

Drug combination extends survival by more than a year in metastatic prostate cancer

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Men with newly diagnosed metastatic, hormone-sensitive prostate cancer lived more than a year longer when they received a chemotherapy drug as initial treatment instead of waiting for the disease to become resistant to hormone-blockers, report scientists from Dana-Farber Cancer Institute and the Eastern Co-operative Oncology Group.

The dramatic results in a multi-center phase III trial should change the way physicians have routinely treated such patients since the 1950s, they said.

"This is the first study to identify a strategy that prolongs survival in newly diagnosed, metastatic [prostate cancer](#)," said Christopher J. Sweeney, M.B.B.S, of Dana-Farber's Lank Center for Genitourinary Oncology. He presented the results of the trial Sunday, June 1, 2014 at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

"The benefit is substantial and warrants this being a new standard treatment for men who have high-extent disease and are fit for chemotherapy," added Sweeney, principal investigator of the E3805 National Cancer Institute-funded study.

"The prolongation in survival seen in the prostate cancer patients participating in Dr. Sweeney's study is very impressive, dramatically longer than the typical 2-6 month prolongation typically observed in successful studies of other metastatic adult solid tumors," said Bruce E. Johnson, MD, Dana-Farber's chief clinical research officer.

In current practice, men newly diagnosed with prostate cancer that has spread widely, and whose cancer depends on male hormones to grow, are started on hormone-blocking medications – androgen deprivation therapy (ADT). Most tumors eventually outgrow their need for hormones and the cancer progresses. Only then do patients begin chemotherapy.

The new trial tested Sweeney's hypothesis that immediately hitting the cancer with chemotherapy in addition to hormone treatment would impair the tumor cells' ability to repair damage, delaying the development of resistance.

The study enrolled 790 men newly diagnosed with metastatic disease; they were randomized to receive ADT alone or ADT with docetaxel (brand name Taxotere®) over 18 weeks. In the ADT-only group, 124 patients were given docetaxel when their cancer worsened. In the ADT-plus-docetaxel group, 45 patients whose disease progressed received additional docetaxel.

At a median follow-up of 29 months, 136 patients in the ADT-only group had died versus 101 in the group that received both drugs. This translated into a median overall survival of 57.6 months for men who received early chemotherapy compared with 44 months in the group given ADT as the only initial treatment – more than a year of additional life.

In the 520 patients who had high-extent disease (whose cancer had spread to major organs and/or the bones), treatment with ADT plus docetaxel had an even greater benefit: these men had a median overall survival of 49.2 months versus 32.2 in the ADT-only group – a difference of 17 months.

Earlier results of the trial were made public by the NCI in December 2013 because of the strong positive findings. Sweeney's presentation at ASCO covers updated and more detailed results.

Most of the striking survival benefit with early use of docetaxel was found in men with a high burden of [metastatic disease](#). Sweeney said more time is needed to assess the benefit of the drug combination in the men with lesser burdens of disease, as their median survival has not yet been reached.

The most serious side effects were neutropenic

fever and neuropathy; one patient died as a result of treatment.

The addition of docetaxel not only lengthened survival but delayed disease progression as measured by an increase in prostate-specific antigen (PSA), the appearance of new metastases, or worsening symptoms. The [men](#) receiving [docetaxel](#) had an average of 32.7 months before the cancer progressed by worsening scan results or symptoms, compared to 19.8 months for hormone therapy alone.

"This study shows that early chemotherapy increases the chances that certain patients with [metastatic prostate cancer](#) have a longer time without symptoms from [cancer](#), and also live longer," Sweeney said.

Provided by Dana-Farber Cancer Institute

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