

# Guidelines Back Prostate Ca Chemoprevention

BY ELIZABETH MEHCATIE

**H**ealthy men with a prostate-specific antigen score of 3.0 or lower should consider taking a 5-alpha reductase inhibitor to prevent prostate cancer, according to newly released clinical practice guidelines.

The guidelines, issued by the American Urological Association and the American Society of Clinical Oncology, apply to men who plan to get yearly PSA tests or regular prostate cancer screening and who have no signs of prostate cancer. In addition, for men who already are taking the drugs (to treat benign prostatic hyperplasia or male-pattern baldness, for example), physicians should discuss continuing the drug specifically to prevent prostate cancer (J. Urol. 2009; 181:1642-57; J. Clin Oncol. 2009 Feb. 24 [doi:10.1200/JCO.2008.16.9599]; www.asco.org/guidelines).

The guidelines are based on evidence from nine randomized, controlled clinical trials, including the Prostate Cancer Prevention Trial (PCPT). "That body of evidence provided proof" that the 5-alpha reductase inhibitors will decrease the risk of prostate cancer in men being regularly screened for the disease, Dr. Barnett S. Kramer said at a press conference held in conjunction with a symposium on genitourinary cancers.

All nine trials have enrolled men undergoing regular screening for prostate cancer. This fact is important, because it has been well-established that screening doubles the risk of being diagnosed with prostate cancer, added Dr. Kramer, cochair of the panel that produced the guidelines.

The PCPT found an overall 25% relative risk reduction for prostate cancer in men who took the 5-alpha reductase inhibitor finasteride for 1-7 years. Because most of the men in this study were white, the results "principally apply only to white men," he noted, adding that subanalyses found no substantive differences among racial or ethnic groups.

It's not clear whether preventive treatment will affect mortality from prostate cancer or whether doses lower than those currently used would be effective in prevention, said Dr. Kramer, associate director of disease prevention at the National Institutes of Health. In addition, "we can't be confident of its effect in men who choose not to be screened."

The 5-alpha reductase inhibitors are known to lower levels of dihydrotestosterone, which can contribute to prostate cancer growth. Their most common side effects include erectile dysfunction, decreased libido, and ejaculatory dysfunction, with rarer cases of gynecomastia.

When the PCPT was published, there was concern over what appeared to be an increase in the rate of high-grade tumors diagnosed among those randomized to finasteride (37% of the prostate cancers in the finasteride arm were high grade, vs. 22% of those in the placebo arm). But a subsequent analysis determined this increase was likely to be

spurious, Dr. Kramer said, adding that his comments represented those of ASCO and the AUA, not the U.S. government or NIH.

Although Dr. Kramer said he believed that cost needs to be part of this discussion, the available data were not strong enough to calculate cost-effectiveness.

Currently, approximately one in six U.S. men gets diagnosed with prostate cancer, the second-leading cause of death

from cancer in men and, after skin cancer, the most common cancer diagnosed in men in the United States.

He pointed out that prostate cancer rates in the United States are among the highest in the world. In addition, since the principal driver of prostate cancer risk is age, the recommendations target "healthy men who fulfill risk criteria by virtue of age."

The guidelines could apply to millions

of men. During the briefing, Dr. Howard Sandler, a prostate cancer specialist at Cedars-Sinai Medical Center in Los Angeles, said he expects there will be many different attitudes about taking a pill every day "for preventing a condition that may not occur."

He said he personally might consider a trial of over a month, and if he developed side effects to the drug, it would not be worth the potential benefits. But

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if he did not develop adverse effects, “ultimately, I would become reassured that taking one pill per day ... might decrease my risk for prostate cancer,” he said, adding that he had not yet decided whether to pursue such preventive treatment.

The ASCO Web site offers physicians a “Decision Aid Tool,” composed of charts and diagrams to help explain the risks and benefits of 5-alpha reductase inhibitors to patients and their families. ASCO also has produced a corresponding patient guide, which is available at [www.cancer.net](http://www.cancer.net).

Dr. Schellhammer has received research funds or support from Glaxo-SmithKline, which markets the 5-alpha reductase inhibitor dutasteride, and from other pharmaceutical companies. Dr. Kramer has no conflicts of interest related to the guidelines.

The annual Genitourinary Cancers Symposium is sponsored by the American Society of Clinical Oncology, American Society for Therapeutic Radiology and Oncology, and Society of Urologic Oncology. ■

*Sherry Boschert contributed to this story.*

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**References:** 1. Cluff RS, Rowbotham MC. Pain caused by herpes zoster infection. *Neural Clin.* 1998;16(4): 813-832. 2. Dworkin RH, O'Connor AB, Backonja M, et al. Pharmacologic management of neuropathic pain: evidence-based recommendations. *Pain.* 2007;132(3):237-251. 3. Dubinsky RM, Kabbani H, El-Chami Z, Boutwell C, Ali H. Practice parameter: treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology.* 2004;63(6):959-965. 4. Lidoderm Prescribing Information. Chadds Ford, PA: Endo Pharmaceuticals Inc; 2008.

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