

FDA Approves ^{11}C -Choline for PET in Prostate Cancer

The U.S. Food and Drug Administration (FDA) announced on September 12 approval of production and use of ^{11}C -choline for PET imaging in recurrent prostate cancer. The Mayo Clinic PET Radiochemistry Facility (Rochester, MN) will be the first approved facility to produce the tracer injection. ^{11}C -choline must be produced in a specialized facility and must be administered to patients shortly after production. Although ^{11}C -choline PET has been performed at a few facilities over the past several years, none were previously approved by the FDA to manufacture the agent. The FDA Modernization Act directed the agency to establish appropriate approval procedures and current good manufacturing practice requirements for all PET products marketed and used in the United States.

" ^{11}C -choline injection provides an important imaging method to help detect the location of prostate cancer in patients whose blood tests suggest recurrent cancer when other imaging tests are negative," said Charles Ganley, MD, director of the Office of Drug Evaluation IV in FDA's Center for Drug Evaluation and Research. "The FDA's approval of ^{11}C -choline injection at the Mayo Clinic provides assurance to patients and health care professionals that they are using a product that is safe, effective, and produced according to current good manufacturing practices."

FDA prescribing information published along with the approval stated that the product "is indicated for PET imaging of patients with suspected prostate cancer recurrence and noninformative bone scintigraphy, CT, or MR imaging. In these patients, ^{11}C -choline PET imaging may help identify potential sites of prostate cancer recurrence for subsequent histologic confirmation. Suspected prostate recurrence is based upon elevated blood prostate specific antigen (PSA) levels following initial therapy. In clinical studies, images were produced with PET/CT coregistration."

The FDA documented the safety and effectiveness of ^{11}C -choline with a systematic review of published study reports. Five studies (included here as references) were cited in the review summary, with a total of 98 patients

with elevated blood PSA levels but no sign of recurrent prostate cancer on conventional imaging. After PET imaging with ^{11}C -choline, patients underwent tissue sampling of abnormalities detected on PET. In each of the studies, at least half the patients with positive PET scans also had recurrent prostate cancer confirmed by histopathologic analysis. However, false-positive PET scans were observed in 15%–47% of patients in these studies. FDA noted that these findings underscore the need for confirmatory tissue sampling. With the exception of rare reports of skin inflammation at the injection site, no adverse effects were reported in association with the tracer.

Although the Mayo site was the only facility approved in the FDA announcement, clinical approval now makes it likely that other centers will seek permission to manufacture ^{11}C -choline. A substantial body of studies with ^{11}C -choline PET indicates that it has utility not only in prostate cancer but in diagnosis of brain tumors and in lung, esophageal, colorectal, and bladder cancers. More than 100 related peer-reviewed articles have appeared in *The Journal of Nuclear Medicine* alone since 1983.

U.S. Food and Drug Administration

REFERENCES

1. Scattoni, V, Picchio, M, Suardi, N, et al. Detection of lymph-node metastases with integrated C-11 choline PET/CT in patients with PSA failure after radical retropubic prostatectomy: results confirmed by open pelvic-retroperitoneal lymphadenectomy. *Eur Urol*. 2007;52:423–429.
2. Rinnab, L, Mottaghy, F, Simon, J, et al. ^{11}C -choline PET/CT for targeted salvage lymph node dissection in patients with biochemical recurrence after primary curative therapy for prostate cancer. *Urol Internat*. 2008;81:191–197.
3. Breeuwsma AJ, Pruijm J, van den Bergh AC, et al. Detection of local, regional, and distant recurrence in patients with PSA relapse after external-beam radiotherapy using ^{11}C -choline positron emission tomography. *Int J Radiat Oncol Biol Phys*. 2010;77:160–164.
4. Richter JA, Rodríguez M, Rioja J, et al. Dual-tracer ^{11}C -choline and FDG-PET in the diagnosis of biochemical prostate cancer relapse after radical treatment. *Mol Imaging Biol*. 2010;12:210–217.
5. García JR, Soler M, Blanch MA, et al. PET/CT with ^{11}C -choline and ^{18}F -FDG in patients with elevated PSA after radical treatment of a prostate cancer. *Rev Esp Med Nucl*. 2009;28:95–100.