Early Pimecrolimus Reduces AD Flares in Children

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SAN DIEGO — Initiating treatment with pimecrolimus cream 1% during the early signs of atopic dermatitis in infants and children significantly reduced the incidence of flares, prolonged flare-free intervals, and reduced the need for a topical corticosteroid, Elaine Siegfried, M.D., reported during a poster session at the annual meeting of the Society for Pediatric Dermatology.

"This is a straightforward study that reflects what people experience in their practices," Dr. Siegfried told FAMILY PRACTICE NEWS. "When you use a steroid-sparing agent like topical pimecrolimus in combination with a steroid, it helps reduce the need for steroid and helps kids get under better control. There were no safety blips."

In what she identified as the first study of its kind, Dr. Siegfried and her associates randomized 275 infants and children aged 3 months to 11 years with mild to moderate atopic dermatitis 2:1 to receive pimecrolimus cream 1% or a control vehicle used to maintain blinding. Bland emollients were applied for dry skin in both treatment groups.

More than half of the patients in the pimecrolimus group (52%) did not experience a single flare, compared with 34% of patients in the control group.

Over a 6-month period, pimecrolimus or vehicle was applied twice daily at first signs and symptoms of atopic dermatitis and continued until resolution or major flare, which was defined as an investigators' global assessment score of 4 or 5. Major flares were treated with the study drug once daily in the morning and with a mid-potent corticosteroid once daily in the evening until resolution, or for a maximum of 3 weeks.

More than half of the patients in the pimecrolimus group (52%) did not experience a single flare, compared with 34% of patients in the control group, reported Dr. Siegfried, a pediatric dermatologist who practices in St. Louis. Only 7% of patients in the pimecrolimus group experienced more than two flares, compared with 23% of controls.

Among study participants who experienced a flare, the time to onset of first and second flare was significantly delayed among those in the pimecrolimus group, compared with controls (55 days vs. 22 days and 44 days vs. 26 days, respectively).

In addition, improvement in pruritus occurred significantly sooner among patients in the pimecrolimus group, compared with controls (a median of 3 days vs. a median of 5 days, respectively), and patients in the pimecrolimus group were exposed to topical corticosteroid for a significantly shorter time, compared with controls (a mean of 11 days vs. a mean of 17 days, respectively).

As for safety, "most adverse events represented typical childhood illness of mild to moderate severity," the investigators wrote in their poster.

A burning sensation at the application site was the most common adverse event reported (2.2% for patients in both treatment groups).

Novartis Pharmaceuticals Corp. funded the study.

In a related Novartis-sponsored poster presented at the meeting, Joseph Fowler, M.D., and his associates found that children who used pimecrolimus 1% for their atopic dermatitis experienced significant improvement of their pruritus by day 2 of treatment.

For the 7-day study, 174 children aged 2-17 years with mild to moderate atopic dermatitis were randomized to receive pimecrolimus cream 1% twice daily or a control vehicle cream.

"On the second day of pimecrolimus cream 1% treatment, pediatric patients with mild to moderate atopic dermatitis and moderate to severe pruritus experienced significant improvement in their pruritus," the investigators wrote in their poster.

"As early as day 3 following initiation of pimecrolimus, significantly more pediatric patients in the pimecrolimus-treatment group experienced complete resolution of pruritus, with 37% of pimecrolimus-treated patients free of pruritus by day 7," they wrote.

Dr. Fowler practices in Louisville, Ky. ■