

WEB EXCLUSIVES

Finasteride Recommended to Prevent Prostate Cancer

BY LENA HUANG

Men may benefit from taking Proscar (finasteride), a drug that can reduce their risk of getting prostate cancer, according to new guidelines issued in February by the American Society of Clinical Oncology and the American Urological Association.

“The recommendation is long overdue,” says Eric Klein, MD, chair of the Glickman Urological and Kidney Institute and professor of surgery at Cleveland Clinic Lerner College of Medicine. “We have the highest level of scientific evidence; a phase III randomized control blinded trial that shows finasteride reduces the risk of prostate cancer by 25 percent.”

The new guidelines are based on the latest information emerging from the Prostate Cancer Prevention Trial (PCPT), a study of 18,882 healthy men ages 55 and older that was originally published in 2003. While the PCPT initially reported a 25 percent risk reduction of prostate cancer in men who received 5 milligrams daily of finasteride as compared to the placebo group, it also showed that of the men in the finasteride group who developed prostate cancer, their tumors were more likely to be high-grade.

“As part of the trial findings, it appeared as though some of the men who were diagnosed with prostate cancer actually had worse prostate cancer than expected, and it was worse than in the placebo group,” says Oliver Sartor, MD, professor of cancer research in the department of medicine and urology at Tulane Medical School in New Orleans. “This was a bit of a paradox—that there was an improvement in the overall cancer diagnosis rate but a worsening of some of the cancers in the finasteride-treated group.”

It was previously thought the drug itself was possibly causing the high-grade cancer. But this past year, researchers analyzed biopsy results from PCPT participants and found that the high-grade cancer was simply more detectable in men who took finasteride because the drug shrinks the prostate, making the cancer more visible.

Klein adds, “The secondary analyses show the concern over this drug causing high-grade cancer is not a biologic phenomenon but is related to the fact that it is easier to find high-grade cancer in men on finasteride. Men should not have any hesitation about that issue anymore.”

Finasteride is part of a class of medications called 5-alpha reductase inhibitors (5-ARIs), drugs that work by blocking the production of a hormone that causes the prostate to enlarge. Avodart (dutasteride), another 5-ARI, was recently found to reduce the risk of prostate cancer by 23 percent in men with elevated PSA levels (2.5 to 10 ng/ml) in an international trial entitled Reduction by Dutasteride of Prostate Cancer Events (REDUCE).

Finasteride is also used under the brand name Propecia to treat male pattern baldness and benign prostatic hypertrophy, or enlargement of the prostate gland. Side effects of finasteride include decreased libido, erectile dysfunction, ejaculatory dysfunction, and breast tenderness.

In regards to the side effects, “There was a companion quality of life study that looked at sexual function over the course of seven years in the men on the PCPT that showed, on a 100-point scale, a three point drop in sexual function score, which may be statistically significant but clinically meaningless,” Klein notes. “No one can reasonably argue there are too many side effects with this drug.”

Barnett Kramer, MD, MPH, lead researcher on the new study and associate director for disease prevention at the National Institutes of Health, notes the results of the data are “not thick enough to calculate a cost benefit analysis” yet. However, he called a local pharmacy in Bethesda, Maryland, that estimated the cost of one pill of finasteride around \$3, which adds up to \$90 a month or \$1,080 a year. Kramer says he did not know if insurance would cover the drug since individual health insurance plans vary.

“This still leaves some remaining questions,” Kramer says. “We do not know the impact of 5-ARIs or finasteride on prostate cancer mortality. We also don’t know if we can use lower doses that would lower the risk, and finally, all we know is the efficacy on men being screened for prostate cancer. We cannot see confidence of its effects in men who choose not to be screened.” Researchers hope to continue follow-up studies on PCPT participants.

Sartor says it is important to note how the AUA and ASCO worded the new recommendation. “It’s not a recommendation that people should be on finasteride or not on it. It’s something you should discuss with your physician if you are interested in prostate cancer prevention,” he says.