

# SOUTHWESTERN NEWS

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## ALPHA BLOCKER GETS HIGH MARKS AS BPH TREATMENT

LAS VEGAS — April 24, 1995 — A drug that helps relax the muscles in the bladder outlet and prostate gland has proved twice as effective as a placebo in reducing the discomforts of benign prostate disease, even in men with severe symptoms, a Dallas researcher reported today at the American Urological Association's (AUA) annual meeting.

Dr. Claus G. Roehrborn, assistant professor of urology at UT Southwestern Medical Center at Dallas, reported on the Hytrin Community Assessment Trial (HYCAT), a one-year clinical study of terazosin. Manufactured by Abbott Laboratories and sold under the brand name Hytrin, it is one of a class of drugs known as alpha blockers approved by the U.S. Food and Drug Administration for treatment of benign prostatic hyperplasia (BPH).

The effects of terazosin were studied in 2,084 men at 15 university medical centers and 143 community clinics and doctor's offices nationwide. The largest and longest randomized, placebo-controlled, double-blinded study of an alpha blocker ever conducted, it also was the first to be conducted primarily in a community-practice setting.

"For the first time we have a trial with results that mimic usual care, results that can be translated directly into urologists' offices everywhere," said Roehrborn.

"The message is clear: terazosin over one year is effective — twice as effective as a placebo — in improving the symptom severity score, even in the most severely symptomatic patients," he said.

BPH symptoms include frequent and difficult urination, a weak urine flow, waking up several times a night to urinate and a feeling after urinating that the bladder has not emptied completely. The AUA has developed a symptom-severity index on a scale of 0 to 35. A score of 0-7 is considered mild; 8-19, moderate; and 20-35, severe. Although terazosin is described as an

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effective treatment for men with moderate to severe symptoms of BPH in treatment guidelines issued by the U.S. Agency for Health Care Policy and Research last year, many practicing urologists believe that alpha blockers are effective only in treating mild to moderate symptoms, Roehrborn said. "Now we can see that this simply is not true."

Alpha-blocker therapy also proved cost-effective, he said. The medical-care costs during the study year for men receiving terazosin were less than the costs of medical care for the placebo group, despite the cost of purchasing the drugs. Most of the additional costs in the placebo group came from hospital admissions for cardiovascular problems.

During the one-year study, 25 percent of the men taking a placebo withdrew, saying that the drug was not helping and their symptoms were getting worse. Among the men receiving terazosin, only 11 percent withdrew because they weren't improving, Roehrborn said.

Another 16 percent of the men receiving terazosin withdrew during the year because of side effects. The most common side effects of alpha blockers are dizziness and weakness. Predictably, fewer placebo patients — 11 percent — withdrew citing side effects, the researcher said.

The clinical trial was funded by Abbott Laboratories and supervised by Roehrborn; Dr. Joseph Oesterling, University of Michigan; Dr. Keith Lloyd, Birmingham, Ala.; Dr. John Lynch, Washington, D.C.; Dr. Robert J. Padley, North Chicago, Ill.; and the HYCAT Investigator Group.

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