

CLINICAL RISK MANAGEMENT IN THE 99M-TC-MIBI QUALITY CONTROL PROCEDURE IN NUCLEAR MEDICINE. CASE STUDY

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ABSTRACT

The work is based on daily work protocols used within a Nuclear Medicine Operating Unit in which all modern radiopharmaceuticals are used and quality control procedures are applied to the latter. It is essential to underline, also with the production of this article, the importance of quality controls and the collaboration of the various figures in the field in order to avoid inappropriate injection of radiopharmaceuticals and to guarantee the safety and appropriateness of the procedures with an effective clinical risk management in contrast and prevent technical errors and penalizing the injection and acquisition of diagnostic tests, sometimes urgent, and indispensable for the diagnosis of even delicate pathologies.

INTRODUCTION

The aim of the work is to highlight and confirm the importance of quality controls on radiopharmaceuticals in nuclear medicine, a mandatory step, not only from a legal point of view, but also from an ethical point of view in order to guarantee patients the injection of suitable radiopharmaceuticals. for use and useful for diagnosis. We want to report the case of the U.O.C. of Nuclear Medicine of the "Moscati" Hospital of Avellino, following the arrival of a new batch of the vector MIBI (methoxy-isobutylisonitrile), used for the execution of cardiac tomoscintigraphies and parathyroid scintigraphies, which showed, at the first quality controls, a discrepancy in the graph depicting the impurities. Moreover, at times, an incorrect physical control in terms of opacity of the preparation has also been documented. Problem solving has shown the usefulness of quality controls also in the context of clinical risk management.

MATERIALS AND METHODS

The case was observed after the arrival of a new batch of MIBI vector (methoxy-isobutylisonitrile) from a company other than the one that usually supplied the vector to the department with the observation, already from the subsequent, first, quality controls on the preparations carried out for the execution of cardiac tomoscintigraphies and parathyroid scintigraphies of a variation in the normal graph depicting the impurities present within the drug labeled with 99mTc with, specifically, the presence of an initial impurity peak, before the actual and corrected peak indicated in the quality control leaflet. The procedure we used with the Radio-TLC method consists in placing 3-4 ml of Ethanol in a beaker. Using a 1 ml

syringe, a drop of ethanol is placed on an aluminum oxide strip 1.5 cm from the lower edge. A drop of 99mTc-MIBI solution is deposited over the drop of ethanol. The chromatography is then developed up to 5.0 cm from the deposition point and the graph relating to the radiochemical purity is obtained. The latter is calculated by setting two areas on the graph and obtaining the relative result which must be greater than 94% for a good radiopharmaceutical preparation. In our specific case, it was tried with various tools to understand the appearance of this anomalous peak which reappeared, in an almost similar way, with each preparation carried out by different operators. The quality control procedure was therefore examined by trying to modify the materials required, for example by modifying the quality of the strips used for chromatography, by modifying the structure or by drying them to eliminate any impurities inherent in the strips themselves.

Even by implementing these changes in the procedure it was observed, however, that the anomalous impurity peak was not eliminated and, on the contrary, remained almost stable in its shape and structure. Only after repeated checks did the 99mTc labeling procedure be examined, faithfully following the leaflet relating to the preparation and labeling of the drug. In this regard, we remind you that the procedure involves the injection of 1-5 ml of Sodium Pertechnetate Tc-99m into the vial of the MIBI kit. The vial is then shaken vigorously 5-10 times and placed in the heating block. After 10 minutes of boiling it is extracted and left to cool down to room temperature and then extract the necessary doses. Attention was therefore focused on the particularity that charac-



Fig.1

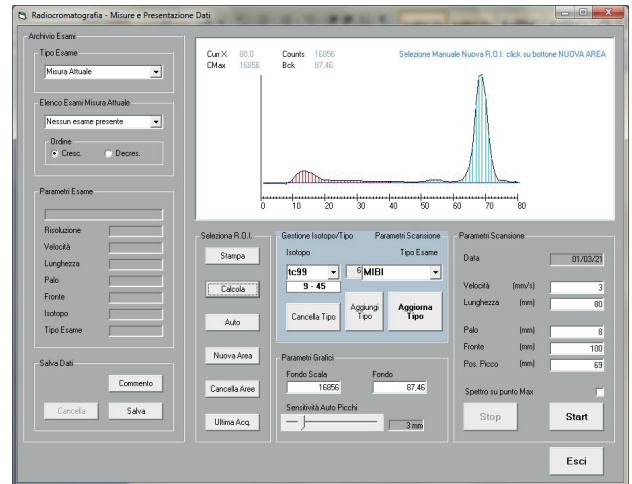


Fig.3

N°	Contri	Val%r	Picco	RF	SX	DX
1	0017540	15.9	14	.065	10	40
2	0032390	84.0	68	.652	40	80

Fig.2

N°	Contri	Val%r	Picco	RF	SX	DX
1	0021909	19.0	14	.065	8	40
2	0092963	80.9	69	.663	40	79

Fig.4

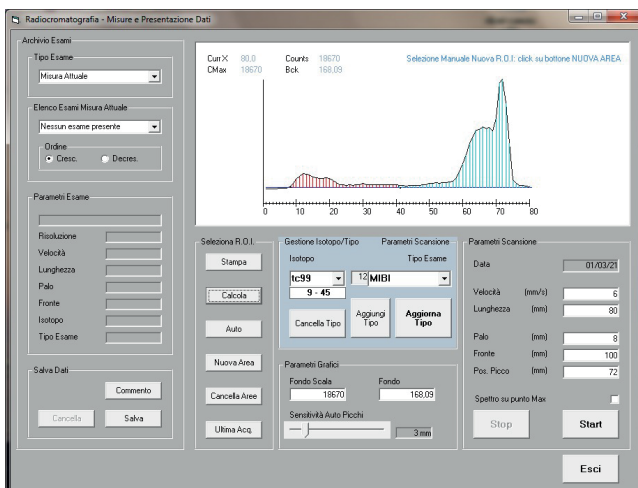


Fig. 5

N°	Contri	Val%r	Picco	RF	SX	DX
1	0039480	17.8	12	.043	8	41
2	0182084	82.1	72	.695	41	80

Fig. 6

Fig. 1, 2, 3, 4, 5, 6 - Comparison of quality controls with dried (1, 2, 5 and 6) and non-dried (3 and 4) strips.

terizes MIBI and that the other preparations do not have, namely the boiling of the tracer after marking. Specifically, the resistance boiling system available to the department was analyzed and it was noted that

the vial containing the tracer did not adhere to the walls of the housing in which the resistance for heating the product was positioned, causing a yoke and a movement of the vial which could, in hypothesis, then confirmed, determine a non-homogeneous and incorrect heating and boiling of the product, consequently. Moreover, since it was necessary to specifically analyze the oven for boiling, it was decided to check the actual temperature reached and indicated by the display on the front of the equipment; then with a specific thermometer provided by the Clinical Engineering service the temperature was monitored, noting, from the first measurement, an excess difference of about 10 ° centigrade with respect to the temperature marked on the display. The bias research method ultimately led to the discovery of an anomaly in the operation of the equipment and a procedural error in the preparation and, specifically, in the boiling of the radiopharmaceutical. Therefore, a request was made to the Clinical Engineering service of the Hospital to send, if possible, a “shirt”, promptly made available, of conductive material, specifically a copper reducer, to be inserted in the oven housing, resistance to obtain a perfect adherence of the vial to the walls and a consequent homogeneous heat distribution. To confirm and verify the presence of the error in the procedure and consequent boiling, we tried to mark the vector and boil the radiopharmaceutical in a bain-marie on a normal kitchen oven, at effective temperature, noting, at the next quality control, the disappearance of the peak anomalous present at the beginning of the investigation and a radiochemical purity of over 95%, with the graph expected from the leaflet. The problem of measuring the temperature by the resistance stove has been solved by setting a temperature 10 ° centigrade higher than the expected one in order to be sure to get to the boiling of the com-

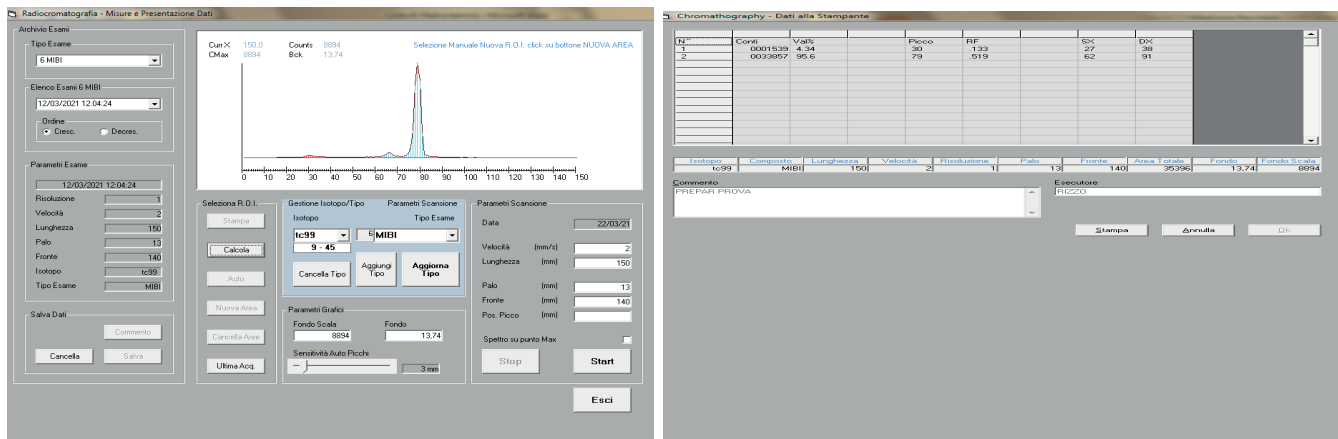


Fig. 7 - MIBI quality control with copper reducer and confirmation of radiochemical purity.

pound which, remember, needs 10 minutes of boiling. Finally, with the appropriate reducer, the quality control was carried out, verifying what had already been hypothesized with the heating in a bain-marie, i.e. that the adhesion of the vial to the heat source and the reaching of the actual temperature that had not previously been observed affects on the labeling and binding of molecules and on the consequent good quality control.

RESULTS AND DISCUSSION

This investigation has allowed, even more, to confirm how a careful analysis of the compounds prepared in nuclear medicine, combined with the attention of the staff assigned to quality controls and good preparation rules, allows to eliminate bias and errors that would lead to production of a radiopharmaceutical unsuitable for use on patients. The legislative aspect is fundamental, especially in Nuclear Medicine, a method that presents, in addition to the acquisition

of PET scintigraphic and tomographic examinations and quality controls on equipment, an important section dedicated to the preparation and quality controls of radiopharmaceuticals used for the acquisition of the exams and which brings with it a professional and ethical responsibility on the part of all personnel operating in Nuclear Medicine who administer and prepare the radiopharmaceuticals (Nuclear Doctor, TSRM, nurses). Furthermore, it has been confirmed that the competence and collaboration between the services and the operating units, in terms of tools and knowledge, always leads to results and resolution of problems in a short time.

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REFERENCES

1. Italian and European Pharmacopoeia. *Procedure for marking and quality control of the radiopharmaceutical 99mTc-MIBI*.