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Teaching Case

Management of a Radiation Therapy Patient With a Leadless Pacemaker

Dongxu Wang, PhD,[a,*] Maria F. Chan, PhD,[a] Joseph Zambri, BS,[a] Phillip Lichtenwalner, MS,[a] James Oliver, BS,[a] Daphna Gelblum, MD,[b] and Dhwani Parikh, MD[b]

[a]*Departments of Medical Physics;* [b]*Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, New York*

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Introduction

Cardiac pacemakers are among the top 10 most frequently implanted medical devices in the United States.[1] Radiation therapy (RT) can have adverse effects on the performance of cardiac pacemakers. As opposed to a standard subcutaneous pacemaker on the upper chest, we sometimes encounter a leadless pacemaker implanted in the right ventricle of the heart. A leadless pacemaker has the same function as a regular pacemaker but is much smaller in size and has no leads. A Micra AV dual-chamber pacemaker transcatheter leadless pacemaker is 95% smaller than typical pacemakers (Fig. 1). The RT dose tolerance should be the same as that of a regular pacemaker.[2-9] Based on the published guidelines, if the patient undergoes RT and the average dose rate at the device is >1 cGy/min, the pacemaker should be programmed into asynchronous pacing mode, the permissible cumulative dose should be less than 500 cGy (the authors follow the institutional limit of 200 cGy), and the beam energy should be <10 MV.[2-9] A leadless pacemaker is sometimes considered a favorable alternative for patients with tumors of the upper chest/lower neck but even then it can be too close to the treatment fields. As such, the management of a leadless pacemaker in RT poses its unique challenges, in that it is not easily further relocated, and in vivo dosimetry is not possible.

Currently there are limited reports with regard to implanted leadless pacemakers in RT. For example, there was one case report published in Europace[10] of a patient with a mediastinal mass who underwent RT with a leadless pacemaker partially in the field; this case documented no remarkable dysfunctions to the leadless pacemaker which received a mean dose of 243 cGy and maximum point dose of 1159 cGy. In this study, we report a case of RT to a patient with left breast cancer whose standard subcutaneous pacemaker was changed to a leadless pacemaker (Micra, Medtronic, Minneapolis, MN) after RT simulation but before RT started.

Case Presentation

The patient is a 69-year-old woman with a cardiac pacemaker; she is not pacing dependent. The patient presented with a stage IIA (cT2N0) triple negative left breast invasive ductal carcinoma status post lumpectomy and sentinel node biopsy. Three months before the treatment of her breast cancer, she had received concurrent chemoradiotherapy for a locally advanced unresectable pancreatic head

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Data presented in this Teaching Case were obtained from a clinical patient of the author's institution. The patients have signed consent to the use of their deidentified clinical information for teaching purpose only. The patient's data will not be shared, other than those presented in this Teaching Case.

*Corresponding author: Dongxu Wang, PhD; E-mail: wangd2@mskcc.org

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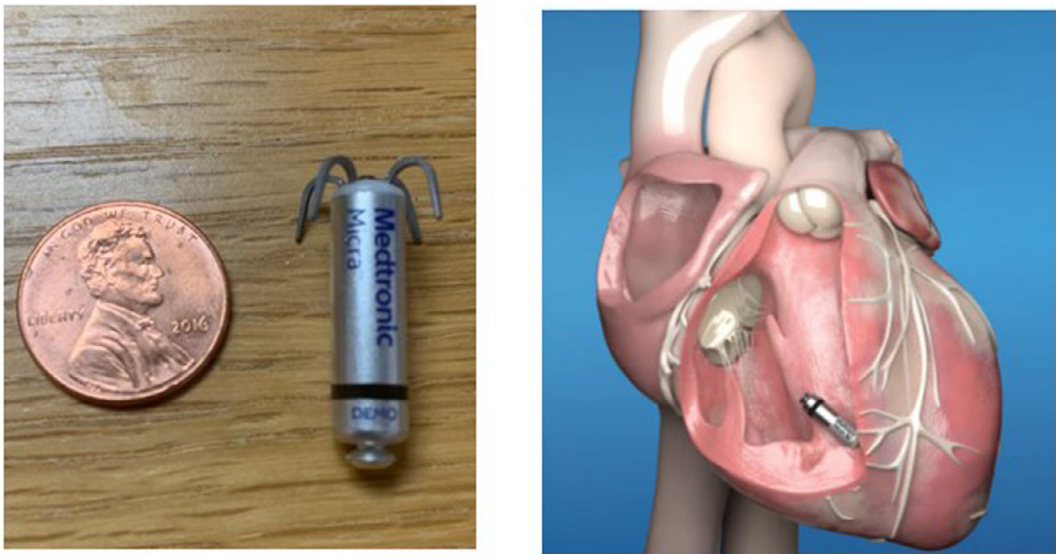

Fig. 1 A, leadless pacemaker relative size to a penny. B, A leadless pacemaker implanted directly into the right ventricle. Reprinted with permission of Medtronic, Inc.

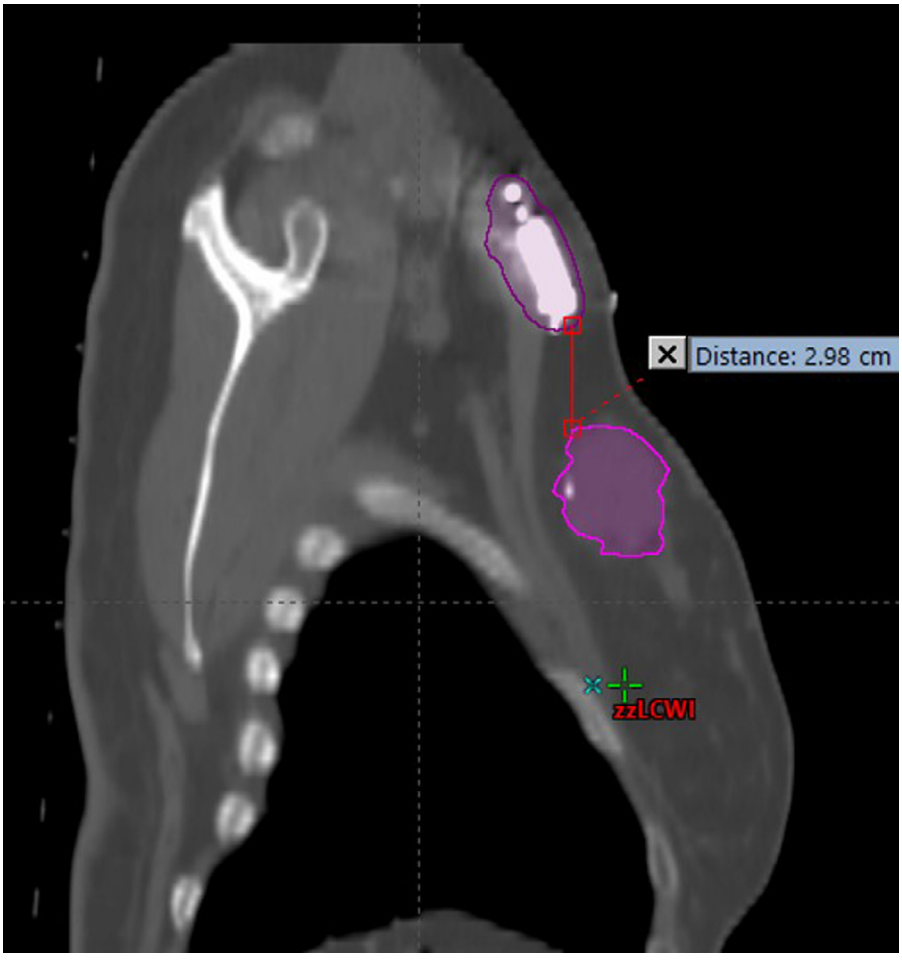

Fig. 2 Initial planning computed tomography image showing the original pacemaker location relative to the left breast lumpectomy site. Pink = lumpectomy contour.

adenocarcinoma at our institution. The pancreas RT dose was 4500 cGy in 25 fractions with a simultaneously integrated boost of 7500 cGy to the gross tumor. The abdominal RT was considered to have marginal overlap with her breast RT. The original pacemaker, implanted subcutaneously on her chest, was estimated to have received a cumulative dose of 14 cGy from the pancreas RT based on in vivo dosimetry. For the left breast RT, after the "FAST-Forward" protocol,[11] the radiation oncologist prescribed 2600 cGy in 5 fractions to the whole breast followed by 1040 cGy boost in 2 fractions to the lumpectomy cavity. The patient was simulated in the supine position using deep inspiration breath-hold technique. The Medtronic cardiac pacemaker (model A2DR01) was visible in the planning computed tomography (CT) images located in the left superior thorax (Fig. 2) and contoured. It was positioned approximately 3 cm superior to the current lumpectomy contour. Owing to the pacemaker's proximity to the lumpectomy site, the whole breast could not be adequately treated without exceeding the institutional cumulative pacemaker limit of 200 cGy (including the previous 14 cGy from pancreatic RT). Closing the superior field border in the initial treatment planning did not help decrease the pacemaker exposure. The case was presented to the institutional breast chart rounds. After considering alternative options such as intensity modulated RT and partial breast irradiation, it was decided that the best approach would be to relocate the pacemaker further away from the breast treatment site. The patient's cardiologist, at a different institution, was then consulted. Four workdays before the scheduled start date of breast RT, the patient had her subcutaneous pacemaker removed and replaced with a leadless Micra AV pacemaker (Medtronic, MN). She stayed in the hospital overnight and was discharged the next day.

The day after the cardiology procedure, the procedure report was obtained from the cardiologist's office; radiologic images were not obtained owing to the procedure being performed in a different hospital. Based on the reading of the cardiology procedure report, it was presumed that the leadless pacemaker would not be in proximity to the breast fields. Treatment planning therefore

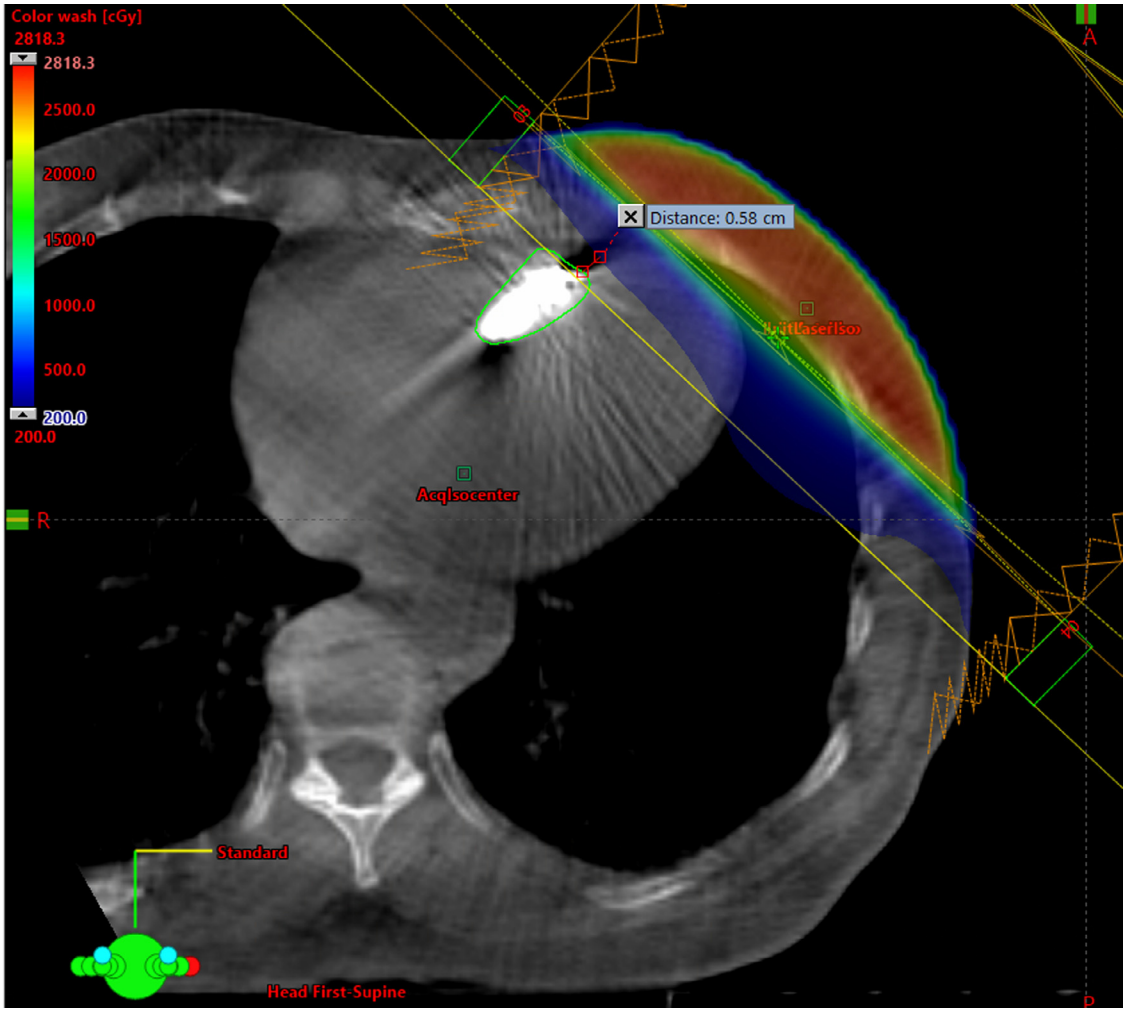

Fig. 3 Cone beam computed tomography image blended in the treatment planning system with a display with 200 cGy isodose colorwash. A 0.58 cm distance was measured between the leadless pacemaker and 200 cGy isodose line.

continued without resimulation but cone beam computed tomography (CBCT) verification was recommended before the start of treatment.

To verify the actual location of the pacemaker, a CBCT was acquired before delivery of the first fraction of treatment. CBCT confirmed no anatomic changes in the treatment site owing to the original pacemaker explantation. The CBCT was saved and registered to the treatment planning CT in the treatment planning system (TPS), so that the leadless pacemaker on CBCT could be blended into the treatment plan. The planned 200 cGy isodose line was evaluated on the CBCT (Fig. 3).

As can be seen from Figure 3, this treatment plan gave little room for setup errors as the 200 cGy isodose line was only measured approximately 0.6 cm (0.58 cm in Fig. 3) from the pacemaker edge. The calculated dose to the pacemaker, without considering setup uncertainty, would be 165 cGy. Additionally, even though the multileaf collimators were blocking the pacemaker, the pacemaker was within the jaws of the initial fields thus allowing for leakage dose, potentially further increasing the dose to the pacemaker. The physician was alerted to these concerns and decided not to proceed with the treatment as planned. The treatment was replanned to further reduce the potential dose to the leadless pacemaker.

The pacemaker was contoured on CBCT and this contour was copied to the planning CT so that the physician could create new fields with more tangential posterior field edges by choosing new gantry angles, collimator angles, and jaw positions, to keep the pacemaker well outside of the field without dose degradation at the treatment site. The revision plan was generated and the maximum pacemaker dose as planned was calculated to be 102 cGy. Subsequent CBCT verification was done again on the first treatment day of treatment using the revised treatment plan. On CBCT, the pacemaker was measured to be approximately 1.1 cm from the 200 cGy isodose line and 0.5 cm from the field edge, as shown in Figure 4. These distances were considered to have met the safe margin, based on the anecdotally observed typical setup

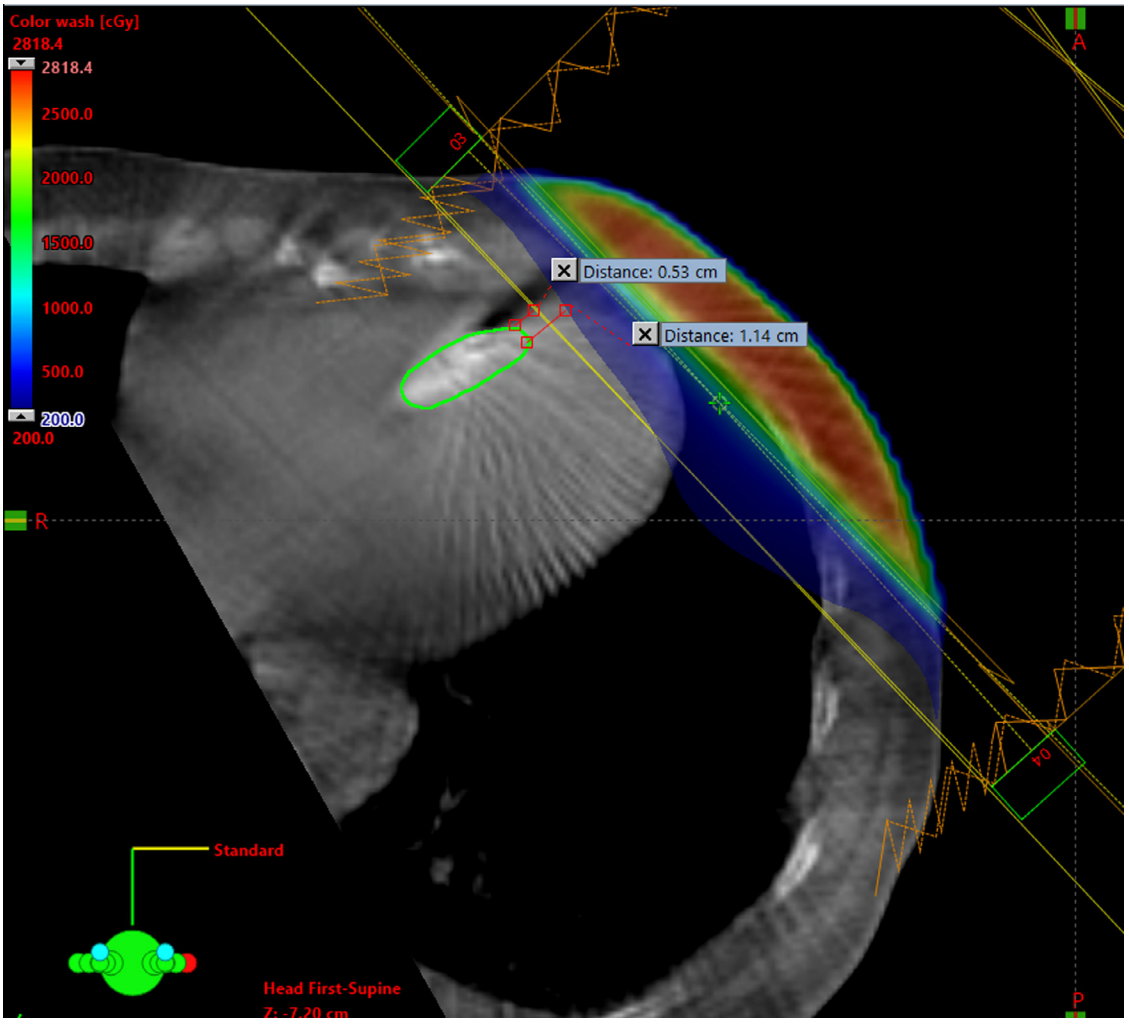

Fig. 4 Cone beam computed tomography image blended in the treatment planning system with a display with 200 cGy isodose colorwash in the revised plan. The leadless pacemaker is about 1.1 cm to 200 cGy dose and 0.5 cm to the field edges.

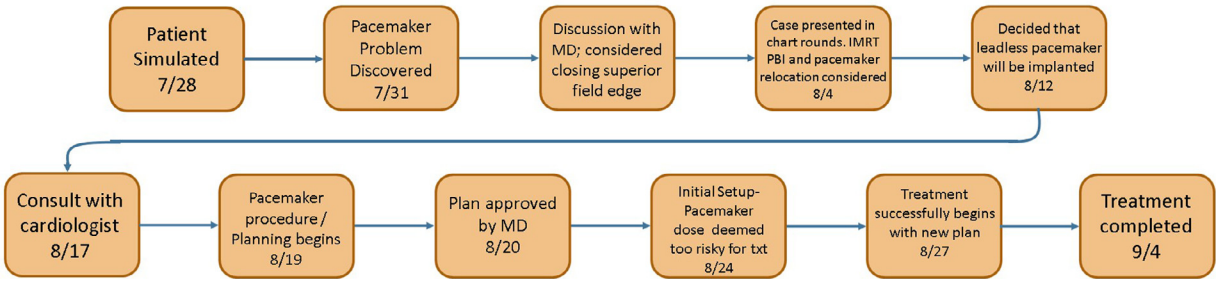

Fig. 5 Timeline of the entire radiation therapy process.

error of <5 mm for the treatment site with daily imaging and deep inspiration breath-hold technique.

Based on the location of the leadless pacemaker on this CBCT, the cumulative pacemaker dose was estimated to be 101 cGy for the entire course of breast RT treatment which was in alignment with the calculated dose in the revised plan. Note that for treatment planning we made the reasonable assumption that the anisotropic analytical algorithm in the TPS is accurate for out-of-field doses at this relatively short distance from the field edge. The authors were aware that in a TPS calculated doses beyond a few centimeters outside the treatment field edge were less accurate. AAPM TG-158 report was a good reference in cases where the pacemaker was far from the field edge.[12]

CBCT was performed before fraction 1 and fraction 2 to verify the pacemaker location (although not used for patient positioning); subsequent fractions used 2-dimensional KV images to confirm the position of the leadless pacemaker. Based on an estimate from quality assurance data, CBCT and KV imaging added no more than 20 cGy total dose. The maximum interfractional position variation for the pacemaker was found to be 1.0 cm, dominantly in the cranial-caudal direction, and the estimated cumulative dose, considering interfraction setup errors, deviated from the plan estimate by no more than 5 cGy. Electrocardiogram was performed during the first fraction of treatment. The breast RT completed successfully without dysfunctions noticed in the pacemaker. Patient had her follow-up visit 6 weeks after the breast RT and reported good recovery and noted no issues with cardiac functions. Figure 5 shows the timeline of the patient in the entire RT process from the simulation to completion.

Discussion

There have been widely adopted guidelines for management of cardiac implanted devices by the *British Journal of Radiology*,[3] the American Association of Physicists in Medicine,[4,5] as well as the Dutch Society of Radiotherapy and Oncology.[6] This case report will not revisit the details of such guidelines. Instead, this report shares the experience at the authors' institution of a single case that presented unique challengers associated with a leadless pacemaker: location verification and inability to perform in vivo dosimetry.

Ideally the patient should have been resimulated after the pacemaker was replaced, but to prevent a delay in start of RT we used the original simulation for treatment planning. Additionally, because the leadless pacemaker sat deep inside the heart, it was impossible to obtain conventional in vivo dosimetry, which is typically done by placing a thermoluminescence dosimeter or an optically stimulated luminescence dosimeter, on the skin surface above the subcutaneous pacemaker. Instead, we obtained verification images before start of each treatment to verify the location of the leadless pacemaker and to calculate dose exposure. In the case reported here CBCT was obtained at setup and before the first fraction of treatment to verify the leadless pacemaker location and calculate dose exposure. This technique should be considered for future cases presenting with similar planning challenges.

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