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INTRODUCTION

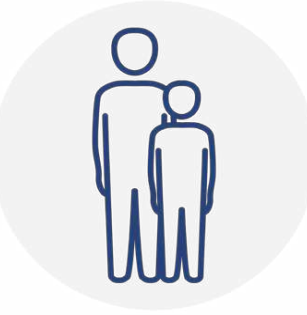
Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease characterized by **xerosis, pruritus, and alternating phases of flares and remission**¹. Clinical guidelines recommend the use of **dermocosmetic care in combination with topical corticosteroids** as first line management to alleviate clinical symptoms and improve patients’ quality of life^{2,3}. The present study aimed to **evaluate the efficacy and tolerability of a balm emollient containing active ingredients (AD balm) compared with a glycerin-based cream (GC)** over a 6-month period in infants and children with AD, with particular focus on the evolution of clinical signs and disease burden.

¹ Lipozenčić J, Wolf R. Atopic dermatitis: an update and review of the literature. *Dermatol Clin.* 2007;25(4):605 -612.
² Jackson EM, Robillard NF. The controlled use test in a cosmetic product safety substantiation program. *J Toxicol Cut Ocular Toxicol.* 1982;1(2):117 -32.
³ Serup J. A double -blind comparison of two creams containing urea as active ingredient. Assessment of efficacy and side -effects by non - invasive techniques and a clinical scoring scheme. *Acta Derm Venereol Suppl (Stockh).* 1992;177:34 -43.[

MATERIALS & METHODS



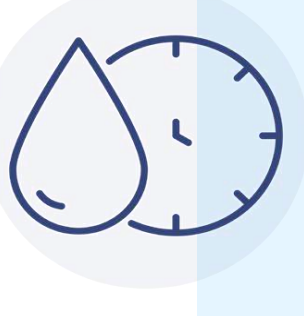
The study was carried out in **Poland between September 2024 and May 2025**, covering the fall, winter and spring seasons.



A total of **88 children aged between 3 months, and 12 years** were included and randomized into two groups of 44 subjects each, receiving either AD balm or a glycerin cream. At baseline, the atopic dermatitis was mild to moderate in severity, with a SCORAD score ranging from 16 to 40 (mean: 26).



At baseline, all subjects received an **8-day course of topical corticosteroids (D-8 to D0), combined with twice daily whole body and facial application of either the AD balm or GC**, assigned at random. After cessation of corticosteroid therapy, participants continued applying the assigned skincare product alone for 6 months (D0 to M6).



SCORAD scores and the impact of the DA on the subjects’ quality of life were assessed at Day 0, Month 2, Month 4 and Month 6.

Relapses reported by the subjects, overall satisfaction with the product and tolerability were also recorded. Changes from baseline (D0), corresponding to the period of skincare use alone, were analyzed. SCORAD sub scores-including **pruritus, insomnia, erythema, and xerosis**-were specifically analyzed. Quality of life was also assessed throughout the study.

Quality of life was monitored throughout the study using validated patient-reported outcome measures. Subjective evaluations also included the self-reporting of atopic dermatitis flares, as well as participants' perceptions of product efficacy, comfort, and overall satisfaction.

Safety and tolerability were assessed at each study visit through clinical examination and participant feedback. Standardized photographs were collected under to document the evolution of skin lesions.

RESULTS

Clinical evaluation

During the 6-month period of exclusive use of the GC (D0–M6), mean SCORAD showed a reduction of 22% at Month 2 and 57% at Month 6 (compared to D0, p>0.001), while **the AD balm demonstrated significant superior efficacy with 52% at M2 and 86% at M6** (compared to D0, p>0.001 versus D0 and GC). **Improvements observed with PO SCORAD closely paralleled those obtained with SCORAD.**

Across all SCORAD sub scores—including disease extent, lesion intensity, and subjective symptoms—the AD balm demonstrated greater improvements than GC. Notably, **pruritus** decreased significantly more with the AD balm (p>0.001 versus GC), with **-48% at M2 and -87% at M6**, compared with -17% and -56%, respectively, with GC. Similarly, **insomnia** decreased significantly more with the AD balm, with **-92%** versus -65% with GC at M6 (p>0.01 between products)

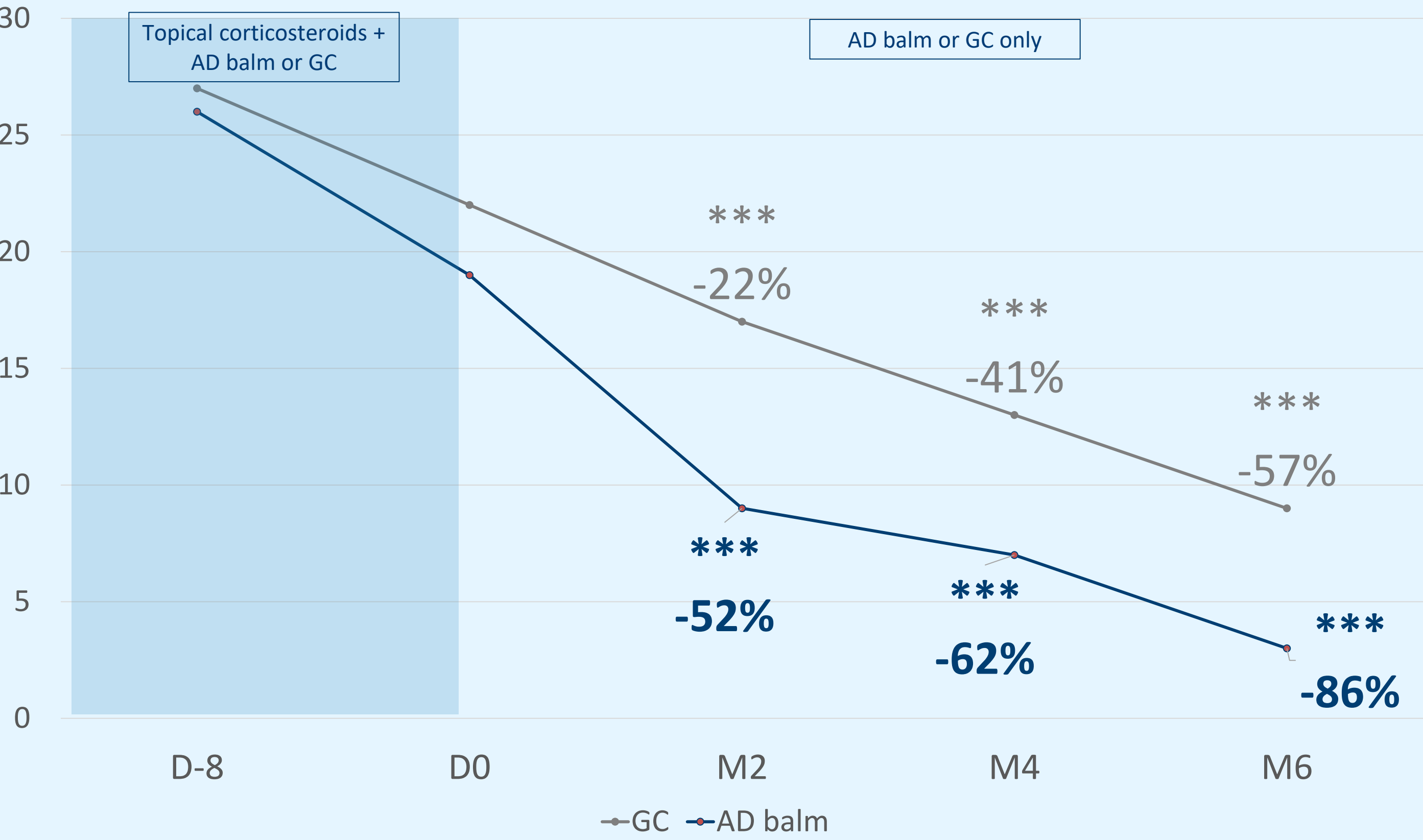


Figure 1 – Evolution in the mean SCORAD score in the two groups compared with D0 (***: p<0.001; paired t-test except for M6/Day 0 in the AD balm group: Wilcoxon test).

-87%*
reduction in
itching

-92%*
Less insomnia

*Clinical scores at M6 versus D0 in the AD balm group (p<0.001; Wilcoxon test)

Quality of life and subject’s assessment

Consistent with clinical improvement, children’s quality of life improved over time. The CDLQI score showed a significantly greater reduction with the AD balm at M6 (-53%) compared with GC (-35%) (p<0.01 between products). This difference was particularly evident for items related to **social life** (question 3 at M6) and **daily activities** (question 5 at M4), with **scores threefold lower in the AD balm group (p<0.01 between products)**. Subjective efficacy of the AD balm was **rated positively by 79-100% of participants**, and overall tolerability was excellent.

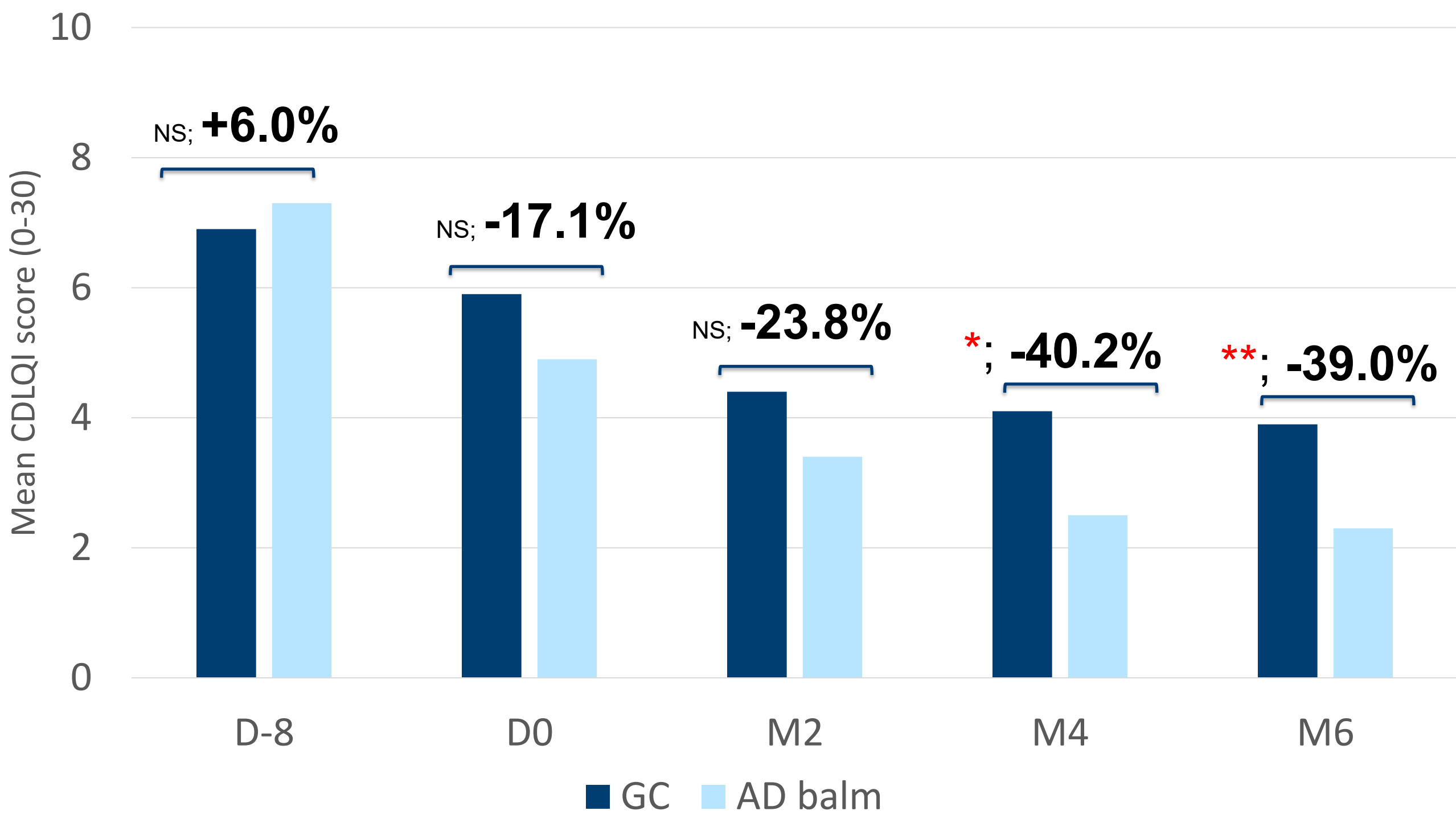


Figure 2 – Evolution in the CDLQI score at each timepoints (NS: Not significant; *: p<0.05; **: p<0.01; Mann-Whitney test) when comparing the AD balm with the GC cream.

Importantly, all subjects using the AD balm experienced a reduction in flare frequency during the 6-month study period compared with the previous 6 months, and 88% reported no flares at all during treatment



Figure 3 – Child with atopic dermatitis, subject no. 66, right elbow flexion

CONCLUSION/DISCUSSION

After 6-months’ use following treatment with topical corticosteroids for inclusion lesions, **the novel emollient developed for AD patients demonstrated significantly superior efficacy compared with a glycerin-based cream in improving disease severity and quality of life** in infants and children with atopic dermatitis. The AD balm reduced SCORAD, improved key clinical and functional signs-including disease extent, erythema, xerosis, pruritus, and insomnia -substantially decreased flare frequency, and enhanced life comfort, **supporting its role as an effective adjunctive skincare in pediatric AD.**