Barrier Products May Play Role in Dermatitls Tx

Products can improve skin hydration and decrease barrier dysfunction, but more studies are needed.

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SAN DIEGO — Barrier products may play a role as adjuvant therapy for patients with atopic dermatitis, but better studies are needed to demonstrate their efficacy.

That’s the conclusion Dr. Andrew C. Krakowski made about three barrier products he discussed at a meeting on skin disorders sponsored by Rady Children’s Hospital: palmitamide monoethanolamine (PEA) nonsteroidal cream (MimyX), hydrophilic cream MAS063DP (Atopiclair), and ceramide-based emulsion (EpiCeram).

These products are $100 (k) medical devices that have been cleared for marketing by the U.S. Food and Drug Administration. The manufacturers claim that they contain ingredients that might help to replace normal epidermal lipids, improve skin hydration, decrease skin barrier dysfunction, and relieve the atopic dermatitis symptoms of stinging, burning, and pruritus.

Such features are important, Dr. Krakowski said, because “we know that barrier dysfunction correlates with atopic dermatitis severity and we think there is a possible increased allergy absorption that happens through the skin of our atopic dermatitis patients. We also know that atopic dermatitis skin is a great setup for microbial colonization, and that puts you at increased risk of secondary infection. We also have good data that a disrepair skin barrier leads to increased transepidermal water loss.”

There are several barrier products currently on the market, but he limited his discussion to the three that have been studied recently:

EpiCeram. Licensed by the University of California and manufactured by Ceregenix Pharmaceuticals Inc., EpiCeram is a combination of ceramides, cholesterol, and fatty acids that is expected to hit the U.S. market this fall, said Dr. Krakowski.

In a multicenter, randomized study sponsored by Ceregenix and presented as a poster at the 2008 annual meeting of the Society of Pediatric Dermatology, investigators compared 4 weeks of twice-daily ceramide-based emulsion to flufticasone propionate in children with moderate to severe atopic dermatitis. (See related story below.)

On day 14, subjects in the fluticasone-one group had statistically and clinically better Scoring Atopic Dermatitis (SCORAD) scores, compared with those in the ceramide-based emulsion group. By day 28, there were no significant differences in SCORAD scores between the two groups.

In a second multicenter, randomized study that included patients from Rady Children’s Hospital, investigators compared 4 weeks of twice-daily ceramide-based emulsion to pimecrolimus in 38 pediatric subjects with mild to moderate atopic dermatitis. No intention-to-treat analysis was performed.

Subjects in both groups demonstrated significant improvement in Investigator Global Assessment (IGA) scores at days 14 and 28. “There was also no significant difference in pruritus between the two groups, but it wasn’t clear if there was any improvement,” said Dr. Krakowski. As first-year dermatology resident at the University of California, San Diego.

Subjects in the ceramide-based emulsion group had no significant improvement from baseline in Eczema Area and Severity Index (EASI) scores by day 14, while subjects in the pimecrolimus group had significantly better EASI scores, compared with their counterparts in the ceramide-based emulsion group. By day 28, there were no differences in median score reductions between the groups.

MimyX. Manufactured by Stelref Laboratories Inc., this water-based product is described as a fragrance-, dye-, and preservative-free emulsion to be used three times a day or as needed. According to the manufacturer’s Web site, it comes as a 140-g tube, with a cost of $101, or about $22 per ounce.

The main ingredient is PEA, which is found naturally in the stratum granulosum and is thought to downregulate inflammatory response. “It’s a cannabinoid agonist that is believed to modulate mast cells and immune cells, theoretically reducing histamines, cytokines, and IL-4, -6, and -8,” Dr. Krakowski added. “It’s also thought to bind to G-protein receptors on cutaneous nerves and decrease the transmission of pruritus.”

In an international open-label study, investigators assessed the effects of the PEA nonsteroidal cream applied at least twice daily for 38 days in 2,456 patients with mild to moderate atopic dermatitis (J. Eur. Acad. Dermatol. Venereol. 2008;22:73-82). Of the participants, 923 were 12 years of age or younger.

By the end of the study, physician assessment of pruritus scores demonstrated that pruritus improved by 56%, erythema by 54%, dryness by 57%, lichenification by 55%, and excoriations by 63%.

The investigators also found that by the end of the treatment period, 65% of children reduced their use of topical corticosteroids, compared with 53% of adults. In addition, 34% of subjects were able to stop using their topical corticosteroid altogether and 12% were able to switch to a lower-potency steroid.

Atopiclair. Manufactured by Graceway Pharmaceuticals LLC, this product contains hyaluronic acid, Vitis vinifera (grape leaf extract), telmestine, glycyrrhetinic acid (licorice extract), and shea butter, a derivative of shea nut. The product is described as dye- and fragrance-free and is used 2-3 times per day or as needed. It comes in a 100-g tube and costs about $34 per ounce.

In a multicenter, randomized, double-blind, vehicle-controlled trial, 106 infants and children with mild to moderate atopic dermatitis applied hydrophilic cream MAS063DP or vehicle three times a day to past, current, or “reasonable future” sites as monotherapy for 43 days (J. Pediatr. 2008;152:854-9). The mean age of subjects was 5 years.

One target lesion was chosen by investigators for assessment. Improvement was measured from baseline in Eczema Area and Severity Index (EASI) scores. By day 14, 53 of 69 patients in the fluticasone group achieved a score of 0 or 1 at day 22, compared with none in the vehicle group.

“The vehicle used in the study wasn’t your normal petrolatum vehicle,” Dr. Krakowski noted. “It was the vehicle the hydrophilic cream came in.”

Pruritus, EASI scores, subject and caregiver assessment of global response, onset and duration of itch relief, and need for rescue medication were all significantly improved in the treatment group, compared with the vehicle group.

“I think barrier products could be helpful as adjuvant treatment for atopic dermatitis,” he commented. “I think the cost of these products needs to be reconciled with their cost-effectiveness; most of these products may not be covered by insurance. We also need better head-to-head, long-term, pediatric-specific trials to demonstrate efficacy of these products for treating flares directly and for maintenance therapy over the long term.”

Dr. Krakowski disclosed having had no relevant conflicts of interest.