Finasteride Unlikely to Induce High Grade Prostate Cancers

An increase in high-grade prostate cancer among men taking the drug finasteride is likely caused by an increased detection of cancers, and not by the development of more high-grade cancers, according to two studies published online September 11 in the Journal of the National Cancer Institute.

The Prostate Cancer Prevention Trial (PCPT) was the first long-term randomized trial of a possible drug to prevent prostate cancer. The trial showed a nearly 25 percent reduction in prostate cancer incidence among men who took finasteride compared with a placebo. But men taking finasteride had greater rates of high-grade prostate cancer than men taking placebo (6.4 percent vs. 5.1 percent). It is unclear whether finasteride causes more high-grade prostate cancers or simply creates a situation where more high-grade cancers are detected.

Yael Cohen, Ph.D., of Gamida Cell in Jerusalem and colleagues tested their hypothesis that finasteride reduces prostate volume and therefore increases the likelihood of finding high-grade cancer cells in a biopsy. Analyzing data from the PCPT, they investigated the association between high-grade prostate cancer and prostate volume.

Detection of high-grade cancers in the placebo group increased as the prostate size decreased. They found that prostate size in the finasteride group was 25 percent smaller than in the placebo group. Therefore, when the prostate size was taken into consideration, there was not a statistically significant difference between the prevalence of high-grade prostate cancer in the two groups.

“If our conclusion that finasteride accelerates the detection of high-grade cancer yet may not promote its development is correct, then the implications regarding the clinical impact of this drug are quite favorable. The occurrence of lower grade tumors of questionable clinical significance would be reduced, and the early detection of more serious tumors would be enhanced,” the authors write.

In a second study, M. Scott Lucia, M.D., of the University of Colorado Health Sciences Center in Denver and colleagues investigated whether finasteride changes the appearance of tumor tissue so that lower-grade tumors are diagnosed as high-grade. The researchers examined surgically-removed prostates and high-grade prostate cancer biopsies from men treated with finasteride and a placebo for signs that finasteride affected prostate size, tumor size, or disease stage.

Like Cohen and colleagues, they found that men treated with finasteride had smaller prostate glands. High-grade tumors were not larger in men taking finasteride, but when they were present in surgically-removed prostates, the tumors were more likely to be detected because the prostates were usually smaller. They also found no major differences in tumor features between the two groups, indicating that it is unlikely that low-grade tumors were being classified as high-grade.

“Although the evidence does not exclude the possibility that finasteride may have induced high-grade prostate cancer in some men, the analysis of prostatectomies from the PCPT does indicate that the relative increase in high-grade tumors in the finasteride group is less than originally believed. This evidence further suggests that increased detection …may have contributed to the finasteride-associated increase in high-grade disease,” the authors write.

In an accompanying editorial, Gerald Andriole, M.D., of Washington University School of Medicine in St. Louis, Mo., and colleagues find the evidence from these two studies important and convincing. “Taken together, the studies…provide substantial reassurance that the increased proportion of high-grade cancer on biopsy in PCPT is not likely to be clinically
relevant,” the editorialists write. Nevertheless it is necessary, they say, to continue research on the effects of finasteride and other similar drugs such as dutasteride on prostate cancer incidence and Gleason score.

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