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Gastroenteropancreatic Neuroendocrine Tumor Patients Imaged Favorably with Somatostatin Receptor Antagonist: Results of a Phase I/II Study Comparing ^{68}Ga-OPS202 with ^{68}Ga-DOTATOC PET/CT

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Background: Radiolabeled somatostatin (sst) receptor antagonists are a promising class of radiotracer for imaging and treatment of neuroendocrine tumor patients. We report here the first clinical data on ^{68}Ga-OPS202 PET/CT in gastroenteropancreatic neuroendocrine tumors (GEP-NET) (ClinicalTrials.gov NCT02162446).

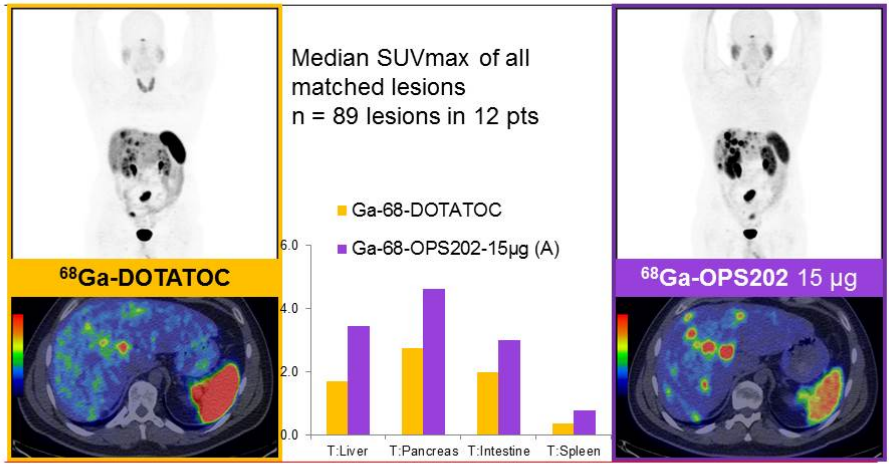
Methods: Metastatic G1/G2 GEP-NET patients, with at least 1 tumor focus on previous ^{68}Ga-DOTATOC PET/CT, were screened for eligibility in an open-label, micro-dosing study. Safety, biodistribution, dosimetry of two single doses of ^{68}Ga-OPS202 (A: 15µg & B: 50µg) and preliminary efficacy in comparison with ^{68}Ga-DOTATOC PET/CT were investigated. ^{68}Ga-OPS202 doses were given within 3-4 weeks interval. All PET/CT were performed on the same scanner, >4 weeks after sst-analogs had been stopped and 1h after i.v. injection of the radiotracer.

Results: Twelve patients were recruited (7 male, 5 female). No grade 3 or serious adverse event (AE) related to ^{68}Ga-OPS202 occurred. Both ^{68}Ga-OPS202 doses (A & B) showed significantly lower uptake in the liver (mean SUVmax±σ) 3.2±0.8 (A)/2.9±0.7 (B), in the spleen 11.7±4.2 (A)/10.1±2.3 (B), in the intestine 3.5±1.3 (A)/2.9±0.7 (B) and in the pancreas 3.2±2.0(A)/2.6±1.4 than ^{68}Ga-DOTATOC, respectively 6.8±2.3, 29.1±10.0, 5.4±1.0 and 4.9±3.2 ($p<0.05$). Matched lesions (lesions visible on all 3 scans) did not differ significantly in terms of tumor uptake (median SUVmax [range]) 10.2[1.4 – 155.5] (A)/9.6 [1.3 – 130.2] (B) vs 10.7[1.2-141.7] for ^{68}Ga-DOTATOC. Liver-metastases-to-liver-background uptake ratios consistently improved >2-fold (mean±σ) 5.7±6.9 (A)/6.0±7.4 (B) vs 3.0±1.9 for ^{68}Ga-DOTATOC resulting in a higher detection rate of liver metastases for ^{68}Ga-OPS202 PET/CT (median) 13 (A), 15 (B) vs 4 liver metastases for ^{68}Ga-DOTATOC. The effective dose for an injection of 150 MBq Ga-68-OPS202 is 3.6 mSv (mean± σ: 2.4 ±1.78E-02 mSv/MBq).

Conclusion: ^{68}Ga-OPS202 is well tolerated and shows increased image contrast compared to ^{68}Ga-DOTATOC PET/CT. The lower hepatic and intestinal and pancreatic uptake may increase the sensitivity and diagnostic confidence in staging GEP-NETs.

Tumor-to-Background Uptake Ratios

Patient 10



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