A Novel New Sodium Hypochlorite Formulated Wash as an Adjunctive Approach to the Management of Pediatric Subjects with Moderate to Severe Atopic Dermatitis Colonized with *Staphylococcus aureus*

Benjamin R. Bohaty, MD,† Kathryn C. Durham, MD,† Gil Abramovici, MD,‡ Dennis P. West, PhD,‡ Amy S. Paller, MD‡ and Adelaide A. Hebert, MD†

†Department of Dermatology, The University of Texas Health Science Center at Houston, Houston, Texas
‡Department of Dermatology, Northwestern University Feinberg School of Medicine, Chicago, Illinois

Background

Staphylococcus aureus (*S. aureus*) colonization and sub-clinical or overt infection represent common clinical findings in patients with atopic dermatitis (AD) and are known to contribute to exacerbation of the overall disease state. Moreover, atopic patients are commonly colonized with S. aureus on both lesional and non-lesional skin (1, 2). Measures to reduce *S. aureus* colonization have been shown to decrease the clinical severity of AD in patients with clinical signs of secondary bacterial infection of the skin (3). Given the key role of *S. aureus* in triggering the inflammation of AD, adjunctive measures such as dilute sodium hypochlorite (bleach) baths have been utilized by many physicians in an effort to decrease colonization, infection rates and, given the role of *S. aureus* as a trigger of inflammation, disease severity.

Bleach baths are widely utilized in pediatrics and adult medicine for *S. aureus* colonized or infected patients. Regular household bleach has a 6% sodium hypochlorite concentration. Sodium hypochlorite at 6% concentration is cytotoxic and damaging to various tissues. However, concentrations below 0.5% are safe for human use. At a concentration of 0.005%, sodium hypochlorite has been shown to be bactericidal and not cytotoxic to fibroblasts. Based on this background, many physicians use bleach baths to deliver a low concentration of sodium hypochlorite to the skin surface for the purpose of treating or cleansing skin colonized with *S. aureus*. Physicians recommend various ways to prepare dilute bleach baths. A common regimen consists of adding ¼ cup of household bleach into a half full tub of warm bath water, and results in an approximately 0.005% sodium hypochlorite concentration (3).

A novel gel cleanser containing a dilute concentration of sodium hypochlorite (0.006%), designed for use in the shower or bath, may be a convenient alternative to bleach baths.

Objective

The purpose of this trial was to evaluate the response of AD in infection-prone moderate-to-severe *S. aureus* colonized subjects who cleansed with a novel new sodium hypochlorite formulated wash once daily. The wash under investigation in this study contains 0.006% sodium hypochlorite concentration and is further diluted when lathered onto the skin with water. This bactericidal product is available in a sealed, easy to use dispenser, which can be used in the bath or shower, lathered on and rinsed off after 1-2 minutes of skin contact.

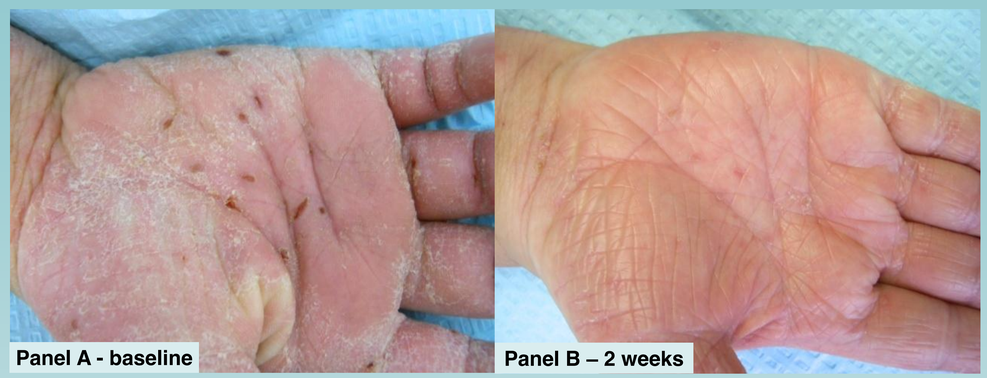

Figure 1 Atopic dermatitis of the dorsal hands at baseline (Panel A) and 2 weeks (Panel B) post-treatment with sodium hypochlorite wash.

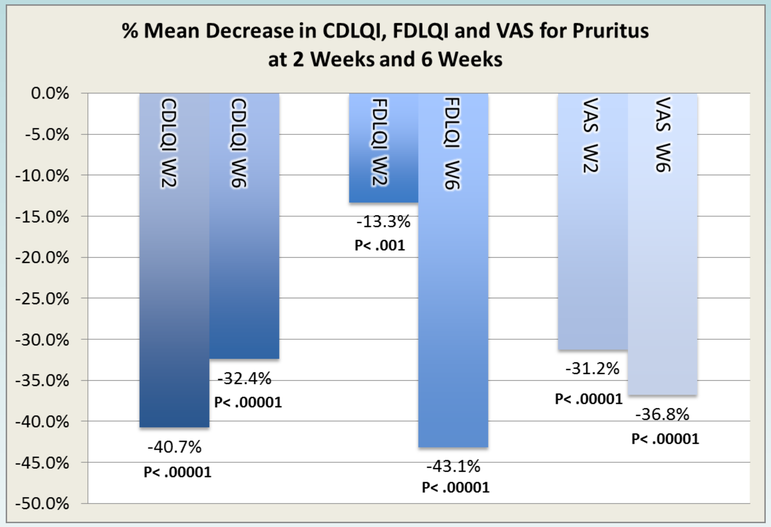

Figure 2 Percent mean decrease in CDLQI, FDLQI and VAS for pruritus at 2 weeks and 6 weeks post-treatment with sodium hypochlorite wash.

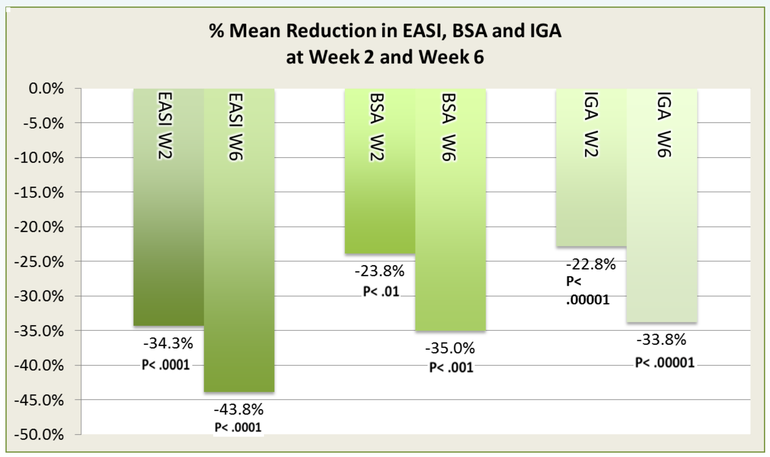

Figure 3 Percent mean decrease in EASI, BSA and IGA at 2 weeks and 6 weeks post-treatment with sodium hypochlorite wash.

Methods

Subjects were recruited from pediatric outpatient dermatology clinics in two large U.S. urban centers. Cutaneous S. aureus colonization was first confirmed by positive bacterial culture of affected skin. Assessments occurred at 3 office visits over a 6-week period (2012-2013) and included Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), Body Surface Areas (BSA), Pruritus Visual Analog Scale (VAS), Children's Dermatology Life Quality Index (CDLQI) and Family Dermatology Life Quality Index (FDLQI) to assess response in this open-label intervention.

Results

The cohort included 40 subjects (62.5% male and with mean age of 8.5±9.0 yrs). Mean change from baseline in IGA at 2 and 6 wks was 0.9±0.9 (22.8% improved; P<.00001) and 1.2±1.1 (33.8% improved; P<.00001), respectively. Mean change in EASI score was 4.8±6.9 at 2 wks (34.3% improved; P<.0001) and 6.2±8.1 at 6 wks (43.8% improved; P<.0001). Mean change in BSA was 6.5±12.5 at 2 wks (23.8% improved; P<0.01) and 10.4±15.2 at 6 weeks (35.0% improved; P<.001). Mean change in VAS was 2.4±2.9 (31.2% improved; P<.00001) at 2 wks and 2.7±3.2 (36.8% improved; P<.00001) at 6 wks. Mean change in CDLQI score was 4.8±5.1 (40.7% improved; P<.00001) at 2 wks and 5.0±5.7 (32.4% improved; P<.00001) at 6 wks. Mean change in FDLQI score was 2.6±4.3 (13.3% improved; P<.001) at 2 wks and 5.3±5.4 (43.1% improved; P<.00001) at 6 wks.

Conclusion

Use of the sodium hypochlorite-formulated wash led to significant decreases in mean IGA, EASI, BSA, Pruritus VAS, CDLQI and FDLQI scores at 2 and 6 weeks of use, and thus represents a simple alternative to bleach baths.

References

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