An Institutional Experience Managing the Care of Patients with CIEDs

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Outlines

• Discuss functionality and components of pacemakers (ICPs) and defibrillators (ICDs)
• Review potential effects of ionizing radiation on CIEDS
• Review published recommendations
• Discuss University of Michigan study
  – Management of CIED patients from simulation to treatment
Motivation

- 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

Arrhythmia

- Disorder of heart rate or rhythm.
  - Bradycardia (too slowly, < 60 beats per min)
  - Tachycardia (too quickly)
  - Fibrillation (irregular pattern)
- If the arrhythmia is serious or of concern, either an implantable cardiac pacemaker (ICP) or defibrillator (ICD) may be implanted.

Purpose of ICP

• Sensing – monitors heart rhythms
• Recording
• Therapy
  – Sends electrical signal to the heart to correct for slow (below threshold) or interrupted heart beat - undetectable by patient
  – Coordinates the chambers of the heart

http://www.jointhepacemakers.com/what-is-a-pacemaker/index.htm#.UtEw7vsnokY

ICP Components

• Battery
  – Powers the generator
• Pulse generator
  – Microprocessor and circuitry - sensing, data capture, storage and control of therapy delivery

http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx
ICP Components

• Leads/electrodes
  – Detects heart’s electrical activity and in some cases patient’s vitals.
  – Transmits electrical impulses to stimulate heart to beat.

http://www.brighamandwomens.org/departments_and_services/medicine/services/evcenter/patient/pacemaker.aspx

Types of ICPs

• Single chamber pacemakers
• Dual chamber pacemakers
• Biventricular pacemakers

Single Chamber ICP

Right atrium - Sinus node (natural pacemaker) is not working adequately, but rest of heart functioning normally.

Right ventricle – when the normal impulses from the atria cannot reach the ventricle.

http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx

Dual Chamber ICP

• One lead is in the right atrium and the other in the right ventricle.
• Coordinates atrial and ventricular contraction, by sequentially pacing atria then ventricle to maximize the heart's pumping ability.
• Most commonly used pacemakers.

http://www.brighamandwomens.org/departments_and_services/medicine/services/cvcenter/patient/pacemaker.aspx
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.

Purpose of ICD

- Sensing – monitors heart rhythms
- Recording
- Therapy
  - Sends electrical signal to the heart to correct for slow (below threshold) or interrupted heart beat
  - Can deliver a high energy pulse to correct dangerous arrhythmias (defibrillation)

Modern ICDs provide same functionality as ICP plus…
Components of ICD

- Battery
- Pulse generator
  - Microprocessor and integrated circuits
  - Capacitor - store and deliver charges
- Leads used for sensing, pacing and defibrillation


Types of ICDs

- Similar to pacemakers, ICDs are available as:
  - Single chamber – lead placed in right ventricle
  - Dual chamber – leads are placed in the right atrium and right ventricle
  - Biventricular – leads are placed in the right and left ventricles, and often a third is placed in the right atrium

http://www.webmd.com/heart-disease/guide/abnormal-rhythms-icd
Traditional Management of ICP Patients

- Based on AAPM Task Group 34 (1994)
- Relevant recommendations:
  - ICP should not be irradiated with primary radiation
  - Dose to the ICP should be estimated prior to RT
  - If total dose to the ICP is expected to be > 2 Gy, ICP should be interrogated prior to RT and weekly during treatment


Limitations of TG 34

- Based on older device technology \(\rightarrow\) obsolete
- Guidelines only address pacemakers, not defibrillators
- Delivery equipment and techniques have changes considerably – 20 year old report
  - Introduction of MLCs and dynamic wedges
  - Introduction of IMRT and SBRT

### What about Vendor Recommendations?

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Device</th>
<th>Dose Limit (Gy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>ICD</td>
<td>No safe dose</td>
</tr>
<tr>
<td></td>
<td>ICP</td>
<td>&lt; 10 Gy</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>ICD/ICP</td>
<td>No safe dose</td>
</tr>
<tr>
<td>Medtronik</td>
<td>ICD</td>
<td>1 – 5 Gy (based on model)</td>
</tr>
<tr>
<td></td>
<td>ICP</td>
<td>5 Gy</td>
</tr>
<tr>
<td>St. Jude</td>
<td>ICD/ICP</td>
<td>No safe dose (but tested to 30 Gy, few errors observed at 20 Gy)</td>
</tr>
</tbody>
</table>

Based on company literature on radiation tolerance of their CIEDs.

### Effects of Ionizing Radiation on CIEDs

- **Modern CIED circuits use complementary metal oxide semiconductors (CMOS)**
- **Pro** - CMOS circuits have led to smaller, more energy efficient and reliable CIEDs
- **Con** - CMOS is known to be susceptible to ionizing and electromagnetic radiation, which may result in transient or permanent device defects
Effects of Ionizing Radiation on CIEDs

- Ionizing radiation creates excess electron hole pairs in the SiO$_2$ layer (insulator) of the CMOS
- Holes trapped in valence band form aberrant electrical pathways in the insulator
- May result in minor or significant malfunctions

In Vitro Studies - Effects of Ionizing Radiation on CIEDs
Influence of High E Photon on ICPs

- 96 explanted ICPs (varying ages) were studied
- Devices irradiated in direct beam with 18MV photons
- Devices were irradiated with varying dose rates up to a total dose of 200 Gy or point of failure

Mouton et al., Physics in Medicine and Biology, 47, 2879-93 (2002).

Issues Due to Irradiation

1. Missing pulse at start of irradiation
2. Amplitude modification of pacing pulse $\leq 10\%$
3. Slowed down rate
4. Accelerated rate
5. Signal deformation
6. Amplitude changes $> 10\%$
7. Silences $> 10$ s
8. Permanent silences

Most common event, 66%

Mouton et al., Physics in Medicine and Biology, 47, 2879-93 (2002).
Influence of RT on Modern ICPs

- 19 new ICPs from 4 different manufacturers were studied
- Irradiated with 6X, primary beam
- Irradiated to 120 Gy or point-of-failure

Hurkmans et al., Radiotherapy Oncology, 76, 93-98 (2005).

Issues due to Irradiation

- Change in the amplitude or duration of the pacing pulse, or loss of signal
- Inhibition of pacing frequency – during irradiation
- Change in sensing thresholds
- Temporary or permanent loss of telemetry
- Battery problems
- Change in lead impedance

Most common event

Hurkmans et al., Radiotherapy Oncology, 76, 93-98 (2005).
Influence of RT on ICDs

- 11 ICDs were irradiated with 6MV photons, 4 different models and/or manufacturers
- 3 irradiation scenarios: direct beam, 5 cm outside field, and lead(s) in field
- A total of 20 Gy was delivered in a fractionated manner


Issues due to Irradiation

- Pacing interference and/or rapid ventricular pacing was noted when the ICD was in direct beam
  - Interference was not observed when the ICD was outside of the beam aperture
  - No correlation was identified between cumulative dose and interference events

What about Neutrons?

- Raitt et al., Chest, 106 (3), 955-7 (1994).
  - Case study: “Runaway pacemaker occurred in a patient undergoing high-energy neutron radiation therapy despite adherence to published safety guidelines.”

  - Secondary neutrons from linacs were demonstrated to cause “soft errors” in nearby electronics. → Transient changes in memory/logic of device

What about Neutrons?

  - One patient (of 33) experienced a default of their device to its initial factory setting.
  - This patient had initially been treated with a 15 MV beam.

  - 14 devices from 4 manufacturers tested (in vitro).
    In six cases, an electrical reset was observed at time of interrogation.
  - Electrical reset present after exposure to high [neutron] fluence.
Potential CIED Errors (Heart Rhythm Society)

- Oversensing – inappropriate inhibition of
  Most frequently observed with EMI interactions
- Effects influencing rate response algorithm
- Resets – Device returned to initial
  Rare but more commonly caused by therapeutic irradiation
- Pulse generator damage or permanent failure
- Damage of the lead tissue interface

Crossley et al., HRS, 8(7), 1114 – 54 (2011).

Potential Risk Factors

- Total dose
- Distance
- Time
- Modality
- Energy
- Dose rate (inconclusive)
Recently Published Consensus-Based Recommendations

Heart Rhythm Society

- Consensus statement on perioperative management of patients with CIEDs
  - Included recommendations on diagnostic and therapeutic radiation
- Members – Cardiologists, Anesthesiologists, and Thoracic Surgeons

Crossley et al., HRS, 8(7), 1114 – 54 (2011).
Heart Rhythm Society

- Diagnostic radiation
  - No significant adverse effects on CIEDs
  - Transient oversensing events have been reported

- Therapeutic radiation
  - Avoid direct irradiation of CIED
  - Total dose to device < 5 Gy
  - Reset have been observed due to secondary neutron exposure

Crossley et al., HRS, 8(7), 1114 – 54 (2011).

Dutch Society of Radiotherapy and Oncology (2012)

- Management of radiation oncology patients with CIEDs
- Members – Cardiologists, Device Technologists, RO physicians, RO physicists

Hurkmans et al., Radiation Oncology, 7, 198-215 (2012).
Dutch Society of Radiotherapy and Oncology (2012)

- **Recommendations**
  - Device should not be directly irradiated
  - Dose to device should be estimated pre-treatment
  - Dose limits:
    - Rather than recommending universal dose limits, patient risk categories proposed


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Dutch Society of Radiotherapy and Oncology (2012)

- Low risk (< 2 Gy and non-dependent) – no extra measures needed
- Medium risk (> 2 Gy < 10 Gy and/or dependent) – emergency equipment present during each txmt, weekly CIED check by pacemaker technician. Personnel trained in resuscitation and CIED tech or cardiologist available.

Dutch Society of Radiotherapy and Oncology (2012)

- High risk (> 10 Gy and CIED relocation not possible)
  - Does the benefit of RT outweigh the CIED related risks?
  - If yes, same precautions as medium risk + daily monitoring

Hurkmans et al., Radiation Oncology, 7, 198-215 (2012).

- To minimize likelihood of adverse events, need to identify patients with CIED as early in the process as possible.
University of Michigan Study

- In 2005, UofM’s depts of Radiation Oncology (RO) and Cardiac Electrophysiology (EP) section established a formal communication process.
- Effectiveness of this program was assessed by retrospectively reviewing patients with CIEDs who received RT between 2005 and 2011.

Workflow for Patient’s with CIEDs

1. Initial Consult w RO
2. Presence of CIED identified
   - Simulation
     - Physics on set
     - Estimate position of device relative to ROI
   - EP Consultation
     - Interrogate device
     - Establish baselines and vitals
     - Assess dependency
Why is this important at sim?

- Several studies have suggested a small risk of CIED oversensing during CT irradiation.
  - ICPs - inappropriate inhibition of pacing output
  - ICDs - unneeded tachycardia therapy
- Effects transient, only observed when CIED generator in direct beam.
- Potential concern for patient’s scheduled for dynamic CT scan (e.g., 4DCT).

Possible Issues Related to MR Imaging

- Image distortion
- Heating at lead tip and tissue interface
- Force and torque on device
- Alteration of programming
- Asynchronous pacing
- Inhibition of pacing
- Electrical reset
- Component damage
- Death


MR-Conditional CIEDs

- Must be mindful of protocols and vendor specifications
  - Current devices tested at 0.5 and 1.5T

Simulation Checklist

• Patient evaluated or scheduled with EP to verify device dependency
• Verify presence of CIED noted in patient’s record
• Estimate distance of device from ROI
  – If it might be in direct beam, contact EP
• Document device make, model and SN

Workflow for Patient’s with CIEDs

Initial Consult w RO

Presence of CIED id’ed

Simulation

EP Consultation

Treatment Planning
Treatment Planning Considerations

- Establish treatment planning objectives and priorities to target and OARs (including CIED)

- Departmental Limits:
  - ICPs – 2 Gy
    - Based on TG34 (Marbach et al.)
  - ICDs – 1 Gy
    - Based on Solan et al. and limits suggested by Medtronic


Treatment Planning Considerations

- Techniques to minimize dose to the CIED:
  - Contour device – Avoidance and estimate dose
  - Avoid high E photon beams
  - Avoid physical wedges
  - Use MLC and/or segmental fields to shield device
Peripheral Dose

Internal Scatter + Collimator Scatter + Leakage
- < 10 cm, main contributors internal and collimator scatter, internal dominates
- 10 – 20 cm, contribution of collimator scan increases, internal still dominates
- ~ 30 cm, internal scatter and leakage equivalent
- > 30 cm leakage dominates

M. Stovall et al., TG. 36, Medical Physics (1995); 22 (1): 63 - 82.

Accuracy of TPS

- Howell et al. investigated accuracy of peripheral dose (PD) calculations for the Eclipse AAA algorithm (v8.6).
- PD were underestimated by an average of 40%.

- Huang et al. performed study using Pinnacle v9.0.
- PD for IMRT plans were evaluated and were underestimated by an average of 50%.

Peripheral Dose Estimates

- TPSs are not commissioned for PD calculations. Their accuracy is known to decrease with increasing distance from the field edge.
- Most clinics estimate PD based on publications.
- Estimates dependent on beam energy, field size, and distance from field edge

Treatment Planning Considerations

- Techniques to minimize dose to the CIED:
  - Contour device
  - Device should not be in the path of primary beam
  - Avoid high energy (>10 MV) photon beams
  - Avoid physical wedges were avoided
  - Use MLC and/or segmental fields to help shield device
Planning Checklist

- Verify that only 6X photons or electrons used and physical wedges avoided
- Estimate distance from device to closest treatment field edge
- Estimate dose/fx and total dose
- Verify device dependency

What if we exceed these limits or cannot avoid direct irradiation?

- Consult with Electrophysiology
  - Is the patient dependent on the device?
  - What is the estimated dose to the device?
  - Should magnets be used? Should the device be turned off or put into a safety mode?
  - Should cardiac monitoring frequency be increased?
  - Should the device be relocated?
Relocating CIED

- Decision made considering all aspects of the patient’s care
- Co-morbidities
- Risk associated with re-implantation
  - Infection (0.4 – 4.0%)
  - Pneumothorax (0.8 – 1.7%)

*Hurkmans et al., Radiation Oncology, 7, 198 – 208 (2012).*

Workflow for Patient’s with CIEDs

- Initial Consult w RO
- Presence of CIED id’ed
- Simulation
- EP Consultation

Treatment Planning

- Verify CIED excluded from imaging fields
- In vivo measurements, if necessary

Treatment Day 1

- Consult EP/RO increasing monitoring and frequency
- Consider replanning
- Repositioning?

*In vivo > limits*
First Day of Treatment

• Should we perform *in vivo* measurements?
• A distance/dose criteria is used:
  – Yes
    • < 10 cm and estimated dose > 2 Gy (ICP)
    or > 1 Gy (ICD)
  – No
    • > 10 cm and estimated total dose < ICP
    and ICD departmental limits

In vivo Dosimeters

• Which dosimeter?
• There are inherent limitations in using *in vivo* dosimeters for PD measurements
  – *In vivo* dosimeters are calibrated in-field whereas measurements are performed out-of-field
  – Energy spectrum out-of-field differs compared to in-field due to the contributions of low energy scattered photons
Diodes

Advantages
• Instantaneous readout

Disadvantages
• Energy, dose rate, angular, and temperature dependence
• Requires wired connection

TLDs

Advantages
• Response independent of dose rate, angle of incidence, and temperature

Disadvantages
• Preparation time (with powders)
• Readout complicated and time intensive
• Fading
• Must be handled carefully to avoid surface contamination
• Thermal annealing time consuming
### OSLDs

**Advantages**
- Response independent of energy (MV photons and electrons), dose rate, angle of incidence, and temperature
- Multiple readouts with minimal loss of signal
- Stable reading (~ 10 - 15 min post irradiation)

**Disadvantages**
- Accumulate residual signal due to deep energy traps
- Sensitive to light, must be kept in light-tight containers


### Day 1 Checklist – Based on Limits

- Place OSLD on CIED under bolus
- Verify imaging fields do not irradiate CIED
- Estimate dose/fx and total dose to device
- Summarize findings
- If estimated dose exceeds departmental limits, notify EP
Between 2005 and 2011, we treated 69 patients with CIEDs (50 ICPs and 19 ICDs) in Radiation Oncology

CIEDs were from one of four leading CIED manufacturer (Biotronik, Boston Scientific, Medtronic, or St. Jude)

Makkar, Prisciandaro et al., Heart Rhythm, 9(12), 1964-68 (2012).

<table>
<thead>
<tr>
<th>Treatment Site</th>
<th>Number of Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen</td>
<td>8</td>
</tr>
<tr>
<td>Breast and thorax</td>
<td>28</td>
</tr>
<tr>
<td>Esophagus</td>
<td>6</td>
</tr>
<tr>
<td>Extremities</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>4</td>
</tr>
<tr>
<td>Upper</td>
<td>6</td>
</tr>
<tr>
<td>Head and neck</td>
<td>33</td>
</tr>
<tr>
<td>Pelvis (prostate, bladder, gyn)</td>
<td>18</td>
</tr>
<tr>
<td>Spine</td>
<td>4</td>
</tr>
</tbody>
</table>

Makkar, Prisciandaro et al., Heart Rhythm, 9(12), 1964-68 (2012).
### University of Michigan Study

<table>
<thead>
<tr>
<th>Treatment Technique</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>3D conformal (including at least one wedge)</td>
<td>35</td>
</tr>
<tr>
<td>IMRT</td>
<td>13</td>
</tr>
<tr>
<td>SBRT (lung)</td>
<td>6</td>
</tr>
<tr>
<td>SRS</td>
<td>1</td>
</tr>
</tbody>
</table>

- 36 patients were treated with at least one high energy (16X) photon beam
- 29 patients were treated with at least one plan in which their CIED ≤ 10 cm from the field edge

Makkar, Prisciandaro et al., Heart Rhythm, 9(12), 1964-68 (2012).

### Results from UofM Study

- ICPs and ICDs were exposed to doses ranging from 0.9 to 505.7 cGy and 4 to 169 cGy, respectively
- However, only two ICD patients experienced a partial reset of their device during their treatment
  - One was treated with 6X/16X plan and device was within 2.5 cm of treatment fields
  - Second was treated with 16X beams that were far from the ICD

Makkar, Prisciandaro et al., Heart Rhythm, 9(12), 1964-68 (2012).
Results from UofM Study

- We suspect partial resets were most likely due to the interaction of secondary neutrons with the ICD circuitry
- Re-planned both cases with 6X and no further events noted.

Makkar, Prisciandaro et al., Heart Rhythm, 9(12), 1964-68 (2012).

Future Direction – TG 203

- In 2010, AAPM created a new task group to establish recommendations for the management of patients with CIED
- Multidisciplinary Team – Physicists, Electrophysiologist, and a vendor consultant (Medtronic)
Status of TG 203 Report

- Report is currently being finalized
- Expect to submit report to parent committee in the next few months
- Similar to the Dutch study, recommendations from report will be based on patient risk categories (5 Gy vs 10 Gy)

Summary

- As the average lifespan of Americans increase, the number of patients with CIEDs presenting for RT will continue to increase.
- Degree of patient monitoring should be based on factors such as CIED distance from field, dose to device, and device dependency.
- With the proper precautions and patient monitoring, patients may safely receive RT.
- Key to success is to build a focused, multi-disciplinary team.
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