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Titel des Beitrags:
Safety, efficacy, and dosage of 1% pimecrolimus cream for the treatment of atopic dermatitis in daily practice.

Abstract:
INTRODUCTION: Although several controlled clinical trials have demonstrated the efficacy and good tolerability of 1% pimecrolimus cream for the treatment of atopic dermatitis, the results of these trials may not apply to real-life usage. The objective of this study was to evaluate the safety and efficacy of a pimecrolimus-based regimen in daily practice. METHODS: This was a 6-month, open-label, multicenter study in 947 patients aged ≥3 months with atopic dermatitis of all severities. The investigators incorporated 1% pimecrolimus cream into patients’ standard treatment protocols on the basis of their clinical diagnosis. Use of topical corticosteroids was allowed at the discretion of the physician. Safety and tolerability were evaluated by monitoring adverse events. Efficacy was evaluated by recording changes in the Investigators’ Global Assessment scores and pruritus scores at each visit. RESULTS: No clinically unexpected adverse events were reported. The discontinuation rate for adverse events was 2.3%. The disease improvement rate was 53.7% at week 1 and 66.9% at week 24. The pimecrolimus-based regimen was particularly effective for the treatment of lesions involving the face (improvement rate: 61.9% at week 1 and 76.7% at week 24). The greatest therapeutic response was experienced
by pediatric patients with mild or moderate disease. Nonetheless, 64% and 65% of infants and children, respectively, with severe/very severe facial disease at baseline were clear/almost clear of signs of atopic dermatitis on their face at week 24. In patients aged<18 years, most of the improvement occurred within the first week of treatment, while in adults a progressive improvement was observed over the entire study period. Worsening of disease by the end of the study occurred in 9.5% of patients and was most frequent in adults (12.6%). The discontinuation rate for unsatisfactory therapeutic effect was 4.8%. The mean number of treatment days was 135.6 (SD 53.2). The mean drug consumption (non-US centers only) was 4.2 g per treatment day. Drug consumption decreased over time as disease improved. In total, 47% of patients who completed the study never used topical corticosteroids over 6 months. CONCLUSION: In daily practice, incorporation of 1% pimecrolimus cream into patients' standard treatment regimen is well tolerated and improves atopic dermatitis in approximately two-thirds of patients. Disease improvement is particularly evident on the face. The greatest therapeutic response is experienced by pediatric patients with mild or moderate disease. In these patients, most of the improvement is observed within 1 week from the start of treatment.