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**Study Finds Observation as Effective as Surgery in Early Prostate Cancer**

***Men Treated Surgically Have No Greater Lifespan in 15-Year Follow-Up***

WASHINGTON -- A major federal study led by the Department of Veterans Affairs found no difference in survival between men with early-stage prostate cancer who had their prostate surgically removed and those who were simply watched by their doctors, with treatment only as needed to address symptoms if they occurred.

“The study results have significant implications for a great number of Veterans in our care,” said Secretary of Veterans Affairs Eric K. Shinseki. “This study is a prime example of how VA’s research program is advancing medical knowledge in areas that are top priorities for Veterans.”

The findings appeared in the July 19 issue of the *New England Journal of Medicine.*

“Our data show that observation provides equivalent length of life, with no difference in death from prostate cancer, and avoids the harms of early surgical treatment,” said lead author Dr. Timothy Wilt. Wilt is with the Center for Chronic Disease Outcomes Research at the Minneapolis VA Medical Center, and the University of Minnesota.

The randomized trial involved 731 men and took place at 44 VA sites and eight academic medical centers nationwide. Eligible trial participants voluntarily agreed beforehand that to take part in the study they would be randomly assigned to one treatment or the other.

Known as the Prostate Cancer Intervention Versus Observation Trial, or PIVOT, the study was conducted and funded by VA’s Cooperative Studies Program, with additional funding from the National Cancer Institute and the Agency for Healthcare Research and Quality.

The first trial group had a radical prostatectomy—surgical removal of the walnut-sized prostate. Surgery is generally performed in the belief it can lower the risk of prostate cancer spreading and causing death. Evidence had been lacking as to the treatment’s effectiveness, especially for men whose cancer was initially detected only on the basis of a blood test—the prostate specific antigen (PSA) test. In most cases, these tumors are not large enough to be felt during a doctor’s exam and do not cause any symptoms.

The second trial group was the “observation group.” In this approach, physicians generally do not provide immediate surgical or radiation therapy. Rather, they carefully follow men and provide treatments aimed at relieving symptoms, such as painful or difficult urination, if and when the cancer progresses and causes bothersome health problems.

The trial followed patients between eight and 15 years.

When Wilt and colleagues analyzed the results, they found no difference in death rates between the two groups, either from any cause whatsoever or specifically from prostate cancer.

In terms of quality of life for men in the study, the surgery group experienced nearly double the rate of erectile dysfunction—81 percent versus 44 percent—and roughly three times the rate of urinary incontinence—17 percent versus 6 percent. Bowel dysfunction was similar between the groups, 12 percent versus 11 percent.

Dr. Robert A. Petzel, Under Secretary for Health, said the trial “provides crucial information that will help physicians and patients make informed decisions on how best to treat prostate cancer, which affects so many Veterans who rely on VA health care.”

Dr. Joel Kupersmith, VA’s Chief Research and Development Officer, added: “This trial, the largest ever comparing these two treatments, provides definitive evidence on a subject that affects millions of Veterans and all men above a certain age.”

While PIVOT found no difference in overall mortality or prostate cancer deaths between the two groups for men who had cancers with a PSA value of 10 or less, the authors say there may be a survival benefit to surgery for men with PSA scores above 10, or other clinical results indicating more aggressive, higher-risk tumors.

Only about one in five men in PIVOT had tumors classified as high-risk. Wilt said this proportion is representative of U.S. men with an early-stage prostate cancer diagnosis based on PSA testing and follow-up biopsy. Prostate cancer is usually slow-growing, and most men with PSA-detected prostate cancer do not die from the disease or develop health problems related to it, even if it is not treated with surgery or radiation.

For more information on the Cooperative Studies Program and VA research overall, visit [*www.research.va.gov*](http://www.research.va.gov)*.*

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