

Should Coal Tar Products Carry Cancer Warnings?

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This article addresses the controversy whether over-the-counter products that contain coal tar concentrations greater than 0.5% must carry cancer warnings. Evidence that topical coal tar is carcinogenic in laboratory animals and humans is reviewed. In addition, the potential risk of internal malignancies arising from the topical use of coal tar is discussed. The view is expressed that the California court decision that such products should carry cancer warnings is correct.

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A recent California court decision ruled that over-the-counter products with coal tar concentrations greater than 0.5% must carry cancer warnings. This decision was challenged by the National Psoriasis Foundation, which expressed the view that coal tar as it is used for psoriasis is not carcinogenic. The US Food and Drug Administration has taken a similar position. This controversy involves 2 questions: 1) Is coal tar a carcinogen? 2) Do coal tar products as used in the treatment of psoriasis cause cancer? A review by Huff¹ revealed considerable evidence that topical coal tar causes cancer in laboratory animals. Zackheim² summarized reports that prolonged use of topical tar preparations caused skin cancers in men. In the largest series, Greither et al³ found 13 skin cancers in patients, mostly men, following prolonged use of tar preparations. The most frequent sites were the genital and adjacent areas. Rook et al⁴ reported 2 squamous cell carcinomas on the upper thigh of a

60-year-old man who had applied tar ointment to the groin for 34 years. An increased risk of cancer in workers exposed to coal tar products has been well documented.⁵

There is no conclusive evidence, however, that coal tar products as generally used in the treatment of psoriasis increase the risk of skin cancer. Nevertheless, the possibility that topical application of coal tar products might cause cancer must be considered.

Therapeutic coal tar has a high content of polycyclic aromatic hydrocarbons, particularly benzo[a]pyrene, and is mutagenic by the *Salmonella*/microsome assay.⁶ A study by Sarto et al⁷ suggested that urinary mutagenicity levels, as well as frequencies of chromosome aberrations and sister chromatid exchanges in lymphocytes, are related to levels of exposure to pure coal tar and coal tar ointment. Van Schooten et al⁸ reported that a single use of coal tar shampoo resulted in an increased urinary excretion of a specific polycyclic aromatic hydrocarbon metabolite, 1-hydroxypyrene, in all 11 healthy study participants. The investigators suggested that repeated use of coal tar shampoos would result in a high internal dose of carcinogenic polycyclic aromatic hydrocarbons.

These findings suggested the need to determine whether patients using coal tar products have an increased risk of developing internal cancers. In an analysis involving the Swedish Psoriasis Association membership, Lindelof et al⁹ found that use of these products was associated with a statistically significant excess risk of breast cancer in men and kidney cancer in women. However, the authors stated that this increased risk might have been the result of multiple statistical testing.⁹

In a subsequent study involving that cohort, Lindelof¹⁰ reported a case-control study that investigated the association between cancer and psoriasis therapy. Four male psoriasis patients with breast

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cancer and 12 female psoriasis patients with kidney cancer were matched with control patients with psoriasis but without cancer. Treatments, in decreasing order of frequency, included topical corticosteroids, tar, UVB, PUVA, Grenz rays, arsenic, methotrexate, and retinoids. The study results showed no significant difference between the psoriasis groups with cancer and those without cancer with respect to previous treatment for psoriasis. Lindelof concluded that, in his small study, the cancers found in psoriasis patients do not seem to be associated with a specific treatment modality.¹⁰

Although the findings reported by Lindelof are somewhat reassuring, additional studies are needed. I still find it worrisome that known carcinogens are absorbed internally through the skin following the application of coal tar products. The acceptance of such a risk might be justified if coal tar products were significantly superior to other topical therapies. However, supportive evidence is not convincing. In 1983, Langner et al¹¹ reported that following improvement of scalp psoriasis after treatment with a coal tar gel, patients who continued to use a tar shampoo had a more prolonged remission than those who used a nontar shampoo. Using a MEDLINE search, I was unable to find any prospective studies comparing the efficacy of coal tar shampoo with that of other shampoos in the treatment of scalp psoriasis. Van de Kerkhoff and Franssen¹² also found no double-blind studies to support the assumption that coal tar shampoos are effective in treating scalp psoriasis. Pierard-Franchimont et al¹³ conducted a double-blind study comparing the efficacy of a tar shampoo versus a nontar shampoo in the treatment of dandruff. The study included patients with severe and extremely severe heavy scaling, as well as patients with milder scaling. Results with the nontar shampoo were superior to those with the tar shampoo. The difficulty in differentiating severe seborrheic dermatitis of the scalp from psoriasis is well-known.

The issue of general availability of coal tar products is not new.¹⁴ The discovery of 50 mg/kg benzo[a]pyrene in cosmetic hair shampoos in Germany led the German government to ban coal tar products in 1992. Subsequently, German cosmetic manufacturers removed coal tar from their products. In 1997, the European Union placed refined coal tars on the list of substances that must be excluded from cosmetic products.¹⁵

I agree with the California court decision that over-the-counter products containing coal tar

concentrations greater than 0.5% should carry cancer warnings. It is time to follow the example of Germany and the European Union and stop using tar-containing shampoos. There are other effective shampoos readily available.

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