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Assessing the risk of CIED malfunction from radiation

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Objectives

- What are the failure modes for CIEDs?
  - Electromagnetic Interference
  - Magnetic fields
  - Dose rate effects
  - High LET interference
  - Cumulative dose
- What is the clinical risk of each?
- How should this risk be assessed?

1. Electromagentic Interference

- EMI could affect signal of CIED
- Poorly investigated (effect not isolated)
  - Several reported events that are likely LET effects
- Effects are minimal and transient (only when field is on)
- Not generally something to worry about

2. Magnetic Fields

- Can have current induction, lead heating, mechanical movement, parameter reset, battery depletion, etc.
- CIED has often been considered a contraindication to MRI
- Lots of changes in the field right now
  - CIED developers are addressing the need to MRI patients
  - MR conditional devices on the market
    - i.e., MRI environment does not pose a known hazard
- Also there are numerous studies of CIED patients receiving scans
  - 0.5-1.5 T

2. Magnetic Fields

- MRI can be done safely for MR-conditional devices
  - 7 trials with ~1500 total patients: 1 serious adverse event
    - Pericarditis requiring lead repositioning
  - Occasional pacing capture threshold change (not statistically significant)
  - Some reports of warming and/or prickling sensation
- Even non-conditional devices show very few effects in clinical studies
  - Most studies (hundreds of patients): no effects
  - Occasional resets and transient effects

- Risk is low (don’t exclude patient from consideration of MRI)
- Risk is not zero (protocols needed)
- Assessment is pretty easy – is there a magnetic field?

3. Dose-rate effects

- Device can suffer interference or become confused by high frequency x-rays
- E.g., CT scan has a period of 2 cycles/s = 120 sig/min. Heart rate?
- Frequency in clinical practice:
  - Low, or at least low impact
- Grant et al (JAMA Oncology, 2015) found 3 noise-events in 249 course of RT
  - **1.2% risk per course**
- Severity
  - Generally mild
  - Transient effects – only relevant when radiation is on
    - Accidental discharge of a ICD would not be good or mild – never reported

3. Dose-rate effects - assessment

- Assessment is hard – we don’t know what we’re looking for!
- Unclear what the dose-rate versus response relationship looks like.
  - Is the risk higher with FFF beams vs normal beams (instantaneous dose rate)?
  - Is the risk higher with 600 MU/min vs 100 MU/min (dose per second)?
  - Is the risk higher with VMAT vs conventional therapy (dose per min)?

- Most experience is based on conventional therapy. Be aware that different dose/time structures may have different risks
- There is no evidence (currently) that the risk is different according to different clinical treatment regimens (not much data)
- Risks are small

4. Risk from high-LET particles

- High LET particles can flip bit status (0->1)
  - Neutrons (not photons or protons)
  - This might be an irrelevant change or a critical one….
- Studied in proton series (42 patients)
- High energy x-ray series (71 patients)

Malfunctions of Implantable Cardiac Devices in Patients Receiving Proton Beam Therapy: Incidence and Predictors

Daniel R. Gomez, MD,* Falk Poenisch, PhD,† Chelsea C. Pinnix, MD, PhD,* Tommy Sheu, BA,‡ Joe Y. Chang, MD, MS, PhD,* Nada Memon, MD,§ Radhe Mohan, PhD,† Marc A. Rozner, MD, PhD,‖,1 and Anne H. Dougherty, MD§,1

Int J Radiation Oncol Biol Phys, Vol. 87, No. 3, pp. 570–575, 2013

Original Investigation

Radiotherapy-Induced Malfunction in Contemporary Cardiovascular Implantable Electronic Devices

Clinical Incidence and Predictors

Jonathan D. Grant, MD; Garrett L. Jensen, BS; Chad Tang, MD; Julianne M. Pollard, PhD; Stephen F. Kry, PhD; Sunil Krishnan, MD; Anne H. Dougherty, MD; Daniel R. Gomez, MD; Marc A. Rozner, PhD, MD

JAMA Oncol. doi:10.1001/jamaoncol.2015.1787
Published online June 25, 2015.

4. Risk from high-LET particles

- Risk of upset per course of RT
  - Proton series: 5/42 = **12% risk per course** (Gomez)
  - High energy x-ray: 15/71 = **21% risk per course** (Grant)

- Type of errors (of the 15 upsets from Grant)
  - 5 data loss
  - 8 parameter reset
  - 2 unrecoverable errors

4. Assessing high-LET risk

- Risk is stochastic
  - upset as likely on the first fraction as on the last
- Question is: how many neutrons are present?
- Neutron dosimetry is ugly
  - Don’t measure anything
- Know when neutrons are present and that they are a bath

≤10 MV photons, electron = NO neutrons

>10 MV photons, proton therapy = neutrons

  - It doesn’t matter how far away the treatment field is

5. Risk from cumulative dose

- Degrading of CIED circuitry leading to degradation or loss of function
- TG-34 focused on this risk: 2 Gy limit

- Cumulative dose effects studied several times
  - Often mix cumulative dose and high energy x-rays…..
  - Hurkmans 2005, Hurkmans 2005, Uiterwaal 2006, Mollerus 2014
    - Just 6 MV beams
- Direct irradiation of CIEDs ex-vivo

5. Risk from cumulative dose

Results from the previous four studies

	Failed by 5 Gy	Failed by 50 Gy
ICPs	0/19 (0%)	2/19 (11%)
ICDs	3/30 (10%)	10/19 (53%)
Total	3/49 (**6%**)	12/38 (**32%**)

High doses often lead to device failure – relatively severe risk

5. Assessing cumulative dose risk
General comments

1. Do it nearest to the treatment field, don't include leads
2. Do it early so you can incorporate into management
   - Estimate before first fraction
     - Calculation: TG-36/TG-158/TPS
   - Confirm on/by first fraction
     - Phantom or in vivo
3. How to assess depends on distance from the field

5. Assessing cumulative dose risk
Within 3 cm of the treatment field

- Within 3 cm of the treatment field
  - (within the 5% isodose curve)
- Use the TPS calculated dose
  - Dose calculation won't be highly accurate because it will not capture the low-energy of the scattered radiation interacting with the high-Z of the CIED
  - Don't worry about this issue (e.g., by over-riding the HU of the device). Just calculate dose normally in the TPS to the CIED contour.
    - Can still over-ride e.g., missing tissue

5. Assessing cumulative dose risk
Within 3 cm of the treatment field

- The TPS is only suitable for assessing dose to the device **within 3 cm** of the treatment field (above the 5% isodose line)
- Further out, the dose estimates are wrong, typically underestimating dose by 50%, with increasing error as the distance increases.
- Don’t use the TPS beyond 3 cm/5% isodose.

5. Assessing cumulative dose risk at intermediate distances

- 3-10 cm from field edge
- Measure the dose to the device

1. Select an appropriate dosimeter, consider necessary corrections
2. Put bolus over detector

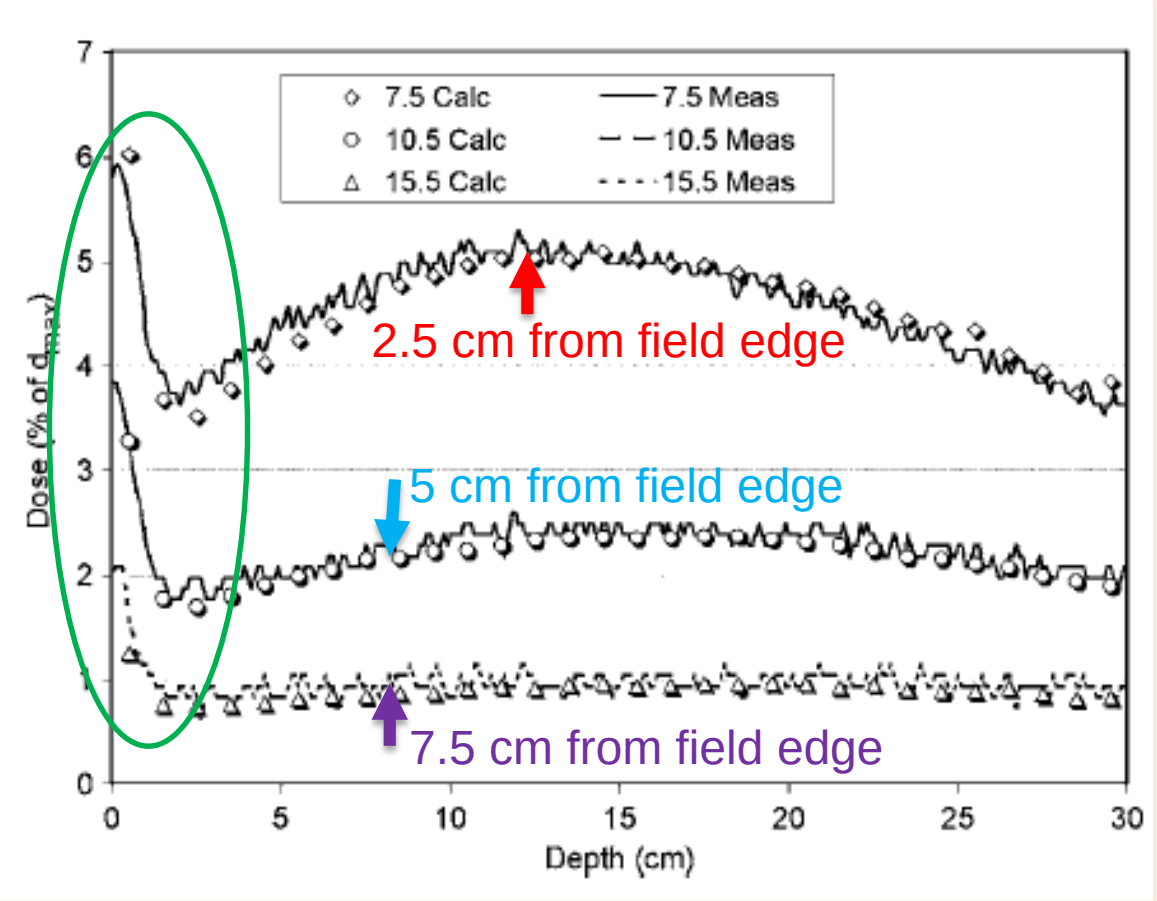
- Most measurement errors/shortcuts will lead to overestimate of dose
  - Acceptable as long as patient is placed in appropriate risk category

5.1 Detector choice and corrections

- Energy is much softer than in-field (300 keV vs. 1.5 MeV)
  - Dosimeters will typically over-respond (higher Z than water)
- Ion chambers
  - Caution for microchambers with high-Z electrodes
    - 50% energy correction. Otherwise minimal issue
  - Caution for high-V for *in vivo* measurements
- TLD/OSLD
  - 10%/25% energy correction
  - TLD-100: sensitive to neutrons (erroneous result in 15/18 MV beam)
- Diodes
  - Energy correction depends on type of diode, but can be >70%

5.2 Bolus over detector

- There is elevated dose at the surface (by a factor of 2+)
- CIEDs are typically located 1-3 cm below skin
- To get reasonable dose measurement, cover device in bolus (~1cm)



Kry et al, Med Phys, 2006

5. Assessing cumulative dose risk >10 cm from the treatment field

- Beyond 10 cm from the field edge:

- Dose almost certain to be less than 2 Gy
  - Use clinical judgement. If there are vertex fields pointed straight at the device it may still warrant a measurement.

- Don’t generally need to worry about the dose at this distance
- No further assessment necessary

Summary

- There are several possible failure modes
- The biggest ones to worry about are
- High LET situations
  - Clear high risk of device upset
- Cumulative Dose
  - Clear high risk of device failure
- Guidelines in TG-203 for assessing the risk for each of these