

For prostate cancer, monitoring is an option, but higher metastasis rate is a risk

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Among otherwise healthy younger men with an early diagnosis of prostate cancer, foregoing aggressive treatment in favor of active monitoring spares patients an abrupt disruption of sexual and urinary function, new research shows.

But a long-awaited clinical trial has found that for men who watch and wait instead of treating their [prostate cancer](#) immediately, prostate cancer is twice as likely to spread beyond the affected gland in the 10 years following diagnosis. Over six years following their entry into the trial, men who proceeded directly to radiation treatment with hormones or surgical removal of the [prostate gland](#) suffered early blows to their quality of life compared to men assigned to the wait-and-see group. But those on active monitoring still reported a gradual decline in their sexual and urinary function.

At the 10-year mark, the findings of the Protec Trial (short for Prostate Testing for Cancer and Treatment) failed to find clear evidence that participants who were assigned to get active surveillance were more likely to die of cancer than were those who got early, aggressive treatment. That's a reassuring finding at a time when growing numbers of men diagnosed with prostate cancer are opting not to proceed quickly to treatment.

But the investigators, who reported their findings Wednesday in the *New England Journal of Medicine*, did discern a weak but troubling trend among men over 65 who got monitoring over treatment: At the 10-year

mark, they were slightly more likely to have died of prostate cancer than were men of the same age and stage of cancer at diagnosis who underwent treatment instead.

That finding fell a bit short of statistical significance - the point at which researchers are confident that an observed trend could not be a random fluke in their data.

But if that trend becomes more pronounced with time, wrote a prostate cancer specialist commenting in the New England Journal, it could change advice given to older prostate cancer patients. Rather than following the national trend in the direction of deferring treatment, wrote Dr. Anthony V. D'Amico of the Dana-Farber Cancer Institute in Boston, otherwise healthy prostate cancer patients over 65 might better be advised to opt for aggressive treatment as soon as they are diagnosed.

The new research comes against the backdrop of debate and uncertainty over how best to treat men whose prostate-specific antigen, or PSA, test indicates relatively early cancer. Slightly more than three-quarters of the men participating in the Protect Trial had such "PSA-detected disease," which specialists now consider at low or intermediate risk for aggressive progression.

Because many such men could live decades without becoming seriously ill, physicians are increasingly recommending active surveillance for them, taking action only if their PSA numbers rise markedly in a single year. And men are choosing that option in greater numbers, given the prospect of erectile dysfunction, low energy and libido and changes in urinary and bowel function that can come with [aggressive treatment](#).

Currently, about half of American men diagnosed with localized prostate cancer opt not to treat it.

"It's a really important public health question," said Dr. Christopher Saigal, vice chair of urology at the University of California, Los Angeles's Jonsson Comprehensive Cancer Center. Prostate cancer remains the most common cancer in men, and with so many men choosing to defer treatment, physicians needed evidence that the practice is safe, said Saigal.

In the new findings, death rates in all the groups were very low and scarcely distinguishable, "and that's great news," said Saigal.

In the "active monitoring" group in the Protect Trial, a man would be considered for treatment with radiation or surgical prostatectomy only if his PSA level rose by more than 50 percent in a given year. About half of the men in the Protect Trial, which was conducted in Great Britain, did end up getting one of the two treatments before the 10-year mark.

The Protect Trial findings made clear that, for men 50 to 69 years old who received a diagnosis of localized prostate cancer, the odds of dying of that cancer over the next 10 years were pretty slim: In a group of 2,264 trial participants, 169 died during the follow-up period of any cause. But only 17 died specifically of prostate cancer over a follow-up period of 10 years - a rate of less than 1 percent.

But 62 men, overall, saw their prostate cancer metastasize over the study's decade-long span, and the distribution of those men was clearly uneven: Men who were assigned to have their prostate gland surgically removed were least likely to see their prostate cancer spread to bones, viscera or lymph nodes. Those who were assigned to be treated with radiation and three to six months of male-hormone suppression were slightly more likely to develop metastases. Even though they were aggressively treated if PSA levels rose abruptly, the men assigned to have their cancer initially monitored were, as a group, more than twice as likely as the others to have it metastacize.

"This group could really help us by reporting in five more years" whether the three groups' death rates begin to show differences, said Dr. Saigal.

Vanderbilt University urology chairman Dr. David F. Penson underscored that, while the latest findings are reassuring, much remains to be answered about how to treat the most common cancer in [men](#).

"I don't think any of us expected this study to answer all our questions definitively and I don't think it did," said Penson, who serves on the PSA screening panel of the American Urological Association. "The key is to figure out who are the right patients to be treated" and who can safely forgo treatment, he said. "And this doesn't do that."

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