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Carbon-11-Acetate PET/CT Imaging for Prostate Cancer: Ongoing Open Clinical Trials at the Arizona Molecular Imaging Center FABIO ALMEIDA, M.D.

In patients with prostate cancer, recurrence after treatment is unfortunately frequent, occurring within 10 years in 20–50% of patients after radical prostatectomy (RP), and in 30–40% of patients after external-beam radiation therapy (EBRT).

Tumor recurrence is commonly assessed by a progressive increase of serum prostate-specific antigen (PSA) that typically precedes the clinically detectable recurrence. After RP, a PSA level $>0.2\text{ng/mL}$, confirmed by two consecutive measures, can be associated with either residual or recurrent disease. After radiation therapy (RT), a PSA value of 2ng/mL above the nadir represents persistent or recurrent disease.

Management of recurrent prostate cancer depends strongly on whether recurrence is confined to the prostatic bed (local failure), to the regional lymph nodes in the pelvis or if distant spread has occurred. Although a trend of increasing PSA has been proposed as a way of predicting a local recurrence versus a distant recurrence, only imaging procedures are capable of discriminating between these scenarios.

Several imaging methods, including computed tomography (CT), magnetic resonance imaging (MRI) and bone scans are currently used, but none of these are very effective at detecting recurrences early enough to help select patients for salvage therapy with a curative intent.

Positron emission tomography integrated with CT, which combines the most advanced performance for both techniques, has become one of the primary tools in the restaging of cancer patients. The PET tracer ^{18}F -FDG (fluorodeoxyglucose) is widely used for a variety of cancers, but has limitations in imaging prostate cancer.

Although ^{18}F -FDG may accumulate in aggressive and undifferentiated tumors, most prostate cancers often present with poor uptake of ^{18}F -FDG, probably because of the high incidence of well-differentiated tumors. Furthermore, ^{18}F -FDG is secreted into the urinary system, often interfering with pelvic pathologic findings and therefore significantly limiting its usefulness.

Among the different PET tracers that have been specifically evaluated for prostate cancer imaging, Carbon-11-Acetate (C^{11} -Acetate) is demonstrating utility for detecting recurrent prostate cancer. Acetate is an essential component of phospholipids of the cell membrane. Cell proliferation and up-regulation of fatty-acid synthase are two mechanisms suggested for the increased uptake of this tracer in prostate cancer.

Due to recent changes in FDA regulation regarding new radiopharmaceuticals such as C^{11} agents, access to C^{11} -Acetate now requires participation in an approved clinical study. The Arizona Molecular Imaging Center has worked with the FDA to open an approved Phase II clinical investigation, and is pleased to offer Carbon-11-Acetate PET/CT imaging studies for localizing recurrent prostate cancer.

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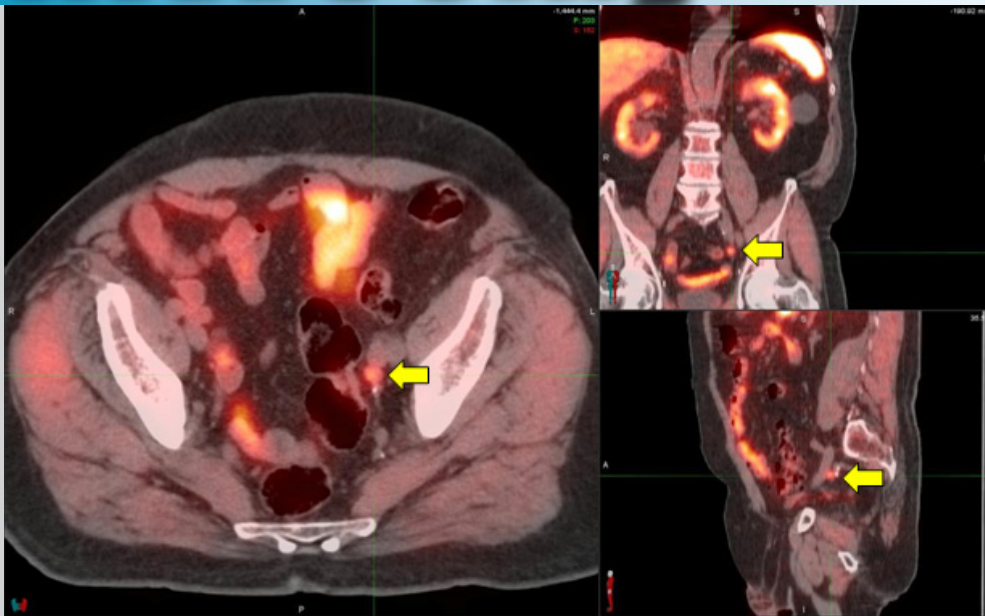


FIGURE 1

Gentleman with prostatectomy 10 years previously. External beam radiation 1 year previously for a rising PSA. The PSA continued to increase up to 6.9 ng/mL. The 3 dimensional Carbon-11 Acetate PET/CT images show a small metabolic lymph node in the left pelvis (yellow arrow). This would not have been diagnosed on CT alone based on its small size. Other areas of 'red' seen on the images are of normal Carbon Acetate in the intestines, kidneys, liver and spleen. No other lesions were seen. The left pelvis node was treated with IMRT and the PSA then decreased to 0.9 ng/mL, confirming involvement of the identified node.

Because this type of scan requires an on-site cyclotron, we are one of the few sites in the country capable of doing these studies. Currently, we are the only FDA-approved private site for C11-Acetate. Our center is also equipped with state-of-the-art PET/CT imaging, which provides an extra advantage in the detection of small lesions. Our C11-Acetate study requires only a single intravenous injection of the tracer. The imaging procedure can be completed in about 20 minutes.

Preliminary results from studies with C11-Acetate PET/CT imaging in our clinical trials have been very encouraging, and are demonstrating a direct benefit to many patients that would not be achievable with any other standard imaging technique.

Figure 1 shows an example of a positive imaging study. In over 110 patients studied thus far, the detection rate of recurrent or metastatic disease has been 85%. When separated into various PSA levels, the detection rate has been 73% for PSA 0.4 – 1.0ng/mL, 89% for 1.0 – 2.0ng/mL and 93% for > 2.0ng/mL. Most patients are still in early follow-up. However, in several patients with initial follow-up after additional therapy (radiation therapy directed toward the recurrence or metastasis), there has been a significant decrease in PSA, confirming the accuracy of the C11-Acetate imaging. There will be much more to come as we proceed with our study.

A second trial is also now open at our center for evaluating the changes in treatment decisions made based on C11-Acetate PET/CT findings. This additional study is designed for those with newly diagnosed prostate cancer to assist with initial treatment decisions, or as part of monitoring prior to other treatment.

For information about participating in these clinical trials, please visit the following links on the ClinicalTrials.gov website:

<http://clinicaltrials.gov/ct2/show/record/NCT01304485>

<http://clinicaltrials.gov/ct2/show/record/NCT01530269>

or call Dr. Fabio Almeida directly at 602.331.1771.