

SOUTHWESTERN NEWS

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FOUR-YEAR STUDY SHOWS LONG-TERM EFFECTIVENESS OF PROSCAR IN TREATING ENLARGED PROSTATES

DALLAS – Feb. 26, 1998 – Results of a four-year study involving 3,040 men have shown that those taking the drug finasteride (Proscar) for enlarged prostate glands reduced their risk of needing surgery or experiencing acute urinary retention by more than half.

Researchers from 95 medical centers reported their results in today's *New England Journal of Medicine*. UT Southwestern Medical Center at Dallas' chairman of urology, Dr. John McConnell, headed the Proscar Long-Term Efficacy and Safety Study (PLESS), the longest trial of drug therapy for men with benign prostatic hyperplasia (BPH).

The study participants either received finasteride or a placebo. Those taking finasteride had a 55 percent reduced risk of needing prostate surgery and 57 percent less risk of developing acute urinary retention, a painful blockage of the urinary tract requiring catheterization.

"This clinical trial demonstrates that finasteride clearly alters the progression of BPH," said McConnell, holder of the E.E. Fogelson and Greer Garson Fogelson Distinguished Chair in Urology. "The most significant finding of this study is the dramatic decrease in the number of men requiring prostate surgery or developing urinary retention."

"Another important outcome of this research is that the beneficial effects of this drug continued over the entire four years of this study," he said. Patients treated with the drug showed a 20 percent reduction in the size of their prostates. Prostates of those taking the placebo continued to increase in size.

The prostate wraps around the urethra at the point where it leaves the bladder. The gland

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produces some of the seminal fluid that carries sperm.

As men age, their prostates enlarge and squeeze the urethra; prompting symptoms that include poor urinary flow, frequent urination, urgency to urinate and nighttime urination. The condition can progress to acute urinary retention or require surgery to prevent further complications such as urinary-tract infections, bleeding and bladder stones. Almost 60 percent of men over the age of 50 experience problems due to prostate enlargement.

Other authors of the study included Dr. Claus Roehrborn, UT Southwestern associate professor of urology; Dr. Reginald Bruskewitz from the University of Wisconsin Center for Health Sciences; Drs. Patrick Walsh and H. Logan Holtgrewe from the Brady Urological Institute of Johns Hopkins University Medical School; Dr. Gerald Andriole from Washington University School of Medicine; Dr. Michael Lieber from the Mayo Clinic; Dr. Peter Albertsen from the University of Connecticut Health Center; Dr. J. Curtis Nickel from Queen's University Faculty of Medicine in Ontario; and Drs. Daniel Wang, Alice Taylor and Joanne Waldstreicher from Merck Research Laboratories.

Support for the study was provided by Merck, Inc., which markets the drug under the name Proscar.

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Benign Prostatic Hyperplasia or Enlarged Prostate

Benign prostatic hyperplasia (BPH) is a disease of the small, walnut-sized prostate gland at the base of a man's bladder. About 60 percent of men over the age of 50 have had symptoms indicating their prostates are enlarged. Almost all men have experienced signs of BPH by the time they are in their 80s.

The prostate gland surrounds the urethra, the tube that carries urine from the bladder out of the body. As men age, the prostate gradually enlarges, compressing the urethra and interfering with normal urine flow. Men then experience symptoms that can be life altering and embarrassing: waking up repeatedly at night to urinate, staining underwear, frequently needing to urinate, or an irregular flow. BPH is a progressive disease that in severe cases can lead to urinary retention, bladder infections, bladder stones and kidney failure. It can progress to the stage where emergency catheterization or surgery is necessary.

A family physician or urologist can diagnose BPH by taking a medical history, checking the symptoms, and doing a digital rectal examination, a urine test, a serum prostate specific antigen (PSA) test and a blood test to measure kidney function.

There are several ways to treat enlarged prostates. For men with mild symptoms, regular checkups and assessment of symptoms with no active treatment is recommended. For those with severe symptoms, surgery may be recommended. Several methods of treatment reduce the size of the prostate with open surgery or with less-invasive techniques that use microwaves or heat. A third treatment method is drug therapy, using an alpha blocker or an inhibitor of the enzyme, 5-alpha reductase. Alpha blockers relax the prostatic smooth-muscle tissue to relieve pressure on the urethra. The inhibitor, finasteride, blocks the action of 5-alpha reductase so that testosterone in the prostate is not converted to dihydrotestosterone, the chemical that stimulates growth of the prostate.

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