

New study reassures on heart risks of prostate cancer treatment

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Hormone-blocking therapy for prostate cancer doesn't raise the risk of fatal heart attacks – as some recent studies had suggested – according to a new report from Dana-Farber/Brigham and Women's Cancer Center.

For men with high-risk prostate tumors, a combination of local treatment and drugs that block male hormones that feed prostate tumors can significantly lengthen survival. In the past few years, however, the U.S. Food and Drug Administration and some professional organizations have raised a caution flag about this treatment regimen, citing a few studies that linked androgen deprivation therapy (ADT) to a higher risk of heart attacks.

But those fears appear unwarranted – at least for men without a history of [heart disease](#) – according the Dana-Farber/Brigham study that is being published in the Dec. 7 issue of the *Journal of the American Medical Association*.

Led by Paul Nguyen, MD, and Toni Choueiri, MD, the scientists performed a meta-analysis of randomized studies involving 4,141 prostate cancer patients. The analysis found no difference in the rate of cardiovascular deaths in men receiving ADT compared with those who didn't. The study couldn't rule out that ADT might elevate the risk of fatal heart attacks in patients with a history of heart disease; the investigators said they plan to look more closely at that population.

"This message should be reassuring for the vast majority of patients

considering androgen deprivation therapy," said Nguyen, a radiation oncologist at Dana-Farber/Brigham. "If you need ADT for your prostate cancer, go ahead and have it. Hormones can save lives."

ADT is frequently used in combination with radiation therapy to treat men whose tumors have unfavorable characteristics or have spread beyond the gland. Side effects from this treatment approach can include weight gain, insulin resistance and imbalances in blood lipids like cholesterol – all of which are risk factors for cardiovascular disease. But whether ADT treatment actually is a risk factor for dying of cardiovascular disease has been controversial.

Concerns were raised in 2006, when researchers reported that ADT was associated with a 44 percent risk of diabetes, an 11 percent increase in heart attacks, and a 16 percent increase in sudden cardiac death. A more recent study found that men older than 65 years who received ADT suffered heart attacks sooner than those who had heart attacks but weren't on hormone-blocking drugs.

Other studies, however, did not find an elevated heart disease risk.

In 2010, the American Heart Association, the American Cancer Society and the American Urological Association issued a joint statement alerting physicians to the potential risk, but said the doctors should decide what therapies to recommend. That same year, the FDA called for labeling on hormone-blocking drugs warning of an increased risk of diabetes, [heart attack](#), sudden cardiac death, and stroke.

"In the past year, these types of warnings were turning public opinion against the therapy," said Nguyen.

Because the risk estimates had emerged from studies that weren't randomized, controlled trials, the researchers undertook a meta-analysis

of trials that met these standards and included data on adverse side effects, as well as the efficacy of ADT. The 4,174 patients enrolled in the eight randomized trials in the meta-analysis mostly had "locally advanced" [prostate cancer](#) that had spread beyond the prostate gland, but hadn't metastasized to other organs.

Nguyen and Choueiri found that cardiovascular deaths occurred in 11 percent of the patients who underwent ADT versus 11.2 percent in the control patients – an insignificant difference. ADT did prolong survival, as shown by the finding that all-cause mortality in the treated patients was 37.7 percent compared with 44.4 percent in the control group.

The researchers broke down the results for shorter versus longer duration of treatments, whether patients had undergone surgery or not, and older versus younger age. This further analysis did not uncover any differences in cardiovascular death risk.

The remaining question, said Choueiri, an oncologist at Dana-Farber/Brigham is whether androgen deprivation might increase risk in men with an established history of previous heart disease, but those data weren't available. "That's a subgroup of about 5 or 10 percent of the patients," he said, and merits further study.

"It's still prudent to be cautious with these patients, and have them be evaluated by a cardiologist before starting treatment," Choueiri said.

He added that the findings "don't exonerate ADT from the increased risks of diabetes, insulin resistance, and weight gain. We don't discount that, but there is benefit in ADT for [patients](#) with high-risk prostate cancers."

Provided by Dana-Farber Cancer Institute

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