



## Navigating a New Frontier: Evaluating Leadless Pacemakers in Proton Therapy



Maciej Dyrbuś (MD, PhD)<sup>1,\*</sup>, Mateusz Tajstra (MD, PhD)<sup>1</sup>, Tomasz Rutkowski (MD, PhD)<sup>2</sup>, Mariusz Gąsior (MD, PhD)<sup>1</sup>, Sławomir Blamek (MD, PhD)<sup>2</sup>

<sup>1</sup> 3rd Department of Cardiology, School of Medical Sciences in Zabrze, Medical University of Silesia, Katowice, Poland

<sup>2</sup> Department of Radiotherapy, Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch, Gliwice, Poland

### ARTICLE INFO

#### Keywords:

Leadless pacemaker  
Proton therapy  
Radiation therapy  
Reset  
Secondary neutrons

As the number of patients with cardiac implantable electronic devices (CIEDs) undergoing radiation therapy has seen substantial growth, the strategies aimed at establishing the most effective and safe pathways of treatment and surveillance are crucial for this group of patients.<sup>1-3</sup> The novel, nontransvenous CIEDs, such as leadless pacemakers (LPMs) or subcutaneous cardioverter-defibrillators, provide an important alternative for specific groups of patients, yet the impact of technological differences between them and the conventional transvenous devices, in the context of radiation therapy, has not been completely studied to date. Taking into consideration all aforementioned factors, we read with a great interest the manuscript “Navigating Complexities: Leadless Pacemaker Management in Proton Therapy for a Pacemaker-Dependent Bilateral Breast Cancer Patient,” which has recently been published in the journal.<sup>4</sup>

The issue of proton therapy in patients with CIEDs has raised many concerns, mostly due to the generation of secondary neutrons, which have been identified as one of the primary causes of device malfunctions, errors, as well as structural damage.<sup>2,5</sup> Thus, in the majority of patients with a CIED, proton therapy is very rarely considered as the therapy of choice. Of note, to the publication of this manuscript, there were neither in vitro nor in vivo data on the safety nor influence of proton therapy on the LPMs.

Although in the manuscript, the authors report on the overall successful clinical course of the patient, there are few important aspects one has to take into account.

First, the authors must be commended for the decision on the implantation of an LPM, leading to a spectacular reduction in the radiation dose. However, the occurrence of 2 electrical resets during the course of

treatment is not negligible. It could be of clinical significance if the authors could provide more information not only on the details of the electrical resets but also on the patient's clinical profile, taking into consideration the patient's dependence on the pacemaker after atrio-ventricular node ablation. In patients with conventional, transvenous CIEDs undergoing proton therapy, the rate of electrical resets was low; thus, the 2 events reported in this case require attention.<sup>6</sup>

Second, it would be of interest if the authors could present more data on the proton therapy that was delivered during radiation therapy (RT), including detailed radiation beam energy as well as the calculated doses of secondary neutrons both for the nominal location of the conventional pacemaker, as well as that for the leadless device. Although proton therapy per se allocates the patient in the high-risk group, the information on the beam energy as well as calculations of neutron generation seems very important, especially since the decision on the implantation of the leadless device was based on the initially perceived risk for the device in its conventional location. Moreover, taking into consideration the lack of prior data on the influence of proton therapy on the leadless devices, the mentioned parameters could provide more data on the choice of this proton therapy over photon therapy, which already has been performed in patients with LPM.

Another issue that is worth discussing is the cardiological surveillance strategy, which has been performed in the analyzed subject. To date, there are too little data to evaluate whether the direct extrapolation of results from conventional devices to nontransvenous CIEDs is feasible and safe. For instance, in our recent analysis, we have demonstrated the occurrence of significant battery depletions of all 3

\* Corresponding author.

E-mail address: [mdyrbus@op.pl](mailto:mdyrbus@op.pl) (M. Dyrbuś).

subcutaneous cardioverter-defibrillators, which were associated with delivering stereotactic body radiation therapy in the anthropomorphic phantom model of a left lung tumor.<sup>5</sup> Such an event was rarely found in conventional devices, especially considering a relatively low dose delivered to the devices at the occurrence of battery voltage reductions. Thus, caution must be made, regarding consideration of the novel CIEDs as equivalent to standard devices in any clinical scenario.

Nonetheless, depending on the clinical profile, the dose and energy of RT, the patients should be risk-stratified, and then the surveillance strategy chosen. As patients undergoing proton therapy in the presence of CIED are classified in the high-risk group, this patient should undergo either weekly device interrogation or, even (according to some recommendations), the CIED should be interrogated at every RT session.<sup>1,3</sup> Taking into consideration the patient's dependence on the implanted pacemaker, the benefit of an early identification of any device malfunctions seems of utmost importance.

In summary, although the article presents a valuable and instructive case, demonstrating an undoubted benefit of combined efforts of radiation therapists, oncologists, and cardiologists, the community would benefit greatly from the inclusion of details regarding proton energy, device surveillance strategy, and the details of electrical resets. Such information seems crucial to establish benefits as well as possible risks associated with the exposure of LPM to radiation therapy in patients with cancer and to allow the clinicians to choose the most optimal clinical pathway.

## Declaration of Conflicts of Interest

None declared.

## References

1. Lyon AR, López-Fernández T, Couch LS, et al. 2022 ESC Guidelines on cardio-oncology developed in collaboration with the European Hematology Association (EHA), the European Society for Therapeutic Radiology and Oncology (ESTRO) and the International Cardio-Oncology Society (IC-OS) [published correction appears in *Eur Heart J*. 2023 May 7;44(18):1621. doi: 10.1093/eurheartj/ehad196]. *Eur Heart J*. 2022;43(41):4229–4361. <https://doi.org/10.1093/eurheartj/ehac244>
2. Indik JH, Gimbel JR, Abe H, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. *Heart Rhythm*. 2017;14(7):e97–e153. <https://doi.org/10.1016/j.hrthm.2017.04.025>
3. Tajstra M, Blamek S, Niedziela JT, et al. Patients with cardiac implantable electronic devices undergoing radiotherapy in Poland. Expert opinion of the Heart Rhythm Section of the Polish Cardiac Society and the Polish Society of Radiation Oncology. *Kardiol Pol*. 2019;77(11):1106–1116. <https://doi.org/10.33963/KP.15063>
4. Saki M, Grewal H, Artz M, et al. Navigating complexities: leadless pacemaker management in proton therapy for a pacemaker-dependent bilateral breast cancer patient. *Int J Part Ther*. 2024;13:100112. <https://doi.org/10.1016/j.ijpt.2024.100112>
5. Mirzaei M, Rowshanfarzad P, Gill S, Ebert MA, Dass J. Risk of cardiac implantable device malfunction in cancer patients receiving proton therapy: an overview. *Front Oncol*. 2023;13:1181450. <https://doi.org/10.3389/fonc.2023.1181450>
6. Tajstra M, Dyrbuś M, Stąpór-Fudzińska M, Rutkowski T, Gąsior M, Blamek S. Safety and feasibility concerns of radiotherapy in the presence of subcutaneous implantable cardioverter-defibrillator. *JACC Clin Electrophysiol*. 2024;10(3):581–582. <https://doi.org/10.1016/j.jacep.2023.12.004>