Potential sources of malfunction of CIEDs in a radiotherapy environment

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PENN RADIATION ONCOLOGY

Acknowledgement

- This is a collective effort of members of TG203

New TG 203

What is in this presentation?

- Current guidelines – protocol (TG-34).
- What are the issues with cardiac devices and radiation deliveries?
- Literature review ("recent") since TG-34 era (1994-2017).
- Failures – case reports.
- Scattered guidelines in literature.
- Sensitivities and potential failures.
- Cardiac devices and RT patients.

Oncology Patients with nakers (1994)

VII. SPECIFIC RECOMMENDATIONS

The following protocol is suggested when evaluating patients for radiation therapy who have an implanted cardiac pacemaker. The task group is cognizant that each patient must be addressed individually and that in some cases it may be in the best interests of the patient to diverge from the recommendations.

(1) Pacemaker implanted patients should not be treated with a betatron.

(2) Pacemakers should not be placed in the direct (unshielded) therapy beam. Some accelerator beams can cause transient malfunction.

(3) The absorbed dose to be received by the pacemaker should be estimated before treatment. Estimation methods can be found in the literature.[4-6]

(4) If the total estimated dose to the pace exceed 2 gray, the pacemaker function shoul prior to therapy and possibly at the start of ea week of therapy. Since total and abrupt failure ers has been seen at cumulative doses betwe gray and significant functional changes have b between 2 and 10 gray, early changes in pacemaker parameters could signal a failure in the 2-10 gray region.[4]

(5) Although transient malfunction from electromagnetic interference is unlikely from contemporary therapy accelerators and cobalt irradiators, the patient should be closely observed during the first treatment with a linear accelerator and during subsequent treatments if magnetron or klystron misfiring (sparking) occurs.

(6) Studies to date have dealt with linear accelerators, betatrons, and cobalt irradiators only. Use of other radiation therapy machines should be evaluated on an individual basis and approached with caution.

Majo radi

- In s … in lite… mar… vari… …ient mar…
- Con… …ve und… …n) whi… …y or mor…
- Inte… …xposure to d… …iation with…

INSTITUTE OF PHYSICS PUBLISHING PHYSICS IN MEDICINE AND BIOLOGY
Phys. Med. Biol. 47 (2002) 2879–2893 PII: S0031-9155(02)32606-X

Dose rate study

Influence of high-energy photon beam irradiation on pacemaker operation

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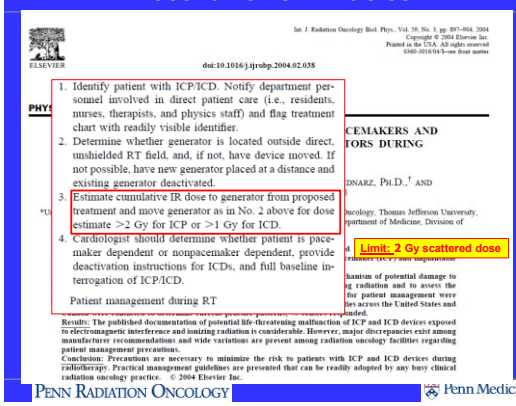
In conclusion, warnings given by manufacturers about the maximum tolerable cumulative radiation doses for safe operation of irradiated pacemakers (5 Gy), even reduced to 2 Gy, are not reliable. The spread of cumulative doses inducing failures is very large since our observations show an important failure at 0.15 Gy, while ten pacemakers withstood more than 140 Gy of cumulative dose. The safe operation of pacemakers under irradiation depends mainly on type and model. It depends also on dose rate. From our observations, for the safe operation of pacemakers a recommendation of a maximum dose rate of 0.2 Gy min^{-1} rejecting direct irradiation of the pacemaker at a standard dose rate for tumour treatment (2 Gy min^{-1}) is made.

Recent Review Articles

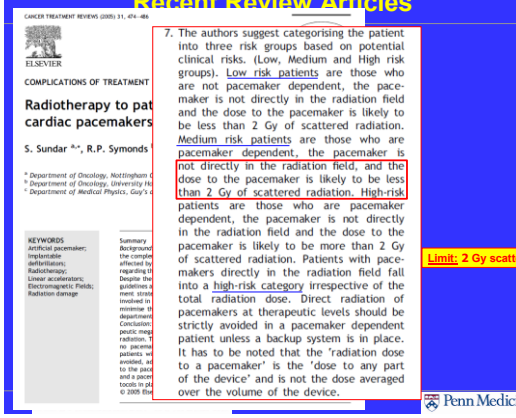


1. Identify patient with ICP/ICD. Notify department personnel involved in direct patient care (i.e., residents, nurses, therapists, and physics staff) and flag treatment chart with readily visible identifier.
2. Determine whether generator is located outside direct, unshielded RT field, and, if not, have device moved. If not possible, have new generator placed at a distance and existing generator deactivated.
3. Estimate cumulative IR dose to generator from proposed treatment and move generator as in No. 2 above for dose estimate >2 Gy for ICP or >1 Gy for ICD.
4. Cardiologist should determine whether patient is pacemaker dependent or nonpacemaker dependent, provide deactivation instructions for ICDs, and full baseline interrogation of ICP/ICD.

Patient management during RT

Limit: 2 Gy scattered dose

Recent Review Articles



7. The authors suggest categorising the patient 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 2 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 to be 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.

Limit: 2 Gy scattered dose

Recent Review Articles

- The ICD should always be located outside the irradiation 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 (17).
- 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 ECG and have ICD-qualified personnel stand by at every fraction. The treating radiation oncologist might consider omitting (part of) these safety measures if consensus is reached on this aspect with the patient's cardiologist and responsible clinical physicist.
- Have standard cardiopulmonary resuscitation equipment directly available.
- If any change in ICD functioning is observed, directly consult with the patient's cardiologist to decide which steps should be taken next.
- Monitor the ICD during the first months after radiotherapy. If functional changes are observed, consider replacement of the ICD.

Limit: 1.5 Gy scattered dose

Recent Review Articles

Effects of Scatter Radiation on ICD and CRT Function

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MICHAEL G. HERMAN, PH.D.,† PAULA J. SCHOMBERG, M.D.,† and DAVID L. HAYES, M.D.‡
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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 radiotherapy 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)-ICDs.*

Methods: *We exposed 12 ICDs and eight CRT-ICDs to 400 cGy of scatter radiation from a 6-MV photon beam. Devices were programmed with nominal 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 radiotherapy at the Mayo Clinic–Rochester between 2002 and 2007 in whom the device was outside the radiation field was also performed. There were 13 patients with devices undergoing radiotherapy 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 radiotherapy.*

Conclusions: *Device reset or malfunction associated with scatter radiation likely represents an unpredictable, rare occurrence. While we see no clear contraindication to radiotherapy in patients with ICDs or CRT-ICDs, precautions should be taken to avoid direct radiation exposure and to closely evaluate patient outcomes before and after the radiation course. (PACE 2008; 31:727–732)*

2008

Recent Review Articles

EXPERT REVIEWS

Radiotherapy-induced pacemaker and implantable cardioverter defibrillator malfunction

Expert Rev. Med. Devices 6(3), 243–249 (2009)

Fernando Tondato, Daniel W Ng, Komandoor Srivathsan, Gregory T Altemose, Michele Y Halyard and Luis R Scott*
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It is well known that ionizing radiation can interfere with cir implantable cardioverter defibrillators. Contemporary complementary metal–oxide silicon in combination with cir sensitive components are especially susceptible to electrom can potentially cause permanent damage. Electromagnetic phenomenon. Radiologic imaging tests have been implicate dysfunction and these events have been mostly transient. Th in Medicine last published recommendations regarding ira publication is outdated and may not be pertinent for the r field of artificial cardiac pacing and defibrillation and in the guidelines are definitely needed.

Keywords: cardiac devices • device malfunction • implantable cardiove • pacemaker • radiation therapy

Key issues

- There are an increasing number of patients with implantable devices who require radiotherapy (RT) for cancer treatment.
- Ionizing radiation can cause damage to sensitive circuitry existing in current implantable devices.
- There is a lack of clinical studies on effects of radiation on implantable devices but there are several reports of serious device dysfunction after RT.
- Implantable devices should not be placed in the direct therapy beam; however, it is important to emphasize that scattered radiation can also interfere with these devices.
- Other types of energy, such as electromagnetic, can be generated during RT. These can also cause interference with implantable devices.
- There are rare reports of transient device malfunction induced by radiologic imaging tests.
- Current guidelines are outdated and are restricted to pacemakers. Updated guidelines are required, including specific recommendations for implantable cardioverter defibrillators.
- Implantable devices should be closely monitored between radiation sessions.

2009

Recent Review Articles

Journal of Medical Imaging and Radiation Oncology 54 (2010) 53–61

ORIGINAL ARTICLE

Effect of radiation therapy on the latest generation of pacemakers and implantable cardioverter defibrillators: A systematic revie

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Conflicts of interest: None.

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doi:10.1111/j.1754-9485.2010.02138.x

Planning

1 3D computer-assisted planning should be utilised (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 wherever possible (including open port films and electronic portal imaging [EPI]). All shielding should originate from the treatment head, such as multi-leaf collimators or pre-mounted lead shielding trays.

3 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 relocation should be considered. At no point should the cumulative dose exceed 5 Gy
- Max ICD dose <1 Gy, or device relocation should be considered.

oncology department employ a policy for the management of pat ICDs and pacemakers, potentially based upon an updated nationa national standard similar to that released by the AAPM in 1994.

Key words: complementary metal oxide semiconductor; implantable cardioverter defibrillator; pacemaker; radiation therapy.

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

2010

Recent Review Articles

J. Radiat. Res., 52, 516–521 (2011) *Regular Paper*

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

Patient management before initiation of radiation therapy

1. Identify patients with an ICP or ICD. Notify department personnel involved in direct patient care.
2. Determine whether the generator is located outside the direct, unshielded radiation therapy field, and if not, have the device moved.
3. Estimate the cumulative ionizing radiation dose to generator for dose estimates < 2 Gy for ICP or < 1 Gy for ICD.
4. Have the cardiologist determine whether the patient is pacemaker dependent or non-pacemaker dependent. Provide deactivation instructions for ICDs, and full baseline assessment of the ICP or ICD.

Seiji ONO[4], ıRA[7], SA[8]

lefibrillators (ICDs) rapy also is increas- g radiation therapy. conducted on meth- , and after radiation nail, fax, or e-mail. :ember 2008. Sixty n therapy by dose-

volume histogram in 26 patients (42%) and by measurement of actual doses in 9 (15%). In one patient, the maximum total dose was 2069 cGy; however, in the other patients, the ICP/ICD Function of ICPs and ICDs was checked before radiation therapy in 38 patie apy in 32 (52%), and both before and after radiation therapy in 29 (47%). I patient with prostate cancer treated by intensity-modulated radiation therapy to the prostate. Even when an ICP or ICD is not within the field of radiation, malfunction of the device may still occur. To minimize the risk to patients, precautions must be taken during the planning and administration of radiation therapy.

2011

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

Case reports of failures-Direct Irradiation

CASE REPORT

The Cardiac Pacemaker Patient

Might the Pacer be Directly Irr

Alexander Tsekos, Felix Momm, Micl

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Acta Oncologica Vol. 39, No. 7, pp. 881–883, 2000

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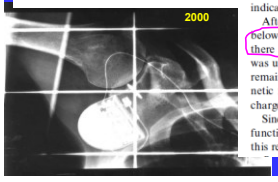
Accepted 22 June 2000



Radiotherapy course. The patient received radiotherapy as an inpatient. Figure 1 shows the pacer in the treatment field. During each fraction we performed an ECG and observed the rhythm on a monitor outside. The cardiologist was with us during the first fraction, and on stand-by for the further fractions. Pacer-function analyses were completed before, in the middle (3 weeks later) and after the radiation course. We irradiated the lymphatic nodes in the right axilla up to a dose of 50.4 Gy without problems. At a fractionation of 5× 1.8 Gy per week, it took us about 6 weeks. The pacemaker functioned without failure during every fraction, but the magnetic frequency of the pacer, which is usually an indicator of the battery load, began to decrease.

After the radiotherapy course the magnetic frequency was below the recommended exchange criteria, but at no time was there a malfunction. At the next control the magnetic frequency was unchanged at 88/min. The pacemaker's stimulation frequency remained at the programmed rate. Four months later, the magnetic frequency returned to normal, indicating a normal battery charge.

Since the end of the radiation course, the pacemaker has functioned perfectly. Follow-up was at 26 months at the time of this report. The patient has been in complete remission since then.

What about the neutrons?

Secondary from high-energy photon beams, proton beams, etc

ELSEVIER

International Journal of Cardiology 130 (2008) e37–e38

International Journal of Cardiology

www.elsevier.com/locate/ijcard

Letter to the Editor

Defibrillator reset by radiotherapy

Dennis H. Lau, Lauren Wilson, Martin K. Stiles, Bobby John, Shashidhar, Hany Dimitri, Anthony G. Brooks, Glenn D. Young, Prashanthan Sanders *

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Received 3 May 2007; accepted 30 June 2007
Available online 27 September 2007

Abstract

The number of patients with implantable cardioverter–defibrillator (ICD) is rapidly increasing due to their expanding indications. Amongst the various types of electromagnetic interferences, little is reported about the effects of radiotherapy. We report a case of electrical reset of a single chamber ICD by scattered irradiation from radiotherapy.

The device first alarmed during his
radiotherapy (EBRT) to the pelvis usi
a four-field planned beam arrangeme
was 2 gray (Gy) per fraction with
fractions (74 Gy). Upon interrogat
indicated that an ICD electrical reset

ICD response to therapeutic radiation is generally unpredictable and may potentially involve various parameters incorporated in individual ICD models. Recognition of other potential lethal events 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

ELSEVIER

Int. J. Radiation Oncology Biol. Phys., Vol. 73, No. 5, pp. 1525–1531, 2009

0360-3016/09/$–see front matter

doi:10.1016/j.ijrobp.2008.06.1903

CLINICAL INVESTIGATION — Implanted Defibrillator

IMPLANTED CARDIAC DEFIBRILLATOR CARE IN RADIATION ONCOLOGY PATIENT POPULATION

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Purpose: To
cardiac defib
their interac
Methods and
period at any
and dose del
During this t
energy beam
received ICI
Results: Dur
of the device
This patient
completed w
Conclusion:
quently in the RT department, and proper management is important. We present a policy for the 2009 treatment of these patients in the radiation oncology environment. © 2009 Elsevier Inc.

It is not only the direct photon exposure of a device that must be considered, but also the potential for a single hit neutron particle interaction. Much like radiation damage to a living. We, therefore, advocate that patients with ICDs be treated with low energy (<10-MV) photons whenever possible. Since the institution of that policy, we have not detected any further reprogramming events. We also continue to vigilantly observe these patients, together with their cardiologists, as they go through treatment.

Single-event upset

Implanted cardiac defibrillator, Radiotherapy, Patient monitoring.

Secondary neutron

Comparison of the Effects of High-Energy Irradiation (10 and 18 MV) on 2 Types of Cardioverter-Defibrillators

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Received Dec 21, 2011, and in revised form May 19, 2012. Accepted for publication May 30, 2

Summary

Patients with implantable cardioverter-defibrillators (ICDs) may require radiation therapy for cancer treatment. The potential effects of 10 MV and 18 MV irradiation were examined in a simulated clinical situation using 2 types of ICDs. The ICDs showed more errors with 18 MV irradiation and there were fewer critical errors with the newer ICD model. ICD errors occurred 140 cm from the isocenter. These results provide a basis for planning of radiation therapy for patients with ICDs.

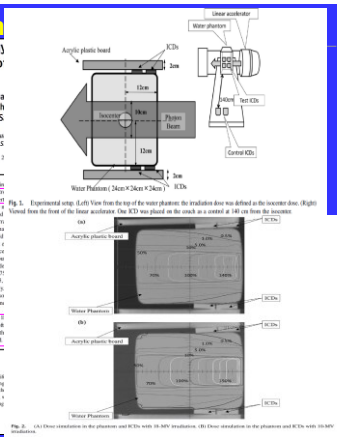


Fig. 1. Experimental setup. (Left) View from the top of the water phantom; the irradiation dose was defined as the isocenter dose. (Right) Viewed from the front of the linear accelerator. One ICD was placed on the couch as a control at 140 cm from the isocenter.

Secondary neutrons

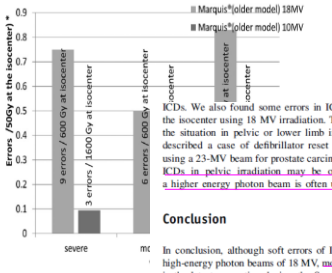


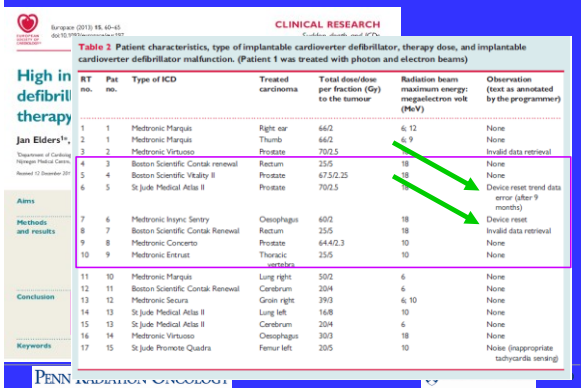
Fig. 3. Comparison of the 2 irradiation energies, showing t

ICDs. We also found some errors in ICDs placed 140 cm from the isocenter using 18 MV irradiation. This distance is similar to the situation in pelvic or lower limb irradiation, and Lau et al described a case of defibrillator reset due to radiation therapy using a 23-MV beam for prostate carcinoma (10). Thus, errors of ICDs in pelvic irradiation may be of particular concern, as a higher energy photon beam is often used in this procedure.

Conclusion

In conclusion, although soft errors of ICDs were observed with high-energy photon beams of 18 MV, most errors were not critical in the latest-generation device, the Secura ICD model. However, the possibility of soft errors of ICDs should be consideration in use of high-energy photon beam irradiation, even when the device is located far from the irradiation field.

Secondary neutrons-Single center experience



CLINICAL RESEARCH

Table 2 Patient characteristics, type of implantable cardioverter defibrillator, therapy dose, and implantable cardioverter defibrillator malfunction. (Patient 1 was treated with photon and electron beams)

RT no.	Pat no.	Type of ICD	Treated carcinoma	Total dose/dose per fraction (Gy) to the tumour	Radiation beam maximum energy: megaelectron volt (MeV)	Observation (text as annotated by the programmer)
1	1	Medtronic Marquis	Right ear	66/2	6; 12	None
2	1	Medtronic Marquis	Thumb	66/2	6; 9	None
3	2	Medtronic Virtuoso	Prostate	70/2.5	18	Invalid data retrieval
4	3	Boston Scientific Contak renewal	Rectum	25/5	18	None
5	4	Boston Scientific Vitality II	Prostate	67.5/2.25	18	None
6	5	St Jude Medical Atlas II	Prostate	70/2.5	18	Device reset trend data error (after 9 months)
7	6	Medtronic Insync Sentry	Oesophagus	60/2	18	Device reset
8	7	Boston Scientific Contak Renewal	Rectum	25/5	18	Invalid data retrieval
9	8	Medtronic Concerto	Prostate	64.4/2.3	10	None
10	9	Medtronic Entrust	Thoracic vertebra	25/5	10	None
11	10	Medtronic Marquis	Lung right	50/2	6	None
12	11	Boston Scientific Contak Renewal	Cerebrum	20/4	6	None
13	12	Medtronic Secura	Groin right	39/3	6; 10	None
14	13	St Jude Medical Atlas II	Lung left	16/8	10	None
15	13	St Jude Medical Atlas II	Cerebrum	20/4	6	None
16	14	Medtronic Virtuoso	Oesophagus	30/3	18	None
17	15	St Jude Promote Quadra	Femur left	20/5	10	Noise (inappropriate tachycardia sensing)

Secondary neutrons

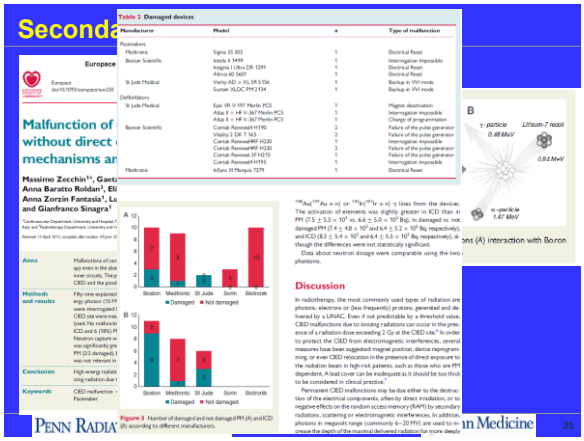


Table 3 Damaged devices

Manufacturer	Model	n	Type of malfunction
Pacemakers			
Medtronic	Sigma SS 303	1	Electrical Reset
Boston Scientific	Intrinsa 3 1499	1	Interrogation Impossible
	Insignia Ultra DR 1291	1	Electrical Reset
	Altrua 60 5601	1	Electrical Reset
St Jude Medical	Verity AD + XL SR 5 156	1	Backup in VVI mode
	Sustain XLDC PM 2134	1	Backup in VVI mode
Defibrillators			
St Jude Medical	Epic VR V-197 Merlin PCS	1	Magnet deactivation
	Atlas II + HF V-267 Merlin PCS	1	Interrogation impossible
	Atlas II + HF V-267 Merlin PCS	1	Change of programmation
Boston Scientific	Contak Renewal4 H190	2	Failure of the pulse generator
	Vitality 2 DR T 163	2	Failure of the pulse generator
	Contak Renewal4RF H230	1	Interrogation impossible
	Contak Renewal4RF H230	2	Failure of the pulse generator
	Contak Renewal 3 H215	1	Failure of the pulse generator
	Contak Renewal4 H195	1	Interrogation impossible
Medtronic	Inforrc III Marquis 7279	1	Electrical Reset

Malfunction of ... without direct ... mechanisms ...

Discussion

Case reports of failures (neutrons, particles)

3337 Influence of Particle Therapy on Implantable Cardiac Devices: An Experimental Study

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ASTRO 2010

Purpose/Objective(s): Although particle therapy is a promising new approach for cancer patients, functional interference is concerned for patients wearing implantable cardiac devices. The purpose of this study is to clarify the influence of proton and carbon-ion radiotherapy on pacemakers (PMs) and implantable cardioverter defibrillators (ICDs).

Materials/Methods: The experimental set-up simulated a condition of the particle therapy for the patients wearing implantable cardiac devices, such as patients with lung cancer or hepatocellular carcinoma, at Proton Medical Research Center (PMRC), University of Tsukuba, and National Institute of Radiological Sciences (NIRS). As we predicted the frequency of the soft error was very low, we set 4 PMs and ICDs at the same time around a water phantom (external size: 24 x 24 x 24 cm^3) to raise the probability of the occurrence of the soft error. Also, 20-mm-thick acrylic plastic boards were placed behind the devices to provide backscatter conditions at each of two particle therapy facilities. To observe the influence of secondary neutrons generated during particle therapy, the devices were placed outside the radiation field. The field size was 10 x 10 cm and Spread-out Bragg peak (SOBP) was 6 cm. Cumulative in-field physical dose for each of the 4 devices were 110 Gy in 8 sessions of irradiation at PMRC and 1276 Gy in 9 sessions at NIRS, respectively. After each radiation fraction, interference by the therapy was checked by the programmer. Data log memorized in the devices were sent to the manufacturer and analyzed in detail.

Results: On ICDs, the frequency of the power-on reset, which was the most serious soft error with programmed pacing mode changed to safety back-up mode temporary, was once per approximately 63 Gy in PMRC and about 116 Gy in NIRS, respectively. Total number of soft errors detected by the programmer was 12 and 18, which was at the rate of once per approximately 37 Gy in PMRC and about 71 Gy in NIRS, respectively. On the other hand, no soft error was observed on PMs. No permanent device malfunction was detected, and always kept sensitivity and generating pulses at least in its initial programmed settings. Also, no telemetry problem between the device and programmer was observed.

Conclusions: The soft error was observed in proton beam irradiation approximately twice as frequent as in carbon-ion irradiation on ICDs. Although particle therapy could have interference hazards linked to secondary neutrons on the function of ICDs, permanent device malfunction had not been observed in this experimental study. Further quantitative analysis in various settings is needed to establish guidelines regarding the particle therapy for cancer patients with implantable cardiac devices.

Author Disclosure: T. Hashimoto, None; H. Hashii, None; T. Isobe, None; A. Ohkawa, None; S. Yonai, None; N. Matsufuji, None; S. Fukuda, None; T. Sakae, None; K. Aonuma, None; H. Sakurai, None.

[illegible] patients with cardiac pacemakers should be monitored by means of electrocardiogram during PBT.

Cardiac pacemaker, Proton beam therapy, Neutron.

pacemaker demonstrated the extreme sensitivity of integrated circuits. Although fast neutron radiotherapy is not commonly used because of its unacceptably high incidence of late morbidity, questions have been raised concerning secondary neutrons produced by external-beam radiotherapy using high-energy photons or by particle therapy.

In proton radiotherapy using the passive scattering irradiation method, proton beams generate secondary neutrons by the reaction with the collimator and several other scattering components [6,20]. On the other hand, Schneider et al. reported that the spot scanning technique showed a dose advantage at a beam line of at least 10 times over the scatter foil technique [21]. In the healthy tissues of their patient (in the non-treated volume), the dose coming from neutrons was approximately 0.002-0.004 Sv per treatment Gy. These contributions to the integral dose from neutrons are very low, so they concluded that the dose deposited by secondary neutrons during proton radiotherapy using the spot scanning technique can be neglected in the treatment region. However, proton beams also generate secondary neutrons and photons by the reaction with several elements that form human body tissue. The internal incidental dose around the center at deeper situated regions accounted for about 60% to 80% of the total incidental dose [14]. Therefore, in proton radiotherapy, it is impossible to completely eliminate the influence of secondary neutrons, even if shielding of external neutrons or active scanning method are used.

Morávek et al. reported that the neutron contribution to the dose behind the peak maximum was at least 3 orders smaller than the total dose at the peak maximum [7]. Furthermore, it decreased exponentially with the distance to the peak maximum. Therefore, they concluded that its influence on the dose distribution is by proton radiotherapy on ICDs. Devices failed at the rate of approximately 1 failure per 15 Gy, which is well below the dose level (60-80 Gy) generally used in proton radiotherapy. The probability of a soft error caused by secondary neutrons induced by proton radiotherapy on ICDs is very small, but it is an inevitable and unpredictable phenomenon. Rodriguez et al. reported on radiation-induced effects in multi-programmable pacemakers and ICDs [22]. Pacemaker malfunction induced by ionizing-radiation exposure is unpredictable because these effects can occur in multiple locations in complementary metal-oxide semiconductor (CMOS) and do so at random. Therefore, errors could potentially be observed even at the minimal delivered dose, and relocation of the device out of the radiation field is not enough to prevent the occurrence of soft errors. Minor errors which cannot be detected by the programmer directly were often observed, suggesting that the device could be damaged by secondary neutrons even if the device malfunction is not apparent. Hard errors of the ICDs were not observed in the present study, and the devices in their initially programmed settings always kept their sensitivity and generating pulses. Further investigation is needed to clarify whether the total cumulative radiation dose to the device results in an increased likelihood of soft errors, and how much the ratio of fast or thermal neutrons contributes to the causes of soft error.

The experimental findings of the present study have resulted in the recommendation in our department for the use of this new cancer treatment modality for patients with cardiac pulse generators. It is essential that patients be monitored carefully during the course of treatment and that the pacing mode and rate be monitored after completion of irradiation in accordance with the degree of dependence on the cardiac pulse

treatments only (according to their descriptions), I would expect the out-of-field neutron scatter to be larger by a factor of 30 to 45 in the entrance region, with this factor decreasing with depth, when compared with out-of-field neutron scatter from the active scanning mode (3). For passive scattering systems, neutrons are generated in the treatment head, beam modulators, scattering devices, and patient-specific apertures or compensators and are the dominant contribution to the total dose downstream from the Bragg peak and out of field (3). The field-defining aperture dominates as a secondary neutron production source because of its proximity to the patient, making the neutron dose dependent on the ratio of field size to aperture opening (4). The out-of-field patient neutron dose increases with beam range/energy and treatment volume (4, 5). Active and modulated scanning systems do not require scattering devices in the treatment head or patient apertures; as a result, the secondary neutron production in the treatment head is reduced, the majority of neutrons being generated in the patient's body (3, 4, 6). Because the devices' resets are due to the scattered neutron production and are random events and do not correlate to the total delivered dose, patients with CIEDs receiving PBT can potentially be treated in the same way as those patients receiving high-energy photon therapy (E > 10 MV), as suggested by Harkmans et al (7) and Makkar et al (8).

In conclusion, I would like to commend the authors for contributing this institutional study and analysis to the limited literature on this subject.

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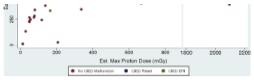

Fig. 3. Scatter plot of neutron and proton doses for all 40 patients. Notably, no patient experienced a reset of a cardiac implantable electronic device (CIED) at a neutron dose of less than approximately 500 mSv. One patient with a liver tumor experienced an elective replacement indicator (ERI) message at 330 mSv that was predicted before radiation. In contrast, the variation in proton doses associated with resets was broad.

Ca

Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices[1]

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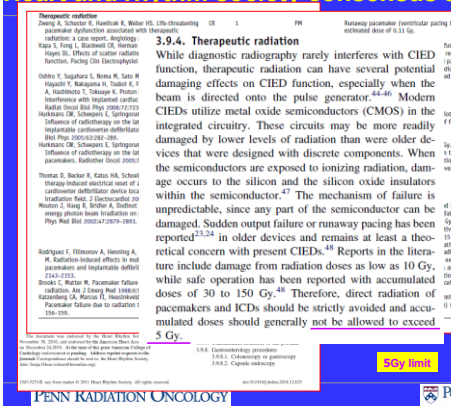
Heart and rhythm society consensus statement



3.9.4. Therapeutic radiation

While diagnostic radiography rarely interferes with CIED function, therapeutic radiation can have several potential damaging effects on CIED function, especially when the beam is directed onto the pulse generator.[44-46] Modern CIEDs utilize metal oxide semiconductors (CMOS) in the integrated circuitry. These circuits may be more readily damaged by lower levels of radiation than were older devices that were designed with discrete components. When the semiconductors are exposed to ionizing radiation, damage occurs to the silicon and the silicon oxide insulators within the semiconductor.[47] The mechanism of failure is unpredictable, since any part of the semiconductor can be damaged. Sudden output failure or runaway pacing has been reported[23,24] in older devices and remains at least a theoretical concern with present CIEDs.[48] Reports in the literature include damage from radiation doses as low as 10 Gy, while safe operation has been reported with accumulated doses of 30 to 150 Gy.[48] Therefore, direct radiation of pacemakers and ICDs should be strictly avoided and accumulated doses should generally not be allowed to exceed 5 Gy.

5Gy limit (2011)

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Sensitivities and potential failures

- Permanent damage from accumulated dose → circuitry is degraded in proportion to accumulated dose:
  - Decrease of output amplitude
  - Increase current drain (not obvious-can lead to sudden failure within months past RT)
  - Erroneous or failed sensor operation (including heartbeat sensing functions)
- Upsets in memory or logic circuits caused by neutrons-SOFT ERRORS:
  - Changes in stored values in memory or transient changes in micro-processor circuitry
  - May not be functionally recoverable
  - Reset of the device → reversion to default parameters
  - Rare cases where reset may delay for hours or even weeks past RT.
- Transient interference from high-dose-rate x-rays (not EMI):
  - Transient effect-no permanent damage, unless accumulated dose is high→
    - Inappropriate sensing of device that lead to ICD shock
    - Non-existent pacing output
    - Reset or other effects
- Electromagnetic interference (EMI) are minimal and of transient nature:
  - ICPs
    - May sense the field as myocardial potential → inhibition of output
    - Inappropriate re-programming
    - Shut off reed switch → fixed pacing
    - Triggering of output
  - ICDs
    - Possible re-programming, transient effect

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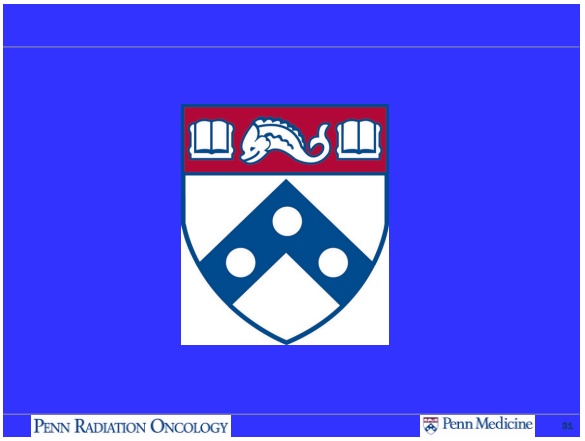
Sources of potential malfunctions for CIEDs during RT processes

- 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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