

## No increased skin cancer risk with topical immunosuppressant ointments

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Adults with the chronic skin condition atopic dermatitis can rest easy in the knowledge that two topical immunosuppressant medications commonly prescribed to treat the condition do not appear to increase the



risk for the most common forms of skin cancer, despite package label warnings to the contrary, researchers from Massachusetts General Hospital (MGH) found.

Looking at data on nearly 94,000 people diagnosed with dermatitis in general or more specifically atopic dermatitis—Maryam M. Asgari, MD, MPH, Professor of Dermatology at MGH and colleagues found that patients who were prescribed topical tacrolimus or pimecrolimus did not have a greater risk for either basal cell or <u>squamous cell carcinomas</u> compared with patients who received prescription topical corticosteroids, the most common topical treatment for dermatitis.

Their findings are published online in JAMA Dermatology.

Tacrolimus and pimecrolimus belong to a class of drugs known as topical calcineurin inhibitors (TCI). The US Food and Drug Administration (FDA) requires that TCI medications carry a "black box" warning about increased risk for skin cancer, although previously published studies have shown conflicting results regarding the use of TCIs and skin cancer risk. The FDA has mandated long-term studies of patients with atopic dermatitis who use these products to get a better handle on their potential for increasing skin cancer risk.

"I thought that the data implicating increased skin cancer risk with TCIs was not robust, and that prompted me to get involved in studying it," Asgari said.

The MGH researchers took advantage of the comprehensive database maintained by Kaiser Permanente Northern California in Oakland, which contains integrated pharmacy and pathology data on 93,746 adults age 40 and older who were diagnosed by a clinician with atopic dermatitis or dermatitis from January 2002 through December 2013.



Since nearly all Kaiser Permanente patients use the health plan's pharmacy, Asgari and colleagues were able to determine the proportions of patients who received prescriptions for TCIs vs. topical corticosteroids, and then compared those data with pathology-verified skin cancer diagnoses.

They found that there was no association between TCI use and risk for either keratinocyte carcinomas overall, or for squamous cell or basal cell carcinomas individually. Looking at different doses, frequency, and duration of TCI use did not change the findings.

"We analyzed the data with multiple sensitivity analyses to explore the association of TCI use and <u>skin cancer</u> risk in detail, which revealed no association each time, so that was very reassuring," Asgari says.

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