CASE REPORT : UNEXPECTED ADVERSE REACTION TO [^{68}Ga]Ga-DOTATOC

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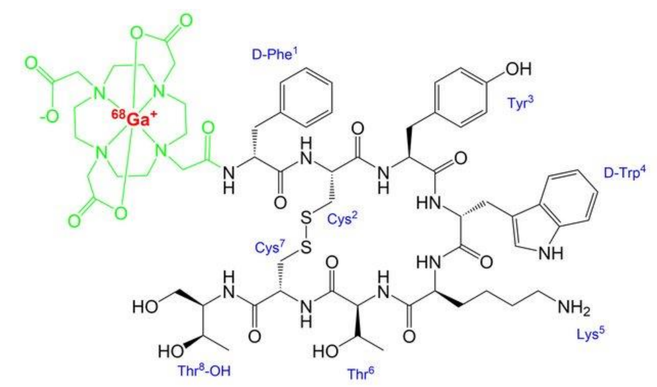
Background & Importance

[^{68}Ga]Ga-DOTATOC = Radiopharmaceuticals preparation composed of gallium-68 (^{68}Ga, from a germanium-68/gallium-68 generator) and a radiopharmaceutical kit, edotreotide (SOMAKIT TOC®) indicated for imaging somatostatin receptor overexpression in patients with gastroenteropancreatic neuroendocrine tumors, in order to localize primary tumors and their metastases in positron emission tomography.



Structure of [^{68}Ga]Ga-DOTATOC, from Hennrich U. *et al.*, 2020[1].

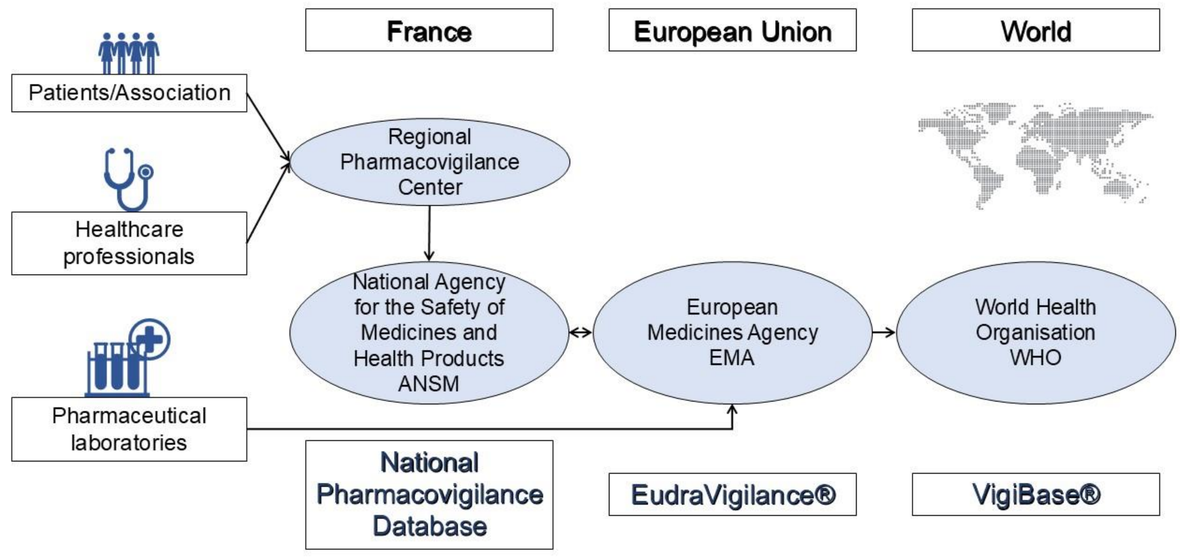
⇨ Adverse drug reactions (ADRs) described are scarce in the literature

Aim & Objectives

Investigate the case of a patient who experienced dysgeusia (metallic taste in the mouth) after administration of [^{68}Ga]Ga-DOTATOC.

Materials and methods

Declaration to our regional pharmacovigilance center and search in the European database of reports on suspected adverse drug reactions, EudraVigilance®.



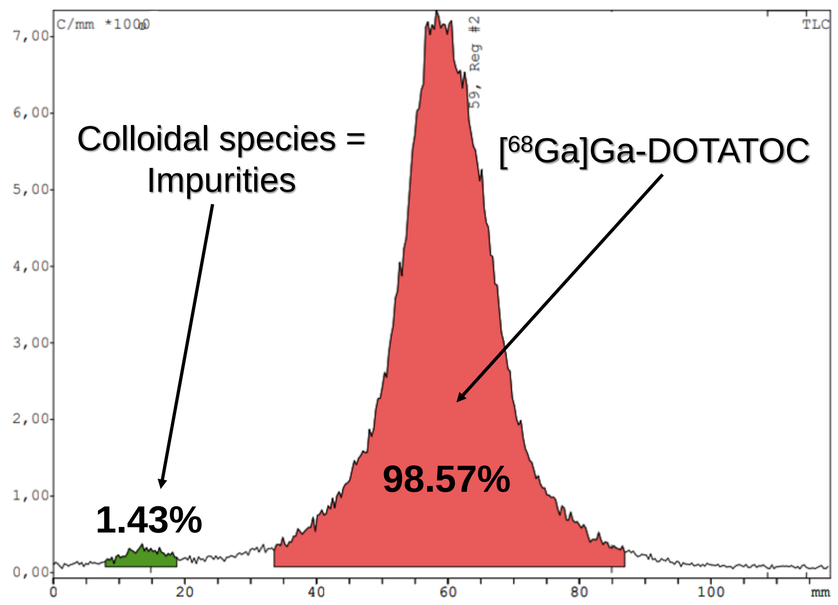
Reporting adverse drug reactions in France, Europe and worldwide, modified from the French National Agency for the Safety of Medicines and Health Products (ANSM)[2].

Results

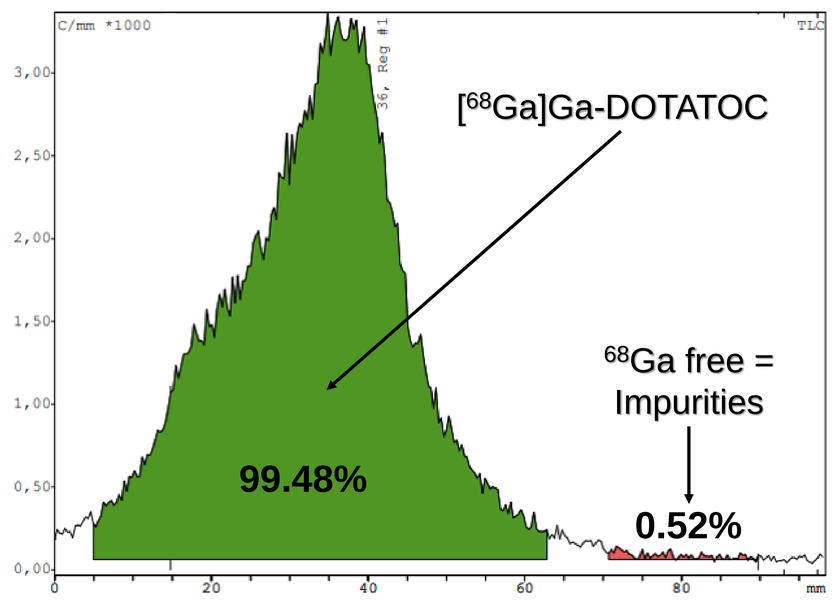
- Quality control results: Measurement of radiochemical purity by thin layer chromatography :

Radiochemical purity (RCP) = Ratio in % of radioactivity of the radionuclide concerned in the chemical form sought, to the total radioactivity of the radionuclide present in the preparation.

$$RCP = \frac{[^{68}Ga]Ga-DOTATOC}{[^{68}Ga]Ga-DOTATOC+[^{68}Ga]Ga-Impurities}$$



Radiolabelling efficiency : colloidal species of gallium-68, compliant if ≤ 3%
Mobile phase : Solution of ammonium acetate in water/methanol 1M 50:50 V/V



Radiolabelling efficiency : of free gallium-68, compliant if ≤ 2%
Mobile phase : Sodium citrate 0.1 M (pH 5)

Compliant with [^{68}Ga]Ga-DOTATOC quality control acceptance criteria

- Pharmacovigilance center : After analysis and assessment of the imputability (causal link between the pathological event and the drug presumed to be responsible) from a chronological, semiological/pharmacological and bibliographical point of view → Reaction probably imputable to [^{68}Ga]Ga-DOTATOC → Preparation not contraindicated for this patient.
- Eudravigilance® : 2 individual cases (out of 60 registered individual cases reporting ADR on Somakit Toc® until 29 September 2024) found in the European pharmacovigilance database presenting dysgeusia.

Conclusion

- Dysgeusia (Metallic taste) = Probably an ADR associated with [^{68}Ga]Ga-DOTATOC
- Pharmacovigilance = Crucial role in identifying and documenting ADRs not described in the literature.
- Possibility of using European and worldwide pharmacovigilance databases for diagnostic and therapeutic radiopharmaceuticals: EudraVigilance® and VigiBase®.

Références : 1 Hennrich U, Benešová M. [68Ga]Ga-DOTA-TOC: The First FDA-Approved 68Ga-Radiopharmaceutical for PET Imaging. *Pharmaceuticals (Basel)*. 2020;13:38. doi: 10.3390/ph13030038
2 Agence nationale de sécurité du médicament et des produits de santé. Nos missions - Organiser les vigilances. ANSM. https://ansm.sante.fr/qui-sommes-nous/nos-missions/assurer-la-securite-des-produits-de-sante/p/organiser-les-vigilances (accessed 4 July 2024)

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