Managing the Care 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
• Members of AAPM TG203
• Joann Prisciandaro

Outline
• Classes of ICPs and ICDs
• Sensitivities and potential failures
• Current guidelines
• Review of ICD and ICP dose limits
• Review of device failures—cases reports
• Patient management

Introduction
• Average life expectancy of Americans has increased from 70.1 (1960 – 65) to 78.1 years (2000 – 05).
• Number of CIED patients presenting for RT has steadily increased.
• Current guidelines are conservative and at times conflicting
• Some vendors recommend no radiation to CIED
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.

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 ≥ 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 → reversion to default parameters
  - Rare cases where reset may delay for hours or even weeks post-treatment

- 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

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).
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

From Med Phys Listservs

Dose rate study

Influence of high-energy photon beam irradiation on pacemaker operation

J. Marcus, A. Hsiang, A. Brillot, B. Booth, and E. Fortegg

In conclusion, warnings given by manufacturers about the maximum tolerable cumulative radiation doses for safe operation of implanted pacemakers (2 Gy) are probably too low. Data are not reliable. There are no studies showing that isoeffective doses are equal to 1.5 Gy, while no pacemakers gastrointestinal (GI) of coronary shows the same damage. Data suggest that isoeffective doses for coronary are higher (0.35 Gy/mGy).

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]

- 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)

- Hudson et al. [Med Imag and RO, 2010] and Seojeima et al. [J. Radiat Res, 2011]
  Limit: 2 Gy scattered dose ICP
  1 Gy scattered dose ICD
Case reports of failures

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 photon beams at a source-to-skin distance (SSD) of 60 cm, using a Varian Clinac 4 linear accelerator. One port, the "right supraventricular 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 3000-3500 rads she developed a tachycardia. The electrocardiogram (Fig. 11) showed that the internal pacemaker was firing irregularly at a rate of 120 beats/min. Analysis of the removed generator showed that pacemaker failure was due to malfunction of the large scale integrated complementary metal oxide semiconductor (CMOS) circuitry and the type of damage was consistent with radiation-induced effects.

The Cardiac Pacemaker Patient

Might the Pacer Be Direcitly In

The patient received radiotherapy as an adjunct. Figure 1 shows the major components and 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 we stood by for the further fractions. Pacemaker function analyses were performed before, in the middle of 10 weeks later and after the radiation. We tolerated the symptom in the right scapula up to a dose of 2040 Gy without problems. At a fractionation of 1.6 to 1.8 Gy per week, it took us about 6 weeks. The pacemaker functioned without failure during every fraction, but the magnetic field at the point, which is essentially an indicator of the battery load, began to decrease.

After the radiotherapy, there was a significant change. The magnetic field was 70% of the recommended level, and at no time was there a restoration At the next control the magnetic field was 50% lower than before. The pacemaker stimulation frequency remained at the programmed rate. Four months later, the magnetic field 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.

Table 1. Case Reports About Fractionated Induced Pacemaker Efficacy

<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 Hours</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>1999</td>
<td>Electroventricular</td>
<td>36.4</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>9</td>
<td>1999</td>
<td>Catheter</td>
<td>35</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>10</td>
<td>2000</td>
<td>No reported</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>11</td>
<td>2001</td>
<td>Linear accelerator</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>12</td>
<td>1984</td>
<td>Linear accelerator</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>13</td>
<td>1985</td>
<td>Linear accelerator</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>14</td>
<td>1986</td>
<td>Linear accelerator</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>15</td>
<td>1987</td>
<td>Linear accelerator</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
<tr>
<td>16</td>
<td>1988</td>
<td>Linear accelerator</td>
<td>30</td>
<td>None</td>
<td>No electrode failure</td>
<td>120</td>
<td>Infiniti-MED</td>
</tr>
</tbody>
</table>

Note: ICD = Implanted cardioverter-defibrillator. A, Device firing in or outside the radiation field.
We learned.....

Clearly defined and up-to-date guidelines and uniform approach to the management of RT patient with implanted cardiac pacemakers is very much needed.
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
### TG203: Patient Management: Patient Oriented Risk Categories

- 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>
<thead>
<tr>
<th>Dose Interval</th>
<th>Low Risk</th>
<th>Medium Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2 Gy</td>
<td>Pacing-independent: Low risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td></td>
<td>Pacing-dependent: Medium risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td>2-5 Gy</td>
<td>Pacing-independent: Medium risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td></td>
<td>Pacing-dependent: Medium risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td>&gt;&gt; 5 Gy</td>
<td>Pacing-independent: Medium risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
<tr>
<td></td>
<td>Pacing-dependent: Medium risk</td>
<td>Medium risk</td>
<td>High risk</td>
</tr>
</tbody>
</table>

---

### Thank You