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## Finasteride and prostate cancer

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5-alpha reductase inhibitors (5ARIs) have been effective in the treatment of benign prostatic hyperplasia (BPH) and androgenetic alopecia (AGA). Proscar® (finasteride 5mg) was approved for the treatment of symptomatic BPH in 1992, and Propecia® (finasteride 1mg) for AGA in 1997. Since FDA approval, 20.5 million and 6.7 million patient years of exposure using Proscar and Propecia, respectively, are recorded with a low adverse event profile. Avodart® (dutasteride 0.5mg) was approved in 2003, with 5.5 million patient years of exposure and similar adverse events profiles. The efficacy of 5ARIs in the prevention of prostate cancer remains controversial, with proponents emphasizing the reduction in low-grade prostate cancer, while others share concerns about the increased incidence of high-grade cancer. Recently, the Food and Drug Administration (FDA) rejected Merck and Co.'s request for a product label change reflecting that Proscar was safe and effective for the reduction in the risk of prostate cancer in healthy men over 55, and GlaxoSmithKline's (GSK) proposed indication for Avodart in the reduction of prostate cancer in men at risk of developing prostate cancer. It is important for hair transplant surgeons to understand this issue to better advise our patients and other physicians.

### Prostate Cancer Facts

Prostate cancer is the second leading cause of cancer death, behind lung cancer, in men in the United States. The American Cancer Society is projecting 240,000 new cases of prostate cancer diagnosis and over 33,020 prostate cancer-specific deaths in 2011. About one-sixth of men in the United States will be diagnosed during their lifetime, with Gleason grade 6 as the most commonly diagnosed.

### Prognostic Factors

Prostate cancer is detected by PSA (prostatic specific antigen) and DRE (digital rectal examination), but diagnosed by needle biopsy (NBP). The original Gleason system graded the histological patterns of the two largest cancerous areas, with grades from 1-5 based on histologic differentiation patterns. The current or modified Gleason system uses the tertiary pattern instead of the secondary most predominant pattern. (See reference below for further discussion.) Gleason 6 or less is low grade or well differentiated, and 8-10 is high grade or poorly differentiated. If untreated, 20% of Gleason 6 patients will die from their disease and if treated by definitive prostate surgery, 10-15% will recur. Prostate cancer tends to be slow growing, and many men will die with their disease and not from it. Routine PSA screening remains somewhat controversial because reduction in death rates from early detection has not been consistently shown. Because of the potential morbidity with radical prostate surgery or definitive radiation therapy, some advocate "watchful waiting," or surveillance, with low Gleason grades. However, 90% of men with Gleason grade 6 will seek definitive therapy.

### Prostate Cancer Screening

The American Cancer Society and the American Urological Association recommend the following screening ages:

- Age 50 for men who are at average risk of prostate cancer and are expected to live at least 10 more years.
- Age 45 for men at high risk of developing prostate cancer: African American men and men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer younger than age 65.
- Age 40 for men at even higher risk (those with several first-degree relatives who had prostate cancer at an early age).
- Regardless of age, yearly screening for PSA level if 2.5ng/ml or higher, and every 2 years for less than 2.5ng/ml.

### Chemoprevention Studies

The two landmark studies evaluating 5ARIs in prostate cancer were the Prostate Cancer Prevention Trial (PCPT) using finasteride 5mg, and the Reduction by Dutasteride of Prostate Cancer (REDUCE) using dutasteride

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