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IMPORTANCE OF RADIOPHARMACEUTICAL INCUBATION TIME: A STUDY OF THE RADIOCHEMICAL PURITY OF THE TECHNETIUM-LABELLED ALBUMIN NANOCOLLOID

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BACKGROUND-AIM

The aim of this work is to evaluate the relevance of the radiopharmaceutical incubation time in the achievement of the radiochemical purity values required for its use.
In our Nuclear Medicine Unit (SS Antonio e Biagio e Cesare Arrigo Hospital, Alessandria), we conducted a study on the radiochemical purity of albumin nanocolloid (GE Healtcare Nanocoll and 99Mo/99mTc generator), in order to understand the methodological variation proposed by the manufacturing company, that expects the execution of quality control and the subsequent administration of the radiopharmaceutical 40 minutes after the labelling and not after 10 minutes. In fact, until 10th October 2012, the 99mTc- albumin nanocolloid could have been used starting from 10 minutes after radiolabeling. Then, the company has implemented a variation concerning methodology, according to which the labelling of the drug resulted to be fully completed after 40 minutes of incubation.

METHODS

1. Radiopharmaceutical Preparation: using a syringe, introduce into the vial provided by the kit, a volume of 1-5 ml of sterile, non-pyrogenic Sodium Pertechnetate 99mTc solution (185÷5550 MBq/5÷150 mCi), extracting an equal volume of gas in order to avoid an excess of pressure inside the vial; then, it should be shaked until complete dissolution.
2. Thin-layer chromatography with stationary ITLC-SG phase and methanol solution mobile phase: water 85:15 v/v.
3. Radiochromatography by Cyclone Plus: a phosphor screen is impressed by ITLC-SG strip prepared and included in the radiochromatography scanner where the reading process occurs.
4. Chromatogram: using the OptiQuant ™ software, the percentage of radiochemical purity is obtained.

RESULTS

The radiochemical purity analysis has been measured after 0, 5, 10, 20, 30, 40, 50 minutes from the labelling of the kit, collecting data of 54 preparations.
The average results obtained are:
90.7% at time 0, 92.7% at 5 minutes, 94.2% at 10 minutes, 96.1% at 20 minutes, 97.5% at 30 minutes, 98.5% at 40 minutes and 99.4% at 50 minutes.

CONCLUSION

The data collection has highlighted that the radiopharmaceutical labelling after 10 minutes from its preparation is not fully complete, as it has shown a value not yet ≥95% as indicated by the manufacturing company; the radiochemical purity outcome results to be compliant after 20 minutes from labelling.
In this way, we have strengthened the variation proposed by the company, according to which it is preferable to prolong the radiopharmaceutical incubation time, from 10 to 40 minutes before performing the quality control and the subsequent patient administration.