Potential sources of malfunction of CIEDs in a radiotherapy environment

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Acknowledgement

This is a collective effort of members of TG203

New Task Group – AAPM TG 203
What is in this presentation?

- Current guidelines – protocol (TG-34)
- What are the issues with cardiac devices and radiation deliveries?
- Failures – case reports.
- Scattered guidelines in literature.
- Sensitivities and potential failures.
- Cardiac devices and RT patients.

In spite of availability of TG-34 and other reports in literature, major discrepancies still exist among manufacturers’ recommendations and wide variations exist among RT facilities regarding patient management and guidelines.

- Contradictory information exists: some devices have undergone deleterious effects at 0.15Gy (0.2Gy/min) while others have shown tolerance up to 20Gy or more dose?
- Interference with EM components, (partial) exposure to direct radiation, exposure to scattered radiation within the patient, other??

Major issues with cardiac devices and radiotherapy equipment

Dose rate study

In conclusion, warnings given by manufacturers about the maximum allowable dose rate in the operation of radiation instruments (1 Gy/min) for 1 Gy are not reliable. The spread of cumulative doses inducing failure is very large, with some observations showing no important failure at 0.15Gy, while others occurred at 0.4 Gy of cumulative dose. The safe operation of pacemakers under irradiation depends mainly on type and model. A depth-dose study is under way. From our observations, for the safe operation of pacemakers, the recommendation of a maximum dose rate of 0.2 Gy/min is made.
Recent Review Articles

Limit: 1.5 Gy scattered dose

Limit: 2 Gy scattered dose

Limit: 2 Gy scattered dose

Limit: 2 Gy scattered dose

The authors suggest categorizing the patients into three risk groups based on potential clinical risks: Low, Medium and High risk groups. Low risk patients are those who are not pacemaker-dependent, the pacemaker is not directly in the radiation field and the dose to the pacemaker is likely to be less than 1 Gy of scattered radiation. Medium risk patients are those who are pacemaker-dependent, the pacemaker is not directly in the radiation field and the dose to the pacemaker is likely to be less than 2 Gy of scattered radiation. High risk patients are those who are pacemaker-dependent, the pacemaker is not directly in the radiation field and the dose to the pacemaker is likely to be more than 2 Gy of scattered radiation. Patients with pacemakers directly in the radiation field fall into a high risk category irrespective of the total radiation dose. Direct radiation of pacemakers at therapeutic levels should be strictly avoided in a pacemaker-dependent patient unless a backup system is in place.

It has been noted that the 'radiation dose to a pacemaker' is the 'dose to any part of the device' and is not the dose averaged over the volume of the device.

The ICD should always be located outside the radiation field.

The absorbed dose to be received by the ICD should be estimated before treatment for documentation purposes. Estimation methods can be found in the literature (7).

Program the ICD temporarily to "monitor only" before each individual irradiation fraction. After consultation with the patient's cardiologist, consider switching the ICD to "monitor only" before the first irradiation fraction and only switch back to therapy mode after the complete treatment is given. Consider that even if the ICD is turned off and on with every treatment fraction, no guarantee can be given that the ICD is still able to deliver a shock if needed.

Monitor the ICD and have ICD-qualified personnel stand by during irradiation. The treating radiation oncologist might consider enlisting an ICD-trained cardiologist to monitor the patient's cardiac responses during the procedure.

If any change in ICD functionality is observed, directly consult with the patient's cardiologist to decide which steps should be taken next.
Recent Review Articles

Effects of Scatter Radiation on ICD and CRT Function

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Background: Effects of direct radiation on implantable cardiac devices have been well studied. However, the effects of scatter radiation are not as clear. Recommendations on management of patients with implantable cardiac devices undergoing radiation are based on limited studies mostly involving pacemakers. We sought to elucidate the effects of scatter radiation on implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT-Ds).

Methods: We exposed 12 ICDs and eight CRT-Ds to 400 rads of scatter radiation from a 6-MV photon beam. Devices were programmed with preset parameters and interrogated prior to radiation, after each fraction, upon completion of the radiation course, and again 1 week later. A retrospective review of patients undergoing radiation therapy at the Mayo Clinic-Rochester between 2010 and 2017 in whom the device was outside the radiation field was also performed. There were 13 patients with devices undergoing radiationtherapy during this time period, 12 of whom were interrogated prior to and after radiation.

Results: Interrogation reports were reviewed for device reset or parameter changes. There was no evidence of reset or malfunction during or after radiation. Also, no episodes of device reset, inappropriate sensing or therapy, or changes in programmed parameters were found in our review of patients undergoing radiation therapy.

Conclusions: Device reset or malfunction associated with scatter radiation likely represents an unrepeatable, rare occurrence. While we saw no clear contraindication to radiation therapy in patients with ICDs or CRT-Ds, guidelines should be in place to avoid long-term radiation exposure, and to closely evaluate patient outcomes before and after the radiation course. (J Am Coll Cardiol 2018;71:1778–1786)

Recent Review Articles

Radiotherapy-induced pacemaker and implantable cardioverter-defibrillator malfunction

Gy scattered dose ICP
1 Gy scattered dose ICD

Key issues:
- There is an increasing number of patients with implantable devices who require radiation therapy for cancer treatment.
- Ionizing radiation can cause damage to semiconductor electronics in current implantable devices.
- There is a lack of clinical studies on effects of radiation on implantable devices, but there are several reports of device dysfunction after RT.
- Implantable devices should not be placed too close to the source of scatter radiation.
- Several types of radiation, such as neutrons and gamma, can cause damage to implanted devices.
- There can be close interfacing with radiation equipment.
- Current guidelines are outdated and need to be revised.
- Proposed guidelines are required to allow specific guidance for future radiation therapy.
- Implantable devices must be closely monitored during radiation sessions.

Recent Review Articles

Effect of radiation therapy on the latest generation of pacemakers and implantable cardioverter-defibrillators: A systematic review and meta-analysis

Planning
1. Computer-assisted planning should be utilized (including CT data) to more accurately assess dose received by the pacemaker and aid in beam arrangement and shielding placement.
2. The device should be shielded and kept at least 5 cm from the collimated radiation field whenever possible (including open port filters and electronic portal imaging (EPI)). Shielding should originate from the treatment head, such as multi-leaf collimators or pre-mounted lead shielding trays.

Limitations:
- Total dose received by the pacemaker/ICD should be kept as low as possible.
- Max pacemaker dose should be kept to ≤2 Gy, or device reactivation should be considered. At no point should the cumulative dose exceed 5 Gy.
- Max ICD dose ≤1 Gy, or device reactivation should be considered.
Recent Review Articles

Radiation Therapy in Patients with Implanted Cardiac Pacemakers and Implantable Cardioverter Defibrillators:

Limit: 2 Gy scattered dose IDP 1 Gy scattered dose ICD

Case reports of failures-Direct Irradiation

The Cardiac Pacemaker Patient

Might the Pacer be Directly Irr...
Defibrillator reset by radiotherapy

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Abstract

The number of patients with implantable cardioverter-defibrillators (ICD) is rapidly increasing due to their expanding indications, among the various types of arrhythmias. However, little is reported about the effects of radiotherapy. We report a case of electrical failure of a single-patient implantable cardioverter-defibrillator (ICD) due to radiotherapy. The device first alerted during his radiotherapy (EBRT) to the pelvis using a four-field planned beam arrangement was 2 Gray (Gy) per fraction with a fraction 7.8 Gy. Upon interrogation, it was found that an ICD electrical reset was necessary to the successful therapy. The ICD response to therapeutic radiation is generally unpredictable and may potentially involve various parameters incorporated in individual ICD models. Recognition of this potential fatal event such as complete device failure, inappropriate shocks due to over-sensing and sudden death are vital in our management of such patient groups.

Secondary Neutrons - Single Center Experience

CLINICAL INVESTIGATION

IMPLANTED CARDIAC DEFIBRILLATOR CARE IN RADIATION ONCOLOGY PATIENT POPULATION

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It is not only the direct photon exposure of a device that must be considered, but also the potential for single-hit neutron particle interaction. Much like radiation damage to living tissue, the neutrons will not only cause direct damage, but also indirectly generate other radiations such as electrons and charged particles. We, therefore, advocate that patients with ICDs be treated with low energies (<10 MeV) photons, whenever possible. Since the institution of that policy, we have not detected any further programming events. We also continue to vigilantly observe these patients, together with their cardiologists, as they go through treatment.

Secondary neutron...
Case reports of failures (neutrons, particles)

A catastrophic malfunction of ICP (its programming code was significantly corrupted) after neutron therapy, at a dose level of 900 cGy.

Case reports of failures (Protons)

Case reports of failures (Protons)
Permanent damage from accumulated dose: Sensitivity is degraded in proportion to accumulated dose. Decrease of output amplitude. Damage to circuits from photons can lead to sudden failure within months past RT. 

Increased or failed sensor operation (including heart rate sensing functions).

Upsets in memory or logic circuits caused by neutrons: SOFT ERRORS. Changes in stored values in memory or transient changes in microprocessor circuitry. May not be functionally recoverable. Reset of the device: Restoration to default parameters. Rare cases where rest may delay for hours or even weeks past RT.

Transient interference from high-dose rate (HDR) x-rays: Treatment effect, no permanent damage, unless accumulated dose is high. Inappropriate sensing of tissue that lead to ICD shocks. Non-sustained pacing output. Reset of other settings.

Electromagnetic interference (EMI) are minimal and of transient nature. ICDs: May sense the field as myocardial potential. Inhibition of output. Inappropriate programming, reset output. Triggering of output.

Heart and rhythm society consensus statement

Sensitivities and potential failures

Effects of CT irradiation on Implantable Cardiac Rhythm Management Devices
Sources of potential malfunctions for CIEDs during RT processes

- Imaging for treatment planning (CT mostly).
- Imaging for Image Guidance (CT, Rad., EMI)
- RT treatment delivery (photons, protons, neutrons, particles, other)
- Use of high energy photons, E>10 MV?
- Dose rate?
- IMRT, SBRT, VMAT, FFF beams
- HDR, breast, MammoSite®
- Other...

**TG-203 RECOMMENDATIONS coming up.....**

**THANK YOU**