1% cream or placebo for initial symptoms, and more potent topical corticosteroids were used for flares not prevented by pimecrolimus 1% cream. Patients were vaccinated at normal scheduled times (4 doses of tetanus and diphtheria and 1 or 2 doses of measles and rubella). Response was evaluated at months 18 and 24 of the 2-year period.

RESULTS. The seropositivity rates of 93.6% for tetanus, 88.6% for diphtheria, 88.5% for measles, and 84.4% for rubella were comparable with those reported in the literature. Seropositivity was not significantly affected by the use of pimecrolimus at the time of vaccinations (±28 days). These seropositivity rates were within the ranges of 87% to 100% for tetanus, 83.3% to 99.3 for diphtheria, 60.5% to 97.1% for measles, and 55.6% to 88.1% for rubella, similar to those reported in age-matched pediatric populations.

CONCLUSION. Topical pimecrolimus in the treatment of atopic dermatitis had no effect on the response to routine childhood vaccination.

REVIEWER COMMENTS. Topical pimecrolimus, similar to topical tacrolimus (J Am Acad Dermatol. 2005;53[2 suppl 2]:S206–S213), had no effect on routine childhood vaccination. These topical calcineurin inhibitors did not affect basic B-cell function as measured by postvaccination titers.

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Efficacy and Safety of Tacrolimus Ointment Treatment for up to 4 Years in Patients With Atopic Dermatitis

PURPOSE OF THE STUDY. This study was designed to evaluate the long-term safety and efficacy of 0.1% tacrolimus ointment in adult and pediatric patients with atopic dermatitis (AD).

STUDY POPULATION. A total of 408 adult and 391 pediatric patients with moderate-to-severe AD who had participated in a previous clinical trial of tacrolimus ointments. The pediatric patients were from 2 to 15 years of age (185 patients aged 2–6 years, and 206 patients aged 7–15 years), and 93.5% of the patients had severe AD.

METHODS. Tacrolimus ointment 0.1% was applied twice daily either intermittently or continuously to the affected areas. Efficacy and safety assessments included percent body surface area affected, Eczema Area and Severity Index score, individual signs of AD, and the incidence of adverse events. Patients were treated for a range of 1 to 1186 days (median: 982 days). A total of 37.5% of the patients in the study were treated for >3 years.

RESULTS. Improvements in efficacy parameters were observed within 1 week of treatment and continued for the duration of the study. Common adverse events included skin burning, pruritus, skin infection, skin erythema, flu-like symptoms, and headache. The incidence of adverse events, including cutaneous infections, did not increase with time on treatment.

CONCLUSION. Tacrolimus ointment therapy is a rapidly effective and safe treatment for the management of AD in pediatric and adult patients for up to 4 years.

REVIEWER COMMENTS. This study shows no long-term adverse effects of this topical calcineurin inhibitor in the treatment of AD. Most patients had >2½ years of treatment without increase in the number or incidence of infections. If these drugs were systemically immunosuppressive, the number of cutaneous or systemic infections would have been expected to increase.

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Efficacy and Tolerability of Pimecrolimus and Tacrolimus in the Treatment of Atopic Dermatitis: Meta-analysis of Randomised Controlled Trials

PURPOSE OF THE STUDY. To determine the efficacy and tolerability of topical pimecrolimus and tacrolimus compared with other treatments for atopic dermatitis.

METHODS. Randomized, controlled trials of topical pimecrolimus or tacrolimus reporting efficacy outcomes or tolerability from the Cochrane Library, Medline, and Embase were identified. Eligible trials were evaluated for efficacy, identified as investigators’ global assessment of response; patients’ global assessment of response; proportions of patients with flares of atopic dermatitis; and improvements in quality of life. Trials were also evaluated for tolerability, identified as overall rates of withdrawal, withdrawal resulting from adverse events, and proportions of patients with burning of the skin and skin infections.

RESULTS. A total of 4186 of 6897 participants in 25 randomized, controlled trials received pimecrolimus or tacrolimus. Both drugs were significantly more effective than a vehicle control. Tacrolimus 0.1% was as effective as potent topical steroids at 3 weeks and more effective than combined treatment with hydrocortisone butyrate 0.1% plus hydrocortisone acetate 1% at 12 weeks (num-
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