Commonly used drug for enlarged prostate slows growth of early-stage prostate cancer

January 23 2012

Dutasteride, a drug that is commonly used to treat enlargement of the prostate, might also slow the growth of early-stage prostate cancer and reduce the need for potentially debilitating treatments that carry risks of impotence and incontinence, according to an article published Online First in the *Lancet*.

"Our trial is the first study to show the benefits of use of a 5α-reductase inhibitor to reduce the need for aggressive treatment in men undergoing active surveillance for low-risk prostate cancer…delaying their time to pathological progression and initiation of primary therapy", explains Neil Fleshner from Princess Margaret Hospital, Toronto, Canada, lead author of the study.

As many as one in five men in the USA will be diagnosed with prostate cancer, but most will have low-risk (low-volume, low-grade) disease. For these men, active surveillance (conservative management) can be appropriate, and involves forgoing immediate treatment in favour of regular assessment and biopsies to monitor the disease.

Dutasteride is a 5α-reductase inhibitor approved for the treatment of benign prostatic hyperplasia, a noncancerous enlargement of the prostate. It works by blocking the conversion of testosterone to dihydrotestosterone (the male sex hormone implicated in the development of prostate cancer) and has been shown to reduce the volume of some prostate cancers.

In the Reduction by Dutasteride of Clinical Progression Events in Expectant Management (REDEEM) study, 302 men aged 48 to 82 years old with low-risk localised prostate cancer and undergoing active surveillance were randomly assigned to once daily dutasteride (0•5 mg) or placebo for 3 years. Participants were given biopsies at 18 months and 3 years to measure time to disease progression, and anxiety related to the disease was assessed using a questionnaire.

Overall, findings showed that treatment with dutasteride significantly delayed prostate cancer progression compared with placebo—38% of the men receiving dutasteride experienced disease progression compared with 48% given placebo.

Additionally, men treated with dutasteride were less likely to have cancer detected in their final biopsy (36% [50 men] vs 23% [31 men] with no cancer detected), and reported significantly lower cancer-related anxiety throughout the study compared with those given placebo.

Adverse events were similar between the two groups. More men in the dutasteride group experienced drug-related side effects compared with those given placebo, consisting mainly of adverse sexual events or breast enlargement or tenderness (24% vs 15%). There were no prostate cancer-related deaths and no instances of disease spread.

In an accompanying Comment, Chris Parker from the Royal Marsden National Health Service Foundation Trust, Sutton, UK cautions: "These data are consistent with the hypothesis that dutasteride reduces the volume of low-grade prostate cancers but has no effect, or even an adverse effect, on the progression of high-grade disease. Thus, although reducing overall prostate cancer detection, dutasteride could plausibly have no effect (or possibly a deleterious one) on prostate cancer mortality."

The authors conclude: "The benefit of dutasteride is to reduce the amount of low-grade cancer, not to reduce the risk of being diagnosed with higher-grade cancer. This reduction leads to fewer men with biopsy-detectable prostate cancer, and therefore fewer treatment interventions. Dutasteride…provides a treatment option for men with low-risk, localised disease."

More information: Paper online at www.thelancet.com/journals/lan… (11)61619-X/abstract

Provided by Lancet