Management of Radiotherapy Patients with Cardiac Implantable Electronic Devices

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Quiz Question #1

What is the safe radiation dose limit for implanted cardiac pacemakers?

1. 0.5 Gy
2. 2 Gy
3. 10 Gy
4. No safe dose threshold

Quiz Question #2

Compared to pacemakers, implanted cardiac defibrillators are:

1. Less sensitive to radiation-induced malfunction
2. More sensitive to radiation-induced malfunction
3. Equally sensitive to radiation-induced malfunction
4. Harder to spell

Quiz Question #3

Compared to older pacemaker models (e.g. discreet uni- or bi-polar transistors) modern CMOS pacemakers are:

1. Less sensitive to radiation-induced malfunction but more sensitive to EMF interference

2. More sensitive to radiation-induced malfunction but less sensitive to EMF interference

3. Equally sensitive to radiation-induced malfunction and EMF interference

4. Far less susceptible to the Vulcan Death Grip

Quiz Question #4

When treating a CIED patient with high-energy photons (e.g., 18 MV), how is proximity of treatment fields to the CIED related to risk of radiation-induced malfunction?

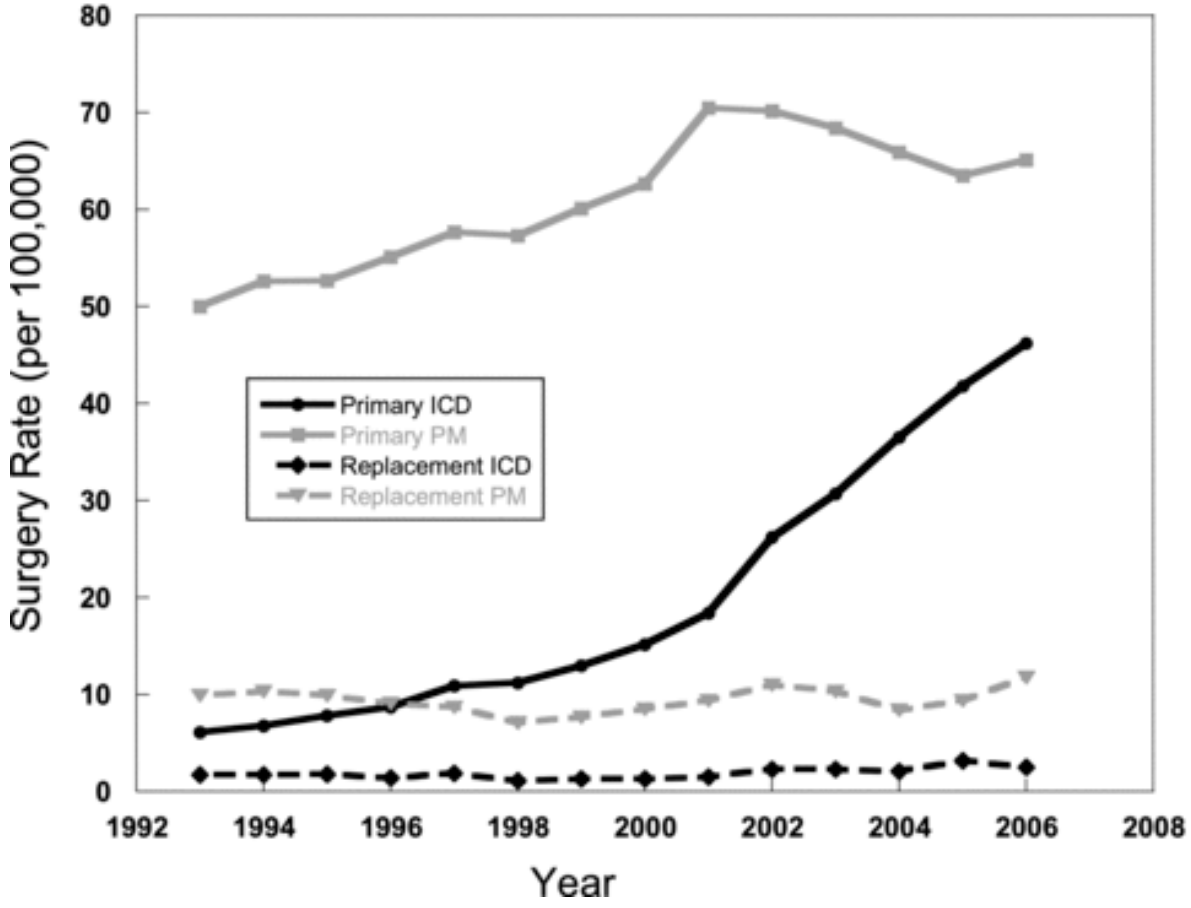
1. Linearly related
2. Related by the inverse-square law
3. Unrelated
4. The same as the ratio of unicorns to leprechauns

A series of CIED-related conundrums: *where it all began*

CIED literature is scattered and conflicting

- **Number of CIED patients receiving radiation therapy is steadily increasing**

CIED literature is scattered and conflicting



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CIED issues motivating this study

- **Number of CIED patients receiving radiation therapy is steadily increasing**
- **Vendor literature concerning “safe” radiation dose limits for these devices is tedious and scattered**

What about Vendor Recommendations?

Vendor	Device	Dose Limit (Gy)
Biotronik	ICD	No safe dose
	ICP	< 10 Gy
Boston Scientific	ICD/ICP	No safe dose
Medtronik	ICD	1 – 5 Gy (based on model)
	ICP	5 Gy
St. Jude	ICD/ICP	No safe dose (but tested to 30 Gy, few errors observed at 20 Gy)

Based on company literature on radiation tolerance of their CIEDs.

JIP 17

Summary of dose limit recommend-ations from four major CIED manufacturers

CIED issues motivating this study

- Number of CIED patients receiving radiation therapy is steadily increasing
- Vendor literature concerning “safe” radiation dose limits for these devices is tedious and scattered
- AAPM TG-34 (published in 1994) is outdated in terms of current CMOS technology and doesn’t include tachycardia devices (i.e. implantable cardiac defibrillators)


ON 5/1/16 SATURN WILL BE THE CLOSEST IT HAS EVER BEEN TO EARTH
IT WILL LOOK LIKE THIS

CIED issues motivating this study

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- AAPM TG-34 (published in 1994) is outdated in terms of current CMOS technology and doesn’t include tachycardia devices (i.e. implantable cardiac defibrillators)
- Sometimes historical policies and/or physician’s instructions have little to no basis in actual data

Brief overview of CIED issues in external beam radiation therapy

CIED issues in EBRT

- **Data on older, transistor-type CIEDs is basically useless today**
- **Modern CMOS (complimentary metal-oxide semiconductor) devices are *less* susceptible to EMF interference but exponentially more sensitive to radiation-induced malfunction[1]**
  - ICP/ICD: accumulation of positive charge carriers in silicon layers leads to aberrant electrical pathways
  - ICD: RAM memory chip sensitive to radiation damage, especially in the presence of neutron dose

CIED issues in EBRT

- Reports of CIED-malfunction in radiation therapy show potential errors from doses **as low as 0.15 Gy**
  - Some of the exact same models showed no errors at all in direct irradiation of **up to 150 Gy**
- Almost no reports of error for CIEDs exposed to irradiation of <2 Gy by <10 MV photons
- Multiple reports of errors due to 18 MV photon beams and <1 Gy delivered at isocenter (regardless of proximity to CIED)
- Defibrillators are more sensitive to radiation damage than pacemakers: in one report, every single ICD exposed to direct irradiation malfunctioned in some way

CIED issues in EBRT

- **"…there does not appear to be any consistent way to to predict how a device will fail or at what dose failure will occur."[1]**
  - Current literature – such as the 2012 comprehensive report of the Dutch Society of Radiotherapy – separates CIED patients into *risk categories*[2]
  - Upcoming TG-203 from the AAPM will supersede the outdated TG-34 report, and from previews given at multiple AAPM meetings it appears that this document will take a similar approach to the study from The Netherlands

Risk categories and recommendations

Definition and quantification of “risks”

- **Virtually impossible to quantitatively approximate the risk of radiation-induced CIED malfunction**
  - Though generally proportional to accumulated dose, there is no clear linear relationship to radiation dose
  - Similar devices (in fact, exact same models) may behave completely differently, suggesting overall stochastic effects
  - Proximity to the treatment fields is irrelevant in the presence of neutron dose
  - Level of device-dependence (also difficult to quantify) is a primary concerning when assessing relative risk

Types of malfunctions reported in the context of radiotherapy

- Transient fluttering effects
- Reset to factory programming
- Decrease in battery life or total loss of electric function
- Decrease in pacing amplitude
- Decrease in shock energy (ICD)
- Erroneous ventricular fibrillation or ventricular tachycardia detection
- Runaway pacemaker or defibrillator
- Shock coil failure (ICD)
- Total , catastrophic defect

“Risk” for CIED-dependent patients

- Palpitations
- Shortness of breath
- Vertigo
- Syncope (pass out due to loss in blood pressure)
- **Even in the transient malfunction setting, the patient’s condition can deteriorate to life-threatening cardiac event**
- Catastrophic decrease in heart rate and blood pressure
- Ventricular tachycardia
- Ventricular fibrillation
- Cardiopulmonary resuscitation may be required, followed by temporary external pacing
- Prohibition of life-saving intervention from ICD

Risk of serious complications in context of CIED malfunction

- Majority of CIED malfunctions are transient, requiring at most reprogramming
- FDA reports risk of CIED malfunction as 1 in 75,000 for pacemakers and 1 in 13,500 for defibrillators[1]
  - **Risk of mortality due to CIED malfunction within the same population was 1 in 300 for ICP and 1 in 275 for ICD[1]**
- 0.7% risk of preventing a life-saving shock by deactivating an ICD for a 6-week course of radiotherapy[2]
- 0.5%-6% risk of serious surgical complications (e.g. pneumothorax, infection) **if CIED must be replaced[2]**

Risk Categories

- **Low Risk**
  - Pacing-independent **AND** <10 MV photons **AND** CIED receives < 2 Gy (and < 1 Gy for ICD)
- **Medium Risk**
  - Pacing-independent **AND** <10 MV photons **AND** CIED receives 2-5 Gy
  - Pacing-*dependent* **AND** <10 MV photons **AND** CIED receives < 5 Gy
- **High Risk**
  - <10 MV photons **AND** CIED receives less ≥ 5 Gy
  - ≥10 MV photon *in any scenario*

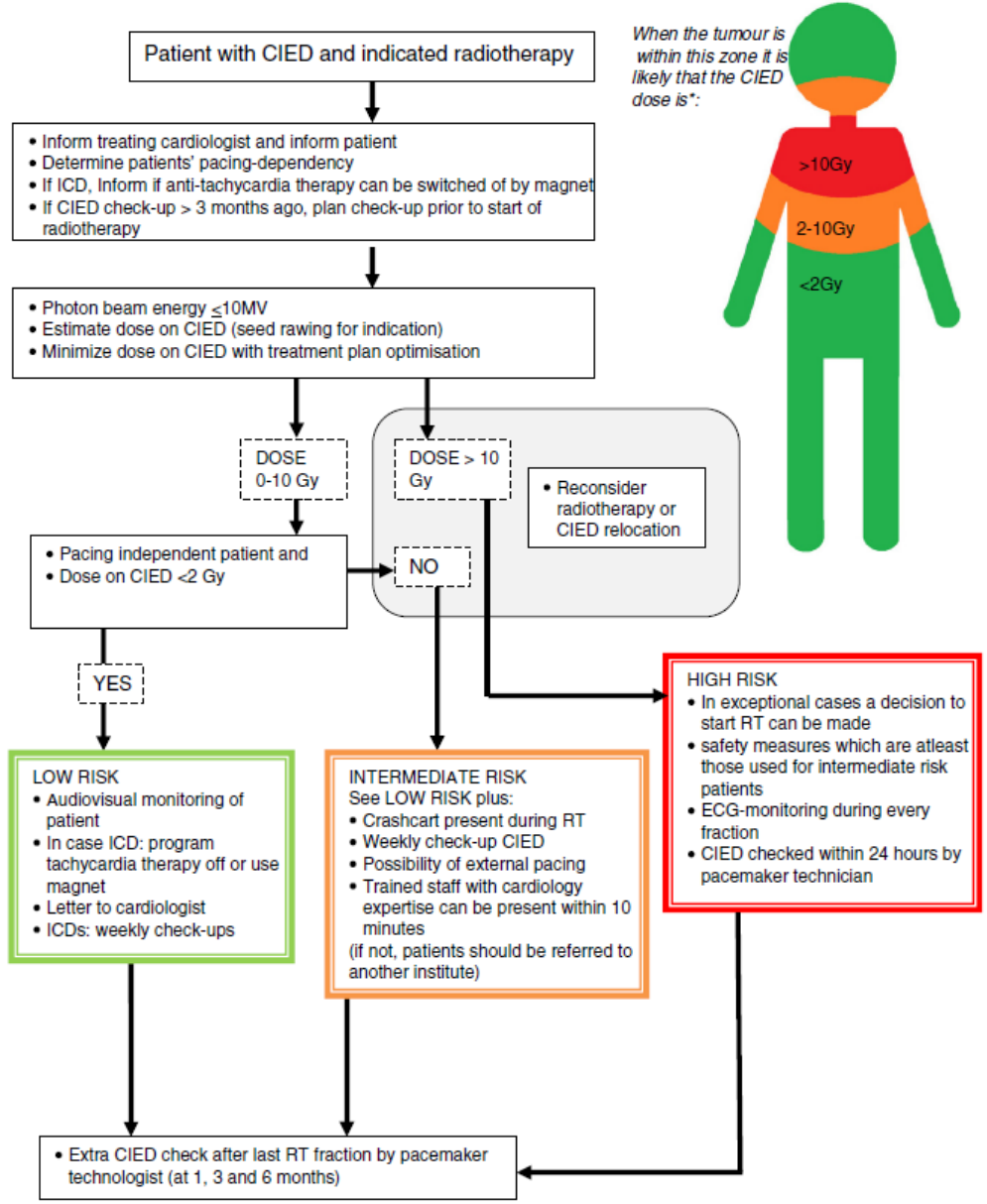

Figure 1 Flow diagram of Dutch guidelines. *Estimation of dose in case of a pectoral placed CIED.

This chart[4] will be adopted by TG-203 but is **ONLY VALID for treatments with ≤ 10 MV** photons (≈60% of EBRT patients)

Risk Categories

- **Notes concerning physical (i.e., hard) wedges:**
  - Scatter from a physical wedge significantly increases dose outside the treatment field[6-9]
  - Treatment planning systems do not estimate dose outside the field well, and especially not in the presence of a physical beam modifier[1-10]
  - For an 18 MV beam, neutron dose is 6.5 times higher (on average) for a hard-wedged beam compared to an open beam[10]

- **For EBRT plans in which physical wedges cannot be avoided, RISK LEVEL must be individually assesed**

Current CIED-management process at NHCI (Atlanta GA)

Current CIED-management process

1. Nursing evaluation and notification of department
2. CT simulation includes pacemaker if within 20 cm of treatment fields
3. Physician and dosimetrist plan and approximate CIED dose
4. Physician and physicist come up with preliminary management plan based upon risk level
5. Physician or physicist contact patient's cardiologist and/or electrophysiologist
6. Pacemaker interrogation services (internal or vendor-provided) is arranged
7. Nursing cardiac monitoring and AED availability arranged if necessary
8. Discharge instructions include a follow-up with cardiologist or electrophysicologist within 1 month (typically two weeks)

Current CIED-management issues

1. **Is the patient CIED-dependent?**
   - This information is ideally determined at the first consult
   - Often, the patient's knowledge is not dependable
   - Often, the cardiologist listed on the patient's ID card is either unreachable or no longer managing the patient
   - **If not certain, patient must have an initial EP evaluation to verify device dependence**
2. **What is the planned dose to the CIED?**
   - Within the approximations of the TPS, *but so is all current literature*
   - **Physician/dosimetrist/physicist select risk category**

Current CIED-management issues

3. **Contact patient's cardiologist or electrophysiologist to discuss management plan**
   - Typically do not wish to complete or sign any paperwork, but it is always offered as a courtesy
4. **Contact either hospital pacemaker services or manufacturer support if at a remote location**
   - Pacemaker services requires a physician's order, but not necessarily a cardiologist
   - While vendor support is usual easy to secure, daily monitoring is not supported by any vendor

Current CIED-management issues

We are making great effort to assimilate current national and international guidelines into our routine management of CIED patients but this is an ongoing and laborious process.

This process requires a multi-disciplinary team of professionals and continual re-evaluation of the management plan, basically for every individual patient.

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