

Large-scale Centralized Radiopharmacies: Is There Any Reason for Concern? An Insight into ^{99m}Tc -radiopharmaceuticals Adsorption and Stability

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Introduction: Worldwide, regulatory issues related to the field of radiopharmacy are switching and turning each day more rigid. Due to these legal constraints and all the related economical consequences, the concept of large-scale radiopharmacies, that label and distribute radiopharmaceuticals in a ready-to-use form, disseminate widely and seem more and more attractive, even in usually less receptive countries. In such a context, issues as the appropriate choice for recipient/methodology (vial or syringe? Multi- or Monodoses?) as well as the adoption of distinct behaviors should be considered relevant.

Aim: It is aimed to disseminate the results obtained on a large study performed to evaluate whether there is any correlation between factors as syringe volume, residence time and type of radiopharmaceutical with adsorbed fraction and stability.

Material and Methods: The most widely used radiopharmaceuticals (^{99m}Tc -Tetrofosmin/ ^{99m}Tc -Sestamibi, ^{99m}Tc -MAG₃/ ^{99m}Tc -DTPA and ^{99m}Tc -MDP/ ^{99m}Tc -HDP) were labeled strictly according to manufacturer's instructions. After radiolabelling, single-doses of each radiopharmaceutical were collected into 1 ml and 2 ml plastic syringes, from the same commercial brand with increasing residence times on the syringes (0.5, 1, 2, 3 and 6 hours). The degree of adsorption to the syringes walls was determined after a real or simulated injection and the activity present at the empty syringes was recorded. Regarding radiochemical stability, the reference sample was the one withdrawn directly from the original vial and subsequent aliquots were tested for each time-point from the syringes immediately before radiopharmaceutical

injection. Radiochemical purity was assessed by thin-layer chromatography, according to manufacturer's or EU Pharmacopeia instructions.

Student's t-Test was used to evaluate differences between means from independent groups (stability on Syringe vs stability on Vial; adsorption on 1ml syringes vs adsorption of 2ml syringes) and Pearson's Test to measure the association between adsorption and time of retention inside the syringe.

Results: Adsorption to plastic material of syringes varies significantly depending on the radiopharmaceutical. As an example, it is presented here the retention fraction for the most frequent situation: 1 ml syringe and 30 minute residence time: 0.65% for ^{99m}Tc -MDP, 2.15% for ^{99m}Tc -DTPA, 8.32% for ^{99m}Tc -MAG3 and 17.9% for ^{99m}Tc -tetrofosmin.

Conclusion: Results demonstrate that adsorption of radiopharmaceuticals to plastic material of syringes should be a topic of concern on the daily practice as this can lead to misdiagnosis due to the administration of activities inferior to the ones needed to obtain good diagnostic information. This can have a major impact on Centralized Radiopharmacies, so special attention should be paid.

Foi decidido que não será apresentada a versão integral deste documento.

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