

Many men with prostate cancer can avoid early surgery

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(Medical Xpress) -- New research suggests that many men with prostate cancer do not need immediate treatment, especially if they have low PSA scores or low-risk tumors that are unlikely to grow and spread.

The multi-center study, published July 18 in the <u>New England Journal of Medicine</u>, compared <u>prostate cancer surgery</u> soon after diagnosis to observation in men with early-stage <u>prostate tumors</u> detected by PSA screening. Overall, most men did not benefit from <u>surgery</u> – it did not reduce the likelihood they would die from <u>prostate cancer</u> or other causes.

But the findings indicate that surgery did reduce mortality in two groups of men – those with relatively high PSA levels (greater than 10 ng/mL) and potentially those with higher-risk, more aggressive tumors.

"For most men with low-risk prostate cancer, there is no evidence they need immediate treatment," says study co-author Gerald Andriole, MD, chief of urologic surgery at the Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine in St. Louis. "But the data suggest that men with high PSA levels and those with more aggressive tumors likely benefit from early surgery, and these men should undergo treatment because their tumors are more likely to be lethal if left alone."

The study involved 731 men, with an average age of 67 and tumors confined to the prostate. The men were randomly assigned to surgery or



observation, meaning they were not actively treated but received therapy later, if needed, to manage pain and other cancer symptoms.

After up to 12 years of follow up, nearly half of the men in the study had died: 47 percent of men who had surgery to remove a prostate tumor and 50 percent of men assigned to the observation group, a difference that is not statistically significant.

But surgery reduced prostate cancer deaths among men with PSA levels greater than 10 ng/mL, an indicator of larger, more aggressive tumors. Of these men, 5.6 percent in the surgery group died, compared with 12.8 percent of those in the observation group.

Fewer deaths from prostate cancer also occurred among men treated with surgery who had high-risk prostate cancer, classified as a PSA level above 20 ng/mL and a score of 8-10 on the Gleason scale, a measure of tumor aggressiveness. In this subgroup, 9.1 percent of men who had surgery died, compared with 17.5 percent for observation.

Throughout the study, deaths from prostate cancer occurred infrequently. Among men treated with surgery, 21 (5.8 percent) died of prostate cancer or treatment, compared with 31 (8.4 percent) in the observation group — a finding that is not statistically significant.

Less than 10 percent of men in the study were in their 40s and 50s, too few to determine whether surgery would lower their mortality. But Andriole says if more of these men had been included in the study and followed for many more years, the data may have shown whether they benefitted from early treatment with surgery.

The study's findings support the results of the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial, which to date has shown that most cancers detected by repeated PSA screening are low risk and that annual prostate cancer screening does not reduce mortality. Andriole is



leading that study and is chairman of the PLCO's prostate cancer committee.

"The findings of these two studies should be reassuring to men with low-risk prostate cancer," says Andriole, who also is the Robert K. Royce Distinguished Professor of Urologic Surgery. "PSA screening commonly results in the discovery of cancers that are generally not a threat to life. This 'over diagnosis' of non-lethal cancers is concerning in and of itself and becomes especially problematic if men with such low-risk cancers are 'over treated' since they are unlikely to benefit from the treatment and may experience side effects like incontinence and impotence."

The results of both the PLCO study and the current study, called Prostate cancer Intervention Versus Observation Trial (PIVOT), were among those considered by the U.S. Preventative Services Task Force, which recently gave PSA screening a Grade D recommendation and generally discouraged its use.

The PIVOT study, led by Timothy J. Wilt, MD, at the Minneapolis Veterans Administration Health Care System, enrolled patients beginning in 1994, at the dawn of the PSA screening era. At that time, the blood test was more likely to find larger, more aggressive tumors because most men were not routinely getting annual PSA screening tests.

Indeed, only 40 percent of men in the PIVOT study had low-risk prostate tumors, defined as a PSA level of less than 10 ng/mL or a Gleason score of less than 7. In more recent years, up to two-thirds of prostate cancers detected by PSA tests are considered low-risk and not likely to cause harm, yet most of these men have receive early treatment with surgery or radiation therapy.

Instead of treatment early on, Andriole says many men with low-risk prostate cancer detected by <u>PSA screening</u> initially can be managed with



"active surveillance." This involves periodic PSA tests and biopsies to monitor tumor growth.

"Active surveillance is apt to be better than observation or immediate treatment in most low-risk patients," says Andriole, who follows several hundred patients at Washington University who have opted for close monitoring rather than treatment soon after their <u>diagnosis</u>. "We watch the PSA very closely and biopsy <u>men</u> periodically, so if a tumor starts growing or becomes more aggressive, we can still successfully treat it."

Thomas Wheeler, MD, at the Baylor College of Medicine in Houston, is the study's senior author.

More information: Wilt TJ, Andriole GA, Culkin D, Wheeler T. Radical prostatectomy versus observation for men with clinically localized prostate cancer: a randomized trial. *New England Journal of Medicine*. July 18, 2012.

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