Safety of Radiotherapy in Patients with Cardiac Implantable Electronic Devices

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Research

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Abstract

**Background:** Patients with cardiac implantable electronic devices (CIEDs) usually have multiple comorbidities, and some require radiotherapy (RTx) for cancer treatment. However, the effect of RTx in patients with CIEDs is unclear. We aimed to examine the effectiveness of RTx in patients with CIEDs, and share our real-world clinical experience in this population.

**Methods:** We recruited patients with a pacemaker or implantable cardioverter-defibrillator who underwent RTx between April 2009 and August 2019. RTx and CIED interrogation data were collected from electronic medical records. Patients who received an RTx cardiology consultation and CIED interrogation before and after RTx were assigned to the proper consultation (PC) group. All others were enrolled in the no-consultation (NC) group.

**Results:** Out of 23 patients, 3 (13.0%) and 20 (87.0%) patients were assigned to the PC and NC groups, respectively. The most common RTx sites were the abdomen and pelvis (34.8%). The mean cumulative dose was 50.1 ± 11.7 Gy, and the mean beam energy was 10.3 ± 4.01 mV. The PC and NC groups showed no significant difference in cumulative dose (51.5 ± 12.1 vs. 45.3 ± 3.9, \(p=0.19\)) or beam energy (10.4 ± 4.03 vs. 7.0 ± 1.41, \(p=0.08\)). There was no significant between-group difference in any pre-RTx CIED parameter. Two patients died during the study period; both were in the NC group. The relationship between death and device malfunction was not clear in either case.

**Conclusions:** Patients with CIEDs frequently do not receive a cardiology consultation before RTx. Although radiotherapy-related CIED complications occur stochastically and are difficult to predict, cooperation between the cardiology and radiation therapy departments, and regular device follow-up are necessary for the safety of these patients.

**Background**

As populations have aged and the indications for implantable cardiac devices have widened, the number of patients who need cardiac implantable electronic devices (CIEDs), such as pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs), has steadily increased.[1–3] Patients with CIEDs usually have multiple comorbidities that require medical attention, and some receive radiotherapy for the treatment of cancer.[4–6] Radiotherapy (RTx) has been associated with CIED dysfunction, which can potentially threaten patient safety.[7] Clinically, RTx doses less than 2 grays (Gy) and between 2 and 10 Gy are categorized as low and medium risk, respectively.[8–10] Nevertheless, CIED malfunctions related to RTx have been reported even in patients receiving safe doses.[7, 11, 12]

Although strategies for the management of RTx in patients with CIEDs have been proposed in various countries, the domestic experience in our context and researchers are still lacking.[10, 13, 14] Additionally, physicians worldwide lack information about the effects of radiation therapy in patients with CIEDs. Therefore, we aimed to examine cases of RTx treatment in patients with PMs or ICDs to share our real-world clinical experience in this population.
Materials And Methods

Study population

We recruited patients with a PM or ICD who underwent RTx between April 2009 and August 2019 in our hospital. In all consultation cases, the patient was referred to the cardiology department for an evaluation of potential RTx-related risks and to determine the RTx dose. These patients underwent CIED interrogation before and after RTx to determine whether some parameters significantly presented a potential risk of device failure or needed a CIED mode change according to RTx. Patients who did not receive a cardiology consultation still underwent RTx as scheduled by the respective departments. Although these patients did not visit the cardiology department in preparation for RTx, they underwent device interrogation during their regular cardiology follow-up.

We evaluated the safety of receiving RTx in patients with all kinds of PMs and ICDs by enrolling consecutive patients. Further, we did not exclude patients based on the device type (conventional or magnetic resonance imaging(MRI)-conditional) or manufacturer. Patients without a CIED at the time of RTx were excluded.

The institutional review board approved the study protocol(IRB number, B-2003/601 – 110), and we performed our research according to the tenets of the Declaration of Helsinki.

Radiotherapy data

Data on RTx treatments were collected from electronic medical records (EMRs) at our hospital. Data included information about the malignant site, RTx start and end dates, the anatomical region irradiated and cumulative tumor dose, the number of fractions and fraction dose (maximal applied during the RTx course), and beam energy (maximal applied during the RTx course). Anatomical regions were classified as the abdomen and pelvis, brain, breast, head and neck, and lung. The abdomen and pelvis classification included the bladder, prostate, inguinal lymph nodes, pelvis, and inferior pubic ramus. The head and neck classification included the tonsils and associated lymph nodes, glottis, nasopharynx, and pyriform sinus.

Pacemaker and implantable cardioverter-defibrillator data

CIED interrogation data were collected from EMRs. The data included information on device class (PM, ICD), device type (VVI, VVIR, DDD, DDDR, single-chamber ICD, dual-chamber ICD), generator manufacturer, device model, and the date of implantation and revision.

Cardiac implantable electronic device preparation for radiotherapy

We defined appropriate RTx preparation as: (1) a cardiology consultation for RTx and (2) a CIED interrogation or mode change before and after RTx. Patients who received both were assigned to the
proper consultation (PC) group. All other patients were considered to have received incomplete preparation and were assigned to the no-consultation (NC) group.

**Statistical analysis**

Student’s $t$, the Wilcoxon rank, and the chi-square tests were used to compare means and proportions of baseline clinical characteristics between the groups. All statistical analyses were performed using R version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria), and $p < 0.05$ was considered statistically significant.

**Results**

**Baseline characteristics**

There were 27 consecutive cases. Four patients were excluded because they received RTx before CIED implantation. Thus, 23 patients with a PM or ICD who underwent RTx during the study period were analyzed (mean age, 72.1 ± 9.7 years [range, 54–93]; male, 17 [73.9%]; Table 1) (Fig. 1). There were 20 patients (87.0%) in the NC group and 3 (13.0%) in the PC group. RTx was mostly performed in the abdomen and pelvis (34.8%), the mean cumulative dose was 50.1 ± 11.7 Gy, and the mean beam energy was 10.3 ± 4.01 mV (Table 1). One patient received gamma knife RTx, and the rest received photon RTx. The most common indication for PM implantation was complete atrioventricular (AV) block, and the DDD type was the most frequently found. All patients with an ICD received it for primary prevention (Table 1).
Table 1
Baseline Characteristics

|                          | Total (n = 23) | NC (n = 20) | PC (n = 3) | p-value |
|--------------------------|---------------|-------------|------------|---------|
| Age at RT                | 72.1 ± 9.7    | 72.2 ± 10.5 | 71.7 ± 5.7 | 0.90    |
| Male (%)                 | 17 (73.9)     | 15 (75.0)   | 2 (66.7)   | 0.76    |
| HTN                      | 14 (60.9)     | 11 (55.0)   | 3 (100.0)  | 0.14    |
| DM                       | 9 (39.1)      | 8 (40.0)    | 1 (33.3)   | 0.83    |
| A.fib                    | 11 (47.8)     | 10 (50.0)   | 1 (33.3)   | 0.59    |
| Stroke                   | 2 (8.7)       | 2 (10.0)    | 0 (0.0)    | 0.57    |
| Anatomic region          |               |             |            |         |
| Abdomen and Pelvis       | 8 (34.8)      | 8 (40.0)    | 0 (0.0)    | 0.18    |
| Brain                    | 4 (17.4)      | 2 (10.0)    | 2 (66.7)   | 0.02    |
| Breast                   | 3 (13.0)      | 2 (10.0)    | 1 (33.3)   | 0.26    |
| Head and Neck            | 5 (21.7)      | 5 (25.0)    | 0 (0.0)    | 0.33    |
| Lung (Rt.)               | 3 (13.0)      | 3 (15.0)    | 0 (0.0)    | 0.47    |
| Cumulative dose (Gy)     | 50.1 ± 11.7   | 51.5 ± 12.1 | 45.3 ± 3.9 | 0.19    |
| Beam types               |               |             |            |         |
| Photon                   | 22 (95.7)     | 20 (100.0)  | 2 (66.7)   |         |
| Gamma Knife              | 1 (4.3)       | 0 (0.0)     | 1 (33.3)   |         |
| Beam energy (mV)         | 10.3 ± 4.01   | 10.4 ± 4.03 | 7.0 ± 1.41 | 0.08    |
| Device age at RTx, Months| 30.1 ± 31.6   | 31.1 ± 32.7 | 23.2 ± 27.0| 0.68    |
| Indication for CIED implantation |         |             |            |         |
| Pacemaker#               |               |             |            |         |
| complete AV block        | 11            | 8           | 3           |         |
| sick sinus syndrome      | 10            | 10          | 0           |         |
| ICD and CRT-D           |               |             |            |         |

A.fib, atrial fibrillation; AV, atrioventricular; CIED, cardiac implantable electronic device; CRT-D, cardiac resynchronization therapy with defibrillator; DM, diabetes mellitus; HTN, hypertension; ICD, implantable cardioverter-defibrillator; NC, no-consultation group; PC, proper-consultation group; RTx, radiotherapy; Rt, right
### Cardiac implantable electronic device parameters and complications

All pre-RTx CIED parameters showed no significant difference between the two groups. Additionally, the post-RTx parameters were not different between the two groups (Table 2).
|                                | NC (n = 20) | PC (n = 3) | p-value |
|--------------------------------|-------------|------------|---------|
| **Impedance (ohms)**          |             |            |         |
| Atrial                         |             |            |         |
| Pre                            | 499.2 ± 91.2| 518.3 ± 105| 0.79    |
| Post                           | 433.4 ± 109 | 485.7 ± 56.7| 0.31    |
| Ventricular                    |             |            |         |
| Pre                            | 619.9 ± 168 | 568.3 ± 84.3| 0.44    |
| Post                           | 562.4 ± 107 | 542.7 ± 86.4| 0.75    |
| **Sensing (mV)**               |             |            |         |
| Atrial                         |             |            |         |
| Pre                            | 3.180 ± 0.9 | 3.23 ± 2.1 | 0.97    |
| Post                           | 3.35 ± 1.28 | 3.03 ± 1.95| 0.81    |
| Ventricular                    |             |            |         |
| Pre                            | 13.0 ± 5.12 | 12.5 ± 4.82| 0.88    |
| Post                           | 13.1 ± 3.85 | 12.7 ± 8.20| 0.96    |
| **Capture threshold (V)**      |             |            |         |
| Atrial                         |             |            |         |
| Pre                            | 0.58 ± 0.34 | 0.58 ± 0.14| 0.98    |
| Post                           | 0.68 ± 0.47 | 0.63 ± 0.13| 0.76    |
| Ventricular                    |             |            |         |
| Pre                            | 0.69 ± 0.37 | 0.75 ± 0.13| 0.60    |
| Post                           | 0.68 ± 0.42 | 0.75 ± 0.13| 0.61    |

NC, non-consultation group; PC, proper-consultation group

No malfunction (0/3, 0%) occurred after RTx in the PC group, and two malfunctions (2/20, 10%) occurred in the NC group. In one of the two malfunctions, the atrial lead impedance decreased from 435 to 171 ohms (S1 Fig). One month after radiation therapy, the patient’s PM program was changed from DDD to
VVI because of the failure of the former to sense P waves. In the other malfunction, atrial and ventricular lead capture failures were observed. The patient had undergone a DDD PM implantation to treat complete atrioventricular block 5 years before RTx, and she was PM dependent (S2 Fig). She was dead on arrival at the emergency room four months after the radiation therapy, and only a pacing “blip” was observed on the electrocardiogram (ECG) at that time (S2 Fig). However, as the patient was receiving only palliative therapy for terminal breast cancer and did not undergo an appropriate PM assessment before and after RTx, it is difficult to distinguish between death secondary to disease progression and death resulting from capture failure.

Discussion

In this study, we documented the real-world clinical courses of CIED recipients undergoing RTx, such as gamma knife and photon RTx, and we noticed that clinicians still lack recognition and preparation regarding RTx-related CIED malfunction. Although the number of subjects was small during the study period, we found that 82.6% of patients with a CIED did not receive proper cardiology consultation for RTx from 2009 to 2019. This study documented that the pre- and post-RTx CIED parameters were not significantly different in patients with or without an appropriate cardiology consultation. However, it is not clear whether the post-RTx parameters in the NC group guaranteed the safety of the CIEDs even if the patients did not report a CIED malfunction after RTx. Although the device parameters of most NC group patients were in the normal range, they could not reflect the circumstances at the time RTx ended because these patients did not receive appropriate device interrogation.

Patients undergoing CIED implantation could have several comorbidities.[15] Accordingly, magnetic resonance imaging (MRI) or RTx could be indicated in a CIED recipient and can affect a CIED.[7, 16–19] The effects of MRI on CIEDs have been documented, and recommendations, including guidelines and prevention protocols, have been reported and used in the clinical field.[2, 20–23] We previously reported that, given appropriate precautions and consultations, MRI, even 3 Tesla MRI, can be performed safely in patients with a CIED.[24] Based on our experience, we developed an automatic consultation system that improved the pre-MRI consultation rate and the safety and quality of care in patients with a CIED.[25] CIED malfunctions related to RTx are easier to miss than those occurring secondary to MRI. One of our patients complained of dizziness after RTx for left breast cancer. She had a DDD-type PM on the right side and received RTx at 43 Gy (S3A Fig). At that time, the ECG revealed non-sustained ventricular fibrillation (S3B Fig). She was assigned to the PC group in this study. This case demonstrated that CIED dysfunction is difficult to identify and rarely reported. Moreover, RTx-related CIED malfunctions occur stochastically and are difficult to predict.[26, 27]

Reports indicate that CIEDs can be affected by direct ionizing radiation and photoneutrons leading to device malfunction.[26, 28] Grant et al. investigated RTx factors that caused CIED malfunctions and recommended non-neutron-producing RTx rather than neutron-producing RTx.[28] However, the mechanism and effects of radiation exposure are not clear. Several studies have demonstrated that safe radiation doses in the presence of a PM or ICD are 2–10 Gy and < 1 Gy, respectively. These levels are
under the curative doses for breast and lung cancer (up to 50–60 Gy).[8–10, 29, 30] In addition to recommendations for appropriate radiation dosage, cooperation between cardiology and radiation therapy departments is necessary for the prevention and proper monitoring of RTx-related complications; however, this multidisciplinary approach seems to be rare in actual practice. Zaremba et al. reported a 3.1% CIED malfunction rate in 453 RTx courses, and 22.6–27.9% of participants underwent device interrogation before and after RTx.[6] Only 21.7% of our study participants underwent appropriate pre- and post-CIED interrogation. Although almost all CIED recipients have a risk of RTx-related device dysfunction, there is no adequate preventive management. Further, clinicians are insufficiently aware of the fact that RTx poses a risk in patients with a CIED. The 2017 Heart Rhythm Society (HRS) consensus statement recommends device relocation if there is a possibility that it could interfere with RTx. Additionally, weekly CIED evaluations are recommended for patients undergoing neutron-producing treatment.[31] Thus, the 2017 HRS consensus statement reinforces the importance of cooperation between radiation and cardiology departments when a patient with a CIED requires RTx (Fig. 2).

In our study, two malfunctions occurred in the NC group. One patient received pelvic RTx (cumulative dose, 60 Gy) for prostate cancer. He complained of orthopnea caused by lung metastasis. When the patient visited the cardiology department for a post-RTx device evaluation, we found that the lead impedance had changed from 435 to 171 ohms (S1 Fig). The other patient received left breast RTx (cumulative dose, 45 Gy). She complained of severe diarrhea after chemotherapy and died after receiving supportive care without any curative cancer treatment. A normal paced rhythm was identified on the patient’s ECG 3 months after RTx (S2 Fig). However, when the patient arrived dead at the emergency department 4 months after RTx, her ECG showed no paced rhythm (S2 Fig). Although neither ECG detected any abnormal event related to the device at that time, we could not rule out device dysfunction definitively. In another case, a 64-year-old woman scheduled to receive left breast RTx was referred to the cardiology department for PM implantation due to AV block. The cardiologist decided that the PM should be inserted in the right chest to avoid interfering with her RTx according to the guidelines (S3 Fig).

Study limitations

Our study has some limitations. First, although we enrolled all patients with PMs or ICDs who underwent RTx, our cohort was small. Thus, it was difficult to compare values between patients. We attempted to overcome this limitation by analyzing the changes in all data and comparing the differences between groups based on consultation status. However, some data, particularly post-RTx interrogation values, were missing, making it difficult to compare the two groups directly. Second, due to the retrospective nature of the study, we could only assess the device function by interrogation, which indirectly reflects potential device dysfunction. Therefore, it was difficult to accurately determine the device condition at the time of death in patients who died. Despite these limitations, our retrospective single-center review included diverse RTx target cases reflecting real-world practice. Furthermore, we believe our study provides important clinical information about the potential for CIED complications associated with RTx.
Conclusion

In conclusion, the number of patients with a CIED referred for RTx consultations was low. Although RTx-related complications are difficult to predict, cooperation between the cardiology and radiation therapy departments and regular follow-up may be necessary to identify device dysfunction and for the safety of the patients. Furthermore, our results may support the establishment of guidelines for the safe management of CIED recipients who require RTx and could provide evidence to guide future research.

List Of Abbreviations

AV block: atrioventricular block,
CIEDs: cardiac implantable electronic devices
ECG: electrocardiogram
EMRs: electronic medical records
Gy: grays
ICDs: implantable cardioverter-defibrillators
MRI: magnetic resonance imaging
NC group: no-consultation group
PC group: proper consultation group
PMs: pacemakers
RTx: Radiotherapy

Declarations

Ethics approval

The Seoul National University Bundang Hospital institutional review board approved the study protocol(IRB number, B-2003/601-110), and we performed our research according to the tenets of the Declaration of Helsinki.

Consent to participate

Not applicable

Availability of Data and materials
Data are available. Please contact corresponding author.

**Competing interests**

None.

**Authors’ contributions**

IYO conceptualized this study. DH collected the data. DH and IYO wrote the initial draft. DH analyzed the data. DH and IYO reviewed the data analysis. JHL, YJC, and IYO reviewed the manuscript and interpreted the findings.

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**Figures**
Figure 1.

Study flow chart
**Figure 2. CIED management for radiation therapy**

- Do a complete CIED evaluation
- Establish treatment plan
- Will the device interfere with adequate tumor treatment?
- Will neutron-producing treatment be used?
- Is the patient pacemaker dependent?

- Yes: CIED relocation is recommended (Class I, LOE C)
- Yes: Weekly complete CIED evaluation is recommended (Class I, LOE B)
- Yes: It may be reasonable to do weekly complete CIED evaluations (Class IIb, LOE B)
- No: Complete CIED evaluation to be completed at conclusion of radiation therapy (Class I, LOE B)
- Continuous visual and voice contact is recommended during each treatment fraction (Class I, LOE C)

2017 HRS expert consensus statement on MR imaging and radiation exposure in patients with CIEDs

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**Figure 2**

2017 Heart Rhythm Society expert consensus statement on radiation exposure in patients with cardiovascular implantable electronic devices

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