Nonsteroid Cream Soothes Kids' Atopic Dermatitis

BY HEIDI SPLETE
Senior Writer

CHICAGO — A nonsteroidal cream that contains glycyrrhetinic acid (2%) and hyaluronic acid is a safe, effective therapy for mild to moderate atopic dermatitis in infants and young children, based on data from 142 patients aged 6 months to 12 years presented at the annual meeting of the Society for Pediatric Dermatology.

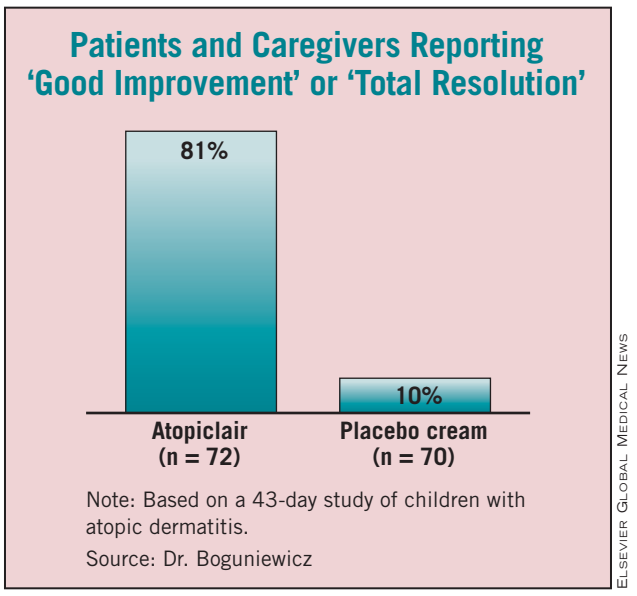
The nonsteroidal cream MAS063DP, which is marketed as Atopiclair, demonstrated safety and effectiveness in adults aged 18-84 years with mild to moderate AD in a randomized, double-blind, placebo-controlled study of 218 patients (J. Drugs Dermatol. 2006;5:236-44).

To assess the safety and effectiveness of the cream in children, Dr. Mark Boguniewicz, of the National Jewish Medical and Research Center in Denver, and his colleagues randomized 72 patients to application of the test cream three times daily and 70 patients to application of a placebo cream three times a day for 43 days. The study was sponsored by Sinclair Pharmaceuticals Ltd. and Graceway Pharmaceuticals LLC.

After 8 days, 39% of the patients in the test group met criteria for "almost clear," whereas none of the placebo patients met these criteria, based on the Investigator's Global Assessment scale. After 22 days, 77% of the test group met criteria for "clear" or "almost clear," whereas none of the placebo patients met these criteria. By the end of the study at 43 days, 78% of the test patients were "clear" or "almost clear," compared with fewer than 7% of the placebo patients.

Itchiness also decreased significantly in the test group during the study period. The average scores (on a scale of 0-100 mm) on the Visual Analog Scale, which compared the same lesion at baseline and on the last day of the study, dropped from 60 mm to 13 mm in the test group and from 66 mm to 57 mm in the placebo group.

By the study's end, 81% of the patients and caregivers in the test group reported either "good improvement" or "total resolution," compared with 10% of the placebo group. Similarly, 81% of patients and caregivers in the test group said that they would "definitely" or "likely" continue to use the cream. All reported adverse events were defined as mild to moderate. The most common complaints—a burning sensation on the skin and fever—occurred with the same frequency in both the test and placebo groups (6.9% vs. 7.1%, respectively). The 26 patients who needed rescue medication at any time during the study included significantly fewer patients from the test group (6 patients) than from the placebo group (20 patients).



Atopiclair is approved by the Food and Drug Administration for marketing in the United States, a spokesperson for Sinclair Pharmaceuticals said in an interview, and "has no restrictions on age or duration of use," according to the product Web site. ■

AD Flares Controlled With Intermittent Tacrolimus Use

BY HEIDI SPLETE
Senior Writer

CHICAGO — Intermittent treatment with tacrolimus ointment kept atopic dermatitis under control with no need for corticosteroids in children and adolescents aged 2-15 years whose conditions had stabilized.

Because concerns persist about the long-term effects of corticosteroid use by children and teens, safe and effective alternatives for the long-term management of atopic dermatitis (AD) are needed. Because the black box warning attached to tacrolimus (Protopic) says that continuous use should be avoided, Dr. Amy S. Paller of Northwestern University, Chicago, and her colleagues designed a plan that involved applying tacrolimus ointment to the affected skin three times weekly for 40 weeks.

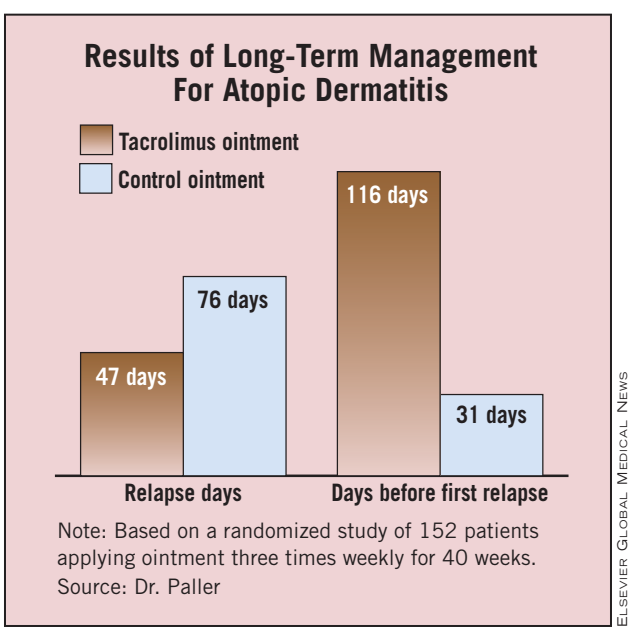
The treatment goal was to prevent flares in patients whose AD had stabilized. The trial of the protocol's safety and effectiveness was sponsored by Astellas Pharma US Inc., and the researchers presented their findings in a poster at the annual meeting of the Society for Pediatric Dermatology.

A total of 206 patients were randomized, but 54 discontinued the study. The most common reason for discontinuation was loss to follow-up (15 patients). Ten children dropped out because of uncontrolled rebound exacerbation of their AD, and five dropped out because of an adverse event.

Overall, the patients who received tacrolimus ointment had significantly fewer relapse days (47) than those who received a control ointment containing alclometasone (76 days). In addition, the tacrolimus patients remained stable for significantly more days before their first relapses (116 days vs. 31 days), the investigators reported.

Although there was no difference between the groups in the number of children who relapsed at least once, only 6% of the children in the tacrolimus group relapsed for up to 3 days during the study period. In the control group, 19% of the children relapsed for up to 6 days.

The most common adverse events reported by tacrolimus patients were burning and itching at the application site, which reflects results from previous safety studies. The incidence of adverse events was similar between the two groups. In general, tacrolimus ointment has a safety record similar to that of corticosteroid ointment for the initial treatment of moderate to severe AD in children, Dr. Paller and her associates noted. ■



Bleach Baths for Reducing S. Aureus in Atopy Underused

BY BRUCE JANCIN
Denver Bureau

MAUI, HAWAII — Bleach baths are a greatly underused tool for reduction of *Staphylococcus aureus* skin colonization in patients with atopic dermatitis, pediatric dermatologists said at the annual Hawaii Dermatology Seminar sponsored by Skin Disease Education Foundation.

Dr. Ilona J. Frieden asked for a show of hands as to how many physicians in the large hall have their atopic dermatitis (AD) patients regularly take bleach baths. Perhaps one-quarter of the audience raised their hands. "I certainly do, and I find it a great way to decrease the need for systemic antibiotics," commented Dr. Frieden, director of pediatric dermatology at the University of California, San Francisco.

"Clorox may be more than just a whitener," added Dr. Sheila Fallon Friedlander of the University of California, San Diego.

She cautioned there is as yet no published definitive proof of efficacy. However, a soon-to-be-published study from Texas Children's Hospital, Houston, did find bleach baths plus regular application of mupirocin in the nares for a year by atopic dermatitis (AD) patients who were chronic carriers of *S. aureus* resulted in a 90% reduction in skin infections requiring antibiotic therapy, compared with the previous year. And the anecdotal experience at the pediatric dermatology centers in which bleach baths have been tried has been quite favorable.

The formula generally used is one-quarter to one-half a cup of regular Clorox bleach—the 6% sodium hypochlorite strength—or an equivalent product in a full tub of water. The concentration is similar to a chlorinated swimming pool. The exposure time is 10-15 minutes two or three times per week.

Dr. Sarah L. Chamlin of Children's Memorial Hospital, Chicago, explained that the antimicrobial effect of the dilute bleach results from hypochlorous acid molecules diffusing through the microbe cell wall and inactivating triosephosphate dehydrogenase, thereby destroying the pathogen's capacity to metabolize carbohydrates. It's the same therapeutic principle as the use of Dakin's solution, a time-honored dermatologic therapy.

The basic formula is one-quarter to one-half a cup of regular Clorox bleach to a full tub of water.

DR. FRIEDEN

Audience members observed that avoidance of excessive bathing—and consequent drying out of atopic skin—is a hallowed principle of AD management. Dr. Friedlander replied that she considers it important to apply an emollient immediately after the bleach baths.

Audience member Dr. Robert A. Moraru, a dermatologist in private practice in New York who uses bleach baths in his AD patients, shared an alternative method of combating the drying effect: Add about a cup and a half of mineral oil to the bath for moisturizing.

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