



SODIUM HYPOCHLORITE BODY WASH AS A MAINTENANCE INTERVENTION TO DECREASE STAPHYLOCOCCUS AUREUS COLONIZATION IN PEDIATRIC PATIENTS WITH ATOPIC DERMATITIS

Tanya Bhattacharya[‡], BS, Benjamin R. Bohaty, MD[†], Lina M. Rodriguez, MD[‡],
Kathryn C. Durham, MD[†], Gil Abramovici, MD[‡], **Lori Asztalos, MD[‡]**, Dennis P.
West, PhD[‡], Adelaide A. Hebert, MD^{†*}, Amy S. Paller, 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

*These Authors Contributed Equally To The Study

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Background



- *Staphylococcus aureus* (*S. aureus*) colonization is higher in patients with atopic dermatitis (AD) (up to 90%) compared to the general population (~20-38%)^{1,2}
- *S. aureus* triggers inflammation and increases the severity of AD
- Measures to reduce *S. aureus* colonization, such as dilute sodium hypochlorite (NaOCl or “bleach”) baths, have been shown to decrease the clinical severity of AD in patients with secondary bacterial infection of the skin³
- Dilute sodium hypochlorite has anti-inflammatory activity through inhibition of NF-κB signaling in *in-vitro* studies and mouse models of radiation dermatitis⁴
- Common dilution regimen consists of ¼ cup of household bleach in a half full tub of warm bath water (0.005% sodium hypochlorite concentration)³

1. Leyden et al. *Staphylococcus aureus* in the lesions of atopic dermatitis. *Br J Dermatol.* 1974; 90(5): 525–30.

2. Balma-Mena et al. *Int J Dermatol.* Colonization with community-acquired methicillin-resistant *Staphylococcus aureus* in children with atopic dermatitis: a cross-sectional study. *Int J Dermatol.* 2011 Jun; 50(6): 682-8.

3. Huang et al. Treatment of *Staphylococcus aureus* Colonization in Atopic Dermatitis Decreases Disease Severity. *Pediatrics.* 2009; 123(5): e808-14.

4. Leung TH, et al. Topical hypochlorite ameliorates NF-kappaB-mediated skin diseases in mice. *J Clin Invest.* 2013;123(12):5361-70

CLn Body Wash (TopMD Skin Care)



- A novel gel cleanser with a dilute concentration of sodium hypochlorite (0.006%) can be used in the shower or bath
- Lathered on and rinsed off after 1-2 minutes of skin contact
- May be a convenient alternative to dilute bleach baths

Objectives



- To evaluate the response of *S. aureus*-colonized, moderate-to-severe AD who cleansed with a 0.006% bleach cleansing body wash once daily
- To characterize *S. aureus* colonization with concurrent AD using skin cultures and PCR.
- To determine if CLn body wash is an effective alternative to bleach baths in patients who like to shower

Study Design



- 6-week prospective study
- Sequentially-enrolled subjects
- Open-label with a study product that contained 0.006% NaOCl in a sealed, child-safe pump dispenser
- Subjects recruited from outpatient pediatric dermatology clinics in two large U.S. urban centers

Methods



- **Inclusion Criteria:**

- 6 months-18 years of age
- Moderate to Severe AD (IGA scores of 3, 4, or 5)
- Positive *S. aureus* skin cultures at screening

- **Exclusion Criteria:**

- Active Infection
- Antibiotic use (systemic or topical) in the previous 4 week period
- Systemic corticosteroid or immunosuppressive therapy in the previous 4 week period
- Bleach bath use in the previous 2 week period

Methods



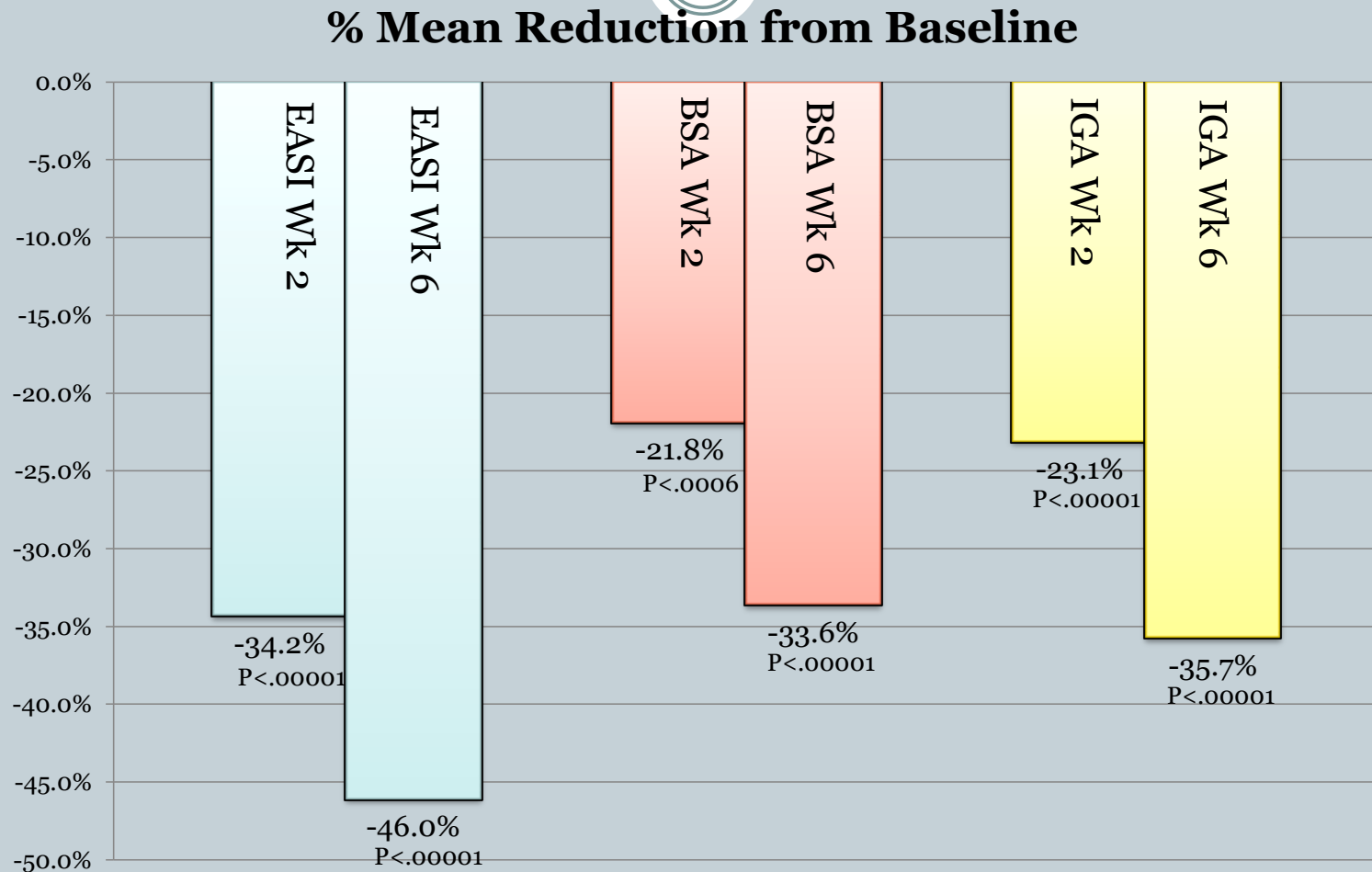
- Subjects evaluated at 3 visits (Baseline, 2 Weeks, 6 Weeks)
- Assessments included:
 - Eczema Area and Severity Index (**EASI**)
 - Investigator Global Assessment (**IGA**)
 - Body Surface Area (**BSA**)
 - Pruritus Visual Analog Scale (**VAS**)
 - Children's Dermatology Life Quality Index (**CDLQI**)
 - Family Dermatology Life Quality Index (**FDLQI**)
 - Patient Satisfaction Questionnaire (**PSQ**) for Problem Areas
- Target lesion *S. aureus* identified via bacterial culture and PCR analysis at baseline and 2 week visits

Results



- **83** subjects were screened
 - 21 subjects excluded for not meeting inclusion or exclusion criteria
 - 12 of the 62 subjects enrolled terminated early due to adverse events, non-compliance, or loss to follow-up
- **50** subjects completed the study
 - 60.0% male
 - Mean age 8.19 ± 9.31 yrs

Results of Clinical Severity Scores

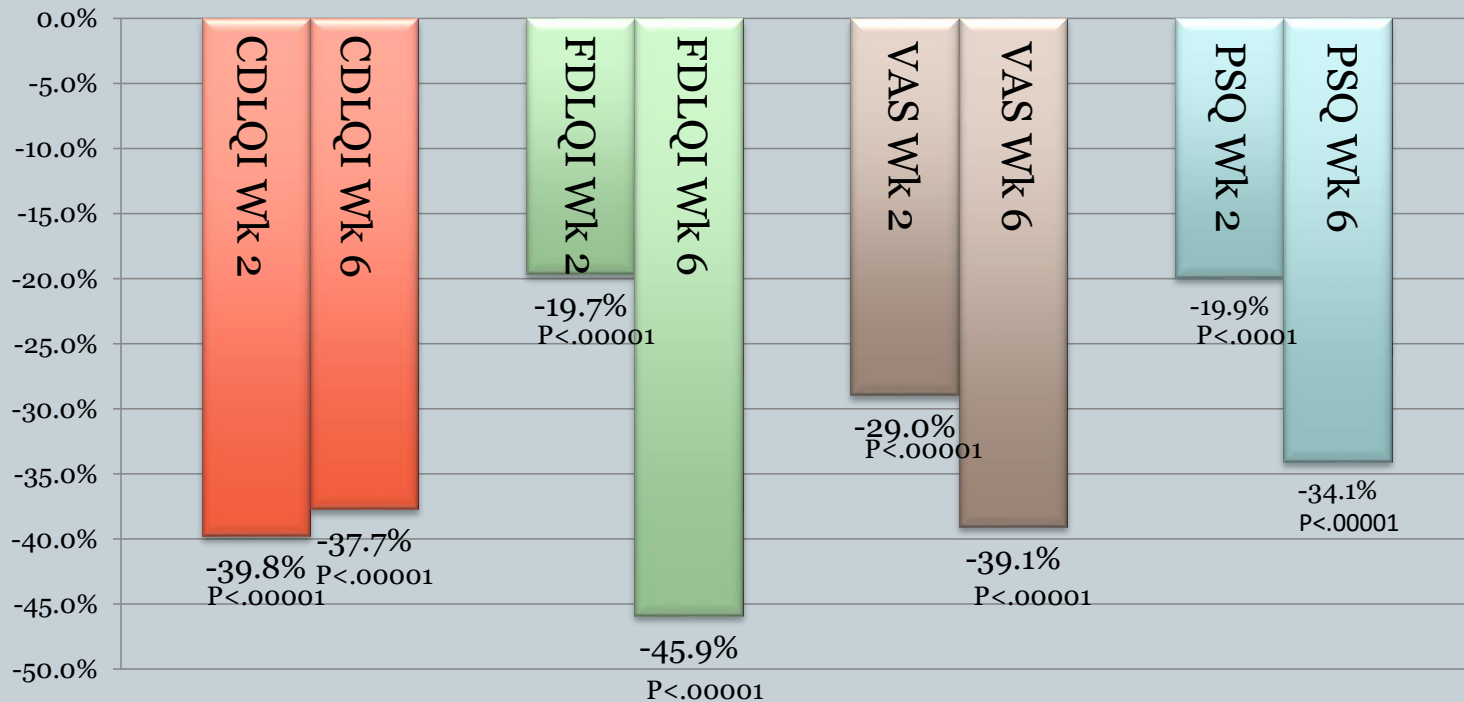


Percent mean decrease in EASI, BSA and IGA at 2 weeks and 6 weeks post-treatment with sodium hypochlorite wash.

Results of Clinical Severity Scores



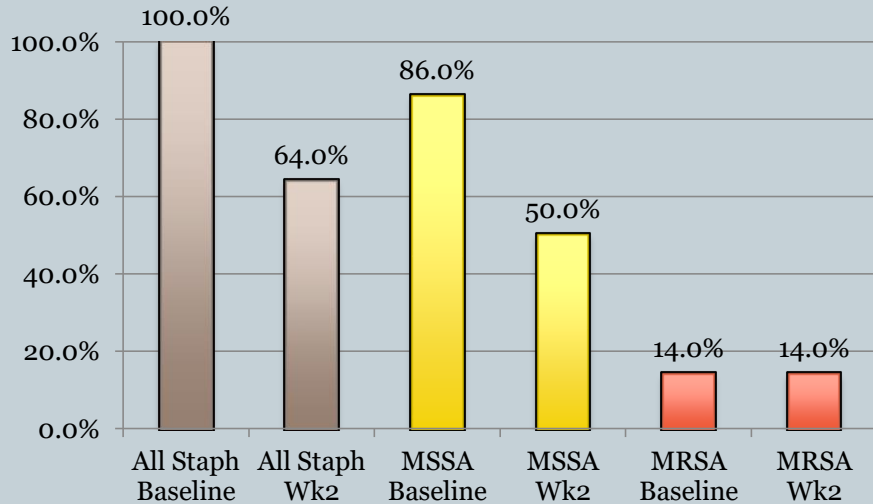
% Mean Decrease in CDLQI, FDLQ, VAS and PSQ



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

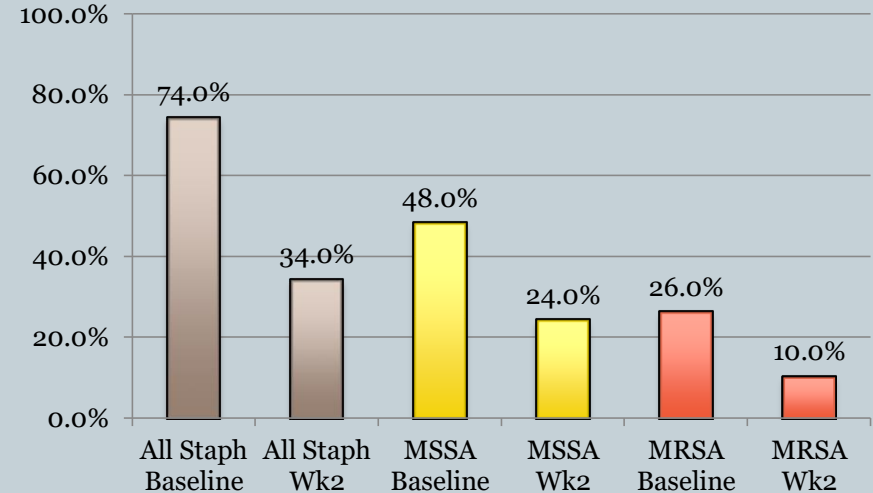
Results of *Staphylococcus aureus* colonization

Percent Subjects with Positive Culture



Percent of patients who tested positive for the presence of *Staphylococcus aureus* during bacterial culture of lesion swab at baseline and 2 weeks.

Percent Subjects with Positive PCR



Percent of patients who tested positive for the presence of *Staphylococcus aureus* during PCR analysis of lesion swab at baseline and 2 weeks.

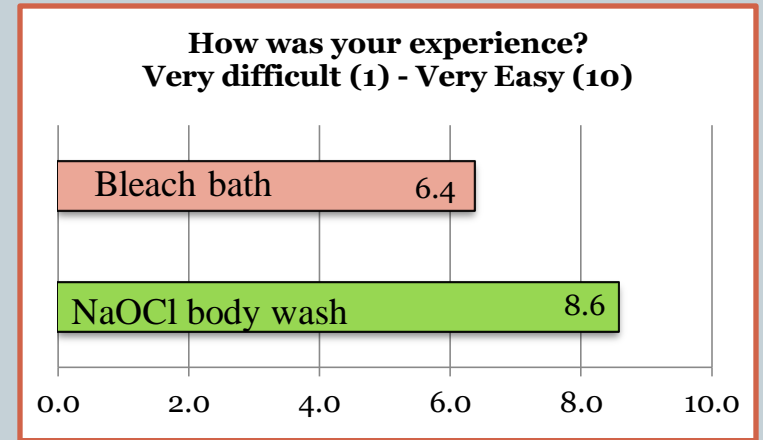
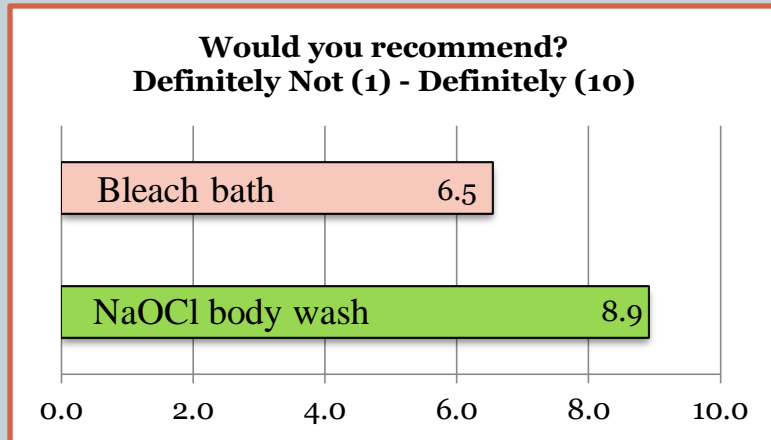
Results



- Atopic dermatitis of the hand and popliteal fossa at baseline (A) and 6 weeks (B) post-treatment with sodium hypochlorite wash



Results- Subject Satisfaction



Post-study survey comparing NaOCl body wash to previous experience with traditional bleach bath (n=38)

Conclusions



- Use of a sodium hypochlorite-formulated body wash led to significant improvement of AD clinical severity scores (IGA, EASI, BSA, Pruritus VAS, CDLQI, and FDLQI scores, PSQ) from baseline to 2 and 6 weeks
- A reduction in the percentage of patients testing positive for *S. aureus* by bacterial culture and PCR analysis was observed after 2 weeks of wash use
- CLn body wash represents a simple and effective alternative to bleach baths

Conclusion



- Despite significant clinical improvement of dermatitis, 64% of subjects remained positive for *S. aureus* by cultures at 2 weeks
- Dilute bleach therapy may be effective maintenance intervention for AD control rather than eradication of *S. aureus* growth.

Questions?