

Reduced Burning and Stinging Associated With Topical Application of Lactic Acid 10% With Strontium Versus Ammonium Lactate 12%

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Burning and/or stinging is one of the most common concerns expressed by patients using topical therapies for treatment of dermatologic disorders. Topical lactic acid preparations often are used to treat dry scaly skin. In this study, we compared the level of burning/stinging reported by participants with application of lactic acid cream 10% containing strontium versus ammonium lactate lotion 12% and cetearyl alcohol lotion. The mean rating of burning/stinging reported for lactic acid cream 10% with strontium and cetearyl alcohol lotion was lower than ammonium lactate lotion 12% ($P < .0001$). Based on the study results, lactic acid cream 10% with strontium causes less burning/stinging than ammonium lactate lotion 12%.

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Topical therapies are important treatment options for patients with certain skin disorders such as atopic dermatitis and psoriasis.^{1,2} Moisturizers specifically are used to target dry scaly lesions,³ as they generally are safe for long-term use on large surface areas and are more easily obtained than many prescription products.⁴

Adverse events associated with many topical therapies can affect patient compliance and brand preference.⁵ In one survey, 12% (196/1609) of participants experienced an adverse skin reaction to cosmetic products and reported switching to another brand to alleviate the condition.⁶ One of the most common concerns expressed by patients who use topical treatments is burning and/or stinging at the site of application.⁷ Burning/stinging can be more pronounced when applying emollients to diseased skin, which has impaired barrier function.⁸

Topical ammonium lactate 12% consists of lactic acid buffered with ammonium hydroxide. It commonly is used to treat dry scaly skin but also has been associated with a certain degree of burning/stinging due to the acidity of the lactic acid.⁹ A newly available topical lactic acid 10% formulation includes strontium, which has a soothing effect.¹⁰

The main purpose of this study was to compare the level of burning/stinging reported on application of a lactic acid cream 10% containing strontium versus ammonium lactate lotion 12% and cetearyl alcohol lotion. The primary hypothesis was that the lactic acid cream with strontium causes less burning/stinging than the ammonium lactate lotion with results similar to the cetearyl alcohol lotion. Cetearyl alcohol was chosen as a comparator due to documented evidence of its low irritancy potential.¹¹ This study used the same skin abrasion technique and 10-point rating scale that was used in prior studies to measure irritancy of topical preparations. For this investigation, petrolatum ointment served as a negative control because of its well-noted soothing properties, while benzyl alcohol lotion 5% acted as a positive control for burning/stinging because of its characteristic irritant nature.^{5,12}

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Methods

Study Design—A single-center, institutional review board–approved study was conducted using a questionnaire to evaluate and compare patient reports of burning/stinging from treatment with lactic acid cream 10% with strontium, ammonium lactate lotion 12%, and cetearyl alcohol lotion.

Participant Eligibility—To be eligible for the study, participants had to provide written and informed consent, be 18 years or older, and have disease-free skin on the anterior thighs. Exclusion criteria included any known hypersensitivity to components of the study products.

Study Products—The study products included lactic acid cream 10% with strontium, ammonium lactate lotion 12%, cetearyl alcohol lotion, petrolatum ointment, and benzyl alcohol lotion 5%. Each application of study product involved 0.2 mL.

Study Details—Five 3-cm² areas of normal skin on the anterior thighs were abraded with a disposable razor blade using 10 upward strokes. A drape was then placed in front of the participant's face to avoid seeing the application of the study products. Participants then were instructed to rate the burning/stinging they experienced from each product on a 10-point scale (1=no symptoms; 10=intolerable burning/stinging requiring removal of the study product). All rating assessments were made 1 minute after each product was applied. Participants were directed to equate a rating of 1 to the sensation felt after application of the petrolatum ointment, which was applied first in 1 of 5 target areas. Next, the benzyl alcohol lotion 5% was applied in a separate target area, and participants were directed to equate a rating of 10 to the resulting burning/stinging sensation. The participants were blinded to simultaneous applications of the lactic acid cream 10%, ammonium lactate lotion 12%, and cetearyl alcohol lotion to the 3 remaining target areas; they were asked to rate each product 1 minute following application.

Study End Point—The primary end point was evaluation of the burning/stinging caused by topical application of lactic acid 10% versus ammonium lactate 12% and cetearyl alcohol.

Results

Study Population—Thirty patients gave written and informed consent prior to study participation; all 30 completed the study with no discontinuations. The mean age of the study participants was 36 years with 63% (19/30) of the participants being women. There were 8 Asian, 9 black, and 13 white study participants.

Primary End Point—The mean rating of burning/stinging was 2.1 for lactic acid cream 10%, 4.8 for ammonium lactate lotion 12%, and 1.6 for cetearyl

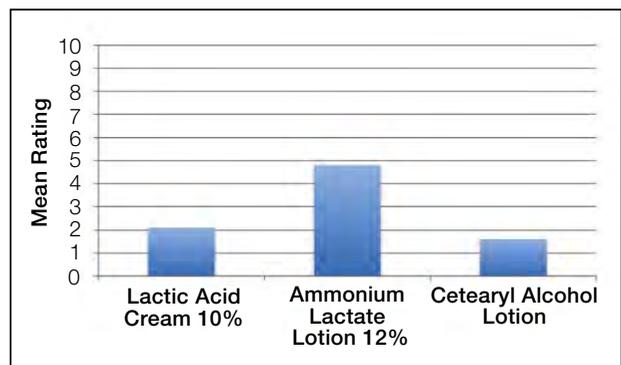
alcohol lotion (Figure). The mean ratings for both lactic acid cream 10% with strontium and cetearyl alcohol lotion were significantly lower than the mean rating for ammonium lactate lotion 12% ($P<.0001$). A paired t test between the mean ratings of burning/stinging for lactic acid cream 10% with strontium and cetearyl alcohol lotion was not statistically significant ($P=.0578$).

Safety—Twenty-seven percent (8/30) of participants experienced mild pinpoint bleeding and mild erythema due to the abrasion technique; all incidences were mild and were not determined to be related to study product. No other adverse events were reported during the study.

Comment

Emollients often are incorporated into treatment regimens for patients with inflammatory dermatoses.¹³ One study demonstrated increased skin hydration (measured by corneometry) and decreased desquamation (measured by corneocyte count) in patients with mild to moderate psoriasis who were treated with 4 weeks of moisturizer therapy.² Thus one of the major therapeutic roles of moisturizers is to provide hydration to treat dry scaly features of skin lesions.¹⁴

Many ingredients in topical products, including moisturizers, can cause various levels of skin irritation characterized as burning/stinging.¹⁵ Patients with diseased skin also are more susceptible to skin irritation due to a disturbance in their normal skin barrier.⁸ Ammonium lactate lotion 12% has been associated with a certain degree of irritation due to the acidity of its main ingredient, lactic acid.¹⁶ Strontium has been shown to decrease this irritation when used in combination with lactic acid.¹⁰



Mean level of burning/stinging on application of lactic acid cream 10% with strontium, ammonium lactate lotion 12%, and cetearyl alcohol lotion. Burning/stinging was rated by participants on a scale of 1 (no symptoms) to 10 (intolerable burning/stinging requiring removal of the study product).

In our study, the mean rating of burning/stinging reported for lactic acid cream 10% with strontium was 2.1 in comparison to 4.8 for ammonium lactate lotion 12% and 1.6 for cetearyl alcohol lotion. A previously published study using the same study design found that hydrocortisone butyrate lipocream 0.1% had low irritancy potential with a burning/stinging score of 2.3,⁵ which was similar to the score for lactic acid cream 10% with strontium in this study.

The abrasion technique used in this study, which also was used in prior studies in the literature, was designed to create uniform disruption of the normal skin barrier.^{5,12} Future studies involving participants who have similar levels of diseased skin would provide more insight into the true rate of burning/stinging caused by these products.

Additionally, the conclusions of this study were limited by the number of study participants. A larger study might have had the power to detect a statistically significant difference in the mean rating of burning/stinging between lactic acid cream 10% and cetearyl alcohol lotion, as no statistically significant difference was detected in this study ($P=.0578$).

Conclusion

The data collected in this study support our main hypothesis that lactic acid cream 10% with strontium causes less burning/stinging than ammonium lactate lotion 12%. Participant reports of burning/stinging from lactic acid cream 10% were more equivalent to cetearyl alcohol lotion.

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