Clinical trial: Adding EBRT to brachytherapy does not improve outcomes for men with intermediate-risk prostate cancer

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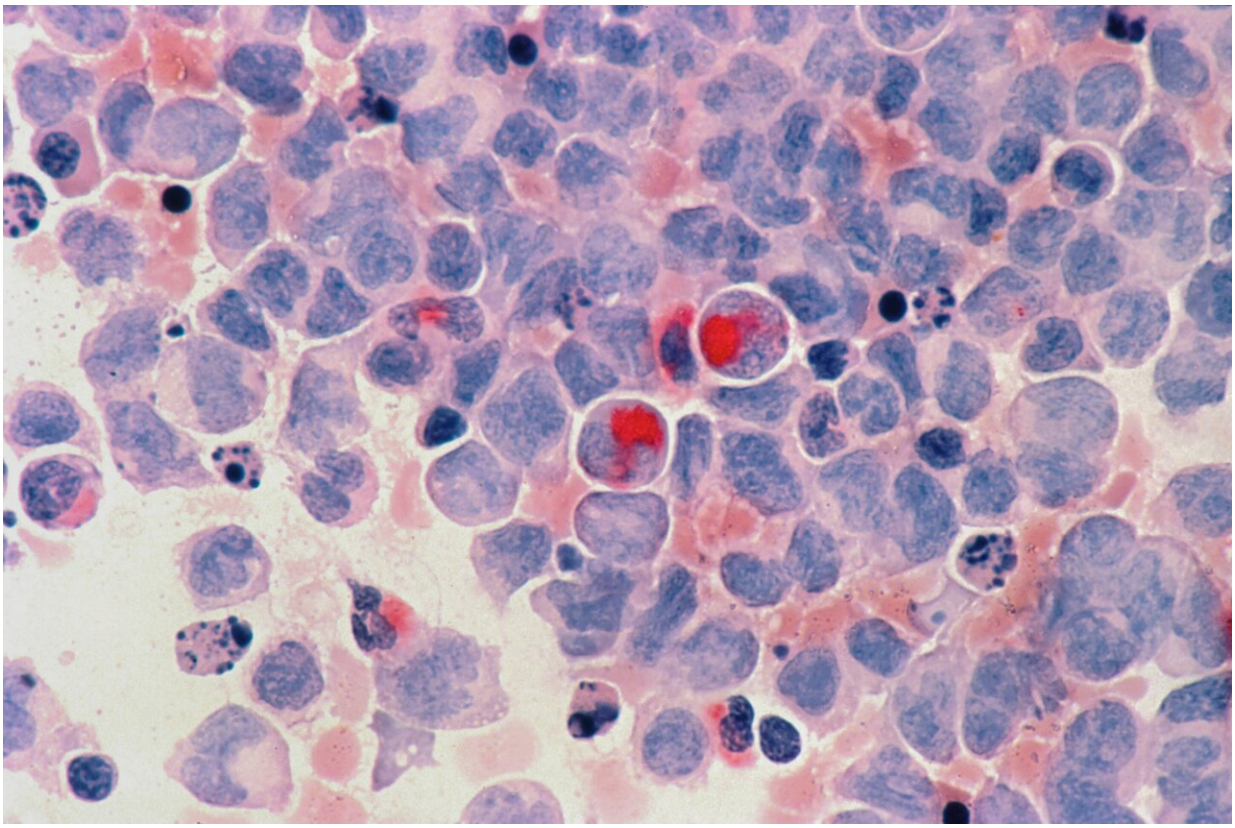

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Results from the NRG Oncology NRG-RTOG 0232 clinical trial adding external beam radiotherapy (EBRT) to brachytherapy (BT) in men with intermediate-risk prostate cancer indicate that there was no improvement in freedom from progression (FFP) rates for patients.

Late adverse events were significantly increased (> 6 months from treatment start) in genitourinary (GU)/gastrointestinal (GI) and analyzed as grade 2+ and as grade 3+ for patients on the trial who received the combination of EBRT and BT (COMBO arm) compared to patients who received BT alone (BT arm).

These results, which were recently published in the *Journal of Clinical Oncology*, suggest that BT should remain the standard of care for this population.

"Many variations and intensifications of both EBRT and brachytherapy have been tested mainly in the higher and lower risk tiers of prostate cancer patients. Intermediate-risk prostate cancer patients represent a vast and heterogeneous grouping, which can make it difficult to find a specific therapy combination that appropriately treats their disease and the variety of risks that are possible within this population while avoiding added toxicity," stated Jeff Michalski, MD, of the Washington University Siteman Cancer Center and the lead author of the NRG-RTOG 0232 manuscript.

NRG-RTOG 0232 randomly assigned 588 men with intermediate-risk prostate cancer to either the COMBO or the BT treatment arm and 579 were eligible/analyzed. The COMBO arm consisted of 287 patients versus 292 on the BT arm.

The primary objective of the trial was to determine whether the combination of EBRT and BT improved 5-year FFP using the ASTRO definition. Secondary objectives of the trial included FFP using the

Phoenix definition, biochemical failure (per ASTRO and Phoenix), disease-specific mortality, local progression, distant metastases, survival, and toxicity.

There was not a significant improvement with the COMBO treatment for 5-year FFP rates by both ASTRO and Phoenix definitions. The 5-year FFP-ASTRO rate (95% CI) was 86% (81-90) on the COMBO arm versus 83% (78-87) with on the BT arm. The 5-year FFP-Phoenix rate was 88% (84-92) on the COMBO arm versus 86% (81-90) on the BT arm.

There were no differences between treatment arms for acute GU and GI toxicities; however, 5-year cumulative incidence of late grade 2 or higher GU/GI toxicities was 43% (37-49) in the COMBO arm and 26% (21-31) in the BT arm (p