An Investigator Blinded Randomized Study Evaluating HOCl in the Treatment of Atopic Dermatitis-Associated Pruritus

Brian Berman, MD, PhD; Mark Nestor, MD, PhD

Center for Clinical and Cosmetic Research and University of Miami Miller School of Medicine

Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by pruritus. It affects up to 20% of children and 3% of adults worldwide, and its prevalence is increasing.1 The impact of pruritus in AD can range from mildly distressing to completely disabling.2

Hypochlorous (HOCl) has been identified as a treatment for pruritus.3 There are 2 mechanisms by which HOCl may reduce pruritus: 1) by its microbicidal qualities, particularly in the case of Staphylococcus aureus; and 2) by its anti-inflammatory qualities, which help reduce the activity of histamine, leukotriene B4, and interleukin-2, all of which contribute to the pathophysiology of itch.4,5

Results

Thirty subjects were enrolled into the study in a 2:1 ratio (treated:untreated), and 29 were included in the final analysis. The mean VAS itch scores between the 2 groups were similar at baseline (Table 1). Mean change in PGA and IGA between baseline and 72 hours were both shown to be significantly different, with a decrease (improvement) in favor of the treatment group (PGA: p-value<0.012; IGA: p-value<0.012) (Figure 1). The mean itch VAS scores between the treated and untreated groups were significantly different between baseline and 72 hours post application, with the percent mean change shown to be significantly lower in the treated group (Figure 2).

At the conclusion of the study, subjects in both groups were separated into those who had less itch (difference in itch between baseline and 72 hours was positive), same itch (difference in itch between baseline and 72 hours was equal to zero), or more itch at 72 hours (difference in itch between baseline and 72 hours was negative) (Figure 3). The analysis showed 73.7% of the subjects in the treated and 30.0% of the subjects in the untreated group experienced a reduction in itching between baseline and 72 hours post application. There were no treatment related discontinuations or SAEs. One subject reported mild to moderate transient facial dryness which spontaneously resolved when that subject applied the gel to the face. Figure 4 shows photographic evidence of a significant decrease in AD characteristics (erythema, dryness, desquamation) at 72 hours.

Figure 1. Mean Change in PGAD3-Di and IGAD3-Di With and Without Treatment with HOCl Gel x 3 day

Figure 2. Mean % Change in Itch VAS With and Without Treatment with HOCl Gel x 3 days

Figure 3. Effect of Treatment with HOCl Gel x 3 days on Itch in Atopic Dermatitis

Figure 4. Subject treated with HOCl before (left) and 72 hours after (right) treatment

Conclusions

This study demonstrated that HOCl leads to a significant reduction in itching associated with AD in as little as 72 hours. Additionally, the twice daily regimen was manageable and easy to follow, as demonstrated by a high rate of compliance.

HOCl is effective over a short period of time with few doses needed. This is a cost efficient and effective method for improving the symptom of pruritus in patients with AD.

References


Supported in part by OnSet and IntraDerm

Photographic evidence was used to confirm evaluations.

Table 1. Baseline Investigator Elicited Itch Score (0-4)

<table>
<thead>
<tr>
<th>Study Group</th>
<th>n</th>
<th>Mean (µ)</th>
<th>Standard Deviation (σ)</th>
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<tbody>
<tr>
<td>TREATED</td>
<td>20</td>
<td>1.55</td>
<td>0.426</td>
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<tr>
<td>UNTREATED</td>
<td>10</td>
<td>1.70</td>
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<td></td>
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<td>Statistical Test</td>
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<td></td>
<td></td>
<td>p-value (p&lt;0.01)</td>
<td>95% Confidence Interval</td>
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<td></td>
<td></td>
<td>0.601</td>
<td>-0.732 - 0.432</td>
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Figure 4. Subject treated with HOCl before (left) and 72 hours after (right) treatment

Change in VAS score 0-72 hours/Baseline
VAS Score x 100%

<table>
<thead>
<tr>
<th>Day 2</th>
<th>Day 3</th>
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<tr>
<td>59.50%</td>
<td>84.50%</td>
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