Management of Radiotherapy Patients Implanted with Cardiac Devices

Moyed Miften, PhD  
Professor and Chief Physicist  
University of Colorado

Dimitris Mihailidis, PhD  
Chief Physicist  
Charleston Radiation Therapy
Acknowledgments

• Coen Hurkmans, PhD
• Chet Reft, PhD
• Members of AAPM TG203
Outline

• Classes of ICPs and ICDs
• Sensitivities and potential failures
• Current guidelines (AAPM TG34)
• Review of ICD and ICP dose limits
• Review of device failures—cases reports
• Patient management
• Dose estimation during RT processes (breakout session)
Implanted Cardiac Devices

• Implanted cardiac pacemakers – ICPs
  provide small electrical stimuli to case cardiac contraction during periods of bradycardia, when the intrinsic electrical activity of the heart is slow or absent.

• Implanted cardioverter defibrillators – ICDs
  generate a large amount of electrical energy in a single output used to defibrillate the heart and prevent cardiac arrest.
Types of ICPs and ICDs

- **ICPs**
  - Single-Chamber: single lead that paces either the right ventricle or right atrium.
  - Dual-Chamber: 2 leads, 1 in the right atrium and 1 in the right ventricle to coordinate signals to and contractions of the atria and ventricles.
  - Biventricular: 1 right ventricular lead and 1 left ventricular lead to stimulate simultaneous contraction of left/right ventricles for more efficient pumping action.

- **ICDs**
  - Single lead with two shock coils.
Sources of potential malfunctions during RT processes

• Imaging for treatment planning (CT mostly).
• Imaging for Image Guidance (CT, MV, EMI)
• RT treatment delivery (photons, protons, neutrons, particles)
• Use of high energy photons, $E \geq 10$ MV
• Dose rate?
• IMRT, SBRT, VMAT, FFF beams, etc.
Sensitivities & potential failures

• Permanent damage from accumulated dose →
circuitry is degraded in proportion to accumulated dose:
  - Decrease of output amplitude
  - Increase current drain → not obvious (can lead to sudden failure within months post-treatment)
  - Erroneous or failed sensor operation (including heartbeat sensing functions)
Sensitivities & potential failures

- **Upsets** in memory or logic circuits caused by neutrons—**SOFT ERRORS**:
  - Changes in stored values in memory or transient changes in micro-processor circuitry
  - May not be functionally recoverable
  - Reset of the device $\Rightarrow$ reversion to default parameters
  - Rare cases where reset may delay for hours or even weeks post-treatment
Sensitivities & potential failures

- Transient interference from high-dose-rate x-rays (not EMI):
  - Transient effect - no permanent damage, unless accumulated dose is high →
    - Inappropriate sensing of device that lead to ICD shock
    - Non-existent pacing output
    - Reset or other effects
- EMI are minimal and of transient nature:
  - ICPs
    - May sense the field as myocardial potential → inhibition of output
    - Inappropriate re-programming
    - Shut off reed switch → fixed pacing
    - Triggering of output
  - ICDs
    - Possible re-programming, transient effect
VII. SPECIFIC RECOMMENDATIONS

The following protocol is suggested when evaluating patients for radiation therapy who have an implanted cardiac pacemaker. The task group is cognizant that each patient must be addressed individually and that in some cases it may be in the best interests of the patient to diverge from the recommendations.

1. Pacemaker implanted patients should not be treated with a betatron.

2. Pacemakers should not be placed in the direct (unshielded) therapy beam. Some accelerator beams can cause transient malfunction.

3. The absorbed dose to be received by the pacemaker should be estimated before treatment. More information can be found in the literature.

4. If the total estimated dose from a single treatment does not exceed 2 gray, the pacemaker manufacturer's recommendation for treatment prior to therapy and possibly at the conclusion of each week of therapy should be observed. Since total absorbed dose in patients has been seen at cumulative doses between 2 and 10 gray, early changes in pacemaker parameters could signal a failure in the 2-10 gray region.

5. Although transient malfunction from electromagnetic interference is unlikely from contemporary therapy accelerators and cobalt irradiators, the patient should be closely observed during the first treatment with a linear accelerator and during subsequent treatments if magnetron or klystron misfiring (sparking) occurs.

6. Studies to date have dealt with linear accelerators, betatrons, and cobalt irradiators only. Use of other radiation therapy machines should be evaluated on an individual basis and approached with caution.
Observations: AAPM TG34

- Recommendations were based on older technology cardiac devices (pacemakers only).
- Considered older data on radiation interactions and for older treatment techniques and delivery methods.
- Since 1994, numerous investigations published in literature have dealt with pacemakers and defibrillators during radiation therapy treatments.
- More detail measurements and computations of out-of-field doses have been performed that would allow a more direct estimation of the cumulative doses deposited to these implanted devices (AAPM TG-158).
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<td>044931</td>
<td>2010-02-18</td>
<td>13:47</td>
<td>FW: Pacemakers and Defibrillators</td>
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<td>044926</td>
<td>2010-02-18</td>
<td>07:50</td>
<td>Pacemakers &amp; Defibrillators (3)</td>
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<td>09:20</td>
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<td>Re. Pacemakers</td>
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<td>2009-12-09</td>
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<td>Pacemaker Dose Limits</td>
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<td>043902</td>
<td>2009-09-10</td>
<td>00:28</td>
<td>For Peter Biggs</td>
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Survey of RT Clinics

A survey by Solan et al [IJROBP, 2004] of practice patterns among 74 RT clinics in the USA and Canada

- 12% of the clinics have no management policy
- 15% have a management policy
- 37% of the clinics consult a cardiologist and 33% of them contact the ICP/ICD manufacture
- 20% of the clinics perform TLD/diode check measurements and 35% of them monitor the patient during RT
- 31% of radiation administering facilities limits the total allowable dose exposure,
- 20% of them follow the AAPM TG-34 guidelines
In conclusion, warnings given by manufacturers about the maximum tolerable cumulative radiation doses for safe operation of irradiated pacemakers (5 Gy), even reduced to 2 Gy, are not reliable. The spread of cumulative doses inducing failures is very large since our observations show an important failure at 0.15 Gy, while ten pacemakers withstood more than 140 Gy of cumulative dose. The safe operation of pacemakers under irradiation depends mainly on type and model. It depends also on dose rate. From our observations, for the safe operation of pacemakers, a recommendation of a maximum dose rate of 0.2 Gy min\(^{-1}\) rejecting direct irradiation of the pacemaker at a standard dose rate for tumour treatment (2 Gy min\(^{-1}\)) is made.
Recent Review Articles

- Solan et al. [IJROBP, 2004]
  Limit: 2 Gy scattered dose ICP
  1 Gy scattered dose ICD

- Sundar et al. [Cancer Treat Reviews, 2005]
  Limit: 2 Gy scattered dose

- Hurkmans et al [IJROBP, 2005]
  Limit: < 1.5 Gy scattered dose

- Kapa et al [PACE, 2008]
  Avoid direct beam exposure

- Gelblum et al [IJROBP, 2009]
  Advocate < 10 MV beams (15MV, single event upset)

  Limit: 2 Gy scattered dose ICP
  1 Gy scattered dose ICD
Soon thereafter a lump was discovered in the right breast. A needle biopsy showed an infiltrating ductal carcinoma and a right simple mastectomy was performed. Postoperative radiation therapy was advised and consisted of delivery of 1000 rads per week through each of 5 ports. Treatments were given with 4-MeV photons at a source to skin distance (SSD) of 80 cm, using a Varian Clinac-4 linear accelerator. One port, the “right supraclavicular fossa” encompassed the area occupied by the pacemaker generator. When the first treatment was given in July, 1981, the electrocardiogram was monitored to determine whether there was any alteration in pacemaker function secondary to electromagnetic interference from the linear accelerator. There was no evidence of pacemaker malfunction.

At a dose of 3000-3600 rads she developed a tachycardia. The electrocardiogram, (Fig. 1) showed that the atrial pacemaker was firing irregularly at a rate of 320 beats/min. Analysis of the removed generator showed that pacemaker failure was due to malfunction of the large scale integrated-complementary metal oxide semiconductor (LSI-CMOS) circuit and the type of damage was consistent with radiation-induced effects.

**In Therapy**

> BERT S. HEUSINKVELD, and

University of Arizona Health Sciences Center,

ion therapy. Pacemaker malfunction occupied by an A-V sequential pacemaker. function of the large scale integrated circuit effects. The newer multiprogrammable previously available. (PACE, Vol. 5,
The Cardiac Pacemaker Patient

*Might the Pacer be Directly Irradiated?*

Alexander Tsekos, Felix Momm, Mi

From the Universitätsklinikum Freiburg, Ge

Correspondence to: A.Tsekos, MD, Radiolc
Freiburg, Germany

Received 13 January 2000
Accepted 22 June 2000

Radiotherapy course. The patient received radiotherapy as an inpatient. Figure 1 shows the pacer in the treatment field. During each fraction we performed an ECG and observed the rhythm on a monitor outside. The cardiologist was with us during the first fraction, and on stand-by for the further fractions. Pacer-function analyses were completed before, in the middle (3 weeks later) and after the radiation course. We irradiated the lymphatic nodes in the right axilla up to a dose of 50.4 Gy without problems. At a fractionation of 5× 1.8 Gy per week, it took us about 6 weeks. The pacemaker functioned without failure during every fraction, but the magnetic frequency of the pacer, which is usually an indicator of the battery load, began to decrease.

After the radiotherapy course the magnetic frequency was below the recommended exchange criteria, but at no time was there a malfunction. At the next control the magnetic frequency was unchanged at 88/min. The pacemaker’s stimulation frequency remained at the programmed rate. Four months later, the magnetic frequency returned to normal, indicating a normal battery charge.

Since the end of the radiation course, the pacemaker has functioned perfectly. Follow-up was at 26 months at the time of this report. The patient has been in complete remission since then.
Letter to the Editor

Defibrillator reset by radiotherapy

Dennis H. Lau, Lauren Wilson, Martin K. Stiles, Bobby John, Shashidhar, Hany Dimitri, Anthony G. Brooks, Glenn D. Young, Prashanthan Sanders*

Cardiovascular Research Centre, Department of Cardiology, Royal Adelaide Hospital and the Disciplines of Medicine and Physiology, University of Adelaide, Adelaide, Australia

Received 3 May 2007; accepted 30 June 2007
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Abstract

The number of patients with implantable cardioverter-defibrillator (ICD) is rapidly increasing due to their expanding indications. Amongst the various types of electromagnetic interferences, little is reported about the effects of radiotherapy. We report a case of electrical reset of a single chamber ICD by scattered irradiation from radiotherapy.

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Keywords: Implantable cardioverter-defibrillator (ICD), Radiotherapy, Electrical reset

ICD response to therapeutic radiation is generally unpredictable and may potentially involve various parameters incorporated in individual ICD models. Recognition of other potential lethal events such as complete device failure, inappropriate shocks due to over-sensing and sudden death are vital in our management of such patient groups.
## Case reports of failures

### Life-Threatening Pacemaker Dysfunction Induced by Radiation:

Robert Hawlicek, MD,

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### Table 1. Case Reports About Irradiation-Induced Pacemaker/ICD Failure

<table>
<thead>
<tr>
<th>Reference No.</th>
<th>Year</th>
<th>Type of Radiation</th>
<th>Dose (Gy)</th>
<th>Type of Failure</th>
<th>Consequence</th>
<th>In/Out</th>
<th>Device</th>
</tr>
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<tbody>
<tr>
<td>8</td>
<td>2004</td>
<td>Linear accelerator</td>
<td>56</td>
<td>Electrical restart</td>
<td>None</td>
<td>Out</td>
<td>Medtronic/VVI-ICD</td>
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<tr>
<td>9</td>
<td>1988</td>
<td>Cobalt 60</td>
<td>35</td>
<td>Runaway</td>
<td>Replacement</td>
<td>In</td>
<td>Intramedics/DVI</td>
</tr>
<tr>
<td>10</td>
<td>2003</td>
<td>Not reported</td>
<td>50</td>
<td>Loss of communication</td>
<td>Replacement</td>
<td>In</td>
<td>Vitatron/DDD</td>
</tr>
<tr>
<td>11</td>
<td>1991</td>
<td>Linear accelerator/ betastron</td>
<td>50</td>
<td>Deprogrammed device</td>
<td>Replacement</td>
<td>Out</td>
<td>Medtronic/?</td>
</tr>
<tr>
<td>12</td>
<td>1984</td>
<td>Linear accelerator</td>
<td>19.8</td>
<td>Fixed ventricular rate</td>
<td>Replacement</td>
<td>In</td>
<td>Intermedics/VVI</td>
</tr>
<tr>
<td>13</td>
<td>1986</td>
<td>Linear accelerator</td>
<td>84.6</td>
<td>Runaway</td>
<td>Replacement</td>
<td>Out</td>
<td>Intermedics/DVI</td>
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<tr>
<td>14</td>
<td>1982</td>
<td>Linear accelerator</td>
<td>36</td>
<td>Runaway</td>
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<td>In</td>
<td>Intermedics/DVI</td>
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<tr>
<td>15</td>
<td>1994</td>
<td>Neutrons</td>
<td>4.8</td>
<td>Runaway</td>
<td>Replacement</td>
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<td>16</td>
<td>1983</td>
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<td>Replacement</td>
<td>In</td>
<td>Intermedics/DDD</td>
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</table>

Note: ICD = implantable cardioverter/defibrillator.

a. Device lying in or outside the radiation field.
# Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices

Cynthia H. McCollough, PhD  
Jie Zhang, PhD  
Andrew N. Primak, PhD  
Wesley J. Clement, BSEE  
John R. Buyxman, PhD

![](image)

**Purpose:** To prospectively measure the response of a variety of models of implantable cardiac rhythm management devices (ICRMDs) to the radiation delivered by computed tomography (CT), for both maximum and typical dose levels.

**Materials and Methods:** Twenty-one ICRMDs (13 pacemakers, eight cardioverter-defibrillators) manufactured by Medtronic (Minneapolis, Minn) were exposed to ionizing radiation from CT systems in both spiral and dynamic acquisition modes at maximum and typical dose levels. Devices were monitored during exposure to check for any operational abnormalities and were interrogated after exposure to check for any residual abnormalities. Total radiation dose and peak dose rate were measured, and the volume CT dose index was recorded.

**Results:** Oversensing was observed in 20 of 21 devices at maximum doses and in 17 of 20 devices at typical doses. Oversensing most often manifested as inhibition, although it occasionally manifested as tracking or safety pacing. Two devices inhibited for more than 4 seconds in spiral mode at clinical dose levels. Oversensing was transient and ceased as soon as the device stopped moving through the x-ray beam or the beam was turned off. The partial electrical reset (PER) safety feature was activated in two models, InSync 8040 and Thera DR. With the exception of PER, programming was not altered. Effects occurred only if the x-ray beam passed directly over the ICRMD.

**Conclusion:** CT irradiation at typical clinical doses results in oversensing of ICRMDs in the majority of devices tested, although the identified effects were predominantly transient.

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* RSNA, 2007

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1 From the Department of Radiology, Mayo Clinic College of Medicine, 200 First St SW, Rochester, MN 55905 (C.H.M., J.Z., A.N.P.); and Cardiac Rhythm Disease Management, Medtronic, Minneapolis, Minn (W.J.C., J.R.B.). Received June 8, 2006; revision requested August 10; revision received November 21; final version accepted December 6. Address correspondence to C.H.M. (e-mail: mccollough.cynthia@mayo.edu).

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Check list for patient management

• **Initial Consultation**
  - Cardiac Device (CD) alert added to patient’s chart
  - Copy of CD card made and filed in patient’s chart
  - Appointment with Cardiac Electrophysiology (EP) scheduled

• **Simulation Check**
  - Patient should be evaluated by EP to verify dependence on device
  - Verify CD alert added to patient’s chart
  - Verify treatment planning directive completed by physician
  - Note added to planning directive to only use 6X photons
  - Contact vendor for dose limit recommendations
Treatment planning check

- Verify only 6X photons used for treatment
- Estimate dose/fraction
- Verify proximity of treatment fields to device
- Add note to patient’s chart to place in-vivo dosimeter prior to fraction #1
- Verify/adjust imaging fields do not irradiate device.
Dose to pacemaker > 2 Gy

- Inform Rad-Onc physician
- Contact EP to inform them of dose and discuss monitoring strategy
  - Move device-- Risk of infection??
  - Adjust monitoring frequency
  - Schedule EP follow on-set for all treatment fractions
  - Monitoring post treatment
We learned......

Clearly defined and up-to-date guidelines and uniform approach to the management of RT patient with implanted cardiac pacemakers are needed.
The patient’s risk is not equal to the risk of a CD defect
The chance on CD malfunction mainly increases with dose and is not accurately known
A practical guideline will be easier to implement

<table>
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<th>&lt; 2 Gy</th>
<th>2-10 Gy</th>
<th>&gt; 10 Gy</th>
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<td>pacing-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>independent</td>
<td>Low risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td>pacing</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
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<tr>
<td>dependent</td>
<td>risk</td>
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**Therapeutic radiation**

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<th>CR</th>
<th>PM</th>
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<tr>
<td>Kapa S, Fong L, Blackwell CR, Herman MG, Schomberg PJ, Reyes II. Effects of scatter radiation on ICD and CRT function. Pacing Clin Electrophysiol 2008;31:727–732.</td>
<td>EX/CS</td>
<td>8</td>
<td>PM</td>
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</tr>
<tr>
<td>Hurmans CW, Schoepers I, Springerum BS, Uitenwaal H. Influence of radiotherapy on the latest generation of implantable cardioverter-defibrillators. Int J Radiat Oncol Biol Phys 2005;63:282–289.</td>
<td>EX</td>
<td>19</td>
<td>PM</td>
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<td></td>
</tr>
<tr>
<td>Thomas D, Becker R, Katus HA, Schoels W, Karle CA. Radiation therapy-induced electrical reset of an implantable cardioverter defibrillator device located outside the irradiation field. J Electrocardiol 2004;37:73–74.</td>
<td>EX</td>
<td>96</td>
<td>PM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodriguez F, Filimonov A, Henning A, Coughlin C, Greenberg M. Radiation-induced effects in programmable pacemakers and implantable defibrillators. PACE 1991;14:2143–2153.</td>
<td>EX</td>
<td>27</td>
<td>PM: 23; ICD: 4</td>
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<td>Katzenberg CA, Marcus FI, Heusinkveld RS, Mammana RB. Pacemaker failure due to radiation therapy. PACE 1982;5:156–159.</td>
<td>EX</td>
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<td>PM</td>
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3.9.8. Gastroenterology procedures
3.9.8.1. Colonoscopy or gastroscopy
3.9.8.2. Capsule endoscopy
New Task Group 203

Task Group No. 203 - Management of radiotherapy implanted cardiac pacemakers and defibrillators.

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No Website on file. | Wiki Lite | Wiki Full | Directory: Committee

Email: You may send email to this group now using gmail or - You may save the address 2012.2TG203@mail.aapm.org to your local address book. This alias updates hourly. Directory.

Charge: Review published literature, evaluate all possible radiations on these devices, provide methods to clinical levels, provide an estimate of the risks for the various associated lethal and non-lethal types of device failure to manage patients with such devices and develop protocols in order to minimize the damage during radiotherapy.


Approved Date(s): Start: 5/11/2010
End: 12/31/2011

Committee: TG203

Keywords:
- Board of Directors [Status]
- Science Council [Status]
- Therapy Physics [Status]
  - Radiation Dosimetry & Treatment Planning SC [Status]
  - Work Group on Radiation Dosimetry [Status]
- TG203 - Management of radiotherapy patient cardiac pacemakers and defibrillators. [Status]

> Active Task Group listing