

Evaluating drug regimens for high-risk prostate cancer

May 1 2018, by Anna Williams

The addition of a chemotherapy drug to adjuvant hormone therapy did not improve survival for patients with high-risk prostate cancer after surgery, according to the findings of a new clinical trial.

The study, published in the *Journal of Clinical Oncology*, was led by Maha Hussain, MD, deputy director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University and the Genevieve E. Teuton Professor of Medicine in the Division of Hematology and Oncology. The study was a National Cancer Institute/The Cancer Therapy Evaluation Program-funded intergroup trial.

Despite significant progress, [prostate cancer](#) remains the second leading cause of [cancer](#) death among American men. In order to improve survival, there has been significant interest in enhancing therapies for patients with cancer that is localized but still considered to be high-risk.

In the years prior to this study, a chemotherapy drug called mitoxantrone was approved by the FDA for the treatment of metastatic castration-resistant [prostate](#) cancer—an advanced form where the cancer has spread and no longer responds to hormone [therapy](#).

In the current study, the investigators hypothesized that adding mitoxantrone to adjuvant hormone therapy would improve overall survival in men with localized prostate cancer who had received a radical prostatectomy—first-line surgery to remove the entire prostate

gland—and also were at high risk of relapse.

The trial, which began in 1999, included close to 1,000 men with localized cancer who had undergone the surgery and had one or more high-risk factors. They were randomized to either receive two years of androgen-deprivation therapy (ADT) alone, or ADT with mitoxantrone plus prednisone (a steroid often administered in conjunction with chemotherapy).

After a median follow-up of 11.2 years, the investigators found that mitoxantrone did not improve overall survival for patients. Disease-free survival rates were also the same in both groups.

Furthermore, [mitoxantrone](#) was associated with a higher rate of leukemia, compared with ADT alone, and the chemotherapy group experienced twice the rate of deaths from other malignancies.

More information: Maha Hussain et al. Phase III Intergroup Trial of Adjuvant Androgen Deprivation With or Without Mitoxantrone Plus Prednisone in Patients With High-Risk Prostate Cancer After Radical Prostatectomy: SWOG S9921, *Journal of Clinical Oncology* (2018). [DOI: 10.1200/JCO.2017.76.4126](https://doi.org/10.1200/JCO.2017.76.4126)

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