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Clinical translation and first in-human use of [^{44}Sc] Sc-PSMA-617 for PET imaging of metastasized castrate-resistant prostate cancer

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PSMA-617 has proven high potential in PSMA radioligand therapy of prostate cancer as well as PET imaging. Considering the relatively short physical half-life of gallium-68 this positron emitter precludes prolonged acquisition periods, as required for e.g. for pre-therapeutic dosimetry. In this context, the positron emitter scandium-44 is an attractive alternative for PET imaging. We report the synthesis and *in vitro* characterization of [^{44}Sc]Sc-PSMA-617 as radiopharmaceutical and clinical translation as part of a first in-human study. PSMA-617 was labeled with scandium-44 obtained from a ^{44}Ti/^{44}Sc radionuclide generator and evaluated *in vitro* and in cell studies using PSMA+ LNCaP cells. A first-in-human investigation was subsequently carried out in a cohort of 4 patients registered for 177Lu-therapy. [^{44}Sc]Sc-PSMA-617 were applied via intravenous injection (i.v.), respectively. A Siemens Biograph 2 PET/CT system was used to acquire initial dynamic PET data in list mode followed by static PET/CT data. Dynamic images were reconstructed as 6 data sets of 300 s each. SUV values in different organs and lesions were measured and compared to [^{68}Ga]Ga-PSMA-11 data of the same patients. Residence times and organ absorbed doses were calculated using OLINDA/EXM software. Quantitative radiochemical yields of ≥98 % were achieved with apparent molar activity of 6.69±0.78 MBq/nmol. [^{44}Sc]Sc-PSMA-617 showed high stability (>95 %) in serum for 24 h. The binding affinity and internalization were determined in PSMA+ LNCaP cells and compared to [^{68}Ga]Ga-PSMA-11. SUV values were significantly lower in the kidneys compared to [^{68}Ga]Ga-PSMA-11. All other measured SUV values did not show a statistically significant difference. The tumor to liver ratios were higher than for [^{68}Ga]Ga-PSMA-11 and no statistically significant differences were observed. Total and % activity were highest in liver followed by kidneys, spleen, small intestine and salivary glands. Kidneys received the highest radiation absorbed dose. In conclusion [^{44}Sc]Sc-PSMA-617 is suitable for PET imaging of prostate cancer tissue enabling pre-therapeutic dosimetry in clinical settings.

Biography

Dr. Elisabeth Eppard is Radiochemist at the Department of Nuclear Medicine of the University Hospital Bonn. After obtaining her diploma in chemistry from the Johannes Gutenberg University Mainz in 2009, she started her Ph.D. at the Institute of Nuclear Chemistry at the group of Prof. Frank Roesch where she worked on radiometal based radiopharmaceuticals obtaining her Ph.D. in 2013. In 2014 she moved to the Department of Nuclear Medicine of the University Hospital Bonn. There Dr. Eppard continued to work with radiometal based radiopharmaceuticals for clinical application. As Junior Research Group Leader she is focusing on the application of scandium-44 for pre-therapeutic dosimetry in clinical routine.

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