.00 (7.00, 8.50)	4.00 (2.00, 5.00)	3.00 (2.00, 4.00)	2.00 (1.00, 3.00)	1.00 (1.00, 3.00)
CDLQI	14.00 (13.00, 15.00)	9.00 (7.00, 10.00)	7.00 (5.00, 8.00)	5.00 (4.00, 6.50)	4.00 (3.00, 5.00)
BSA	24.00 (19.00, 36.50)	16.00 (11.25, 26.50)	13.00 (8.00, 21.00)	10.50 (6.00, 17.00)	8.50 (5.00, 15.00)

Data in the table are presented as median (IQR). AD:atopic dermatitis; BSA:body surface area; CDLQI:Children's Dermatology Life Quality Index; EASI:eczema area and severity index; IQR:interquartile range; P-NRS:pruritus numerical rating score; SCORAD:SCORing Atopic Dermatitis.

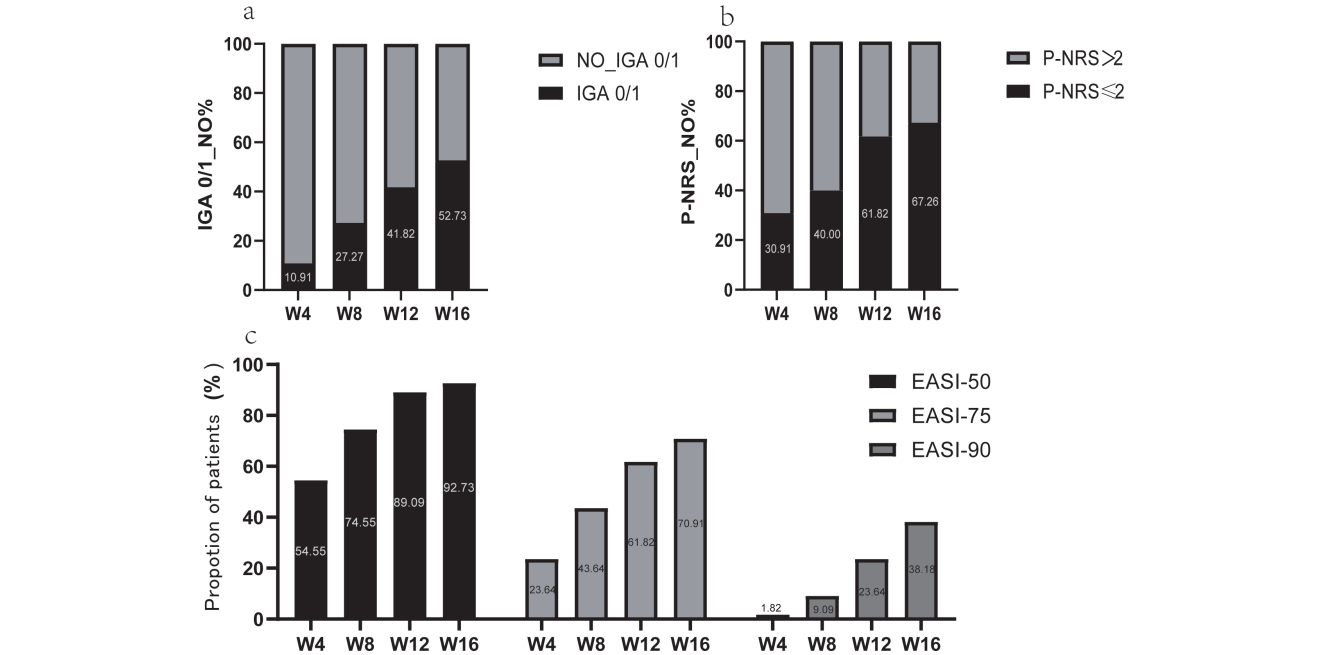


Fig. 2. Key efficacy over time for proportion (%) of 55 patients (6–17 years) with moderate-to-severe AD achieving (A) IGA 0/1, (B) P-NRS≤2, (C) EASI-50, EASI-75, EASI-90 after treatment with stapokibart. AD, atopic dermatitis; IGA, Investigator Global Assessment; P-NRS, pruritus numerical rating score; EASI-50, at least a 50% improvement from baseline in eczema area and severity index; EASI-75, at least a 75% improvement from baseline in eczema area and severity index; EASI-90, at least a 90% improvement from baseline in eczema area and severity index.

severe AD. At the time of writing, stapokibart is not approved by the U.S. Food and Drug Administration (FDA); therefore, if referenced in a U.S. regulatory context, the use described in this report would be considered an unapproved/investigational use. Within the first 4 weeks of treatment, all key outcome measures (EASI, SCORAD, P-NRS, CDLQI and

BSA) declined substantially from baseline, with more than half of patients achieving an EASI-50 response and approximately one-third reaching a P-NRS score ≤2. These early changes suggest that most patients experienced meaningful improvements in skin lesions, pruritus and health-related quality of life during the initial treatment phase. By W16, responses were

Table III. Baseline characteristics of 55 patients aged 6–17 years with moderate-to-severe AD stratified by body weight

Characteristic	Weight<30 kg (n=14)	Weight≥30 kg (n=14)	p-value
Sex, male, no. (%)	5 (35.71)	26 (63.41)	0.14
Age, mean (SD), years	7 (1.04)	15.07 (2.34)	<0.001
Duration of AD, median (IQR), years	2.00 (1.50, 2.58)	4.50 (3.30, 5.50)	<0.001
Weight, mean (SD), kg	22.79 (3.69)	52.29 (9.08)	<0.001
BMI, mean (SD)	15.41 (0.97)	19.41 (1.57)	<0.001
Family atopic history, no. (%)	9 (64.29)	18 (43.90)	0.19
Patients with≥1 concurrent allergic condition, no. (%)	8 (57.14)	28 (68.29)	0.522
Allergic rhinitis_his	4(28.57)	17 (41.46)	0.391
Asthma_his	1(7.14)	4 (9.76)	1.000
Food allergies_his	3(21.43)	12 (29.27)	0.734
Allergic conjunctivitis_his	1(7.14)	2 (4.88)	1.000
Previous treatments, no. (%)			
Antihistamine	9(64.29)	29 (70.73)	0.742
Immunosuppressive drugs: cyclosporine A	0(0)	2 (4.88)	1.000
Oral JAK inhibitors	0(0)	2 (4.88)	1.000
Dupilumab	1(7.14)	7 (17.07)	0.664
Topical corticosteroids	7(50.00)	27 (65.85)	0.292
Topical calcineurin inhibitors	7(50.00)	15 (36.59)	0.376
Clinical scores (baseline)			
IGA score of 3, no. (%)	13(92.86)	37 (90.24)	1.000
IGA score of 4, no. (%)	1(7.14)	4 (9.76)	1.000
EASI score, median (IQR)	10.45(9.00, 14.55)	9.90 (7.30, 14.05)	0.685
SCORAD, median (IQR)	46.45(42.47, 56.33)	45.10(39.90, 52.90)	0.390
P-NRS, median (IQR)	8.00(7.25, 8.75)	7.00(7.00, 8.00)	0.409
BSA, median (IQR)	22.50(19.25, 34.00)	24.00(19.00, 37.00)	0.720
CDLQI, median (IQR)	14.00(14.00, 15.00)	14.00(13.00, 15.00)	0.710
Frequency of subcutaneous injection of Stapokibart, median (IQR)	4.00(4.00, 4.00)	8.00(7.00, 8.00)	<0.001

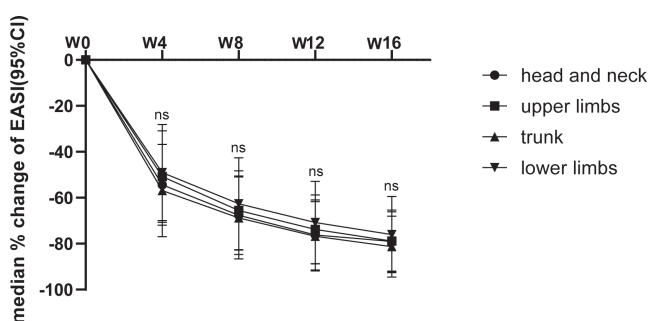


Fig. 3. Percentage change from baseline in regional EASI scores in 55 patients (6–17 years) with moderate-to-severe AD treated with stapokibart. Percent change from baseline = (regional EASI at each visit - baseline regional EASI) / baseline regional EASI × 100%. Statistical significance was assessed by Kruskal-Wallis test: ns, no significance ($P > 0.05$). AD, atopic dermatitis; EASI, eczema area and severity index.

further consolidated: EASI-50, EASI-75 and EASI-90 response rates reached 92.73%, 70.91% and 38.18%, respectively; about half of the cohort achieved IGA 0/1, and more than 67% had P-NRS ≤ 2, indicating a marked reduction in overall disease burden.

When efficacy was analysed by anatomical region, percentage reductions in EASI scores from baseline for the head and neck, upper limbs, trunk and lower limbs were similar, with no statistically significant differences between regions. This pattern suggests that stapokibart confers relatively uniform clinical benefit across multiple body sites. Previous studies have reported that some patients treated with dupilumab exhibit comparatively less improvement in head and neck lesions than in truncal or limb involvement, resulting in so-called “head and neck-predominant” or “residual” disease (8, 9). In contrast, our data did not show a clear efficacy gap between head and neck and other regions with stapokibart, implying that this agent may achieve comparable disease control in traditionally challenging areas such as the head and neck. Nonetheless, this potential advantage over earlier biologics requires confirmation in head-to-head comparative trials and larger real-world cohorts.

The weight-stratified subgroup findings suggest that the predefined dosing regimen yields broadly comparable short- to mid-term outcomes under real-world conditions. In this cohort, only at W4 did the ≥30 kg group show a greater percentage reduction in EASI and a higher EASI-75 response rate than the <30 kg group; from W8 onward, efficacy was essentially similar between the two subgroups, and both achieved high response levels by W16. This time-dependent pattern is consistent with the PK characteristics of monoclonal antibodies in paediatric populations: at a given dose and dosing interval, patients with higher body weight typically have a larger distribution volume and greater total proteolytic capacity, which can increase clearance and distribution of the drug, thereby lowering overall exposure and trough concentrations (10–12).

In our regimen, children weighing <30 kg received dosing every 4 weeks, with effective maintenance levels being gradually established over the initial phase, whereas those ≥30 kg received dosing every 2 weeks, with a more intensive schedule that likely offset the impact of body weight on exposure and facilitated attainment of adequate maintenance concentrations earlier in treatment. As treatment continued, drug exposure in both subgroups likely stabilized and converged, which is consistent with the absence of meaningful between-group differences in efficacy from W8 to W16. These observations support the feasibility of the current weight-based maintenance schedule in paediatric patients aged 6–17 years with moderate-to-severe AD. At the individual level, however, early response patterns at 4–8 weeks, concomitant medications and adherence may warrant careful consideration when deciding whether to transiently intensify or de-escalate dosing intervals. Such individualized adjustments should ultimately be guided by prospective data and, ideally, by PK or biomarker-based exposure-response analyses.

Limitations

Several limitations of this study should be acknowledged. First, this was a single-centre retrospective analysis with a modest sample size, and the <30 kg subgroup included only 14 patients, which limits statistical power and makes the weight-stratified comparisons more vulnerable to random variation. Second, follow-up was restricted to 16 weeks, providing no information on long-term efficacy, durability of response or late-emerging safety signals, and the absence of a parallel control group introduces potential selection and information bias. Third, we did not systematically assess serum drug concentrations or immunologic biomarkers, which precluded a more detailed exploration of exposure-response relationships or mechanistic explanations for subgroup differences. Finally, because the study population consisted exclusively of paediatric patients aged 6–17 years with moderate-to-severe disease, the generalizability of these findings to milder AD or to younger age groups remains uncertain. These factors may affect the external validity and robustness of our conclusions and underscore the need for confirmation in larger, multicentre cohorts with longer follow-up.

Conclusion

Overall, our data indicate that stapokibart provides rapid improvement by W4 and consolidation of clinical benefit by W16 in children and adolescents with moderate-to-severe AD, with substantial reductions in disease activity and pruritus burden and relatively

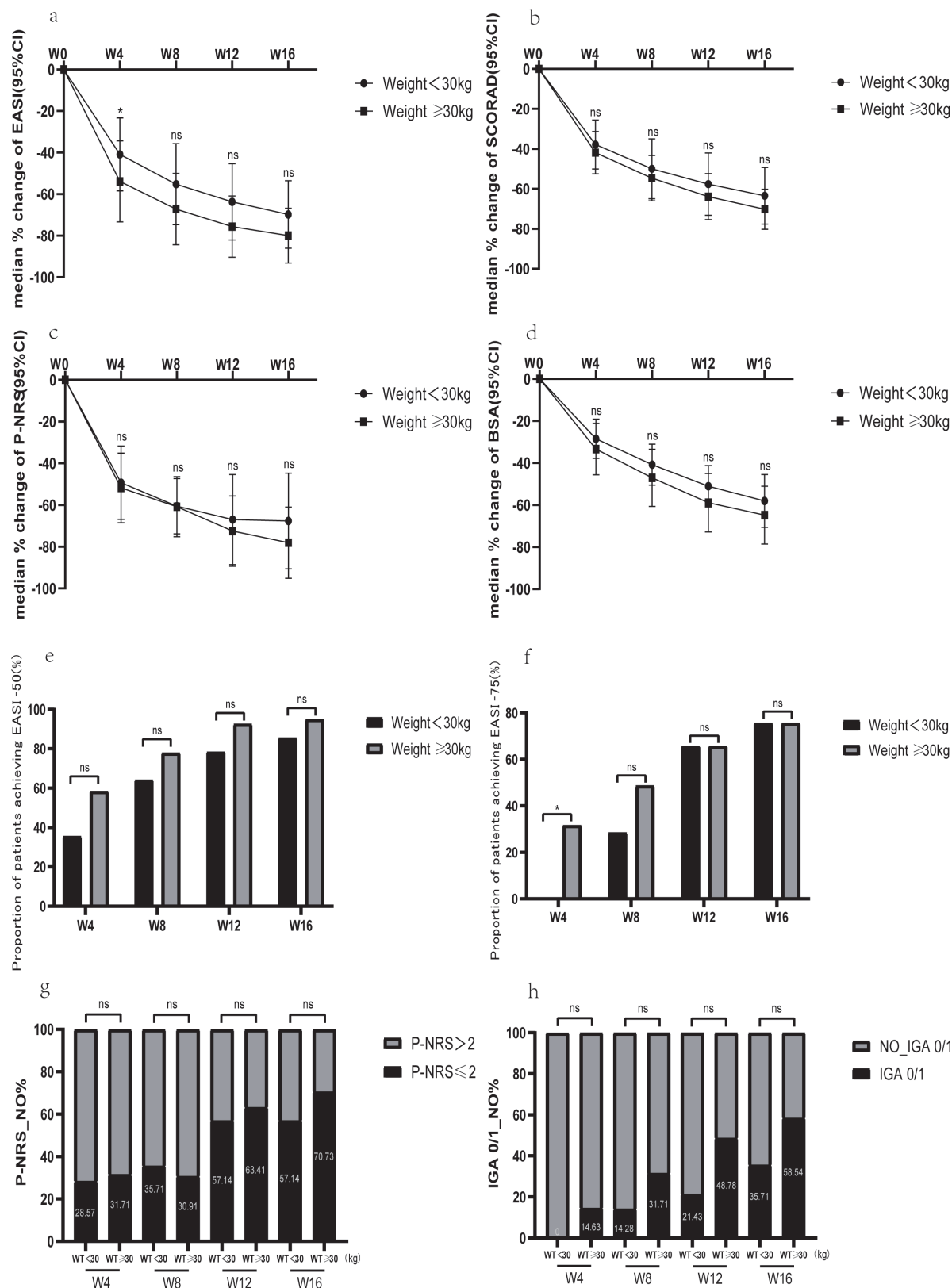


Fig. 4. Weight-stratified efficacy of stapokibart in patients (6–17 years) with moderate-to-severe AD (<30 kg vs ≥30 kg). Percent change from baseline in (A) EASI, (B) SCORAD, (C) P-NRS, (D) BSA. Proportion (%) of patients achieving (E) EASI-50, (F) EASI-75, (G) P-NRS≤2, (H) IGA 0/1. Statistical significance was assessed by the Mann-Whitney test or Fisher exact test: * $p < 0.05$; ns, not significant ($p > 0.05$). AD, atopic dermatitis; EASI, eczema area and severity index; SCORAD, SCORing Atopic Dermatitis; P-NRS, pruritus numerical rating score; BSA, body surface area; EASI-50, at least a 50% improvement from baseline in eczema area and severity index; EASI-75, at least a 75% improvement from baseline in eczema area and severity index; WT, weight.

uniform efficacy across different anatomical sites. The weight-based maintenance regimen tested here appears to deliver broadly comparable short- to mid-term outcomes across body-weight strata in routine practice. Taken together, these findings support stapokibart as a promising therapeutic option for paediatric patients with moderate-to-severe AD, while highlighting the need for longer-term, controlled and multicentre studies to better define its benefit profile across weight categories, disease durations and regional phenotypes and to refine individualized dosing strategies.

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Data availability statement: De-identified individual participant data that underlie the results reported in this article, together with the analysis scripts, are available from the corresponding author upon reasonable request. The data are not publicly available due to ethical and privacy restrictions involving paediatric participants.

Ethics committee: This retrospective observational study was approved by the relevant medical ethics committee (approval no. KY2025-R372).

The authors have no conflicts of interest to declare.

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