

ASSAY FOR MOLYBDENUM-99 BREAKTHROUGH IN PAKGEN, PINSTECH GENERATORS: A CLINICAL AUDIT AT AKUH, KARACHI

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PJR April - June 2012; 22(2):44-45

ABSTRACT

BACKGROUND: Molybdenum-99 breakthrough is a rare but potential cause of enormous and unjustified radiation exposure to patients and technologist in nuclear medicine. Recommended limit of ⁹⁹Mo in an eluate is 0.15 uCi of ⁹⁹Mo / mCi of ^{99m}Tc. **AIM:** The purpose of this clinical audit was to measure the Mo-99 concentration in eluate of PAKGEN (⁹⁹Mo-^{99m}Tc generator) before administering to patients as a part of Good Medical Practice (GMP). **METHODS AND RESULTS:** This clinical audit was conducted at The Aga Khan University Hospital, Karachi from January to May 2012 and during this period we evaluated 44 ⁹⁹Mo-^{99m}Tc generators (PAKGEN). In 369 elutions during this audit period, we did not find any evidence of ⁹⁹Mo breakthrough. **CONCLUSIONS:** This clinical audit proves that PAKGEN generators supplied by IPD, PINSTECH, Islamabad had good performance and proved generally to be a reliable source of ^{99m}Tc-pertechnetate. The application was safe and fulfilled the requirements for good medical practice.

Key words: Radionuclide Generator, Molybdenum-99 breakthrough, Good medical practice, eluate

Introduction

Technetium-99 (^{99m}Tc, 6 hour half life and a photopeak of 140 KeV) is the work horse of every nuclear medicine department and is obtained by the eluting a Molybdenum-99-Technetium-99m (⁹⁹Mo-^{99m}Tc) generator. Molybdenum-99 has a physical half life of 66 hour and decays by beta emission to ^{99m}Tc (87%) and ⁹⁹Tc (13%), emitting photons of 740 and 778 keV.¹ Ideally, ^{99m}Tc eluates contain no radionuclide impurity. Molybdenum-99 breakthrough is a radionuclide impurity caused by generator aging or a mechanical defect and it also extracted from the column during this elution process and could be administered to the patients. The dose coefficient for ⁹⁹Mo is about 50 times higher than that of ^{99m}Tc.² The International

Atomic Energy Agency (IAEA) safety standard recommends that any eluate containing more than 0.15 uCi of ⁹⁹Mo / mCi of ^{99m}Tc should not be injected to human.³ If it happens than it would result in enormously high radiation exposure to patients and technologists. To avoid such incidents, in USA, a licensee is required to perform the test to detect Mo-99 breakthrough and retain records in accordance with 10CFR35.204 at least for first elution.^{4,5}

Aims

The purpose of this clinical audit was to measure the ⁹⁹Mo concentration in eluate of PAKGEN (⁹⁹Mo-^{99m}Tc generator) before administering to patients as a part of Good Medical Practice (GMP).

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Methods

This clinical audit was conducted at Nuclear Medicine Section Department of Radiology and Department of Nuclear Cardiology, Aga Khan University Hospital, Karachi from January 2012 till May 2012. We receive two PAKGEN (540 mCi each) on a weekly basis from Isotope Production Group of PINSTECH, Nilore Islamabad. Each elution was checked for ^{99}Mo breakthrough using ^{99}Mo special lead pig. $^{99\text{m}}\text{Tc}$ is then assayed directly in the plastic sleeve. Activity (μCi) of ^{99}Mo is divided by activity (mCi) of $^{99\text{m}}\text{Tc}$ to obtain a ratio and acceptable limit was $<0.15 \mu\text{Ci}/\text{mCi}$ of $^{99\text{m}}\text{Tc}$.

Results

From Jan 1, 2012 till 30 May, 2012 we received 44 PAKGEN IPD, PINSTECH, Islamabad. Total 369 elutions were done which included 264 primary and 105 secondary elutions on same day after 6 hr. The reference activity of each generator was 20 GBq (540 mCi). The median Mo-99/Tc-99m ratio was 0.01 μCi $^{99}\text{Mo}/\text{mCi}$ of $^{99\text{m}}\text{Tc}$ (range: 0.0 -0.06) which was well within regulatory limits ($<0.15 \mu\text{Ci}/\text{mCi}$ of $^{99\text{m}}\text{Tc}$). There was no incidence of Molybdenum-99 breakthrough in 369 elutions of 44 PAKGEN generators.

Discussion

Currently radiation based imaging modalities have been playing a fundamental role in diagnostic and therapeutic arena. Certainly this raised concern over alarming radiation exposure to patients especially the pediatric population and various strategies have been recommended by various bodies to minimize unjustified exposure.

In nuclear medicine, radiation exposure could be minimize by reducing the injected dose and increasing time of acquisition or by using semiconductor gamma camera and also software modification like resolution recovery software or iterative reconstruction. However, radiation exposure from ^{99}Mo is rare but gives exorbitantly high radiation dose to patients and technologist which is unjustified and avoidable. According to Australian radiation protection and nuclear safety agency (ARPNSA) report, 11 cases of ^{99}Mo breakthrough were reported in 2011.⁶ A strict quality check of generator column and checking of each elution are the basic fundamental steps to combat this incident. In this clinical audit over a period of 5 months, there was no incidence of ^{99}Mo breakthrough in any

of 369 elutions of 44 PAKGENS. Important to note that out these 369 elutions, 105 were secondary elutions which may have a theoretical risk of column break. These results spell about a stringent quality control being practiced by supplier of PAKGEN. It also stress upon need of checking every elution as a part of GMP to avoid possible chance of post-delivery column breakthrough and unjustified radiation exposure to patients and technologist themselves.

Conclusions

This clinical audit proves that PAKGEN generators supplied by IPD, PINSTECH, Islamabad had good performance and proved generally to be a reliable source of $^{99\text{m}}\text{Tc}$ -pertechnetate. The application was safe and fulfilled the requirements for good medical practice.

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