Celebrex inhibited the burden of skin cancer in high-risk patients

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People with the heritable disorder of the skin called Gorlin syndrome who are genetically predisposed to develop basal cell carcinoma of the skin may have a new chemoprevention therapy on the horizon.

According to results of a placebo-controlled, randomized, double-blind, Phase II study, the use of celecoxib was effective in inhibiting the development of basal cell carcinomas in a relatively rare group of patients who are highly susceptible to carcinoma. These findings are published in the January issue of *Cancer Prevention Research*, a journal of the American Association for Cancer Research.

Celecoxib, sold under the brand name of Celebrex by Pfizer Inc., is a non-steroidal anti-inflammatory drug (NSAID). Patients with Gorlin syndrome typically develop hundreds or even thousands of basal cell carcinomas in their lifetime.

Ervin H. Epstein Jr., M.D., senior scientist at the Children's Hospital of Oakland Research Institute, Oakland, Calif., said the goal of this study was to reduce the number of basal cell carcinomas in patients with this rare disorder who are most at risk for this form of cancer.

"The underlying idea is if we can find something in these high-risk patients that could be translatable to the 'normal' population, then we could ultimately use that form of chemoprevention to reduce the numbers of skin cancer in all people," he said.

Epstein and colleagues randomized 60 patients with basal cell carcinoma to receive either 200 mg of oral celecoxib two times a day or placebo. After about two years, patients who received placebo had a 50 percent increase in basal cell carcinoma per year compared with a 20 percent increase among those who received celecoxib.

"We found some beneficial effect of preventing tumors in patients treated with the NSAID," Epstein said.

Furthermore, there was no difference in the rate or severity of side effects between patients in either group.

In a separate editorial, also published in the January issue of Cancer Prevention Research, Charles M. Rudin, M.D., Ph.D., wrote that "this new study of cyclooxygenase inhibition, together with recent data on the efficacy of the hedgehog pathway inhibition, offer new hope for patients at a high risk for basal cell cancer."

"Basal cell carcinoma is an incredibly common disease, far and away the most common cancer in people. The potential for a therapy that would impact the incidence of this would be huge," said Rudin, associate director for clinical research at the Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins.

Rudin told the American Association for Cancer Research that while the clinical results of this study do not have an immediate impact for patients with basal cell carcinoma, Epstein and colleagues have set a precedent for future clinical trials.

So how do these findings translate to the clinic?

In another accompanying editorial, also published in the same issue of Cancer Prevention Research, Jack L. Arbiser, M.D., Ph.D., wrote that

these results demonstrate a pivotal role in the pathogenesis of basal cell carcinoma and point towards combination therapy among those with this form of cancer.

"This has implications for public health," said Arbiser, professor of dermatology in the Department of Dermatology at Emory University School of Medicine.

Although the results of this study showed positive results in reducing cancer, Epstein suggested that concerns remain about the potential cardiovascular side effects (i.e., stroke or heart attack) that may be associated with this drug. More studies are needed to validate the safety and efficacy of the use of celecoxib in this population.

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