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The role of radiopharmaceutical [^{99m}Tc]Tc-MIBI in the evaluation of parathyroid adenoma and osteoporosis in young patients—a case report supporting its integration into standard clinical practice

Ismet Bajrami[1,2,3], Fakir Spahiu[2,3], Ylli Kaçiu[3], Emilija Janevik[2], Elena Drakalska[2], Sinisa Stojanoski[4], Armend Jashari[2,3*]
[1]University of Business and Technology UBT-Higher Education Institution Republic of Kosovo. [2]Faculty of Medical Science "Goce Delcev" University Stip, Republic of North Macedonia. [3]Nuclear Medicine Department in Clinical University Centre of Kosovo. [4]Institute of Pathophysiology and Nuclear Medicine "Acad Isac S. Tadzer", Faculty of Medicine University of "Ss. Cyril and Methodius", Skopje North Macedonia
*__Corresponding author__: armendjashari@yahoo.com

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Aim: This study aims to evaluate the sensitivity and specificity of [^{99m}Tc]Tc-MIBI as a radiopharmaceutical and parathyroid scintigraphy as a diagnostic tool for identifying parathyroid adenomas.
The patient presented in this paper as a case report can serve as confirmation of the effectiveness of the implementation of this method and supports its integration into our standard clinical practice.
Materials and methods: Data were obtained from a 32-year-old male patient reported to our department with generalized skeletal pain using a SPECT gamma camera and after injection of [^{99m}Tc]Tc-MIBI radiopharmaceutical at a dose of 555 MBq.
The patient was first referred to our department for a bone scan. A full body scan showed multiple foci suggestive of metabolic bone disease. A parathyroid scintigraphy was performed which revealed suspected adenoma which with biopsy-confirmed parathyroid adenoma.
Results: The parathyroid scintigraphy revealed the intensive focal accumulation of the [^{99m}Tc]Tc-MIBI in the left distal lobe of thyroid grand. The patient undergo surgery—lobectomiam gl. thyroidea lat sin et parathyroidectomiam lat. sin. HP findings were: adenoma glandula parathyroides lat. sin.
The bone pain was stopped after surgery and the level of the parathormone PTH was decreased. The patient recovered after surgery and released from hospital with osteoporotic therapy.
Conclusion: The SPECT camera-based evaluation of patients with recurrent or persistent hyperparathyroidism can provide valuable insights to prevent osteoporosis and other complications associated with untreated parathyroid adenoma. The high sensitivity and specificity of [^{99m}Tc]Tc-MIBI scintigraphy, combined with routine preoperative SPECT localization, are increasingly becoming standard practices.
Keywords: Tc99m-MIBI, Scintigraphy, Radiopharmaceutical, Diagnostic tool, Sensitivity

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In-hospital production and quality control of radiotracer [^{68}Ga]Ga-NODAGA-Exendin-4 on Trasis EasyOne synthesizer

Sonja Van den Block[1,2], Julien Masset[3], Charles Vriamont[3], Sophie Bourgeois[2],Vicky Caveliers[1,2]
[1]Vrije Universiteit Brussel (VUB), Molecular Imaging and Therapy Research Group (MITH), Laarbeeklaan 103, 1090 Brussels, Belgium. [2]Vrije Universiteit Brussel (VUB), Universitair Ziekenhuis Brussel (UZ Brussel), Nuclear Medicine Department,, Laarbeeklaan 101, 1090 Brussels, Belgium. [3]Trasis, Liège, Belgium.

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Aim: [^{68}Ga]Ga-NODAGA-Exendin-4 is a promising radiopharmaceutical for positron emission tomography (PET) in pancreatic β-cell imaging to non-invasively detect, diagnose, and preoperatively localize insulinomas [1]. Exendin-4 is a peptide analogue of glucagon-like peptide-1 (GLP-1) and binds with similar affinity to the GLP-1 receptor which is highly expressed in human insulinomas. The synthesis protocol of [^{68}Ga]Ga-NODAGA-Exendin-4 was reported earlier [2] but in this work we aimed at synthesizing the radiotracer in an automated production process on a Trasis EasyOne synthesizer in a hospital-based radiopharmacy.
Materials and methods: ^{68}Ge/^{68}Ga-generator Galli Eo™ (IRE-Elit Radiopharma, Fleurus, Belgium) was used to produce the radionuclide, and was connected to the EasyOne synthesis module (Trasis SA, Ans, Belgium). The chemicals, reagents and consumables for the radiolabelling procedure were commercially provided as single use kits (Trasis SA, Ans, Belgium). EDTA-Tween solution was obtained from ABX advanced biochemical compounds (Radeberg, Germany). The GMP grade precursor peptide Lys^{40}(NODAGA)-Exendin-4 (Acetate) was purchased from piCHEM GmbH (Raaba-Grambach, Austria). The radiolabelling was optimized using different incubation temperatures and times in combination with variable starting masses of the peptide. Quality control methods included visual inspection of the final product, determination of pH, radiochemical and radionuclide identity, radiochemical purity (RCP) by reverse phase high pressure liquid chromatography (RP-HPLC) and instant thin layer chromatography (iTLC), colloid detection by iTLC, bacterial endotoxins by limulus amebocyte lysate (LAL)-test, and filter integrity test. The ^{68}Ge-breakthrough of the generator was tested periodically. Sterility testing of the final product was done after conditional release, verifying the absence of microorganisms, essential for final release.
Results: The optimized automated synthesis of [^{68}Ga]Ga-NODAGA-Exendin-4 was performed with the following parameters: 10µg of precursor and incubation time of 15 min at 85°C. Acetate buffer was used during the labelling step, guaranteeing a stable pH while limiting the formation of ^{68}Ga-colloids. It resulted in a sterile final product > 500MBq with a RCP > 95%, comprising both oxidized and non-oxidized [^{68}Ga]Ga-NODAGA-Exendin-4, as the oxidized form of the tracer does not impact its quality [3,4]. Results show an apparent molar activity > 250GBq/µmol and a decay corrected (DC) overall radiochemical yield (RCY) of 81,6 ± 3,8% (n = 3). Three validation batches confirmed both the robustness of the synthesis process and the reproducibility in production yield and quality of the radiotracer.
Conclusion: [^{68}Ga]Ga-NODAGA-Exendin-4 was successfully synthesized on a Trasis EasyOne using the IRE ^{68}Ge/^{68}Ga-generator Galli Eo™, making the radiopharmaceutical available to a broader community. It can be used for application in clinical settings, routine productions, and translation to a GMP facility for further use in clinical trials.

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