

New data show benefit of finasteride in preventing prostate cancer

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A comprehensive re-evaluation of the largest prostate cancer prevention study ever completed produced new findings suggesting that men and their doctors should consider a more aggressive approach that includes finasteride to prevent the development of prostate cancer.

A pathologic analysis of that same study sheds light on the significance of the cancers found in that study. Additionally, this study highlights the role of prostate specific antigen (PSA) scores in treatment decision-making. Researchers found that even those men who have a low PSA screening value can have cancer that is difficult to cure.

The two studies will be published online in advanced of the June 2008 issue of *Cancer Prevention Research*, a journal of the American Association for Cancer Research.

The original study, the Prostate Cancer Prevention Trial (PCPT), had randomized 18,822 men to receive either a placebo or an agent known as finasteride, currently approved to control prostate growth, for seven years. Results showed that while finasteride reduced prostate cancer risk by 25 percent, it appeared to increase development of more aggressive prostate cancer in some men. Because of this finding and concerns that tumors detected had low PSA values and might be of little risk to patients, since the study's original publication in 2003, few doctors have recommended finasteride for prostate cancer prevention.

From a new analysis of PCPT data using advanced statistical modeling

techniques and a complete assessment of prostate tissue biopsies, they concluded that these concerns are now resolved: finasteride actually reduced the risk of developing prostate cancer more than researchers had originally thought, did not increase development of more aggressive cancers, and the majority of tumors prevented were those that could spread and cause death.

These new findings suggest that men should take an “individualized” approach to prostate cancer prevention, said Ian M. Thompson, M.D., Chair of the Department of Urology at the University of Texas Health Sciences Center at San Antonio, who is senior author on both studies, and was also lead author for the Southwest Oncology Group (SWOG) on the original PCPT results paper, which was published in July 2003.

“Because we now know that men with even low PSAs can develop prostate tumors, if a man is worried about his risk, regardless of PSA score, he can take an agent that is now proven to be effective in lowering that risk,” Thompson said.

Researchers looked at whether finasteride actually increased aggressive cancers in some men, and by studying biopsies and prostate gland tissue that had been removed, concluding that it did not. “Finasteride actually shrank the prostate gland, so it appeared in initial studies that more cancer was being found in biopsies of men who took the drug,” said Mary Redman, Ph.D., a biostatistician at the Fred Hutchinson Cancer Research Center.

“What that means is that the cancer took up more prostate tissue in men who were treated, and that is why it was easier to find in a biopsy. Cancer was probably missed more often in biopsies of men on a placebo drug because the prostate gland itself was larger,” Redman said.

Redman found that in addition to a 25 to 30 percent reduction in prostate

cancer development overall in men taking finasteride, there was no evidence that the drug increased the rate of aggressive tumors and likely decreased their rate by 27 percent.

“We think men should not be concerned about finasteride increasing their risk of these aggressive tumors” she said.

The second study examined whether the cancers detected in the men in the trial who had a low PSA level had clinically significant disease. With about 75 percent of the tumors detected on the study were classified as those which could potentially take a man’s life, researchers concluded that there is no clear-cut PSA threshold that can be considered normal.

All patients in PCPT were to have a biopsy of their prostate gland at some point during the seven-year trial, so investigators evaluated characteristics of the biopsy in relation to each man’s PSA score. Current practice is to consider a PSA score of below four as normal and above four as abnormal.

What they found, according to lead author Scott Lucia, M.D., a pathologist at the University of Colorado, Denver, was that while a large majority of the participants diagnosed with prostate cancer had a PSA that was considered normal, 72 percent of all tumors diagnosed from biopsies in both treated and untreated men were considered significant. In short, the finding of significant disease couldn’t be predicted by the PSA score, he said. Most patients in the study who had a PSA score of four or less and then had prostate cancer diagnosed by a routine biopsy were found to have significant prostate cancer, while some men who had a high PSA were found to have insignificant cancer.

That doesn’t mean that the researchers support reducing the level by which PSA scoring should trigger therapeutic intervention, Lucia said. “Over 90 percent of men in the country diagnosed with prostate cancer

opt for treatment, yet we also found that even at higher PSA levels, men are being treated for tumors that would not have threatened their health,” he said. “This is the dilemma of PSA screening. While lower cut-off levels, those below four, increase risk of detection of insignificant disease, cure is more likely; conversely, more significant disease is detected with higher levels but at a greater risk of incurable disease.”

It does mean that men need to speak with their physicians about their PSA, when they should be biopsied, and about potential use of finasteride, which can reduce their risk, so that they will make a decision that is right for them, researchers say. For example, Lucia says, a man whose family members have been diagnosed with the disease may decide to have a biopsy even though his PSA is below four. If cancer is found then may opt to undergo treatment; if cancer is not found, he may choose to use finasteride to prevent the cancer from developing. Another man may decide to put off a biopsy, regardless of PSA score, if he is worried about side effects of treatment.

“These are not easy decisions, especially when we know now that we cannot rely on what the PSA looks like it is telling us,” Lucia said.

Emphasizing the importance of prevention, “if given the option of having my prostate cancer found early, getting it treated and then getting over the side effects of treatment or never getting cancer in the first place, I’d choose prevention any day,” said Thompson.

Source: American Association for Cancer Research

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