

# Critical Challenges in Pluvicto Therapy: Incontinent and Anticoagulated Patients

James R. Crowley

*Carilion Clinic, Roanoke, Virginia*

As molecular therapy continues to grow, unanticipated challenges may arise, requiring the institution's therapeutic team to reevaluate its therapeutic protocol to identify and address potential situations and challenges that may occur. This practical pointer will focus on the novel prostate cancer therapy Pluvicto ( $^{177}\text{Lu}$ -vipivotide tetraxetan) and 2 unique situations and challenges of treating patients at the Theranostic Center at Carilion Clinic, an outpatient facility dedicated to targeted molecular therapy.

**Key Words:** Pluvicto; incontinence; anticoagulation; decontamination; protocol

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**P**rostate cancer is the second most common cancer in men. One in 8 men will be diagnosed with prostate cancer in their lifetime, and 1 in 41 will die of the disease (1). Pluvicto ( $^{177}\text{Lu}$ -vipivotide tetraxetan; Novartis), a well-tolerated therapeutic, is indicated for the treatment of adults with prostate-specific membrane antigen–positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy (2). Patients are selected after PET/CT imaging with an approved prostate-specific membrane antigen 11 imaging agent to confirm prostate-specific membrane antigen expression in tumors. The recommended Pluvicto dosage is 7.4 GBq (200 mCi) intravenously every 6 wk for up to 6 doses or until disease progression or unacceptable toxicity.

## SITUATION 1

Our initial experience with Pluvicto was with clinical trials with strict patient selection criteria and procedure protocols; however, once clinical patients started arriving, we discovered unique challenges associated with patient incontinence. Initially, the documents we complete to verify a patient is releasable mirrored those associated with Lutathera ( $^{177}\text{Lu}$ -DOTATATE; Novartis) and  $^{131}\text{I}$ , but prostate cancer is a very different disease, and many men have

difficulty with their urine. Pluvicto, with a physical half-life of 6.647 d, is quickly eliminated in the urine. The use of pads, diapers, and self-catheterization with the associated radioactive waste products created challenges associated with patient release.

## SITUATION 2

A patient at the clinic completed his Pluvicto therapy and was discharged from the department. About 5 min later, the nurse navigator received a call that her patient was at the front of the facility, dripping blood. The nurse and nuclear medicine technologist retrieved and returned the patient to the treatment room to redress the injection site and assess potential contamination from the dripped blood. Around 30 blood drops with radioactivity measuring more than 4 mR/h were identified in the hallway and exiting the building (Fig. 1). The authorized user and radiation safety officer were notified. The radiation safety officer determined that the blood drops contained removable contamination and worked with his team to clean and manage the situation, which included modifying access to contaminated areas during cleaning, and rerouting patient flow via alternate entrance and exit points. Cleanup involved several techniques. The tile floor of the hallway was decontaminated with bleach wipes, Radiacwash (Biodex Medical Systems, Inc.), and elbow grease. The carpet in the entrance was removed and stored. The droplets of blood outside were cleaned as much as possible and then diluted with water. The entrance and hallway were reopened on completion of the decontamination process.

## SITUATION ANALYSIS

An in-depth analysis by the therapeutic team identified multiple unanticipated consequences related to each situation.

There was a clear need to enhance patient education and coaching before discharge. Patient medical knowledge is often low, and it is important to explain how to apply pressure to the injection site and how to manage blood, urine, and waste safely.

Pluvicto patients may demonstrate unique challenges in the subsequent hours after administering the 7.4 GBq (200 mCi) therapeutic dose. The relatively rapid discharge after treatment leaves significant activity in circulation; thus, any unanticipated event may be complicated by radiation exposure.

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For correspondence or reprints, contact James R. Crowley (jrcrowley@carilionclinic.org).

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**FIGURE 1.** Radioactive blood drops in hallway (A) and outside building (B).

The routine use and disposal of radioactive pads, diapers, or self-catheterization equipment may directly impact patient release. Landfill radiation detectors are very sensitive. Radioactive patient waste products inadvertently put into the regular trash may exceed landfill radiation detector limits. Enhanced patient education on good hygiene, radioactive contamination, and waste disposal was necessary.

Patients on anticoagulant medication are at greater risk of bleeding after injection. Careful medication assessment before therapy and using a pressure dressing rather than an adhesive bandage, coupled with an extended wait time for observation, may be necessary.

Droplets of blood contaminated the patient's clothing, requiring retention of the patient's clothing and provision of a change of clothing (scrubs) for the patient to wear at home.

Contamination in the main hallway highlighted the need to enhance the contamination protocol, including staff assistance in patient wayfinding and navigation when main thoroughfares are closed.

### **THERAPEUTIC PROTOCOL REVISION**

As a result of these situations, the therapeutic team at Carilion Clinic enhanced its therapeutic protocol with the following.

A literature review demonstrated examples of scenarios in which radioactive trash set off alarms at local landfills. Virginia is an agreement state, and with the assistance of

Virginia's Department of Health, which regulates the clinic's radioactive materials license, a plan for patient waste storage and protocol adjustments was developed, including additional time in the department and occasionally inpatient therapy when patients cannot care for themselves. Of note, it is important that each clinical site work closely with its regulatory agency to meet the requirements associated with its radioactive materials license.

Adjustments in preparation and time spent interviewing patients before patient arrival were made.

The clinic moved to nurse navigators who were trained in radiation safety. These nurses worked closely with the medical health physicist and technologists to develop a program to educate patients regarding urine contamination, good hygiene (especially in the first 24 h), and the importance of proper waste handling and disposal.

A patient supply kit, provided at discharge with additional education to reinforce good hygiene, was created, including gloves and cleaning pads.

A time-out to confirm the correct patient, correct procedure, and relevant medical issues (e.g., patient on anticoagulation therapy) was implemented. With multiple therapies occurring at the same time and radiopharmaceuticals arriving in the same color box, pig, etc., it is vital that we treat this procedure like the invasive procedure that it is.

An anticoagulation protocol has been developed to extend the observation time (10 min) to confirm that the dressing is adequate and that no blood is visible. The patient is instructed to apply pressure and elevate the arm to minimize blood seepage.

Scrubs have been added to the checklist for therapeutic protocols. The department retains contaminated clothing, and the patient is provided scrubs to wear home.

Patient education and collateral information has been developed at a fifth-grade reading level. Additional time and demonstration have been added to the education process to help patients understand, value, and participate in their care. Although there is no perfect tool, teach-back education and pictures are helpful.

Staff education has been enhanced to include the revised therapeutic protocol and recommended tools and procedures to minimize contamination and clean-up.

With the assistance of the emergency preparedness department and the radiation safety team, an action plan has been

developed to escalate and gather resources as needed in the event of a spill, including additional staff to assist with patient wayfinding, cleaning/decontamination, and supply acquisition as needed.

As the volume of molecular therapy expands, additional protocols and procedures will be necessary to manage and minimize situations such as this. Patient education plays an important part in this process. The method and effort invested in educating patients are important to keep them and everyone else safe.

## **DISCLOSURE**

No potential conflict of interest relevant to this article was reported.

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