Administering Radioligand Therapy: Day of Delivery Workflow and Radiation Safety Precautions

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KEY FINDINGS & CONCLUSIONS

- Since the approval of [^{177}Lu]Lu-PSMA-617 for patients with metastatic castration-resistant prostate cancer (mCRPC), questions exist on the logistics and safety of radioligand therapy (RLT) delivery. Here, we outline US-specific recommendations to support the multidisciplinary team (MDT) to deliver RLT
- Key considerations include facility and personnel preparation, education on the appropriate handling and maintenance of radiation safety, monitoring for adverse events and emergencies, and patient and caregiver education
- Fully preparing the MDT for RLT with clearly defined roles, mitigating risk of complications, and fully informing HCPs on radiation safety considerations around RLT will ultimately improve patient experiences

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INTRODUCTION

- Radioligand therapy (RLT) represents an emerging treatment modality approved for use in the treatment of oncology, including in patients with metastatic castration-resistant prostate cancer (mCRPC)[1]
- Based on the results from the phase 3 VISION study (NCT03511664), the prostate-specific membrane antigen (PSMA)–directed RLT lutetium-177 vipivotide tetraxetan ([^{177}Lu]Lu-PSMA-617) became the first RLT approved for patients with mCRPC[2,3]
- However, despite the growing body of literature on RLT, there remains a paucity of practical guidance detailing the precautions and considerations before, during, and after administration
- Here, we present a workflow for the day of delivery to assist the multidisciplinary team (MDT) in safely and effectively delivering treatment, highlighting key radiation safety and practical considerations for US physicians, with a focus on the only approved agent for the treatment of mCRPC: [^{177}Lu]Lu PSMA 617

METHODS

- A comprehensive literature review identified underreported aspects of RLT delivery
- Published literature, guidelines, and the authors' clinical expertise were utilized to develop practical guidance

WHAT ARE THE KEY RADIATION SAFETY AND PRACTICAL CONSIDERATIONS ON THE DAY OF DELIVERY?

Preparation for administration

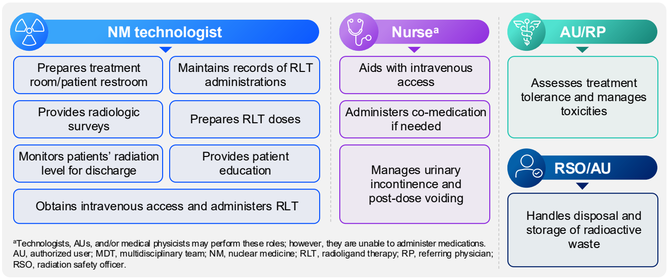
Pre-treatment testing and scheduling of RLT

- Laboratory tests should be performed prior to each treatment cycle[4,5]
  - Common tests include complete blood cell count, a basic metabolic panel, and prostate-specific antigen test
  - Tests are recommended ≤5 days before each cycle;[4] however, conducting these 2–3 weeks before instead can allow for reassessment of borderline cases
- RLT should be ordered from the manufacturer 2 weeks prior to the day of treatment[6,7]
  - As [^{177}Lu]Lu-PSMA-617 is administered every 6 weeks,[1] treatment requires coordination of patient schedules and the availability of the authorized user (AU) and treatment team
- Communication between the referring physician and the treatment team is essential to ensure accurate scheduling of patient appointments, treatment room availability, and dosing

Roles of the MDT

- Delivery of RLT requires an MDT of professionals with clearly identified roles[6] (**Figure 1**)
- The MDT should include an AU and radiation safety officer (RSO); these can be the same person
  - The RSO primarily manages radiation safety and advises other MDT members on minimizing radiation exposure

Figure 1. Roles of the MDT involved on the day of RLT delivery



[a]Technologists, AUs, and/or medical physicists may perform these roles; however, they are unable to administer medications. AU, authorized user; MDT, multidisciplinary team; NM, nuclear medicine; RLT, radioligand therapy; RP, referring physician; RSO, radiation safety officer.

Room preparation

- Prior to RLT, the treatment room and washroom should be prepared appropriately[8] (**Figure 2**)
  - Plastic-backed paper should be added to surfaces at risk of contamination and plastic applied to touchpoints[8]
  - Bathrooms should have clear signage containing radiation warnings and instructions for use[9]
- Scheduling of a designated room should account for time to prepare the room, conduct the therapy, and clean up and release the room

Figure 2. Example preparation of the treatment room and the washroom

Image adapted from *Establishing a robust radioligand therapy program: A practical approach for North American centers* by Mittra ES, et al. 2024 Licensed under CC BY 4.0.

- All necessary equipment must be obtained ahead of time and adapted to the administration method
  - [^{177}Lu]Lu-PSMA-617 can be administered via 3 methods: intravenously as an injection using the syringe method, as an infusion using the gravity method, or as an infusion using the peristaltic pump method[1]

Dose preparation

- The RLT dose should be checked for particulate matter and discoloration (acceptable coloration is colorless to slightly yellow)[1]
- Prior to treatment, a time-out should be performed to verify the correct patient, drug, and activity[10]
- Before administration, the intravenous line should be flushed with ≥10 mL saline[1]

Administration

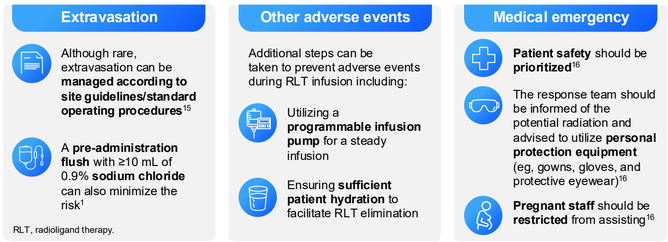
Radiation safety

- Throughout the day, "As Low As Reasonably Achievable" (ALARA) principles of time, distance, and shielding should be used to limit radiation exposure[11]
- The reported occupational exposure to staff is low for [^{177}Lu]Lu-PSMA-617 (0.5–1.5 millisievert);[12] however, shielding, gloves, and tongs should be used when handling [^{177}Lu]Lu-PSMA-617 or contaminated materials[1]
  - During administration, [^{177}Lu]Lu-PSMA-617 should be kept in a lead-shielded vial and a syringe shield utilized if administering via syringe[1]
  - The amount of radioactivity in the vial should be confirmed with a dose calibrator both prior to and after administration[1]
- Although uncommon, collection and handling of samples ≤3 days after dosing should observe ALARA and universal contamination precautions[13]
  - Any radioactive waste should be decayed until it reaches background radiation levels and then disposed of with biohazard waste[8]
- Any patient escorts must remain in the waiting area until discharge. In exceptional circumstances where escorts must be present, radiation safety precautions should be followed such as ensuring good hand hygiene and using gloves[14]

Management of complications

- During administration, a nuclear medicine technologist, the AU, or another trained individual should monitor for infusion problems such as blockage or extravasation[10] (**Figure 3**)

Figure 3. Management of complications during administration



RLT, radioligand therapy.

Post-administration

Patient discharge

- Prior to discharge, patients must meet radiation safety release criteria;[7] release limits vary widely between institutions but are based on the estimated exposure to the public
- On discharge, patients should be advised of precautions to prevent radiation exposure, including:[1,7]
  - Limiting close contact (<3 feet) with household contacts for 2 days and with children and pregnant women for 7 days
  - Refraining from sexual activity for 7 days
  - Sleeping in a separate bedroom from household contacts for 3 days, from children for 7 days, and from pregnant women for 15 days
- Patients should be made aware of self-care instructions (eg, keeping hydrated and urinating frequently), where to seek emergency treatment after RLT, and what information they should provide the treating physician

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