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A National Cancer Institute-sponsored Clinical Trials Network
headquartered at the University of Michigan

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Drug known to reduce prostate cancer risk also aids early diagnosis of aggressive form of the disease

Study resolves lingering question about possible downside of finasteride

ANN ARBOR, Mich. — Men now have another good reason to consider taking finasteride, a well-known generic drug that shrinks an enlarged prostate and reduces the risk of getting prostate cancer by 25 percent. A new study from the Southwest Oncology Group strongly suggests that for men at risk of the disease — which strikes one in six men — finasteride also raises the odds that physicians will find fast-growing prostate cancers early, when they are most easily treatable.

“It appears that a man concerned about prostate-cancer risk, who is having a PSA test on a regular basis, will not only reduce his risk of prostate cancer if he takes finasteride, but will help find the cancers that pose the highest risk,” says Ian M. Thompson, M.D., the study’s senior author and a urologist at the University of Texas Health Science Center in San Antonio.

The new results, embargoed until 4 p.m. Sept. 11, appear online ahead of print publication Sept. 18 in the Journal of the National Cancer Institute.

"This report provides an important interpretation of results that confounded an overall favorable interpretation of the Prostate Cancer Prevention Trial initially, and should help lessen fears that finasteride somehow causes more aggressive prostate cancer,” says Frank L. Meyskens, Jr., M.D., Southwest Oncology Group associate chair for cancer control and prevention.

The Southwest Oncology Group (SWOG), headquartered at the University of Michigan and one of the nation’s largest National Cancer Institute-sponsored clinical trial networks, conducted the study to further analyze data from its National Cancer Institute-sponsored 18,882-man seven-year Prostate Cancer Prevention Trial, which in 2003 found that finasteride was an effective prevention agent. The Food and Drug Administration has not approved finasteride for use in cancer prevention; the drug is approved for treating enlarged prostate.

Four years ago, Southwest Oncology Group researchers closed the Prostate Cancer Prevention Trial (PCPT) early to report very good news. Study results showed that

finasteride, commonly used to treat enlarged prostate, could also make a man one-fourth less likely to get prostate cancer.

But that positive overall result — which potentially could keep around 50,000 men from developing prostate cancer each year — was clouded by a troubling finding: Men who took the drug but still developed prostate cancer by the end of the study had higher rates of detected high-grade tumors, an aggressive form of the disease, than did men in the placebo group.

The follow-up study, along with two others published recently, strongly suggests that finasteride makes it easier for physicians to detect high-grade cancers early by improving screening tests and prostate biopsy itself. The two previous studies show that finasteride improves the effectiveness of the two main measures of possible problems: digital rectal examination and the PSA (prostate specific antigen) blood test, which measures hormone changes associated with the disease. In some men who have low PSA test results, cancer is present but not found in time.

“Finasteride makes the PSA test perform better, so we can find the cancer earlier,” Thompson says. “Our current study also shows that by shrinking the prostate gland, finasteride makes a biopsy more sensitive for any cancers that are present.” That increased accuracy is very important, he adds, because if a biopsy reveals a slow-growing cancer but fails to spot a fast-growing one, a doctor and patient may take a “wait and see” approach when prompt treatment is actually needed.

In part because of concerns about possible drawbacks, most urologists, when asked about finasteride, say they seldom prescribe it as a prevention drug, despite the positive 2003 PCPT findings, Thompson says. Now, with several studies allaying concerns about the drug’s possible drawbacks, including concerns about sexual dysfunction, Thompson believes men should be told routinely about the potential benefits of finasteride when they come to the doctor’s office for a PSA test, in much the same way patients at risk of heart disease are told about the benefits of statin drugs.

When the PCPT trial results were announced in 2003, it was unclear whether finasteride produced biological changes that could lead to more high-grade cancers. Researchers in the follow-up study analyzed tissue from biopsies and in men in the finasteride and placebo groups to compare hormonal levels and disease extent. They compared prostate size at the time of biopsy in the two groups. They also examined tumor grade and extent in men in the study who went on to have their prostates removed.

They found no significant differences in degenerative hormone changes when they examined high-grade tumor biopsies in men in both groups. However, the men taking finasteride had smaller prostates. Their biopsies correctly identified a higher proportion of high-grade tumors found later when their prostates were removed, compared to men in the placebo group.

In the study, the researchers conclude that finasteride may have contributed to the increased rate of high-grade cancers detected in the PCPT by making the prostate smaller, helping the biopsy find the cancer. They did not find evidence that the drug caused changes in tumor composition that might contribute to aggressive cancer, though they don’t entirely rule out the possibility that finasteride may have led to high-grade prostate cancer in some men in the study.

“The results suggest that high-grade cancer was detected earlier and was less extensive in the finasteride group than in the placebo group,” the researchers write.

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The Southwest Oncology Group (http://swog.org) is one of the largest cancer clinical trials cooperative groups in the United States. Funded by research grants from the National Cancer Institute, part of the National Institutes of Health, the group conducts clinical trials to prevent and treat cancer and to improve the quality of life for cancer survivors. The group's network of more than 5,000 physician-researchers practice at nearly 550 institutions, including 16 National Cancer Institute-designated cancer centers. Headquartered in Ann Arbor, Mich. (734-998-7130), the group has an operations office in San Antonio, Texas and a statistical center in Seattle, Wash.

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