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Effect of Finasteride on the Prostate Gland: The Question Revisited

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In the March/April issue of the *Forum*, a review article of a study on the possible adverse effects of finasteride was published. I have heard from both practitioners and representatives from Merck that some physicians have drastically changed their prescribing habits of Propecia®, including discontinuing prescribing the medication altogether. This is somewhat surprising, although I had expected that there would be a change in the information given to the patients or a change in the requirement for baseline PSA values; I did not expect to see a complete discontinuation of a medication that seems to be a valuable adjunct to our armamentarium of treatments for hair loss.

Briefly stated, a small study by Cote, et al.,[1] showed that in a select group of male patients, over the age of 50, with PSA greater than 4ng/ml, and showing high-grade PIN lesions on a pre-study biopsy, showed that there seemed to be a statistically higher incidence in the formation of prostate cancer lesions in the group of patients on finasteride (5mg/day) as compared to a control group. The study had some inherent problems, which included a small sample size and a pre-selection bias (elevated PSA). It should also be noted that the dose was five times that used in Propecia®. The authors of this study also stated that the biopsies performed could introduce a bias. That is, the initial random sextant biopsies of the prostate gland may not have detected an occult carcinoma in both the treatment and observation groups. After being treated with finasteride, the resulting prostate gland volume is reduced by approximately 19%, thereby increasing the chance of finding a cancerous lesion in the treatment group. In addition to this, the group of untreated patients had an extremely low rate of prostate cancer (.04 %) as compared to approximately 10%–13% shown in other studies for patients with elevated (>4ng/ml) PSA levels. This would skew the statistical analysis when comparing the treatment group to the control group. That is, if the control group had a significantly low percentage of patients with cancer as compared to the population norm, and the treatment group had the normal rate of cancer occurrences, the analysis would show a significant statistical difference, and it would appear as though the treatment group had a significant elevation in the rate of occurrence over the control group.

In a study by Andriole, et al.,[2] entitled "Treatment with Finasteride Preserves Usefulness of Prostate Specific Antigen in the Detection of Prostate Cancer: Results of a Randomized, Double-Blind, Placebo-Controlled Clinical Trial," the detection rate of prostate carcinomas was

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