

## Adding advanced PET scans to radiation plans for prostate cancer increases FFS rates

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Adding the advanced PET radiotracer fluciclovine to conventional imaging to help guide radiation treatments for recurrent prostate cancer can improve disease-free survival rates, a new study finds. Among patients whose prostate cancer had returned after surgical removal of their prostate, 75.5% whose treatment integrated the PET molecular imaging were disease-free after three years, compared to 63% for whom only conventional imaging techniques were used to plan treatment. The increased survival rate persisted for up to four years. Findings from the randomized phase II/III EMPIRE-1 trial (NCT01666808) will be presented today at the American Society for Radiation Oncology (ASTRO) Annual Meeting.

"The decision to offer post-prostatectomy <u>radiation</u> therapy is complex, because conventional imaging can leave unanswered questions on the best approach to treatment planning," said co-principal investigator Ashesh B. Jani, MD, FASTRO, a

professor of <u>radiation oncology</u> at the Winship Cancer Institute of Emory University in Atlanta. "What this research has found is that integrating advanced molecular imaging into the treatment planning process allows us to do a better job of selecting patients for radiation therapy, guiding radiation treatment decisions and planning and ultimately, keeping patients' cancer under control."

"This is the first study of its kind to look at the role of PET in influencing a cancer control endpoint," added David M. Schuster, MD, a nuclear radiology specialist and professor at Emory University who collaborated with Dr. Jani on the study as coprincipal investigator. "That's a very high bar for an imaging study."

Prostate cancer is one of the most common types of cancer, and a leading cause of cancer death, among men in the United States. An estimated one in nine men will be diagnosed with prostate cancer in his lifetime. Removing all or part of the prostate is a common treatment, but for 20-40% of men, prostate specific antigen (PSA) levels may nonetheless rise after surgery, signaling a return of cancer cells. Furthermore, failure rates for postsurgical radiation treatments remain high. "This is prostate cancer that, by virtue of being recurrent, has demonstrated its capacity to be aggressive," explained Dr. Jani.

Conventional imaging techniques, such as bone scans, computerized tomography (CT) or magnetic resonance imaging (MRI), are typically used to guide radiation therapy decisions and treatment plans for these recurrent cancers by identifying if tumors are present in the body. Molecular imaging with <u>positron emission tomography</u> (PET) scans, which look instead for higher levels of injected radiotracer activity within cancer cells, has been effectively used to guide treatment of many cancers



by more accurately detecting the presence and location of developing tumors. Though previous PET studies have led to changes in how prostate cancer is managed, an ensuing improvement in patient outcomes had not been demonstrated until this point.

This study used a type of PET known as [fluorine-18, or 18F] fluciclovine (brand name Axumin). For this scan, patients are given radioactive tracers containing a synthetic amino acid. Because cancer cells use more amino acids than other cells, the cancer is more easily detected when it accumulates more of this type of radiotracer.

"This is a jump ahead of the traditional way of looking at things," said Dr. Jani. "It helps us to pinpoint the location of the prostate cancer recurrence." Research by the team previously established a role for fluciclovine in guiding postprostatectomy radiation therapy treatment decisions and target volumes.

The Emory Molecular Prostate Imaging for Radiotherapy Enhancement, or EMPIRE-1 trial (NCT01666808), enrolled 165 patients who had undergone prostatectomies, but who later showed abnormal PSA blood test scores, indicating their cancer was returning. All patients underwent conventional imaging (bone scans, CT or MRI) for initial treatment planning. Patients were then randomized into two groups. The first group received radiation therapy based on these initial treatment plans. The other group was given fluciclovine PET scans and treated based on the additional findings.

After three years, the study showed patients who were treated based on the more advanced imaging results had a higher disease-free survival rate (p=0.003), which persisted for four years (51% for those in the conventional arm, versus 75.5% in the advanced imaging arm, p

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