RO-ILS®
RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

CLARITY PSO
A Patient Safety Organization

RO-ILS CASE STUDY 12

IS THAT A PACEMAKER NEAR THE TREATMENT VOLUME?

Introduction

The treatment planning process begins with a simulation and incorporates the critical process of accurately distinguishing various structures and contouring both target and avoidance structures. Every patient with cancer has unique characteristics that may create challenges when developing the optimal treatment plan. In addition to limiting doses to critical structures, implanted medical devices must be taken into consideration. Cardiovascular implantable electronic devices (CIED), such as pacemakers, can present a problem with planning certain radiation treatments. A pacemaker is a small device implanted in a patient's chest or heart to help regulate the heartbeat. Traditionally, pacemakers included leads (Figure 1a) to deliver electrical impulses to the heart; however, in 2016, the FDA approved leadless pacemakers (Figure 1b). Figure 2 displays the relative size comparison; leadless pacemakers are approximately the size of a AAA battery. There has been an increase in utilization of leadless pacemakers; nonetheless, they remain a small portion of the 200,000 pacemakers implanted annually.[1] Radiation oncology professionals must be aware of advancements in other fields, such as cardiology, given the multidisciplinary nature of a person's health.

Figure 1[2]: Diagram of (a) Traditional Pacemaker and (b) Leadless Pacemaker

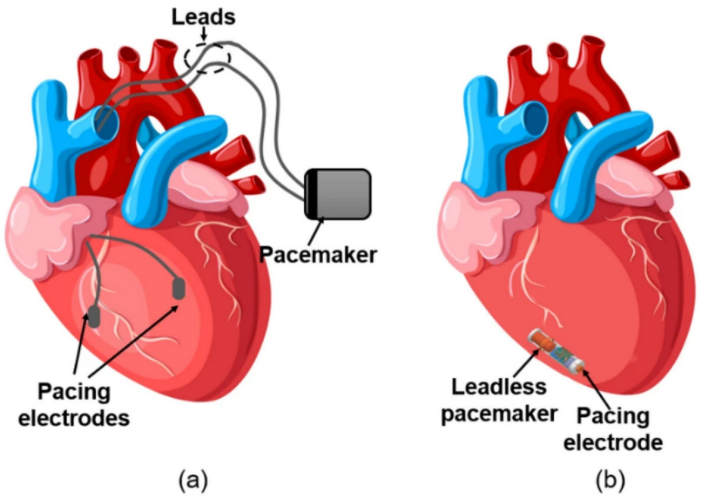


Figure 2[3]: Photo of Different Pacemaker Devices

Event Overview

Overview: A patient with metastasis to the sternum and thoracic spine was scheduled to have palliative radiation therapy. Treatment had to be rescheduled due to a CIED that was not accounted for during treatment planning.

Details:

- Patient was diagnosed with secondary bone metastasis to the sternum, and the T3/T4 spine required palliative radiation therapy.
- The patient's pacemaker was noted during the nursing assessment and consultation.
- However, there was no verification or follow-up related to the implanted device.
- The radiation oncologist prescribed 3000 cGy in 10 fractions to the left sternum and T3/T4 spine.
- During planning, the pacemaker was incorrectly identified on imaging as a breast expander.
- The plan was developed with two opposing beams.
- The left anterior oblique beam was planned using 10 MV; the right posterior oblique beam was planned using 15 MV.
- A dosimetrist completed the plan and a radiation oncologist approved it.
- During the initial physics chart check, a physicist identified the CIED that was approximately 5 mm from the field edge.
- The device was found before the start of radiation delivery, so the treatment was adjusted.

Contributing Factors

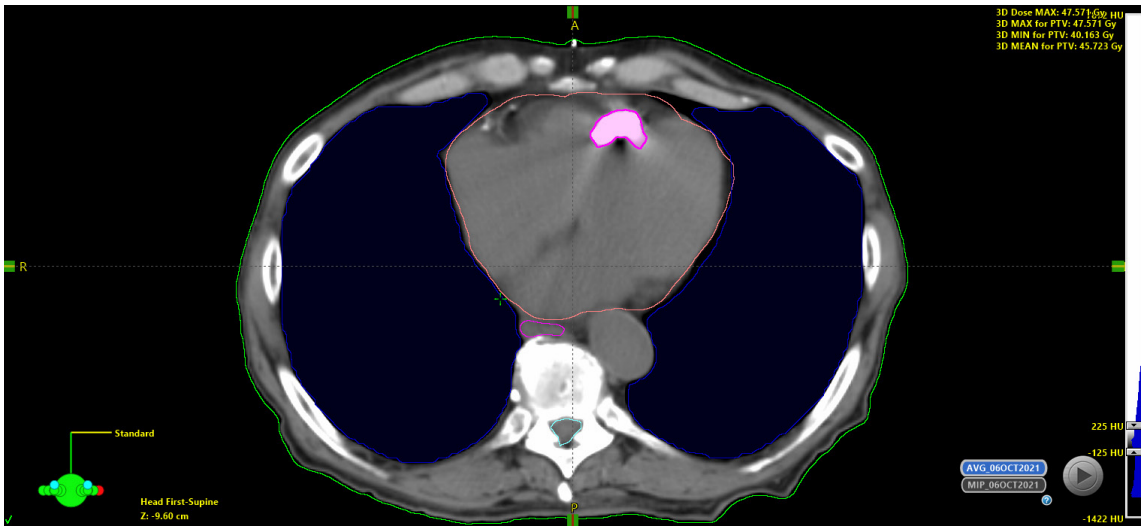
- Missing comprehensive, written documentation related to the CIED (e.g., detailed, follow-up information related to the CIED).
- Poor communication between teams.
- Incorrect identification/assumption of structures on images.
- Lack of adherence to policy or inadequate policy.
- Lack of attention during simulation and planning.

Lesson Learned/Mitigation Strategies

1. **Safety fundamentals are key to avoid errors.**
   The fundamentals of documentation, standard protocols and detailed checks are common threads in many RO-ILS events, including this one. A thorough patient history allows the radiation oncology team to learn vital information concerning the patient being treated. Key information (e.g., prior radiation, implanted devices) must be documented in a consistent location and manner, as this is the preferred method to communicate with other staff. This allows practices to leverage the functionalities of electronic medical records such as setting up alerts to actively notify staff of important information. Additionally, standard processes must be in place to follow up and evaluate the relevance of the patient-specific information. For example, if a patient is found to have a CIED, a cardiologist should be contacted to provide more details about the patient's device. The cardiologist determines whether the patient's CIED is dependent or independent.[4] With this follow-up information, the radiation oncology team can determine how best to proceed with treatment. For example, if the patient is not pacemaker-dependent, there is the option to switch the device off during treatment. Practices should consider what redundancies are in place to confirm patient-specific information is known and accounted for in radiation treatment.

2. **Clinicians should be cognizant of advancements in other specialties.**
As technology advances, it is important that the radiation treatment team stay vigilant and up to date on advancements in other medical fields. With the development of leadless pacemakers and other small implantable devices, it is imperative that radiation oncology team members question what they are seeing on images. Figure 3 shows a treatment plan with a leadless pacemaker implanted in the right ventricle contoured in pink. Modern technology supports smaller and more powerful equipment that may be mistaken for other devices, whether they be CIEDs or other implantable devices (e.g., deep brain simulation devices, insulin pumps). Therefore, vigilance is needed.

Figure 3: Leadless Pacemaker Contoured on CT



3. **Treatment considerations to explore when a patient has a CIED.**
CIEDs are highly radiosensitive devices used to regulate the patient's heartbeat, and therefore, malfunctions can lead to dangerously erratic device function, putting the patient at risk. To limit radiation effects on the CIED, preference is given to not direct beams of radiation near the device if it can be avoided. Additionally, utilizing lower energies (<10 MV) to avoid neutron generation is preferable to meet the general maximum dose thresholds to the CIED of <500 cGy (though vendor guidance may provide higher or lower thresholds).[5] The use of in vivo dosimetry, such as optically stimulated luminescent dosimeters or thermoluminescent dosimeters, for monitoring dose to the device should also be discussed. A half beam block technique and repositioning isocenters to avoid the CIED are other possible options. These considerations minimize risk of device damage while treating the disease. Device functionality can also be tested after treatment.

4. **"Near miss" events provide learning opportunities.**
This case study is an excellent example of a "near miss." Although the event did not reach the patient, it reiterates the importance of reporting non-incidents as there are many learning opportunities. The physicist's initial chart check identified the CIED, preventing a therapeutic event. While this process was effective in catching the error, the event highlights other deficiencies and poses questions for all practices to consider.

SAFETY CHECK

1. What pre-treatment processes are in place to identify and investigate CIEDs and other implanted devices?
2. Is there a clear, standardized process to document and communicate the presence of CIEDs and other implanted devices?
3. How are CIEDs and other implanted devices addressed at your practice?

Resources

- ASTRO Academy Course (2021): A review and analysis of managing commonly seen implanted devices for radiotherapy patients.
- AAPM TG 208 Report (2019): Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators.
- HRS Consensus Statement (2017): Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices.

References

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5. Miften M, Mihailidis D, Kry SF, et al. Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators: A Report of the AAPM TG-203. *Med Phys.* 2019 Dec;46(12):e757-e788. doi: 10.1002/mp.13838. Epub 2019 Nov 1.

