



First-in-human imaging and dosimetry of novel integrin $[^{18}\text{F}]\alpha\nu\beta_6$ binding peptide in patients with metastatic carcinoma

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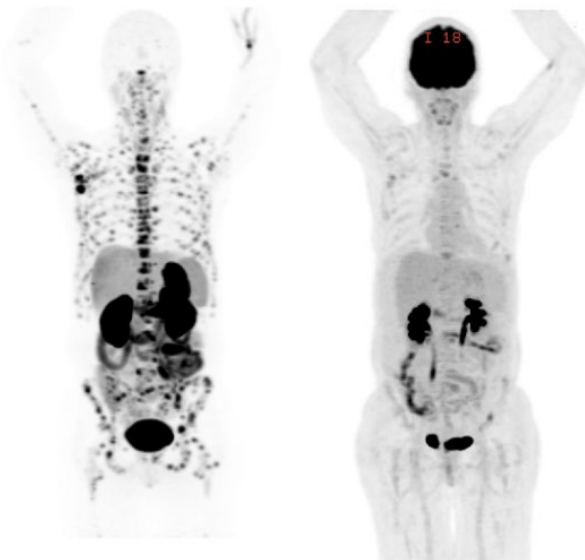
Introduction: The goal of this study was to evaluate the biodistribution and dosimetry of an integrin $\alpha\nu\beta_6$ -binding peptide ($[^{18}\text{F}]\alpha\nu\beta_6$ -BP) for the noninvasive imaging of a diverse range of malignancies with PET.

Methods: Patients with a prior diagnosis of either metastatic lung, colon, breast, or pancreatic cancer were enrolled. Each patient received a maximum injected dose of 10 mCi of $[^{18}\text{F}]\alpha\nu\beta_6$ -BP. PET/CT Imaging was performed at four time points (30, 60, 120, 180 minutes post injection) with ultra low dose CT at 30, 120, and 180 min, and low dose at 60 min. Regions of interest were drawn at all time points for representative organs and tissues using a GE Advantage workstation or Server. Decay corrected clearance curves and biodistribution models were generated for all drawn regions. Dosimetry data were calculated using OLINDA 1.1 software.

Results: Between December 2016 and January 2020, 26 eligible patients (11M, 15F ages 39-78) were enrolled. $[^{18}\text{F}]\alpha\nu\beta_6$ -BP was predominantly renally excreted with highest radioactivity in the kidneys and bladder (from excretion) followed by the gastrointestinal tract. Minimal radioactivity was seen in the normal brain, lungs, liver, heart, vascular system and bone marrow. Furthermore, sub-centimeter metastases to these organs were detected. The mean effective dose for $[^{18}\text{F}]\alpha\nu\beta_6$ -BP was 0.717 mSv/mCi.

Discussion: $[^{18}\text{F}]\alpha\nu\beta_6$ -BP was predominantly renally excreted and $[^{18}\text{F}]\alpha\nu\beta_6$ -BP PET/CT imaging can detect both primary tumors and metastases. The biodistribution was reproducible and predictable. The degree of radioactivity seen in lesions between similar tumor types varied by size; it was superior to standard tracer agents such as $[^{18}\text{F}]\text{fluorodeoxyglucose}$ ($[^{18}\text{F}]\text{FDG}$) (Figure).

Conclusion: Imaging using $[^{18}\text{F}]\alpha\nu\beta_6$ -BP has an immediate clinical benefit for the detection of multiple tumor types. Dosimetry values for $[^{18}\text{F}]\alpha\nu\beta_6$ -BP are comparable to those for other standard PET imaging agents.



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Figure: 56 yo female with history of ER+ / HER2- (BRCA 1&2 negative) breast cancer status post bilateral mastectomy and multiple chemotherapy regimens for multiple recurrences. (Left) $[^{18}\text{F}]\alpha\nu\beta_6$ -BP PET/CT imaging (SUV max scale 15) revealed diffuse, intense osseous lesions throughout the axial and appendicular skeleton and in multiple right axillary and cervical lymph nodes. (Right) Follow-up $[^{18}\text{F}]\text{FDG}$ PET/CT one week later (SUV max scale 7) showed very little uptake in the osseous or lymph nodes of the right axilla.