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Effect of Dutasteride on the Risk of Prostate Cancer

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ABSTRACT

Background We conducted a study to determine whether dutasteride reduces the risk of incident prostate cancer, as detected on biopsy, among men who are at increased risk for the disease.

Methods In this 4-year, multicenter, randomized, double-blind, placebo-controlled, parallel-group study, we compared dutasteride, at a dose of 0.5 mg daily, with placebo. Men were eligible for inclusion in the study if they were 50 to 75 years of age, had a prostate-specific antigen (PSA) level of 2.5 to 10.0 ng per milliliter, and had had one negative prostate biopsy (6 to 12 cores) within 6 months before enrollment. Subjects underwent a 10-core transrectal ultrasound-guided biopsy at 2 and 4 years.

Results Among 6729 men who underwent a biopsy or prostate surgery, cancer was detected in 659 of the 3305 men in the dutasteride group, as compared with 858 of the 3424 men in the placebo group, representing a relative risk reduction with dutasteride of 22.8% (95% confidence interval, 15.2 to 29.8) over the 4-year study period ($P < 0.001$). Overall, in years 1 through 4, among the 6706 men who underwent a needle biopsy, there were 220 tumors with a Gleason score of 7 to 10 among 3299 men in the dutasteride group and 233 among 3407 men in the placebo group ($P = 0.81$). During years 3 and 4, there were 12 tumors with a Gleason score of 8 to 10 in the dutasteride group, as compared with only 1 in the placebo group ($P = 0.003$). Dutasteride therapy, as compared with placebo, resulted in a reduction in the rate of acute urinary retention (1.6% vs. 6.7%, a 77.3% relative reduction). The incidence of adverse events was similar to that in studies of dutasteride therapy for benign prostatic hyperplasia, except that in our study, as compared with previous studies, the relative incidence of the composite category of cardiac failure was higher in the dutasteride group than in the placebo group (0.7% [30 men] vs. 0.4% [16 men], $P = 0.03$).

Conclusions Over the course of the 4-year study period, dutasteride reduced the risk of incident prostate cancer detected on biopsy and improved the outcomes related to benign prostatic hyperplasia. (ClinicalTrials.gov number, NCT00056407 [[ClinicalTrials.gov](#)].)

Source Information

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