# Two Ointments Show Similar Efficacy for Vitiligo

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MONTREAL — Clobetasol propionate and tacrolimus ointments offer similar efficacy for treatment of pediatric vitiligo, according to a prospective, randomized, double-blind clinical trial.

Both topicals were superior to placebo in this study of 100 pediatric patients.

In addition, facial vitiligo lesions responded quicker than did nonfacial ones to either active treatment in the 6-month study, Dr. Nhung Ho said at the annual conference of the Canadian Dermatology Association.

Fifty boys and 50 girls were randomized to one of three groups.

Thirty-three applied clobetasol propionate 0.05% ointment (available as a generic) for 2 months, then placebo ointment for 2 months, followed by clobetasol again for 2 months.

The on-and-off cycle design was used to minimize safety concerns, said Dr. Ho, a pediatric dermatologist at the Hospital for Sick Children in Toronto.

The second group, of 34 patients, applied tacrolimus 0.1% ointment (Protopic, Astellas Pharma US Inc.) for 6 months, and the remaining 33 patients applied a placebo for 6 months.

Participants were aged 2-16 years and vitiligo affected less than 20% of their body surface area at baseline.

They were enrolled at either a dermatology outpatient clinic or a private office between June 2005 and December 2007. A research grant from Astellas Pharmaceuticals funded the study.

Three assessors reviewed standardized photos at baseline, 2, 4, and 6 months.

Successful response was defined as more than 50% repigmentation of the vitiligo lesions.

There were 45 participants with facial vitiligo and 55 others with nonfacial lesions.

In the facial group, 58% responded to clobetasol propionate and 58% responded to tacrolimus.

The effect was lower for those with nonfacial lesions: Thirty-nine percent responded to clobetasol propionate and 23% to tacrolimus, Dr. Ho said.

Both active treatments were significantly better than placebo. A total of 24% of the placebo patients—7 of 29 who completed the study—responded, 5 responded partially and 2 responded with greater than 50% repigmentation, the pediatric dermatologist said.

There were no significant adverse events reported. Some patients experienced transient erythema but no atrophy occurred.

Possible limitations of the study include its short duration and "a humble number of patients," Dr. Ho said.

**Facial lesions responded quicker than did nonfacial ones to both clobetasol propionate and tacrolimus treatment in the 6-month randomized clinical trial.**

Vitiligo affects an estimated 1%-4% of the world's population. It presents in children of all races, with predominance in girls, and approximately 50% of lesions develop before age 20 years.

The pathogenesis of childhood vitiligo is still unknown, the pediatric dermatologist noted.

Evidence supports the use of topical therapies for localized pediatric vitiligo lesions.

For example, moderate- to high-potency topical corticosteroids caused repigmentation of vitiligo lesions for 45 of 70 children (64%) treated in one retrospective study (J. Am. Acad. Dermatol. 2007;56:236-41).

Another 24% (17 children) showed no change in their lesions, and 11% (8 children) had their vitiligo worsen.

Systemic absorption (29% of participants had abnormally high cortisol levels) was a caveat in this study.

In another retrospective study of 57 pediatric patients, tacrolimus ointment caused at least a partial response in 89% of facial vitiligo lesions (J. Am. Acad. Dermatol. 2004:51:760-66).

Response to the topical tacrolimus ointment was lower for vitiligo lesions on the trunk and extremities, with at least a partial response reported by 63% of the pediatric patients. ■