From:	Ron Lattanze
To:	Dimmick, Lisa; Einberg, Christian; Williams, Kevin; Lopas, Sarah; Daibes Figueroa, Said; Howe, Donna-Beth; Jamerson, Kellee
Subject:	[External_Sender] FW: Radiopharmaceutical extravasations
Date:	Monday, May 31, 2021 4:58:15 PM
Attachments:	image001.png Radiopharmaceutical Extravasation Case Studies.pdf

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I attended a webinar on Wednesday organized by AltusLearn, a healthcare online educator. The topic was radiopharmaceutical extravasations. In addition to several nuclear medicine and radiation experts, two vascular access experts presented. I reached out to these nurses and asked for information about the two extravasation cases they shared. I have attached a summary of these two cases for your consideration.

These cases of obvious significant extravasation are examples of the adverse tissue reactions that were described in the petition and that are possible from a significant therapeutic or diagnostic extravasation. They represent mishandling of medical isotopes and obvious patient harm (though admittedly, this harm showed up days to weeks later). According to the vascular access experts, these cases are not outliers. These experts and others who work to provide vascular access training and expertise to hospitals and outpatient clinics across the US see cases like this on a regular basis. As you know, these issues are not being reported to states and the NRC.

These two examples, and the many more that are happening every day in the US, are preventable, significant, harmful cases of irradiation to once healthy tissue that should require patient and physician notification and regulatory reporting. These cases should be studied for root cause. Findings should be disseminated to all other nuclear medicine centers so that these same mistakes will not be repeated.

In these examples, both nuclear medicine centers were unaware that they had extravasated the patients. If nuclear medicine centers were prospectively monitoring the quality of their radiopharmaceutical administrations, both of these cases could have been immediately mitigated and patient harm drastically reduced. With monitoring, the technologists would have suspected something was wrong in less than one minute. In both cases, imaging the arm minutes later would have confirmed that excess radiation was present at the injection site.

The image and patient-specific monitoring information would have helped the center calculate dosimetry with a few minutes of work. Prompt mitigation upon confirmation of extravasation, such as applying warm compresses, massaging the area, moving the arm, flushing the site with saline, and surgical intervention (if needed) could have minimized the inadvertent radiation dose to the patient's tissue and prevented significant harm. To complete their obligation to the patient, clinicians should consider repeating the procedure when appropriate and clinically following these patients for several years to examine the latent effects of ionizing radiation to healthy tissue.

Thank you for your attention to this matter.

Sincerely,

Ron Lattanze

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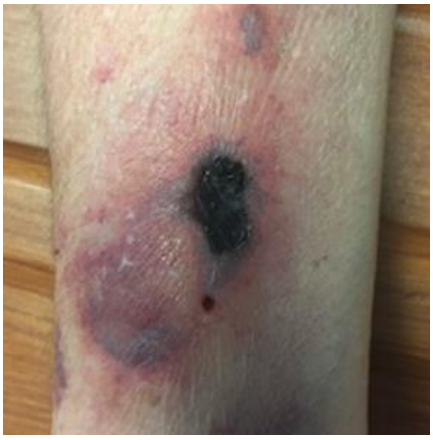
LUCERNO DYNAMICS

Radiopharmaceutical Extravasation Case Studies

Extravasations of **therapeutic** and **diagnostic** radiopharmaceuticals can harm patients. When some or all of the prescribed dose fails to enter circulation, target lesions absorb less radiopharmaceutical than was intended. This may result in under-delivery of therapy or a misdiagnosis of the patient's diagnostic image. In addition, concentrated radiopharmaceutical at the site of an extravasation may irradiate tissue with a high absorbed dose of radiation. Symptoms resulting from the absorbed dose may take weeks, months, or even years to develop.

Therapeutic Radiopharmaceutical Case - A 29-year-old male was treated for non-Hodgkin's Lymphoma with ZEVALIN® (Yttrium-90 ibritumomab tiuxetan). He arrived in nuclear medicine with a pre-existing 24-gauge IV catheter in his forearm. A nuclear medicine technologist administered the ZEVALIN® via the existing catheter, and the patient was discharged 2 days after treatment.



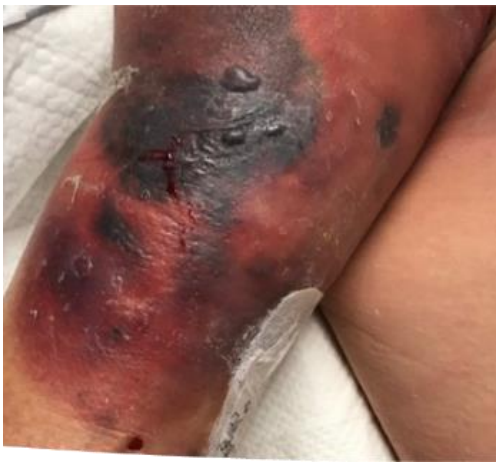
Yttrium-90 (^{90}Y) produces beta particles (average energy of 933 keV). When used as a therapy, its purpose is to kill cells. When extravasated, these beta particles travel 5-10mm while depositing their energy into the surrounding healthy tissue. The physical half-life of ^{90}Y is 64 hours—99% of the administered activity has decayed after 3 weeks.

Twenty-five days later, the patient returned to his oncologist complaining of blackened skin "where the IV was" and was referred to the Emergency Department. The Emergency physician contacted nuclear medicine and was told to apply ice and to elevate the arm (likely ineffective instructions for this situation). A review of the medical records found that the technologist had used the existing IV catheter and had not ensured the catheter was functioning correctly.

An 80 kg patient will be administered 32 mCi of ZEVALIN®. If just 10 mCi had been extravasated into 5 cc of tissue (an estimate of the size of the black area in the image above), the tissue would have received an extraordinary, absorbed dose of ~3,000 Gy.

Diagnostic Radiopharmaceutical Case - A 44-year-old male with end-stage cardiac failure underwent a Myocardial Perfusion Scintigraphy procedure using a ^{99m}Tc radiopharmaceutical. The patient presented with a functioning 18-gauge midline catheter in the basilic vein. Because midlines are routinely contraindicated for radiopharmaceutical use, the nuclear medicine team placed an 18-gauge IV in the patient's cephalic vein. Two doses (10 mCi and 32 mCi) of radiopharmaceutical were administered through the 18-guage IV during the procedure.

The most commonly used medical radioisotope, ^{99m}Tc, emits 140 keV gamma rays that leave the body with minimal energy deposition in the tissue. However, 11% of ^{99m}Tc decays emit internal conversion electrons with an average energy of 119 keV. When extravasated, the internal conversion electrons travel ~5 mm while depositing their energy in healthy tissue. The physical half-life of ^{99m}Tc is 6 hours—99% of the administered activity has decayed after 36 hours.



Several days later the patient developed skin discoloration in the upper arm that was treated with ice (likely ineffective treatment for this situation). Seven days after the procedure, vascular access experts used venous doppler ultrasound to confirm that the midline catheter was operating properly and that the tissue and skin damage was along the patient's cephalic vein as a result of the ^{99m}Tc extravasation from the 18-gauge IV.

To increase blood flow to the region, the vascular access experts removed the midline from the basilic vein. Nonetheless, the patient's skin sloughed away over the next several days. Five weeks later the patient expired from other causes.

In this case, assuming that 75% of the dose was extravasated into 15 cc of tissue (the black and blistered area in the image above), the tissue received an absorbed dose of approximately 9 Gy.