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Performance Assessment of Clinical Technicium-99m Generator by Moly Assay Test in a Tertiary Care Hospital

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Abstract
The most commonly used radioactive isotope is Technetium-99 (Tc-99m) is principle component in nuclear medicine department used in diagnostic procedures. It is obtained as the decay product of Molybdenum-99 (Mo-99) and has half-life of 66 hours and its energy is not suitable for diagnosis. Study presented here is about the assay for Moly assay test performed as routine clinical practice before each elution. The generators received in a tertiary care facility are GE healthcare Drytec™ generator (UK). To verify the Mo-99contamination standard Moly assay canister and dose calibrator the CRC-15R (CAPINTEC Inc, USA) were used. From January 07, 2015 to February 02, 2016 total 336 elutions were performed. Through the course of time most of the generators eluted have shown very low value of Moly assay test (0.0039 µCi / mCi) which is very less as compared to limit proposed in protocols (0.150 µCi / mCi). The study reflects good manufacturing and quality control of the GE healthcare Drytec™ generator which provides an evidence of safe medical practices.
Keywords: Elution, Tc-99m generator, Moly Assay test MAT, kurtosis, skewness

Introduction

Nuclear medicine procedures use radiopharmaceuticals and in the course of a diagnosis, radioactive isotopes are administered to patients and the radiation emitted is detected. The ability to produce functional images and quantify physiologic processes at a molecular level distinguishes Nuclear Medicine from other imaging modalities such as General Radiography, Medical Sonography, and Magnetic Resonance Imaging (MRI).

In nuclear medicine diagnostic studies the radioactive isotope is labeled with a pharmaceutical forming a radiopharmaceutical that will be injected in the human body through IV, ingestion etc. The pharmaceutical leads the radioactive tracer towards specific organ or path which is to be imaged. The most commonly used radioactive isotope in nuclear medicines Technetium-99m (Tc-99m, T½ = 6 hours and a photo peak of 140 KeV) which is an isomer Technetium-99 having an extremely long half-life $2.1x10^5$ years [1]. It is obtained as the decay product of Molybdenum-99 (Mo-99) has half-life of 66 hours and mean gamma energy of 760 KeV which is not suitable for diagnosis.

As the parent half-life is long enough, the Tc-99m is shipped to radio pharmacies and hospitals in radiation-shielded cartridges known as technetium generators; a typical generator is shown in Figure 1. The decay scheme of Mo-99 is shown in Figure 2. The Tc99m or technetium generators are shipped with reference to Molybdenum activity.

The Tc-99m is typically recovered by passing a saline solution through the alumina column in the generator, a process known as eluting the generator. The saline removes the Tc-99m but leaves the Mo-99 in place. However during elution it may occur due to mechanical damage of generator some amount of Mo-99 may be present in Tc-99mwhich undesirable for diagnostic scans and increase the patient as well technologist's personal dose. The dose coefficient for Mo-99 is about 50 times higher than that of Tc-99m [23]. The International Atomic Energy Agency (IAEA) safety standard recommends that any eluate containing more than 0.15µCi of Mo-99/ mCi of Tc-99m (0.015% of Mo-99) should not be injected on human [4,5,6].

Methods and materials

In every morning the Tc-99m is eluted (extracted) from the Tc-99m generator as described. As the Moly-Assay Test (MAT) which is to assay molybdenum breakthrough is performed in nuclear medicine for every elution in morning this procedure provides the Mo-99 concentration used in any Medical Centre. The GE Healthcare Drytec™ generators are used at the tertiary care hospital in which the study has been performed. This is an important step before administering the medicine to patients in conjunction with safe medical practices. If the eluent passes the MAT then it is suitable to be administered to patient and further for medical imaging by gamma camera [2]. Adopting the protocols the generators received per week through air shipment on Saturdays, the generator were assayed for Mo-99 breakthrough test at each elution on daily basis, six days per week starting from Monday. To verify the Mo-99contamination standard moly-assay canister and dose calibrator the CRC-15R (CAPINTEC Inc, USA) were used [12]. The vial containing the eluent $[^{99}mTcO_4]^-$ is placed in the Moly assay

canister which enough lead thickness to absorb low energy gamma ray photons of Tc-99m and allows the high energy gamma rays from Mo-99 to be detected be dose calibrator as activity of Mo-99. The activity of Molybdenum obtained is then divided by the activity of Technetium to assay the contamination in the eluent.
For the present study the data of MAT and activity of Technetium was analyses from January 07, 2015 to February 02, 2016 total 336 elutions were performed. The analyses were performed using MS Excel® along with its descriptive statistics tool.

Results

At each elution the values of activity for Tc-99m and Mo-99 were recorded. The activity of received generator at start of week was approximately 540 to 525 mCi. The mean ratio of activity of Mo-99 to activity of of Tc-99m was found to 0.0039 µCi / mCi which is very less than the recommended limit .A fractional analysis gives that the mean value is 67 % away from the proposed limit; other values of the descriptive statistical analysis are listed in 错误!未找到引用源。.

Instead of showing the MAT values for each generator a histogram is plotted so that the frequency of Mo/Tc can be visualized. The value skewness of data suggests that it highly positively skewed as shown in histogram chart in Figure 3; however the kurtosis will be high due to positively skewed data. Maximum no. of values of Mo / Tc ratio lies within the range of 0.0050 to 0.0100.

Discussion

The power of nuclear medicine lies in its ability to provide exquisitely sensitive measures of a wide range of biologic processes in the body. Other medical imaging modalities such as magnetic resonance imaging (MRI), X-ray imaging, and x-ray computed tomography (CT) provide outstanding anatomic images but are limited in their ability to provide biologic information [9]. But on the other side the unwanted radiation exposure to patient from the other isotopes present in the nuclear medicine is an important aspect for radiation protection.

Radiation exposure from Mo-99 is rare but gives high radiation which exceeds the acceptable limits to patients and technologist. Moreover if any Mo-99 is injected into a patient, the liver absorbs the Mo-99 and receives unnecessary radiation [11]. According to Australian radiation protection and nuclear safety agency (ARPNSA) report: Six patients received additional doses of between 5 mSv and 20 mSv due to molybdenum-99 breakthrough from a molybdenum-99/technetium-99m generator [6]. Molybdenum entering the human body is also distributed to the whole body and deposition to the bones has comparatively long biological half-life of 1000 days. Such amounts of radiation possess greater threat to patient's health [14]. The assessment of performance for technetium generators for other manufactures are also studied with respect to their practices [13 , 14]

Conclusion

The analysis presented in this study provides means of assessing radionuclide purity for the daughter isotope as for this case Tc-99m. The achieved values of the MAT for time duration presented in the study shows that the quality control of these Tc generators are very precise and mechanical structure of generator is reliable as no damage was observed internally as well as externally. As per analysis over this time period it was found that overall radionuclide contamination were within limits as per recommendation. This reflects the Technetium-99m generators manufactured by GE Healthcare follow great quality control procedure and damages to the generator are not observed. The observation for Mo-99 contamination is a regulatory requirement but such studies are also helpful and functions as feedback from the user end for the improving the manufacturing process. It also provides evidence of safe medical practices by the institution for patients.

Conflict of interest

None

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Table 1: Descriptive statistics

Mean	0.0039
Standard Error	0.0003
Median	0.0024
Mode	0.0100
Standard Deviation	0.0047
Sample Variance	0.0000
Kurtosis	51.8649
Skewness	5.1525
Range	0.0576
Minimum	0.0000
Maximum	0.0576
Count	336
Comparison with limit (fractional decrease)	67%

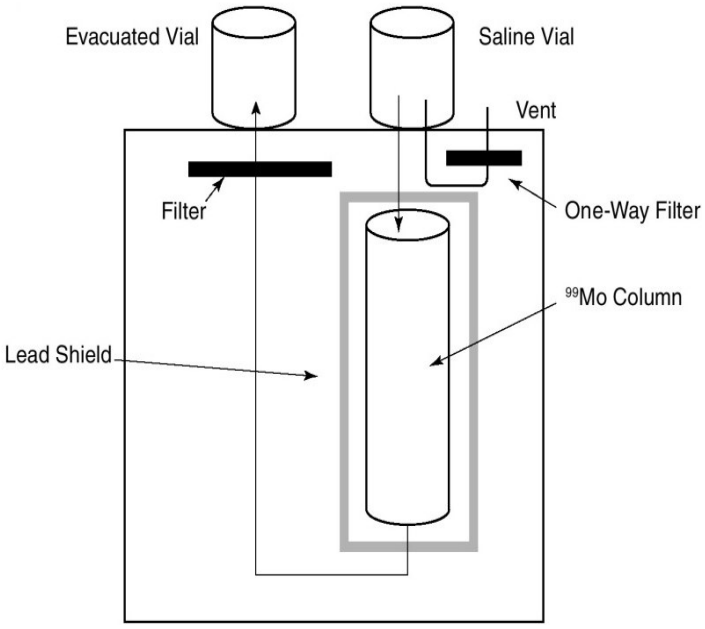

Figure 1: Tc-99m generator, internal view [8]

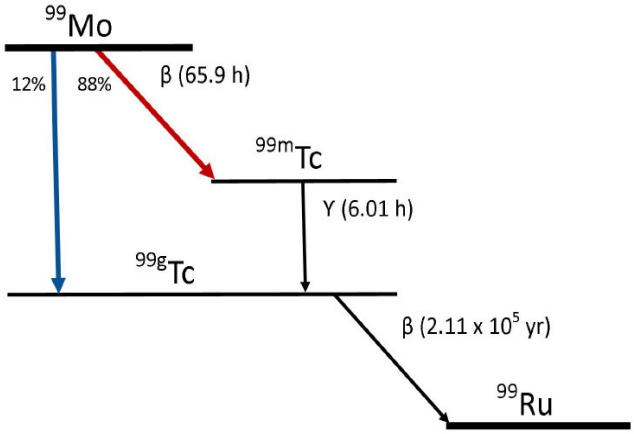

Figure 2: Graphical depiction of the Mo-99 decay chain [10]

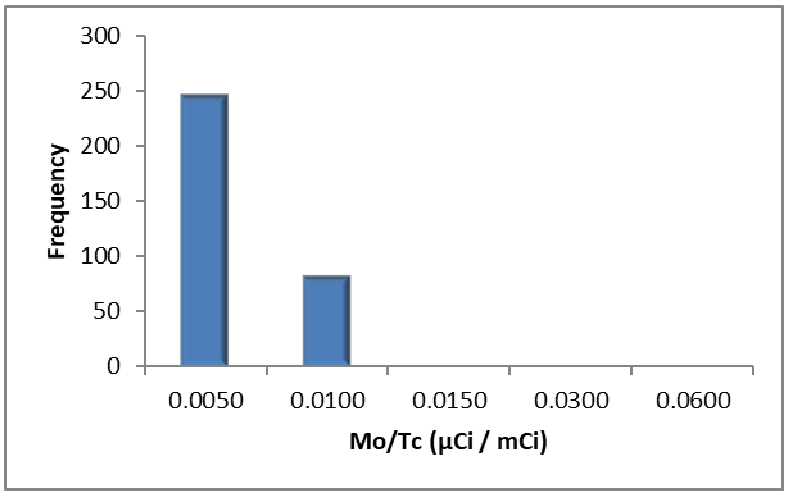

Figure 3: Histogram for Mo/Tc