Management of patients with implantable cardioverter-defibrillators and pacemakers who require radiation therapy

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BACKGROUND Radiation therapy (RT) may pose acute and long-term risks for patients with cardiac implantable electronic devices (CIEDs), including pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs). However, the frequency of these problems has not been accurately defined.

OBJECTIVE The purpose of this study was to determine the prevalence of CIEDs among patients requiring RT and report the common CIED-related problems when patients are managed according to a standard clinical care path.

METHODS In a single tertiary-care center, we prospectively screened all patients requiring RT and identified patients with ICDs or PMs. We collected clinical data about their cancer, RT treatment plan, and CIED. Radiation dose to the device was estimated in all patients, and any device malfunction during RT was documented.

RESULTS Of the 34,706 consecutive patients receiving RT, 261 patients (0.8%, mean age 77.9 ± 9.4 years) had an implantable cardiac device: 54 (20.7%) ICDs and 207 (79.3%) PMs. The site of RT was head and neck (27.4%), chest (30.0%), and abdomen/pelvis (32.6%). Using our care path, 63.2% of patients required continuous cardiac monitoring, 14.6% required device reprogramming, 18.8% required magnet application during RT, and 3.4% required device repositioning to the contralateral side before RT. Four patients (1.5%) had inappropriate device function during RT: 3 experienced hemodynamically tolerated ventricular pacing at the maximum sensor rate, and 1 experienced a device power-on-reset. No patient died or suffered permanent device failure.

CONCLUSION Nearly 1% of patients receiving RT in this series has a PM or ICD. However, with a systematic policy of risk assessment and patient management, significant device-related complications are rare.

KEYWORDS Pacemaker; Implantable cardioverter-defibrillator; Radiation therapy; Malfunction; Care path

ABBREVIATIONS **CIED** = cardiac implantable electronic device; **CMOS** = complementary metal oxide semiconductor; **ICD** = implantable cardioverter-defibrillator; **MSKCC** = Memorial Sloan–Kettering Cancer Center; **PM** = pacemaker; **RT** = radiation therapy

Introduction

Use of cardiac implantable electronic devices (CIEDs), including pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs), along with radiation therapy (RT) has increased significantly over the past 2 decades.[1,2] As each of these therapies is increasingly indicated in older patients, it is not surprising that many patients who require RT have some type of CIED. Although it has been demonstrated that RT can cause both transient malfunction of PMs and ICDs as well as permanent damage to device circuitry,[3–6] precise estimates of this risk are not known. As a result, there are no widely accepted guidelines on how to best manage these patients, although individual institutions have developed local guidelines.[7–10]

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Modern CIEDS incorporate circuitry composed of complementary metal oxide semiconductor (CMOS) transistors, which allows devices to be smaller, reliable, and energy efficient but makes them susceptible to the effects of ionizing radiation.[11–13] This effect may range from mild corruption of their programming to power-on-reset or complete failure of the device. The likelihood of damage increases with cumulative radiation exposure to the device.[11–15] RT may also acutely affect the function of CIEDs through the generation of electromagnetic noise or other phenomena.[8,16]

This single-center study sought to determine the prevalence of CIEDs among patients receiving RT, systematically report the common CIED-related problems in this population, and evaluate a management care path, which was modeled on guidelines for perioperative management of PMs and ICDs[17] and refined using the published literature of the effects of RT on CIEDs.[11–16]

Methods

At a single tertiary-care center between February 2008 and December 2012, we prospectively screened consecutive patients scheduled to undergo RT and identified those patients with an ICD or PM. Patients treated with only orthovoltage therapy were excluded. Clinical and RT treatment plan information as well as CIED-related data, including device location and PM dependency (defined as no intrinsic rhythm >40 bpm), were collected.

Before RT initiation, cumulative radiation exposure to the device, including doses from previous RT therapies, was estimated in all patients. According to this dose, patients were assigned to 1 of 3 dose categories: category 1 (0–2 Gy), category 2 (2–20 Gy), or category 3 (>20 Gy) (Table 1). In a subset, radiation dose was directly measured by placing thermoluminescent dosimeters on the proximal edge of the device for the first 3 treatment fractions. In situations where the measured dose resulted in a change of dose category, patients were managed according to the new assigned category (Table 1).

All patients were managed according to a standard clinical care path (Figure 1). According to our algorithm, patients were classified as high risk for acute complications of electromagnetic interference if they had an ICD; were PM dependent or had an estimated cumulative radiation exposure >20 Gy; or if radiation was to be delivered to the thoracic region. Patients who did not meet these characteristics were identified as low risk (Figure 1). All patients were treated on a linear accelerator (6-, 10-, and 18-MV X-ray beams; Varian Medical Systems, Palo Alto, CA) and monitored according to "high"- or "low"-risk features (Figure 1). A magnet was applied to all ICDs during RT for deactivation of antitachycardia therapies and shocking function (Figure 1). In 2009, our policy changed, and magnet placement was reserved for only the high-risk subgroup of patients in whom treatment fields involved the upper chest or neck. In 2012, magnet application was discontinued in all patients. All episodes of device malfunction were documented, including changes in patients' physical status during RT. All patients were evaluated after completion of RT to assess for late damage to their CIEDs. This observational study was approved by our local ethics committee. This study was approved by our local ethics committee and did not require patient-level consent.

Table 1 Approach to CIEDs based on estimated cumulative radiation dose

	Estimated cumulative dose to CIED		
Type of CIED	<2 Gy	2–20 Gy	>20 Gy
PM independent	Monitor only, no CIED relocation	Monitor only	Consider CIED relocation
PM dependent		Consider CIED relocation	
ICD			

CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; PM = pacemaker.

Statistical analysis

Continuous data are given as mean and standard deviation or median and percentiles (25th–75th), where appropriate. Categorical variables are summarized as counts and proportions.

Results

Of the 34,706 patients receiving RT between February 2008 and December 2012, 261 (0.8%) had a CIED: 207 (79.3%) PMs and 54 (20.7%) ICDs (Table 2). Of these patients, 67 (25.7%) were PM dependent. Clinical characteristics and RT treatment features of the study population are summarized in Table 2. Treatment regions included head and neck (27.4%), chest ipsilateral to device (9.3%), chest contralateral to device (15.2%), bilateral chest (5.6%), abdomen (3.3%), pelvis (29.3%), and limb (4.4%). Nine patients (3.4%) were treated sequentially to 2 separate regions of the body. The estimated dose to the device exceeded 2 Gy in 8% of cases. When *in vivo* measurements were performed in 29 patients (11.1%), CIEDs were exposed to a median dose of 100 cGy (P25–P75; 29–295 cGy). In 93% of cases, the total dose was delivered in multiple treatment fractions (ranging from 3 to 40 fractions).

According to our algorithm, 165 patients (63.3%) were classified as high risk, and 96 (36.7%) patients were classified as low risk. Eighty-two patients (49.7%) were high risk for acute complications of electromagnetic interference, 51 (30.9%) were at chronic high risk for cumulative radiation exposure, and 32 (19.4%) were at risk for both conditions.

Within the high-risk group, 9 patients required CIED relocation. Of these patients, all were PM recipients, 4 of whom were PM dependent. Seven (78%) were older than 80 years, and 44% were male. In 8 cases (67% with breast cancer), the radiation field was planned to 1 chest side, so the device was relocated to the contralateral side before RT