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Synthesis of [18F]PSMA-1007 for Imaging Prostate Cancer by using an automated module and clinical studies

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Background

Radiopharmaceuticals targeting the enzyme, PSMA over expressed in prostate and other cancers are now widely used in nuclear medicine. 68Ga-PSMA-11 has become a widely accepted tracer for imaging prostate cancer. The nuclear medicine centres which do not have access to 68Ge/68Ga generator are interested in using 18F tracers for imaging prostate cancer. PSMA-1007 is a ligand having molecular structure similar to PSMA-617 which is widely used for 177Lu/225Ac therapy of prostate cancer. We describe here the production of [18F]PSMA-1007 using Neptis Syntheziser and a commercially available cassette.

Methodology

No carrier added 18F was produced in a 11 MeV Siemens HP cyclotron. Production of [18F]PSMA-1007 was carried out using NEPTIS mosaic RS automated synthesizer procured from Neptis, Belgium installed in clean room with class B area. Radioactivity measurements were done using Capintec dose calibrator. Oxygen-18 enriched water and [18F]-PSMA cassettes that include all chemicals were procured from ABX, Germany. The precursor PSMA-1007 was used in the production which was supplied along with cassette by ABX. TLC was performed using AR2000 TLC scanner procured from Eckert and Ziegler. The mobile phase used for TLC is Acetonitrile and Water 60/40 (V/V). Residual solvents were analyzed by Agilent Gas chromatography. Clinical studies were done in patients referred to the nuclear medicine department for PET imaging of prostate cancer.

Results and discussion

The [18F]PSMA-1007 was prepared in two step synthesis. Followed by labelling, [18F]PSMA-1007 was trapped on a preconditioned C-18 cartridge and eluted with 30% ethanol and passed through Chromafix PS-H+ cartridge. The final product was collected through a 0.22 ⊠ Millipore filter connected to a 30 mL vial. The total duration of [18F]PSMA-1007 production was 45 minutes. The radiochemical yields of [18F]-PSMA-1007 are 28 ± 8% (decay uncorrected, end of the synthesis) and 38 ± 10% (decay corrected to start of the synthesis). The radiochemical purity was always >98 %. [18F]PSMA-1007 was used in multiple nuclear medicine departments. PET-CT images are acquired 2 hour post injection of 200-300 MBq of the radiopharmaceutical in prostate cancer patients. The images were reconstructed with standard software and evaluated by nuclear medicine physicians. PET-CT images were comparable to [68Ga]PSMA-11. Compared to 68Ga-PSMA-11 images some differences in physiological uptake sites of the tracer were noted with [18F]PSMA-1007 images; eg. the consistent tracer uptake in gall bladder owing to the hepatobiliary route of excretion of [18F]PSMA-1007. However, the reporting nuclear medicine physicians appreciated the image quality of [18F]PSMA-1007 images and judged the image quality of [18F]PSMA-1007 images at par with 68Ga-PSMA-11 for imaging prostate cancer.

Conclusion

[18F]PSMA-1007 was prepared in higher yields and in Curie quantities using a cassette based nucleophilic synthesis in a Neptis automated synthesizer under GMP conditions. The synthesis yields were sufficient to deliver the activity to multiple nuclear medicine centres. [18F]PSMA-1007 is a tracer that can be routinely prepared in a cyclotron and distributed to NM centres for assessment of prostate cancer.

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