C22

Generator Produced ^{68}Ga for Clinical Preparations of [^{68}Ga]DOTATOC for Imaging Neuroendocrine Tumor Patients: Initial Studies at the University of Iowa

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Background and Objectives: Gallium-68 (^{68}Ga) somatostatin analogs are the gold standard for PET imaging of neuroendocrine tumors, yet have not been embraced in the United States. In this study, an automated system for preparation of a ^{68}Ga labeled somatostatin analog ([^{68}Ga]DOTA-Tyr^3-octreotide or [^{68}Ga]DOTATOC) is evaluated based on system performance and quality control parameters. The system was used to prepare patient doses for biodistribution research studies in human subjects and results compared to Octreoscan™ SPECT.

Methods: The automated system (ModularLab PharmTracer, Eckert-Ziegler, Berlin, Germany) combines a titanium dioxide based germanium-68 (^{68}Ge)/^{68}Ga generator (IGG100 Eckert-Ziegler) with a computer-controlled system that employs complete, single-use, sterile, GMP-grade, cassettes. In this study, 1.85 GBq ^{68}Ga was eluted to an in-line cation exchange resin, which retains ^{68}Ga. Purified ^{68}Ga was eluted with acetone/0.02 M HCl to a glass reaction vessel containing 30 µg DOTATOC (acetate buffer, pH 4). Radiolabeling was carried out for 6 min (95 °C). Acetone is removed by vent to waste. Final [^{68}Ga]DOTATOC was purified by C-18 cartridge and eluted in 1:1 95% ethanol:water to the product vial through a sterilizing filter (and diluted with saline). QC parameters were measured by standard techniques.

Results: Sterile, pyrogen-free [^{68}Ga]DOTATOC was prepared in 32 min. Reagent preparation and system setup requires about 30 minutes of technician effort. QC metrics were acceptable: specific activity > 25 MBq nmole^{-1}, radiochemical purity >98%; pH 6; acetone, ethanol, and pyrogen levels within limits. Excellent tumor contrast was observed in these initial biodistribution studies in human subjects.

Conclusions: The system enabled rapid [^{68}Ga]DOTATOC preparation. QC parameters were well-within specifications. Initial studies in human subjects displayed excellent tumor contrast. PET/CT images were clearly superior to matched patient paired SPECT images obtained using Octreoscan. The system and integrated software can be adapted readily for training of personnel and daily operations.