Expert compares PSMA imaging agents, discusses PSMA vs Axumin in prostate cancer

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Now that there are 2 FDA-approved PSMA-PET imaging agents, urologists and other clinicians are asking about the differences between them, as well as how PSMA-PET imaging compares to the previously approved next-generation imaging agent fluciclovine F 18 (Axumin).

In an education session at the 2021 LUGPA Annual Meeting, Steven Rowe, MD, PhD, provided some of the background on the PSMA-PET imaging revolution in prostate cancer and offered his insight on these important questions.[1]

Background

In 2016, the FDA approved fluciclovine F 18 for PET imaging in men with suspected prostate cancer recurrence based on elevated PSA levels following prior treatment. Over the subsequent years, PSMA-PET imaging emerged as a new frontier in prostate cancer diagnosis and treatment, reaching its initial peak with the December 2020 FDA approval of Gallium 68 PSMA-11 (Ga 68 PSMA-11) for PSMA-PET imaging in men with suspected prostate cancer metastasis who are potentially curable by surgery or radiation therapy, as well as in men with suspected prostate cancer recurrence based on elevated serum PSA levels. Subsequently, in May 2021, the FDA approved piflufolastat F 18 (Pylarify) for identifying suspected metastasis or recurrence of prostate cancer.

Ga 68 PSMA-11 vs piflufolastat F 18

In a Q&A session following Rowe's LUGPA presentation, discussant Neal Shore, MD, director of the Carolina Urologic Research Center, Atlantic Urology Clinics, Myrtle Beach, South Carolina, asked, "So, May 26 of this year, Pylarify got full FDA approval across the country; I think it's in most markets and I know CMS is reimbursing and many commercial payers are too. The Gallium PSMA got approved at UCLA and UCSF about a year ago now. Please compare and contrast Ga 68 PSMA-11 and piflufolastat F 18."

In response, Rowe said, "My general sense about the 2 PSMA-PET imaging agents—and I think we're probably going to wind up with about half a dozen PSMA-PET imaging agents approved at some point—is that they're both great and better than anything that we've had before. And I think that to power a study that would head-to-head compare them in a prospective way to some oncological outcome is something that's going to take hundreds

and hundreds of patients and be so expensive that it's probably prohibitive. So, I don't know that we're ever going to have sort of this definitive answer that piflufolastat F 18 is better than Ga 68 PSMA-11, or vice versa.

"That said, F 18 as a radionuclide has a certain image quality and practical images relative to Ga 68; it has a longer half-life and can be made in generally much larger quantities. So, centrally producing it and sending it out to sites is a little more practical than it is with Ga 68. However, we do have a distribution model for Ga-68 dotatate PET/CT scan for neuroendocrine tumors that's been very successful in the US and Europe and other places. So, I think that, where there's a will there's a way and I definitely expect Ga 68 PSMA-11 to be available nationwide in the not too distant future.

"So, there are some image quality advantages with F 18—looking at the scans side-by-side, it's a little clearer; it's a little less noisy. But the vast, vast majority of findings are going to be visible on both and I don't think that on the whole, any of the top-level data really ever differentiates the 2 scans."

PSMA-PET imaging vs fluciclovine F 18

Shore next asked Rowe to compare PSMA-PET imaging with fluciclovine F 18.

"The FDA approval is a little bit broader for PSMA-PET imaging. Fluciclovine F 18 is only approved for recurrent disease, whereas PSMA is also approved for initial staging. So, that's sort of an advantage for PSMA that's been foisted upon us by regulators.

"I think in the recurrent population, as you get to relatively high PSAs of 2 and above, the sensitivity or detection efficiency on all these radiotracers converges and is better than anything we've had a few years ago and definitely better than our conventional imaging has been.

"At really low PSA levels—the 0.2 to 0.5 range—particularly with biochemical recurrence, there seems to be a distinct sensitivity advantage for PSMA. And that's a clinically relevant note for men that are being considered for a lot of salvage treatments or an attempt to cure. So, I do think that PSMA has an advantage over fluciclovine F 18 in that context," said Rowe.

Reference

1. Rowe, S. Society of Nuclear Medicine and Molecular Imaging: Special Session. PSMA Imaging: Is Conventional Imaging Obsolete? 2021 LUGPA Annual Meeting. November 11-13, 2021; Chicago, IL.