

INTRODUCTION

Atopic dermatitis (AD) is a chronic inflammatory skin condition that affects diverse ethnic groups with varying prevalence. The National Health and Nutrition Examination Survey, which evaluates the health and nutritional status of adults and children in the U.S., found that 19.3 percent of African American children have atopic dermatitis, compared to 16.1 percent of white and 7.8 percent of Asian children. Further analysis of this data revealed that U.S. African-American children are 1.7 times more likely to develop atopic dermatitis than white children even when adjusting for confounding factors such as socioeconomic background, environmental conditions and healthcare insurance coverage.¹ This disproportionate impact coupled with additional unique skin conditions in this population further highlights the need for research and identification of therapeutic agents that are effective on the multicultural skin.

OBJECTIVE

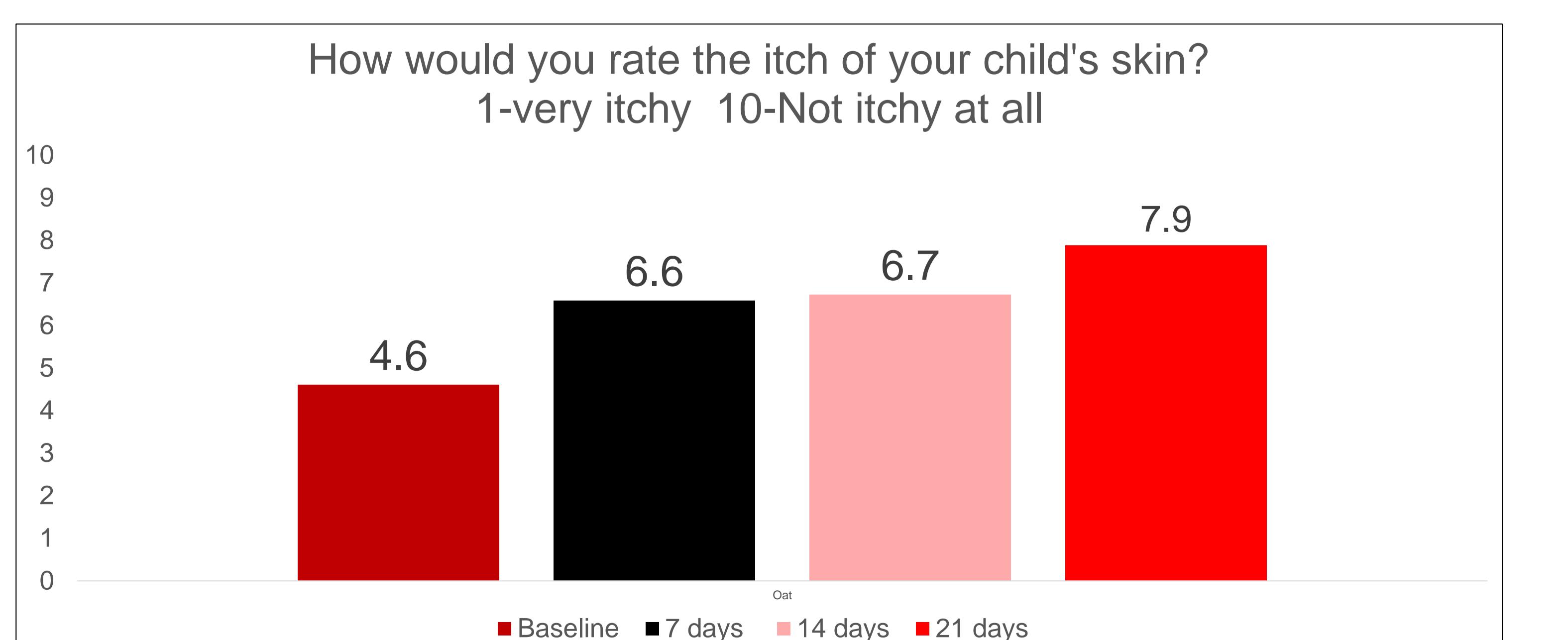
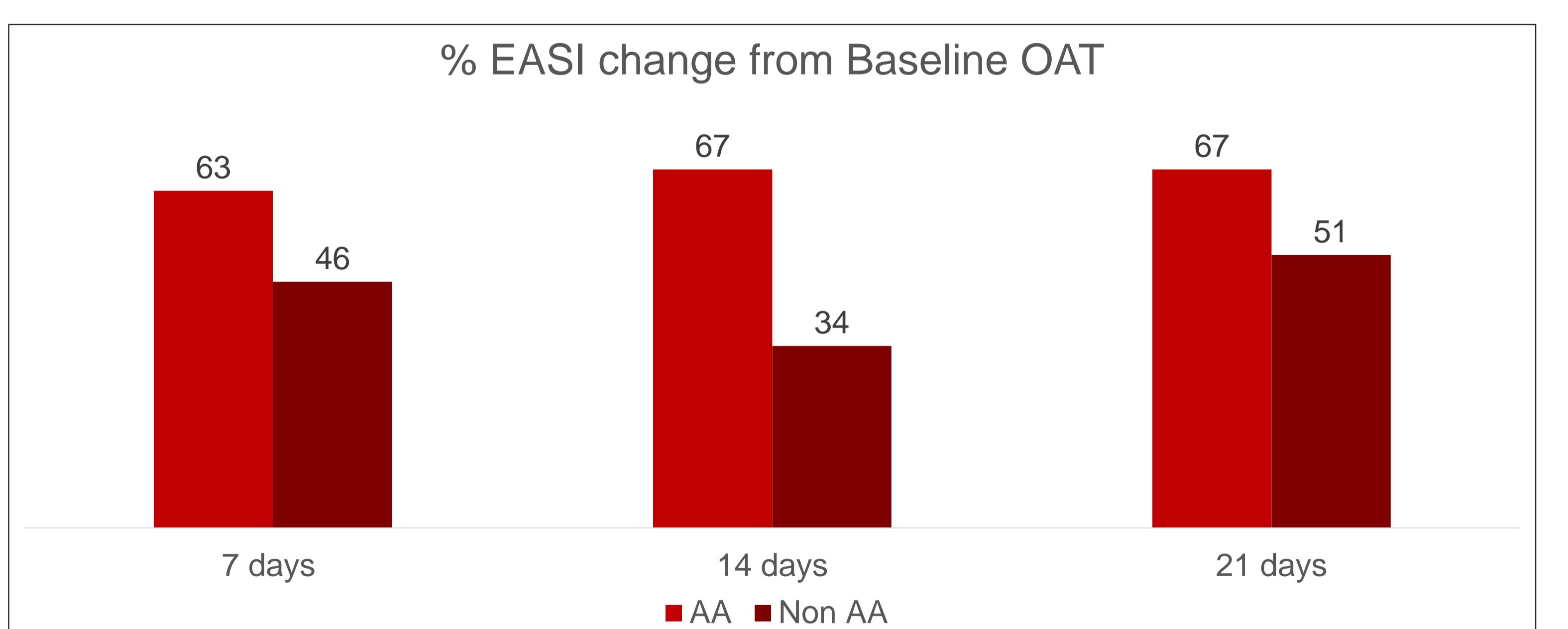
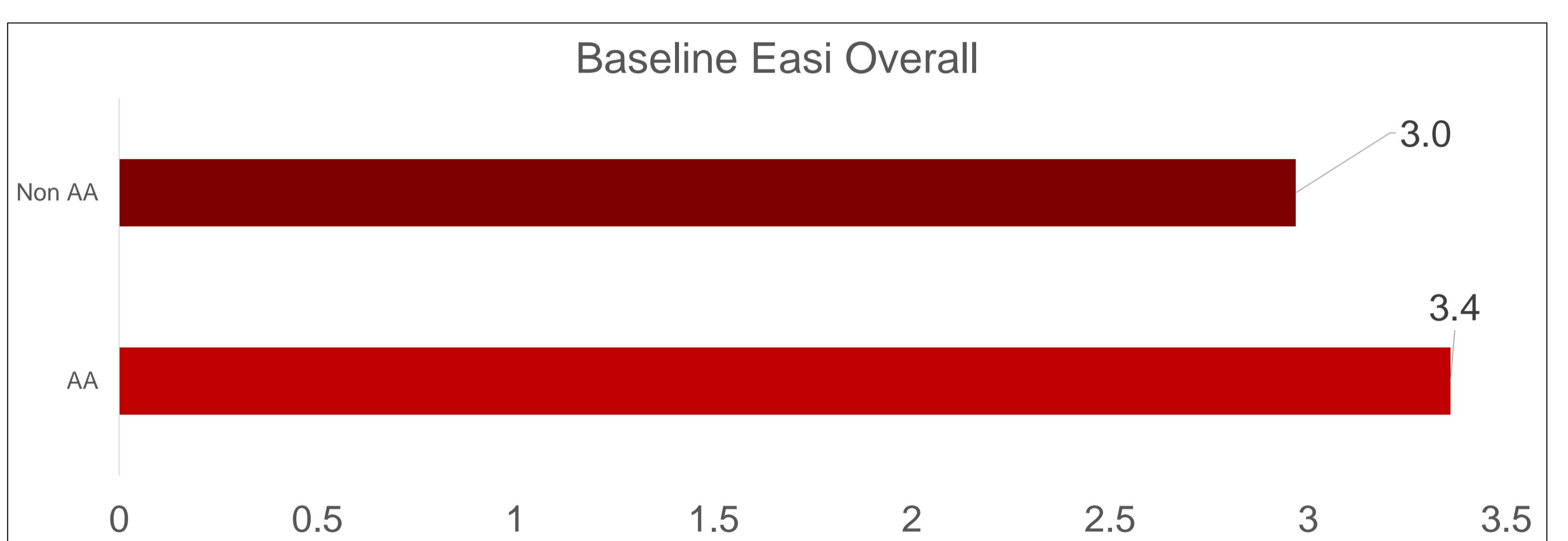
The objective of this trial was to evaluate the efficacy and tolerance of an over-the-counter colloidal oatmeal skin protectant cream in African American children with mild to moderate atopic dermatitis (AD).

METHODS

As part of a larger trial examining the efficacy and safety of a 1% OTC colloidal oatmeal compared to a prescription barrier cream, this investigation studied 49 AA children, ranging from 2 - 15 years of age with mild to moderate AD. Subjects were randomly assigned to colloidal oatmeal (CO) or a prescription barrier repair cream (BRC) and were instructed to use assigned products at least twice daily or as needed for three weeks. Assessments of AD severity and improvement were made by the Investigator using the Eczema Area and Severity Index (EASI) at Baseline and Days 7, 14 and 21. Subjective assessment of itch and other eczema related assessments were made via questionnaires at each time point using a 10 point scale.

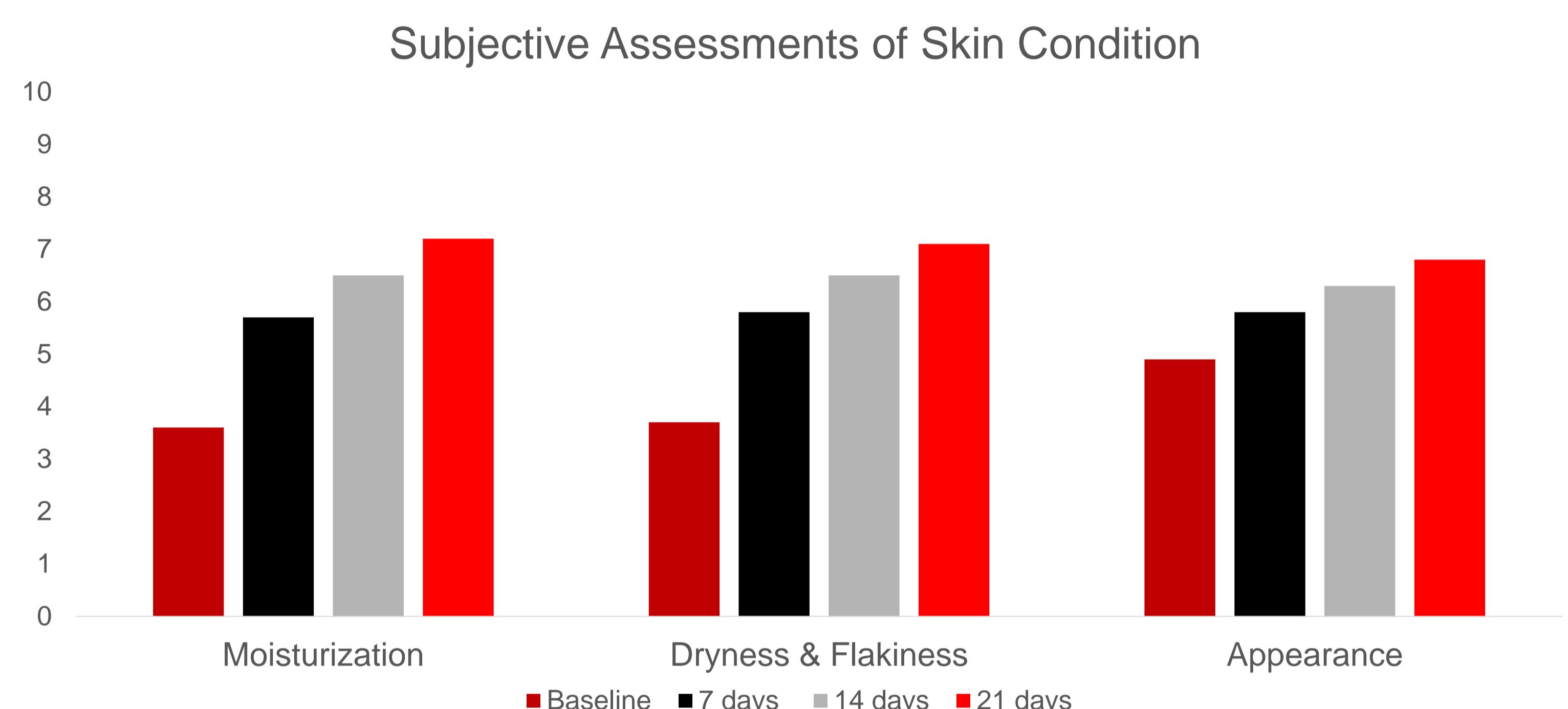
RESULTS

The Baseline EASI scores for the AA subjects (n=49) was 3.4 and for the non-AA subjects (n=41) was 3.0. Colloidal oatmeal did provide rapid improvement in AD symptoms in the AA subjects by Day 7 – 63% and a 46.0% improvement in non-AA subjects by Day 7. The improvements in both groups continued throughout the study. The parents' subjective ratings of itch by Day 7 improved by an average of 2 points on a 10-point scale. While all subjective assessments improved by day 7, the greatest improvements were seen for moisturization (2 pts), dryness and flakiness (2 pts). Similar results was seen for the barrier cream. Both treatments were well tolerated in the study. One subject experienced pruritis and rash that resolved the same day without any change to IP dose/frequency.



RESULTS (continued)

Below is a representation of the subjective assessment of the child's skin condition. Of the three assessments included below, moisturization and dryness & flakiness saw a 2-point increase after the first week using the OTC colloidal oatmeal cream.



How would you describe the level of moisturization of your/your child's skin? 1-Poorly moisturized 10-Very moisturized

How would you rate any dryness/flakiness on your/your child's skin? 1-Very dry/flaky 10-Not dry or flaky at all

How would you rate the appearance of your/your child's skin (in areas affected by eczema)? 1-Poor 10-Good

CONCLUSIONS

The results from this investigation suggest that colloidal oatmeal was effective and provided rapid improvement in AD symptoms by Day 7 based on Investigator and subjective assessments in African American children when used daily.

The colloidal oatmeal cream was well tolerated in the study. No subjects withdrew due to adverse events and there were no SAEs reported in the study.

Colloidal oatmeal cream is a safe, cost-effective over-the-counter (OTC) treatment approach for managing mild to moderate AD in the population studied.

REFERENCES

- J Invest Dermatol. 2011 Jan;131(1):67-73.