Review of Cardiac Implantable Electronic Devices (CIEDs) and Potential Device Malfunctions due to Radiotherapy

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Rationale for Updating AAPM Report 45 / Task Group 34

Published studies show that the radiation sensitivity of contemporary cardiac pacemakers vary, depending on the manufacturer and model. Since the problem of radiation exposure still affects relatively few (percentage-wise) pacemaker patients, it is unreasonable to propose that all pacemaker manufacturers radiation burden their devices. To do so would incur a significant expense that would eventually have to be passed on to all cardiac pacemaker patients. If necessary, a pacemaker can be moved to an area outside the radiation treatment volume in order to preclude failure from overexposure.

Learning Objectives

1. Review of Implantable Cardiac Pacemaker (ICP) and Implantable Cardiac Defibrillator (ICD) devices
2. Discuss conditions in clinical use that can induce device malfunctions

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Vendor Device Dose Limit (Gy) 2014

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Device</th>
<th>2014</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott (St. Jude)</td>
<td>ICD</td>
<td>No safe dose (limited to 30 Gy, few errors observed at 20 Gy)</td>
<td></td>
</tr>
<tr>
<td>Biotronik, Inc.</td>
<td>ICD</td>
<td>No safe dose</td>
<td></td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>ICD/ICD</td>
<td>No safe dose</td>
<td></td>
</tr>
<tr>
<td>Medtronic</td>
<td>ICD</td>
<td>1 – 5 Gy (based on model)</td>
<td>5 Gy</td>
</tr>
<tr>
<td></td>
<td>ICP</td>
<td>5 Gy</td>
<td>5 Gy</td>
</tr>
</tbody>
</table>
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- Average life expectancy of American has increased from 75 (1960–65) to 79 years (2015–20)
- Between 1993-2009 ICP utilization increased by 55.6%
- In 2014, an estimated 351,000 ICP and 60,000 ICD implant procedures were performed for inpatients in the United States

Greenspon et al., Journal of American College of Cardiology, 2012; 60(16): 1540-1545.

Role of CIEDs

- Correct for cardiac arrhythmia
  - Bradycardia (heart rate is too slow, < 60 beats per min)
  - Tachycardia (heart rate is too fast, > 100 beats per min)
  - Fibrillation (irregular rhythm)
- If the arrhythmia is serious or of concern, a CIED, such as an ICP or ICD, may be implanted

Purpose of ICPs

- Sense heart rhythms
- Record
- Therapy
  - Sends an electrical pulse to the heart when arrhythmias are detected to pace the heart
  - Some designs – coordinate the chambers of the heart (i.e., ventricles)

ICP Components

- Leads/electrodes
  - Senses and transmits electrical impulses
- Pulse generator
  - Records heart rhythms
  - Controls therapies
  - Generates pulses to correct for arrhythmia
- Battery
  - Powers the generator

ICP Designs

- Single chamber ICPs
- Dual-chamber ICPs
- Biventricular ICPs
RADIATION ONCOLOGY

**Single Chamber ICP**
- Right atrium
  - Sinus node not working adequately, but rest of heart functioning normally
- Right ventricle
  - Normal pulses from the right atrium do not reach the ventricle

[Link](https://www.youtube.com/watch?v=GIMOa0HvLE0)

**Dual-Chamber ICP**
- One lead is placed in the right atrium and a second in the right ventricle
-Coordinates atrial and ventricular contraction, by sequentially pacing atria then ventricle to maximize the heart's pumping ability.

[Link](https://www.youtube.com/watch?v=GIMOa0HvLE0)

**Biventricular ICP**
- Leads are placed in the right and left ventricles, and typically a third lead is added to the right atrium.
- The addition of the lead in the left ventricle works to contract the left and right ventricle simultaneously.

[Link](https://www.youtube.com/watch?v=GIMOa0HvLE0)

**Leadless ICPs**
- First approved by FDA in 2016
- Advantages of these CIEDs include a reduction in lead and subcutaneous pocket complications, and hospitalization
- Offered by several leading ICP vendors (e.g., Medtronic, Boston Scientific, Abbott [St. Jude])

**Purpose of ICDs**
- Sense heart rhythms
- Record
- Therapy
  - Sends an electrical pulses to the heart when arrhythmias are detected to pace the heart → Pacing
  - Some designs – coordinate the chambers of the heart (i.e., ventricles)
  - Delivers high voltage pulse (~800V) to the heart when life-threatening arrhythmias are detected

**ICD Components**
- Lead/electrodes
  - Senses and transmits electrical impulses
- Pulse generator
  - Records heart rhythms
  - Controls therapies
  - Generates pulses to correct for arrhythmias
- Capacitor
  - Stores and delivers high-voltage shocks
- Battery
  - Powers the generator

ICD Designs

- Single chamber ICDs
  - Lead placed in right ventricle
- Dual-chamber ICDs
  - Leads placed in the right atrium and right ventricle
- Biventricular ICDs
  - Leads placed in the right atrium and ventricle, and the coronary sinus which is adjacent to left ventricle

Effects of Ionizing Radiation on CIEDs

- Modern CIED circuits use complementary metal oxide semiconductors (CMOS)
- Pros - CMOS circuits have led to smaller, more energy efficient and reliable CIEDs
- Cons - CMOS is known to be susceptible to ionizing and electromagnetic radiation, which may result in transient or permanent device defects

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Effects of Ionizing Radiation on CIEDs

- Ionizing radiation creates excess electron-hole pairs in the SiO₂ layer of the CMOS
- Holes trapped in band gap form aberrant electrical pathways in the insulator
- May result in minor or significant malfunctions

Cumulative Dose Effects

- Most commonly cited interaction between CIED and radiotherapy

Potential Risk Factors

- Clinical conditions
  - Cumulative dose effects
  - Neutron-induced upsets
  - Dose-rate effects
  - Magnetic field effects
  - Electromagnetic interference

Cumulative Dose Effects

- 18 ICPs from five manufacturers
- Irradiation conditions
  - 8 MV photons
  - 10x10 cm² field
  - 100 cm SSD
  - 2 cm depth
  - 2.8 Gy/2 to 70 Gy or point of failure
- 11 of 18 ICPs experienced permanent failures
- First failure observed at 16.8 Gy

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Cumulative Dose Effects

- 96 explanted ICPs (varying ages)
- Irradiation conditions:
  - 18 MV photons
  - 15x15 cm² field
  - 100 cm SSD
  - 10 cm polystyrene depth (10.2 cm equivalent depth in H₂O)
  - Up to 200 Gy or point of failure
  - Dose rates: 0.05 – 8 Gy/min
- Spread of total dose failures – as low as 0.15 Gy, but 10 ICPs withstood > 140 Gy without failure


Cumulative Dose Effects

- 19 new ICPs from four manufacturers
- Irradiation conditions
  - 6 MV photons
  - 10x10 cm² field
  - 100 cm SSD
  - 1.6 cm depth
  - Up to 120 Gy or point of failure
- All devices experienced point of failure at ≥ 90 Gy
  - Complete loss of signal (pacing pulse) - 7 ICPs
  - Lost telemetry capabilities - 3 ICPs

Hurkman et al., Radiother Oncol, 2005; 76(1):93-98.

Cumulative Dose Effects

- Potential effects of high cumulative dose
  - Changes in pacing pulse
  - Changes in sensing threshold
  - Temporary or permanent loss of telemetry capabilities
  - Changes in pacing frequency
  - Battery depletion
  - Changes in lead impedance
  - Complete loss of signal

Miften et al., Med Phys, 2019; 46(12): e757-e788.

Neutron-Induced Upsets

- Prospective survey of 62 patients (60 with ICPs and 2 with ICDs) from 29 institutions
- Device was outside of the txmt field in all patients, but inside of imaging field in 21 patients
- Patients received a total dose of 20 – 74 Gy, median 50 Gy
- Device was evaluated for 52 patients (before, during, or after RT)
- One ICP malfunction was noted – patient treated with 15 MV beam, IMRT to prostate, total dose 74 Gy in 37 fx. Device re-initialized between 46 – 56 Gy.

Neutron-Induced Upsets

- Retrospective survey of 69 patients (50 with ICPs and 19 with ICDs)
- Device was outside of the txmt field in all patients, 1.5 cm to > 40 cm
- Patients received a total dose of 4 – 77.7 Gy
- Two ICP malfunctions were noted for patients treated with at least one 16 MV photon beam - partial resets of device, one device < 2.5 cm from bmt field

Makkar et al., Heart Rhythm, 2013; 9(12): 1964-1968
Priscianfano et al., JACC, 2015; 16(1): 254-263

Neutron-Induced Upsets

- Retrospective study of 215 patients (123 with ICPs and 92 with ICDs)
- Patients received a median dose of 33 Gy
- 15 devices (4 ICPs and 11 ICDs) experienced single-event upsets in patients treated with high energy photon beams (15 or 18 MV)

Grant et al., JAMA Oncol, 2015; 1(5): 624-632

Neutron-Induced Upsets

- 96 explanted ICPs (varying ages) were studied
- Dose rates: 0.05 – 8 Gy/min
- 70% of ICPs failed at dose rates of 8 Gy/min
- No failures observed at or below 0.2 Gy/min
- Reported failures
  - Amplitude decrease of electrical signal > 10%
  - Silences of electrical signal ≥ 10 s
  - Permanent silence

Mouton et al., Phys Med Biol, 2002; 47: 2789-2893,
Miften et al., Med Phys, 2019; 46(12): e757-e788.

Dose-Rate Effects

- Confounding factors:
  - Cumulative dose: up to a total dose of 200 Gy
  - Devices irradiated in direct beam with 18MV photons


Magnetic Field Effects

- Heating at lead tip and tissue interface
- Force and torque on device
- Alteration of device programming
- Inappropriate function and therapies
- Electrical reset
- Component damage
- Death

Indik et al., Heart Rhythm, 2017; 14(7): e97-e153.
Electromagnetic Interference

- EM noise around modern linacs is minimal
- Potential sources in current practice
  - EMI guidance systems
  - Gating technologies
- Potential effects
  - Inhibit therapies
  - Shut-off of reed switch – result in fixed pacing rate
  - Trigger unnecessary therapy
  - Permanent silence


Recommendations

- Cumulative dose < 5 Gy
- Generator should be kept 5 cm from field edge, whenever feasible
- Avoid high energy photons (>10MV) and irradiation with proton or neutron beams
- Maintain low dose-rates to the device (< 0.01 Gy/min)
  - Soft recommendation, there are uncertainties associated with this effect
- Use precautions when MR imaging patients
  - Ensure device is MR conditional and be familiar with conditions in which the device was tested

Miften et al., Med Phys, 2019; 46(12): e757-e788.

Summary

- As the average lifespan of Americans increase, the number of patients with CIEDs presenting for radiotherapy will continue to increase
- Be familiar with the different types of CIED that are used, and how the device functions
- Understand the potential clinical conditions that can induce CIED malfunctions
- With the proper precautions and patient monitoring, patients may safely receive RT