Unlikely that topical pimecrolimus associated with increased risk of cancer

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The topical medicine pimecrolimus to treat eczema (atopic dermatitis or AD) in children appears unlikely to be associated with increased of risk of cancer based on how it was used in group of children followed for 10 years, according to an article published online by *JAMA Dermatology*.

Eczema is a common and chronic inflammatory skin condition that most frequently occurs in the first decade of life. The U.S. Food and Drug Administration (FDA) and the European Union Medicines Agency have approved few topical agents to treat eczema in children, but in 2001 the FDA and the European Medicines Agency in 2002 approved pimecrolimus to treat eczema in children at least 2 years old. A "black box warning" describes the potential risk of malignancy associated with the topical use of pimecrolimus, a topical calcineurin inhibitor (TCIs). Oral calcineurin inhibitors were originally approved as immunosuppressive treatments for patients after solid organ transplant to prevent rejection although these treatments are associated with an increased risk of cancer, especially skin cancer and lymphoma. The Pediatric Eczema Elective Registry (PEER) study was started in 2004 as part of the postmarketing commitments for the approval of pimecrolimus, according to the study background.

David J. Margolis, M.D., Ph.D., of the University of Pennsylvania, and coauthors analyzed data through May 2014 to evaluate the risk of cancer by comparing expected rates from the Surveillance, Epidemiology and End Results (SEER) program. Overall, the PEER study enrolled 7,457 children (26,792 person-years) and the children used an average of 793 grams of pimecrolimus when enrolled in the study.

As of May 2014, five malignancies were reported: two leukemias, one osteosarcoma and two lymphomas. No skin cancers were reported, according to the study results. None of the findings regarding incidence (risk) of the disease were statistically significant.

"Based on more than 25,000 person-years of follow-up, it seems unlikely that topical pimecrolimus as it was generally used in the PEER cohort to treat AD is associated with an increased risk of malignancy," the study concludes.

In a related editorial, Jon M. Hanifin, M.D., of Oregon Health and Science University, Portland, writes: "The study by Margolis and colleagues in this issue of *JAMA Dermatology* will hopefully help to improve the management of AD, countering the concerns raised by FDA warnings."

"The positive and optimistic report of pimecrolimus postmarketing surveillance by Margolis et al should help reduce the physician and pharmacist concerns that have restricted the use of these effective topical alternatives to corticosteroids. The interim results should help bring relief to a larger segment of the many young individuals with AD," Hanifin concludes.

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