Managing the Care of Radiotherapy Patients Implanted with Cardiac Devices

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Acknowledgments

- Members of AAPM TG203
- Joann Prisciandaro

Outline

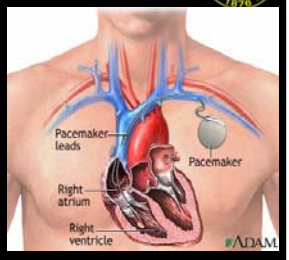
- Classes of ICPs and ICDs
- Sensitivities and potential failures
- Current guidelines
- Review of ICD and ICP dose limits
- Review of device failures– cases reports
- Patient management

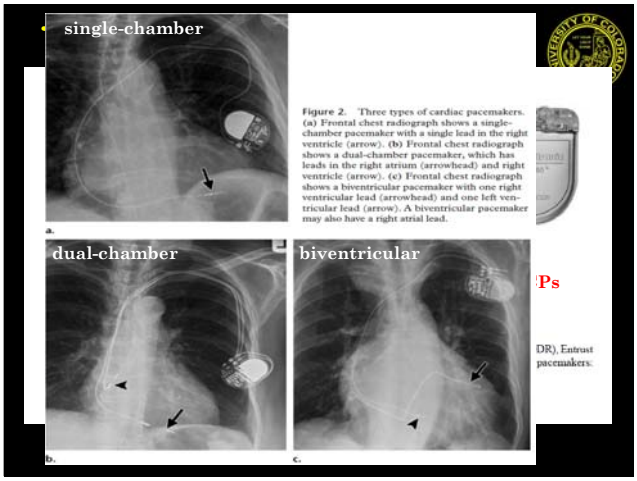
Introduction

- 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

Implanted Cardiac Devices

- Implanted cardiac pacemakers – ICPs
  provide small electrical stimuli to case cardiac contraction during periods of bradycardia, when the intrinsic electrical activity of the heart is slow or absent.
- Implanted cardioverter defibrillators – ICDs
  generate a large amount of electrical energy in a single output used to defibrillate the heart and prevent cardiac arrest.





Sources of potential malfunctions during RT processes

- Imaging for treatment planning (CT mostly).
- Imaging for Image Guidance (CT, MV, EMI)
- RT treatment delivery (photons, protons, neutrons, particles)
- Use of high energy photons, E ≥ 10 MV
- Dose rate?
- IMRT, SBRT, VMAT, FFF beams, etc.

Sensitivities & potential failures

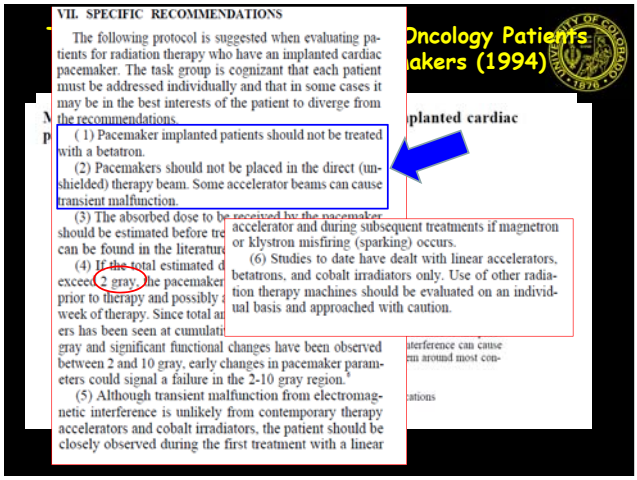
- Permanent damage from accumulated dose → circuitry is degraded in proportion to accumulated dose:
  - Decrease of output amplitude
  - Increase current drain
    → not obvious (can lead to sudden failure within months post-treatment)
  - Erroneous or failed sensor operation (including heartbeat sensing functions)

Sensitivities & potential failures

- 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 post-treatment

Sensitivities & potential failures

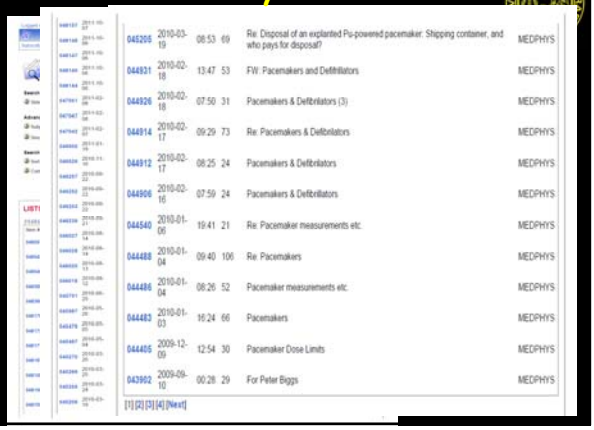
- Transient interference from high-dose-rate x-rays (not EMI):
  - Transient effect-no permanent damage, unless accumulated dose is high →
    - Inappropriate sensing of device that lead to ICD shock
    - Non-existent pacing output
    - Reset or other effects
- EMI are minimal and of transient nature:
  - 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



Observations: AAPM TG34

- Recommendations were based on older technology cardiac devices (pacemakers only).
- Considered older data on radiation interactions and for older treatment techniques and delivery methods.
- Since 1994, numerous investigations published in literature have dealt with pacemakers and defibrillators during radiation therapy treatments.
- More detail measurements and computations of out-of-field doses have been performed that would allow a more direct estimation of the cumulative doses deposited to these implanted devices (AAPM TG-158).

From Med Phys Listservs



046205	2010-03-19	08:53	69	Re: Disposal of an explanted Pu-powered pacemaker. Shipping container, and who pays for disposal?	MEDPHYS
044931	2010-02-18	13:47	53	FW: Pacemakers and Defibrillators	MEDPHYS
044926	2010-02-18	07:50	31	Pacemakers & Defibrilators (3)	MEDPHYS
044914	2010-02-17	09:29	73	Re: Pacemakers & Defibrilators	MEDPHYS
044912	2010-02-17	08:25	24	Pacemakers & Defibrilators	MEDPHYS
044906	2010-02-16	07:59	24	Pacemakers & Defibrillators	MEDPHYS
044540	2010-01-06	19:41	21	Re: Pacemaker measurements etc.	MEDPHYS
044488	2010-01-04	09:40	106	Re: Pacemakers	MEDPHYS
044486	2010-01-04	08:26	52	Pacemaker measurements etc.	MEDPHYS
044483	2010-01-03	16:24	66	Pacemakers	MEDPHYS
044405	2009-12-09	12:54	30	Pacemaker Dose Limits	MEDPHYS
043902	2009-09-10	00:28	29	For Peter Biggs	MEDPHYS

[1] [2] [3] [4] [Next]

Survey of RT Clinics

A survey by Solan et al [IJROBP, 2004] of practice patterns among 74 RT clinics in the USA and Canada

- 12% of the clinics have no management policy
- 15% have a management policy
- 37% of the clinics consult a cardiologist and 33% of them contact the ICP/ICD manufacture
- 20% of the clinics perform TLD/diode check measurements and 35% of them monitor the patient during RT
- 31% of radiation administering facilities limits the total allowable dose exposure,
- 20% of them follow the AAPM TG-34 guidelines

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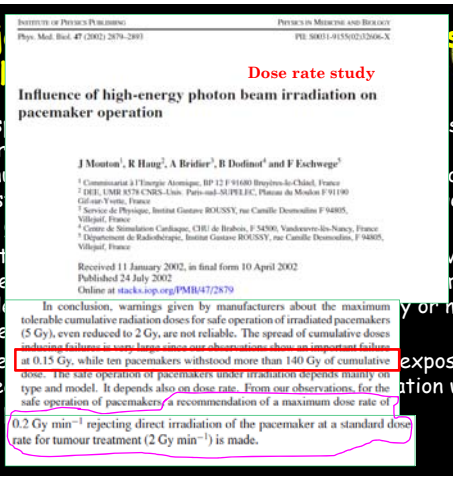

Phys. Med. Biol. 47 (2002) 2879–2893 — PII: S0031-9155(02)32606-X

Dose rate study

Influence of high-energy photon beam irradiation on pacemaker operation

J Mouton[1], R Haug[2], A Bridier[3], B Dodinot[4] and F Eschwege[2]

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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.

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Recent Review Articles

- Solan et al. [IJROBP, 2004]
  Limit: 2 Gy scattered dose ICP
  1 Gy scattered dose ICD
- Sundar et al. [Cancer Treat Reviews, 2005]
  Limit: 2 Gy scattered dose
- Hurkmans et al [IJROBP, 2005]
  Limit: < 1.5 Gy scattered dose
- Kapa et al [PACE, 2008]
  Avoid direct beam exposure
- Gelblum et al [IJROBP, 2009]
  Advocate < 10 MV beams (15MV, single event upset)
- Hudson et al [Med Imag and RO, 2010] and Seojeima et al [J. Radiat Res, 2011]
  Limit: 2 Gy scattered dose ICP
  1 Gy scattered dose ICD

Soon thereafter a lump was discovered in the right breast. A needle biopsy showed an infiltrating ductal carcinoma and a right simple mastectomy was performed. Postoperative radiation therapy was advised and consisted of delivery of 1000 rads per week through each of 5 ports. Treatments were given with 4-MeV photons at a source to skin distance (SSD) of 80 cm, using a Varian Clinac-4 linear accelerator. One port, the "right supraclavicular fossa" encompassed the area occupied by the pacemaker generator. When the first treatment was given in July, 1981, the electrocardiogram was monitored to determine whether there was any alteration in pacemaker function secondary to electromagnetic interference from the linear accelerator. There was no evidence of pacemaker malfunction.

At a dose of 3000-3600 rads she developed a tachycardia. The electrocardiogram, (Fig. 1) showed that the atrial pacemaker was firing irregularly at a rate of 320 beats/min.

n Therapy

BERT S. HEUSINKVELD, and

rsity of Arizona Health Sciences Center,

ion therapy. *Pacemaker malfunction occupied by an A-V sequential pacemaker. function of the large scale integrated circuced effects. The newer multiprogramose previously available. (PACE, Vol. 5,*

acemaker

Analysis of the removed generator showed that pacemaker failure was due to malfunction of the large scale integrated-complementary metal oxide semiconductor [LSI-CMOS] circuit and the type of damage was consistent with radiation-induced effects.

CASE REPORT

The Cardiac Pacemaker Patient

Might the Pacer be Directly Ir

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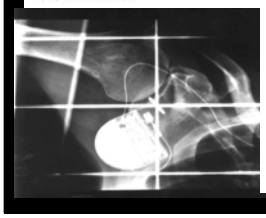

Radiotherapy course. The patient received radiotherapy as an inpatient. Figure 1 shows the pacer in the treatment field. During each fraction we performed an ECG and observed the rhythm on a monitor outside. The cardiologist was with us during the first fraction, and on stand-by for the further fractions. 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.

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International Journal of Cardiology

International Journal of Cardiology 130 (2008) e37–e38

www.elsevier.com/locate/ijcard

Letter to the Editor

Defibrillator reset by radiotherapy

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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.

Keywords: Implant

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.

Case reports of failures

Case Reports

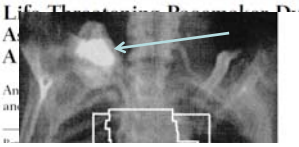

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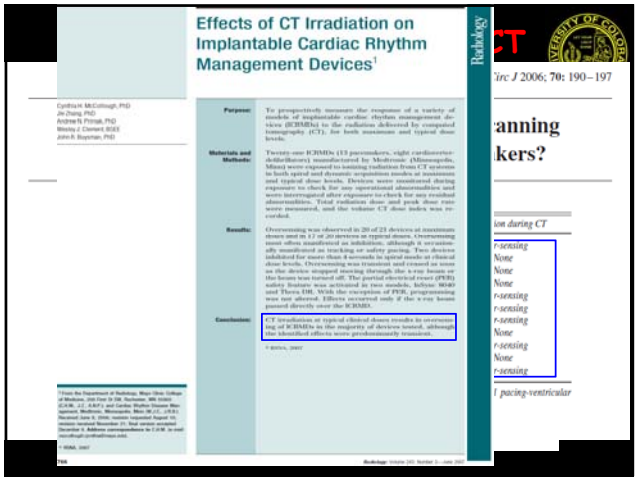
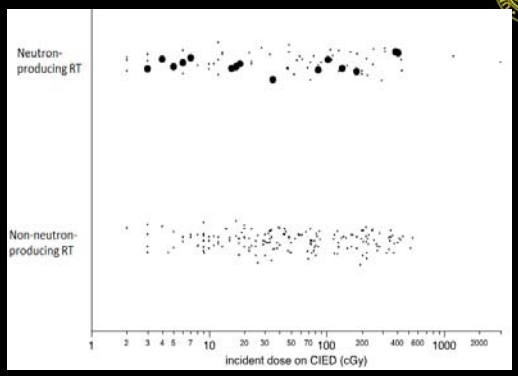
Table 1. Case Reports About Irradiation-Induced Pacemaker/ICD Failure

Reference No.	Year	Type of Radiation	Dose (Gy)	Type of Failure	Consequence	In/Out[a]	Device
8	2004	Linear accelerator	56	Electrical restart	None	Out	Medtronic/VVI-ICD
9	1988	Cobalt 60	35	Runaway	Replacement	In	Intramedics/DVI
10	2003	Not reported	50	Loss of communication	Replacement	In	Vitatron/DDD
11	1991	Linear accelerator/ betatron	50	Deprogrammed device	Replacement	Out	Medtronic/?
12	1984	Linear accelerator	19.8	Fixed ventricular rate	Replacement	In	Intermedics/VVI
13	1986	Linear accelerator	84.6	Runaway	Replacement	Out	Intermedics/DVI
14	1982	Linear accelerator	36	Runaway	Replacement	In	Intermedics/DVI
15	1994	Neutrons	4.8	Runaway	Replacement	Out	Pacesetter/VVI
16	1983	Linear accelerator	20	Runaway	Replacement	In	Intermedics/DDD

Note: ICD = implantable cardioverter/defibrillator.
a. Device lying in or outside the radiation field.



Single Upset Events



Grant et al, AMA Oncol (2015).

We learned……

Clearly defined and up-to-date guidelines and uniform approach to the management of RT patient with implanted cardiac pacemakers is very much needed.

New Task Gro 203

Check list for patient management

- **Initial Consultation**
  - Cardiac Device (CD) alert added to patient's chart
  - Copy of CD card made and filed in patient's chart
  - Appointment with Cardiac Electrophysiology (EP) scheduled
- **Simulation Check**
  - Patient should be evaluated by EP to verify dependence on device
  - Verify CD alert added to patient's chart
  - Verify treatment planning directive completed by physician
  - Note added to planning directive to only use 6X photons
  - Contact vendor for dose limit recommendations

Treatment planning check

- Verify only 6X photons used for treatment
- Estimate dose/fraction
- Verify proximity of treatment fields to device
- Add note to patient's chart to place in-vivo dosimeter prior to fraction #1
- Verify/adjust imaging fields do not irradiate device.

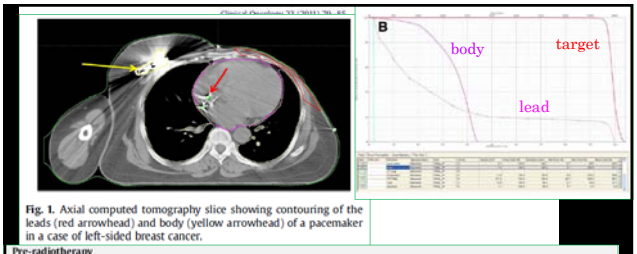


Fig. 1. Axial computed tomography slice showing contouring of the leads (red arrowhead) and body (yellow arrowhead) of a pacemaker in a case of left-sided breast cancer.

Pre-radiotherapy
Take a detailed cardiac history.
Consult a cardiologist for recording baseline cardiac and pacemaker function (full device interrogation and electrocardiography).
Liaise with a cardiologist and a pacemaker centre to know dependency rates, the need to reprogramme pacemakers and threshold doses.
Assess the necessary level of cardiac monitoring for individual patients.
Estimate the absorbed dose to the pacemaker and keep <10 Gy using asymmetric jaws, blocks, multileaf collimators and wedges wherever appropriate.
Reposition the pacemaker if a safe dose cannot be achieved or if pacemaker is located within 3 cm of proposed radiotherapy portal to avoid inaccuracies in dose calculation.
Notify department personnel involved in direct patient care.
Avoid using magnetic resonance imaging or positron emission tomography in radiotherapy planning as these are potential sources of electromagnetic interference .
Always contour the pacemaker body, electrode and lead separately as an organ at risk.
Treatment on a linear accelerator has a higher chance of electromagnetic interference than a cobalt unit, may be considered in select high-risk patients.
Always opt for another non-radiotherapy treatment modality if it will be safer and equally valid.
Consider using brachytherapy in appropriate cases.

Dose to pacemaker > 2 Gy

- Inform Rad-Onc physician
- Contact EP to inform them of dose and discuss monitoring strategy
  - Move device-- Risk of infection??
  - Adjust monitoring frequency
  - Schedule EP follow on-set for all treatment fractions
  - Monitoring post treatment

TG203: patient management: patient oriented risk categories

- The patient's risk is not equal to the risk of a CD defect
- The chance on CD malfunction mainly increases with dose and is not accurately known
- A practical guideline will be easier to implement

	< 2 Gy	2-5 Gy	>> 5 Gy
pacing-independent	Low risk	Medium risk	High risk
pacing dependent	Medium risk	Medium risk	High risk

Risk Categories for Patients with Implantable Cardiac Devices

Therapist Procedures for Patients with Pacemakers or Defibrillators

Low Risk Patient

- Confirm that the resident has set up interrogation schedule (interrogation before 1st fraction and after last fraction)
- Nurse monitoring not required
- If defibrillator (AICD), use a magnet
- If not a defibrillator, confirm with resident whether a magnet should be used during treatment*
- Nanodot on the first fraction during imaging and treatment

Medium Risk Patient

- Confirm that the resident has set up interrogation schedule (interrogation before 1st fraction and weekly)
- Radonc nurse monitor during every fraction
- If defibrillator (AICD), use a magnet
- If not a defibrillator, confirm with resident whether a magnet should be used during treatment*
- Nanodot on the first fraction during imaging and treatment

High Risk Patient

- Confirm that the resident has set up interrogation schedule (interrogation before 1st fraction and before & after every fraction)
- Radonc nurse monitor during every fraction
- If defibrillator (AICD), use a magnet
- If not a defibrillator, confirm with resident whether a magnet should be used during treatment*
- Nanodot on the first fraction during imaging and treatment

* Magnet should be accessible in case of emergency

Cardiology Clinic Pager 303-266-1302
(number entry only)

Thank You