

Efficacy of a Novel Sodium Hypochlorite Cleanser in Atopic Dermatitis

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INTRODUCTION

Staphylococcus aureus infections are common complications in patients with atopic dermatitis (AD) and may contribute to exacerbation of the disease. Atopic patients are commonly colonized with *S. aureus* on lesional and non-lesional skin.^{1,2} Antibiotic treatment of clinically infected areas can often improve the bacterial infection as well as the overall severity of AD.

Given the increasing incidence of recurrent skin infections caused by *S. aureus*, adjunctive measures such as dilute sodium hypochlorite (bleach) baths have been adopted by many physicians in an effort to decrease infection rates and disease severity.³ There is some controversy in the literature regarding the efficacy of bleach baths in improving AD in patients without an active clinical infection, as one study noted limited benefit⁴ while another showed that dilute bleach baths improved AD.⁵

OBJECTIVES

The purpose of this pilot study was to evaluate the efficacy of a novel cleanser containing sodium hypochlorite (CLn™ Body Wash) as adjunctive therapy in patients with moderate to severe AD. Additionally, this study will evaluate tolerability and patient satisfaction of the cleanser.

METHODS

A single-center feasibility study was performed over a 4-month period with eleven atopic patients. Inclusion criteria: a) patients 6 months of age and older, b) positive *S. aureus* lesional skin cultures at baseline, and c) moderate to severe AD, as measured by an Investigator Global Assessment (IGA) score of 3 and above on a 5-point scale. Exclusion criteria: a) clinically significant active infection (i.e., heavy oozing, pus drainage, abscesses, boils, or swelling) at baseline visit, and b) topical or oral antibiotic use in the prior 2 weeks.

Patients that met criteria were instructed to bathe 3 days per week with the sodium hypochlorite cleanser. During the 12-week study period, patients lathered with the cleanser from the neck down, and rinsed after 45-60 seconds. During the study period, patients were to continue their individualized standard AD treatment regimen, including topical and/or systemic therapies.

RESULTS

Eleven patients, (4 males, 7 females) 2 to 15 years of age with active AD, participated in this feasibility study. At baseline, 7 patients were receiving maintenance topical therapies while 4 patients were managed on systemic therapies in addition to their topical regimen. Clinical follow-up data, including change in Body Surface Area (BSA), IGA scores, and bacterial counts, is summarized in Table 1.

Improvement in the BSA and IGA scores was observed. The mean reduction from baseline in BSA at follow-up was 15% at 2 weeks (n = 5), 14% at 4 weeks (n = 8), 22% at 6-8 weeks (n=4), and 24% at 10-12 weeks (n=6). The mean IGA score improved from baseline as evidenced by a reduction of 1.6 at 2 weeks (n = 5), 1.3 at 4 weeks (n = 8), 1.6 at 6-8 weeks (n=4), and 1.8 at 10-12 weeks (n =6).

Only 1 of the 15 atopic patients screened was excluded due to a negative baseline culture. Of those included in the study, we observed a decreasing trend in the quantitative *S. aureus* counts.

Clinical Follow-Up

Case	BSA	IGA	Bacterial Cultures
1a*	25% reduction	2 grade improvement	1 grade decrease/no change
1b**	10% reduction	2 grade improvement	2 grade decrease
1c***	No change	2 grade improvement	culture not done
2a*	No change	1 grade improvement	1 grade decrease/no change
2b**	20% reduction	1 grade improvement	1 grade decrease/no change
2c***	30% reduction	3 grade improvement	1 grade decrease
3**	20% reduction	1 grade improvement	2 grade decrease/1 grade decrease
3***	20% reduction	1 grade improvement	2 grade decrease
4**	No change	No change	2 grade decrease
5*	10% reduction	2 grade improvement	3 grade decrease/no change
6*	40% reduction	3 grade improvement	2 grade decrease/1 grade decrease
7a*	No change	2 grade improvement	3 grade decrease/1 grade decrease
7b**	20% reduction	2 grade improvement	2 grade decrease/1 grade decrease
7c***	8% reduction	3 grade improvement	No change/2 grade decrease
8a**	30% reduction	1 grade improvement	1 grade decrease
8b***	30% reduction	1 grade improvement	No change/2 grade decrease
8c***	56% reduction	1 grade improvement	2 grade decrease/2 grade decrease
9a**	25% reduction	2 grade improvement	1 grade decrease/2 grade decrease
9b**	25% reduction	1 grade improvement	2 grade decrease/No change
9c***	29% reduction	1 grade improvement	2 grade decrease/No change
10**	No change	No change/slight flare	No change/1 grade decrease
11a*	10.5% reduction	1 grade improvement	1 grade decrease
11b**	12% reduction	2 grade improvement	No change

* = 2 wk follow-up; ** = 4 wk follow-up; *** = 6-8 wk follow-up; **** = 10-12 wk follow-up; + = discontinued topicals
BSA and IGA assessments at follow-up visits are compared to baseline scores. Bacterial quantitative data compared to baseline culture.

Case Examples

Case 1



Baseline 2 weeks 12 weeks

Case 2



2 weeks 4 weeks 12 weeks

Case 5



Baseline 2 weeks

Case 6



Baseline 2 weeks

Case Examples

Case 7

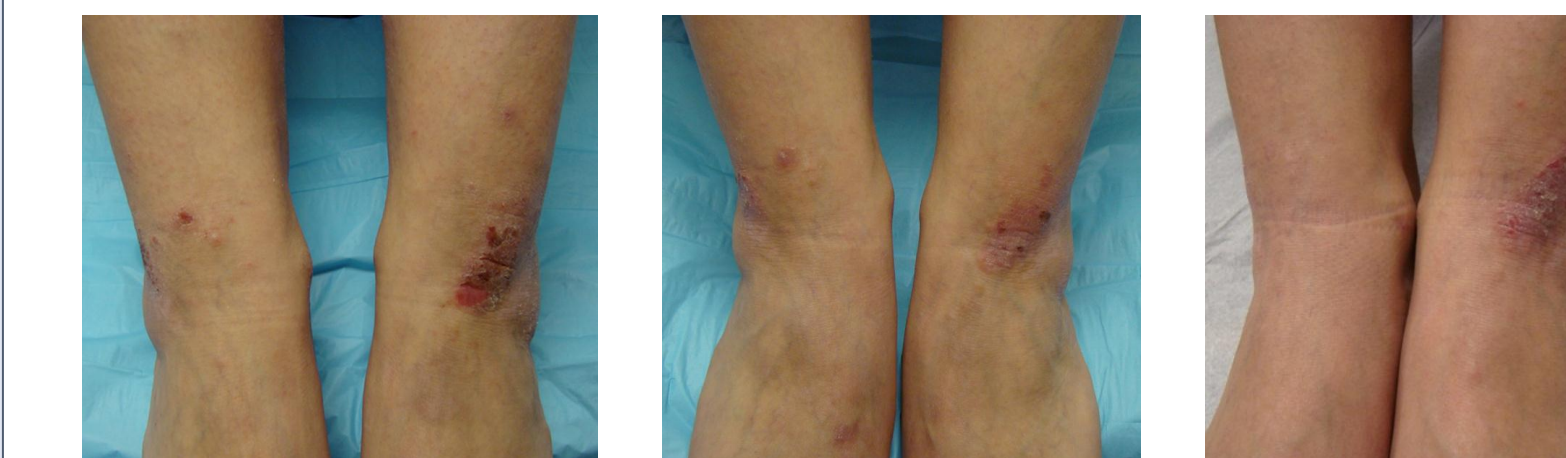


Baseline 2 weeks 10 weeks



Baseline 2 weeks 10 weeks

Case 8



Baseline 4 weeks 12 weeks

Case 9



Baseline 4 weeks 12 weeks

Case 11



Baseline 8 weeks

CONCLUSIONS

Our study supports that atopic patients are commonly colonized and infected with *S. aureus*. Historically, the use of bleach baths has been limited by poor patient compliance. Our feasibility study shows that a novel sodium hypochlorite gel cleanser used in the shower dramatically improves the skin and reduces *S. aureus* colony counts in AD. This study supports the concept of using a sodium hypochlorite cleanser as adjunctive therapy in AD.

The cleanser in our study was well tolerated by all patients and was preferred over traditional dilute bleach baths. Further studies are planned to evaluate the clinical efficacy of this sodium hypochlorite cleanser, its quantitative effect on *S. aureus* colonization, and patient outcomes in AD and other dermatologic conditions.

REFERENCES

- Leyden JJ, Marples RR, Kligman AM. *Staphylococcus aureus* in the lesions of atopic dermatitis. Br J Dermatol. 1974;90(5): 525-530.
- Balma-Mena et al. 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.
- Browning et al. Sodium Hypochlorite (Bleach) Baths: A Potential Measure to Reduce the Incidence of Recurrent, Cutaneous *Staphylococcus aureus* Superinfection among Susceptible Populations. SPD Poster Presentation 2006, Montreal, Canada.
- Bath-Hextall FJ et al. Interventions to reduce *Staphylococcus aureus* in the management of atopic eczema: an updated Cochrane review. Br J Dermatol. 2011 Jan;164(1):228.
- Huang et al. Treatment of *Staphylococcus aureus* Colonization in Atopic Dermatitis Decreases Disease Severity. Pediatrics. 2009 May;123(5): e808-14.

DISCLOSURES

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