


MANAGEMENT OF RADIOTHERAPY PATIENTS WITH IMPLANTED CARDIAC DEVICES

**Dimitris Mihailidis, Ph.D.,
Charleston Radiation Therapy Consultants
Charleston, WV 25304**




WHAT IS IN THIS PRESENTATION?

- Types of ICDs and ICPs.
- Current guidelines – protocol (TG-34).
- What are the issues with cardiac device and radiation deliveries?
- Review of literature since TG-34 area.
- Failures – case reports and scattered guidelines.
- Sensitivities and potential failures.
- Cardiac devices and RT patients.
- Dose estimation. During RT processes.
- Recommendations.


Implantable Cardioverter-Defibrillators

An overwhelming majority of sudden cardiac deaths from coronary disease (approximately 31% of total deaths) can be attributed to sudden cardiac death (SCD).



ICDs
ICPs

Fig. 3. [Top] Five ICDs [Left to Right]: InSync Maximo model 7304, Concerto model C154DWK (VVE-DDDR), Entrust model D154ATG, Maximo DR model 7278, and Virtuoso model D154AWG; [Below]: four implantable pacemakers: Adapta model ADDR01, Versa model VEDR01, Sensia model SEDR01, and Empulse2 model E2DR01.



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 accelerator and during subsequent treatments if magnetron or klystron misfiring (sparking) occurs.
- (4) If the total estimated dose exceeds 2 gray, the pacemaker should be evaluated one week prior to therapy and possibly one week of therapy. Since total dose has been seen at cumulative gray and significant functional changes have been observed between 2 and 10 gray, early changes in pacemaker parameters could signal a failure in the 2-10 gray region.
- (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
- (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.

radiation therapy Patients with implanted cardiac devices

FROM MED PHYS LISTSERVS

Accession Number	Date	Author	Title	Journal		
044917	2010-03-19	045206	2010-03-19	08:53 69	Re: Disposal of an explanted Pu-powered pacemaker: Shipping container, and who pays for disposal?	MEDPHYS
044918	2010-02-16	044931	2010-02-16	13:47 53	FW: Pacemakers and Defibrillators	MEDPHYS
044919	2010-02-16	044926	2010-02-16	07:50 31	Pacemakers & Defibrillators (3)	MEDPHYS
044920	2010-02-17	044914	2010-02-17	09:29 73	Re: Pacemakers & Defibrillators	MEDPHYS
044921	2010-02-17	044912	2010-02-17	08:25 24	Pacemakers & Defibrillators	MEDPHYS
044922	2010-02-16	044909	2010-02-16	07:50 24	Pacemakers & Defibrillators	MEDPHYS
044923	2010-01-06	044540	2010-01-06	19:41 21	Re: Pacemaker measurements etc.	MEDPHYS
044924	2010-01-04	044480	2010-01-04	09:40 108	Re: Pacemakers	MEDPHYS
044925	2010-01-04	044486	2010-01-04	08:26 52	Pacemaker measurements etc.	MEDPHYS
044926	2010-01-03	044483	2010-01-03	16:24 66	Pacemakers	MEDPHYS
044927	2010-01-00	044466	2010-12-00	12:54 30	Pacemaker Dose Limits	MEDPHYS
044928	2010-09-10	043902	2010-09-10	00:28 29	For Peter Biggs	MEDPHYS

INSTITUTE OF PHYSICS PUBLISHING
Phys. Med. Biol. 47 (2002) 2879-2893

PHYSICS IN MEDICINE AND BIOLOGY
PII: S0031-9155(02)3266-X

Dose rate study Influence of high-energy photon beam irradiation on pacemaker operation

J Mouton¹, R Haug², A Bridier³, B Dodinot⁴ and F Eschwege⁵

¹ Commissariat à l'Energie Atomique, BP 12 F 91180 Bruyères-le-Châtel, France
² IREB UMR 8574 CNRS-Univ. Paris-sud SEBELAC, Pitié-Salpêtrière F 91190 Gif-sur-Yvette, France
³ Service de Physique, Institut Gustave ROUSSY, rue Camille Desmoulins, F 94805 Villejuif, France
⁴ Centre de Stimulation Cardiaque, CHU de Brabois, F 54500 Vandœuvre-lès-Nancy, France
⁵ Département de Radiothérapie, Institut Gustave ROUSSY, rue Camille Desmoulins, F 94805, Villejuif, France

Received 11 January 2002, in final form 10 April 2002
 Published 24 July 2002
 Online at stacks.iop.org/PMB/47/2879

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.

reports and lines. ices Gy tolerance partial) to other??

RECENT REVIEW ARTICLES

Int. J. Radiation Oncology Biol. Phys., Vol. 59, No. 3, pp. 897-904, 2004
Copyright © 2004 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/04/\$ - see front matter
doi:10.1016/j.ijrobp.2004.02.038

PHYSICS

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.

MAKERS AND RISKS DURING TREATMENT

S. Sundar ***,
R.Z. Ph.D., † AND
C. Thomas Jefferson University,
Department of Medicine, Division of
Cardiac Electrophysiology, Philadelphia, PA

Limit: 2 Gy scattered dose

Summary: The authors suggest categorizing 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 irradiation 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.

RECENT REVIEW ARTICLES

CANCER TREATMENT REVISIONS (2008) 21, 674-686
Copyright © 2008 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/08/\$ - see front matter
doi:10.1016/j.ijrobp.2008.06.1903

Radiotherapy-induced Cardiac Complications

S. Sundar ***,
R.Z. Ph.D., † AND
C. Thomas Jefferson University,
Department of Medicine, Division of
Cardiac Electrophysiology, Philadelphia, PA

Limit: 2 Gy scattered dose

The authors suggest categorizing 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 irradiation 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.

RECENT REVIEW ARTICLES

Int. J. Radiation Oncology Biol. Phys., Vol. 62, No. 3, pp. 281-289, 2005
Copyright © 2005 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/05/\$ - see front matter
doi:10.1016/j.ijrobp.2005.07.049

ST GENERATION OF HLLATORS

F. SPRINGORUM, B.Sc., † AND
J. SPRINGORUM, B.Sc., † AND
J. SPRINGORUM, B.Sc., †

Limit: <1.5 Gy scattered dose

Background: The effects of scatter radiation on 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. (PACC 2008; 31:727-732)

RECENT REVIEW ARTICLES

Int. J. Radiation Oncology Biol. Phys., Vol. 67, No. 3, pp. 1525-1531, 2009
Copyright © 2009 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/09/\$ - see front matter
doi:10.1016/j.ijrobp.2008.06.1903

IMPLANTED CARDIAC DEFIBRILLATOR CARE IN RADIATION ONCOLOGY PATIENT POPULATION

DAPHINA Y. GELBERG, M.D.,[#] AND HOWARD AMOLS, PH.D.[‡]

Department of [#]Radiation Oncology and [‡]Medical Physics, Memorial Sloan-Kettering Cancer Center, New York, NY

Single-event upset

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 five-year-old computer, a 2.5-year-old pacemaker or defibrillator is also susceptible to damage by a single neutron particle. 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.

RECENT REVIEW ARTICLES

Int. J. Radiation Oncology Biol. Phys., Vol. 75, No. 3, pp. 1525-1531, 2009
Copyright © 2009 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/09/\$ - see front matter
doi:10.1016/j.ijrobp.2008.06.1903

CLINICAL INVESTIGATION **Implanted Defibrillator**

IMPLANTED CARDIAC DEFIBRILLATOR CARE IN RADIATION ONCOLOGY PATIENT POPULATION

DAPHINA Y. GELBERG, M.D.,[#] AND HOWARD AMOLS, PH.D.[‡]

Department of [#]Radiation Oncology and [‡]Medical Physics, Memorial Sloan-Kettering Cancer Center, New York, NY

Single-event upset

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 five-year-old computer, a 2.5-year-old pacemaker or defibrillator is also susceptible to damage by a single neutron particle. 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.

RECENT REVIEW ARTICLES

Int. J. Radiation Oncology Biol. Phys., Vol. 75, No. 3, pp. 1525-1531, 2009
Copyright © 2009 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/09/\$ - see front matter
doi:10.1016/j.ijrobp.2008.06.1903

EXPERT REVIEWS **Radiotherapy-induced Cardiac Complications**

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.

Fernando Tondato,
Daniel W Ng,
Komandoor Srivaths,
Gregory T Altemose,
Michelle V Halyard,
and Luis R Scott[†]

[†]Author for correspondence
Department of Cardiac
Electrophysiology, Mayo Clinic
5777 Mayo Boulevard, Phoenix
AZ 85054, USA
Tel: +1 480 342 0239
Fax: +1 480 342 1606
scott.luis@mayo.edu

Implantable cardiac defibrillator, Radiotherapy, Patient monitoring.

RECENT REVIEW ARTICLES

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

ORIGINAL ARTICLE

Effect: Planning

Impact: A 5y

F 5y study:

- 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.

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

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.

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

n Therapy

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.

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

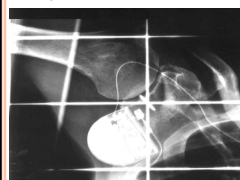
Might the Pacer be Directly Irradiated?

Alexander Tsekos, Felix Momm, Mi...

From the Universitätsklinikum Freiburg, Germany

Correspondence to: A.Tsekos, MD, Radioc Freiburg, Germany

Acta Oncologica Vol. 39, No. 7, pp. 881–883, 2000
Received 13 January 2000
Accepted 22 June 2000



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 remained at 88/min. The pacemaker's stimulation frequency returned to normal, indicating a normal battery charge.

ELSEVIER 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

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

Cardiovascular Research Centre, Department of Cardiology, Royal Adelaide Hospital and the Disciplines of Medicine and Physiology, University of Adelaide, Adelaide, Australia

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.

Keywords: Implantable cardioverter-defibrillator; Radiation therapy; Defibrillator; Radiotherapy

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

Function of ICD after radiation: A case report

Robert Hawlicek, MD

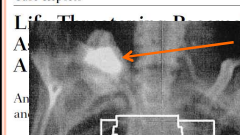


Table 1. Case Reports About Irradiation-Induced Pacemaker/ICD Failure

Reference No.	Year	Type of Radiation	Dose (Gy)	Type of Failure	Consequence	In/Out*	Device
8	2004	Linear accelerator	56	Electrical restart	None	Out	Medtronic/VH-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/VI
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/VI
16	1983	Linear accelerator	20	Runaway	Replacement	In	Intermedics/DDD

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

Int. J. Radiation Oncology Biol. Phys., Vol. 72, No. 3, pp. 221-227, 2008
Copyright © 2008 Elsevier Inc.
Printed in the USA. All rights reserved.
0360-3015/08/\$ - see front matter
doi:10.1016/j.ijrobp.2008.01.062

3337 Influence of Particle Therapy on Implantable Cardiac Devices: An Experimental Study **ASTRO 2010**
T. Hashimoto¹, H. Hashii¹, T. Ito², A. Ohkawa¹, S. Yonai¹, N. Matsufuji¹, S. Fukuda¹, T. Sakai¹, K. Aonuma¹, H. Sakami¹
¹Prion Medical Research Center, University of Tsukuba, Tsukuba, Japan, ²National Institute of Radiological Sciences, Chiba, Japan, ³Department of Cardiovascular Medicine, University of Tsukuba, Tsukuba, Japan

Purpose/Objective: 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 therapy 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 Prion 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 wire phantom (external size: 24 x 24 x 24 cm³) to raise the probability of the occurrence of the soft error. Also, 20-min-thick acrylic plastic boards were placed behind the device to provide backscatter conditions at each of two particle therapy facilities. To observe the influence of secondary neutrons generated during particle therapy, detectors were placed around the radiation field. The field size was 100 x 10 cm and spread-out Bragg peak (SOBP) was 6 cm. Cumulative in-field physical dose for each of the 4 devices were 130 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 K.Ds, the frequency of the proton beam, which was the most serious soft error with programmed pacing mode changed safety back to mode temporary, was once per approximately 61 Gy at PMRC and about 116 Gy at 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 at 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 malfunctions 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. Ito, None; A. Ohkawa, None; S. Yonai, None; N. Matsufuji, None; S. Fukuda, None; T. Sakai, None; K. Aonuma, None; H. Sakami, None.

Cardiac pacemaker, Proton beam therapy, Neutron.

HEART AND RHYTHM SPECIALTY CONSENSUS STATEMENT (2011)

The Heart Rhythm Society Expert Consensus Statement on the Therapeutic Application

Author	Class	Level	Summary	
Zweig, S, Scholer, F, Radtke, B, Weber, H, et al. (15th International Symposium on Cardiac Electrophysiology and Arrhythmology)	CR	1	PM	Rotatory pacemaker (ventricular pacing to rate limit) after an optimized dose of 0.15 Gy.
Kaga, S, Fong, L, Bhatnagar, D, Burman, M, Schomburg, P, et al. (Effects of cardiac radiation on ICD and CRT function, Pacing Clin Electrophysiol 2008;31:227-232)	EV/CS	ICD & CRT-D (12 & 8)	PM; 7; ICD: 4; CRT: 1	There was no evidence of reset or malfunction during or after radiation. Also, no episodes of device reset, inappropriate sensing or therapy, or change in programmed parameters were found in their review of pacemaker radiotherapy. Proton beam therapy was not associated with any changes.
Ohno, Y, Sugihara, S, Noma, M, Sato, M, Sakahara, Y, Saka, T, et al. (Influence of radiation on the latest generation of implantable cardioverter defibrillators, Int J Radiat Oncol Biol Phys 2005;62:383-389)	EV/CS	ICD	PM	11 ICD models directly exposed to radiotherapy with sensing interference in all 11. Complete loss of function in 4 between 0.5 Gy and 1.5 Gy.
Helmreich, M, Schepers, S, Sprungmann, M, Ullrich, H, et al. (Influence of radiotherapy on the latest generation of implantable cardioverter defibrillators, Int J Radiat Oncol Biol Phys 2005;62:383-389)	EV/CS	ICD	PM	Seven pacemakers lost output at 120 Gy. Eight pacemakers showed inhibition during irradiation in the direct beam. Five pacemakers did not show any radiation at all. No malfunctions were observed at dose levels exceeding 24 Gy. Electrical reset observed.
Thomas, D, Becker, R, Katus, HA, Scholz, W, Kalle, CA, et al. (Radiotherapy induced electrical reset of an implantable cardioverter defibrillator device located outside the irradiation field, J Electrocardiol 2007;37:1-14)	CR	1	ICD	The authors felt that warnings provided 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 greatest cumulative dose resulting failure was large with one failure noted at 0.5 Gy, while ten pacemakers endured more than 100 Gy of cumulative dose.
Mouton, J, Haug, R, Brindley, A, Doolan, E, et al. (Influence of high energy photon beam irradiation on pacemaker operation, Phys Med Biol 2002;47:2879-2893)	CR	1	PM	The authors felt that warnings provided 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 greatest cumulative dose resulting failure was large with one failure noted at 0.5 Gy, while ten pacemakers endured more than 100 Gy of cumulative dose.
Rodríguez, J, Hilmann, A, Henning, A, Coughlin, C, Greenberg, M, et al. (Radiotherapy induced effects in multigenerational pacemakers and implantable defibrillators, PACE 1991;14C:1143-1153)	EV/CS	ICD	PM; 22; ICD: 4	17 pacemakers exposed to photon radiation failed before delivery of 50 Gy and 40% permanently exposed to electron radiation failed before 70 Gy. For ICDs an increase in charging time associated with cumulative radiation dose was identified. Pacing at the upper rate limit after receiving radiation.
Brooks, C, Mutaz, M, Pacemaker failure associated with radiation, Am J Hosp Med 1988;33:191-193	CR	1	PM	
Katzberg, CA, Marcus, FL, Hershfield, ES, Kaminaga, HB, et al. (Pacemaker failure due to radiation therapy, PACE 1982;5:156-159)	CR	1	PM	

102-0378 Use and reuse © 2011 Heart Rhythm Society. All rights reserved. 6/29/2012 10:46:30 AM

NEW TASK GROUP

Task Group No. 203 - Management of radiotherapy implanted cardiac pacemakers and defibrillators.

Approved Date(s): 5/17/2010
Email: You may send email to this group using gmail.com. You may save the address 2022_7620203@mail.jgcn.org in your local address book. This also updates hourly.

Charge: Review published literature, evaluate all possible relationships in these devices, provide methods to do levels, provide an estimate of the risk for the use of associated letter and non-letter types of device for to manage patients with such devices and develop order to minimize the damage during radiotherapy.

Bylaws: Not Referenced. Rules: Not Referenced.

Approved Date(s): 5/17/2010
Email: 12/31/2011

Committee: TG203

Keywords:

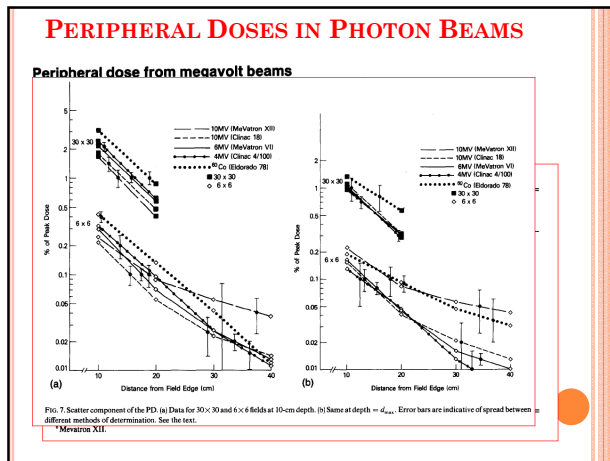
- (B) Board of Directors [Status]
- (B) Science Council [Status]
- (B) Therapy Physics [Status]
- (B) Radiation Dosimetry & Treatment Planning SC [Status]
- (B) Work Group on Radiation Dosimetry [Status]
- TG203 - Management of radiotherapy implanted cardiac pacemakers and defibrillators.** [Status]
- (B) Active Task Group listing

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 function)
- 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

SOURCES OF POTENTIAL MALFUNCTIONS FOR ICDs & ICPs 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, etc.
- Other...



DOSE ESTIMATION: PHOTON OUT-OF-FILED DOSE

Wedges

Physical wedges → increase out of field dose by 2-4 times (Sherazi et al, 1985, *Int J Radiat Oncol Biol Phys*)

Dynamic or universal wedges → no increase (Li et al, 1997, *Int J Radiat Oncol Biol Phys*)

$CRR = CRR \times f_{pw}$ (step 10)

In these equations the parameters and corrections are defined as follows:

- $PD\%$ = peripheral dose in % of dose at d_{max}
- f_{pe} = correction for photon energy
- f_{pfs} = correction for patient thickness also
- f_{pdp} = correction for depth of PD point
- f_{poc} = optional correction for couch attenuation
- f_{pl} = correction for field elongation
- f_{pw} = correction if wedge is used
- f_{pr} = fraction of PD contributed by related radiation
- f_{psk} = correction if shielding blocks are used
- f_{pa} = attenuation correction of CRR for depth of PD point

2.2. Tangential beams

The program also offers the option to calculate the PD for

MLC

Secondary MLC → no impact on out-of-field dose (Matic et al, 2002, *J Appl Clin Med Phys*)

Tertiary MLC is extra shielding → decrease out of field dose by 30-50% (Stern, 1999, *Med Phys*)

3.1. Constraints and Limitations

When using the program the user has to realize that certain constraints have to be considered. The PD percentages which form the basis for the calculations, are related to the dose at d_{max} . This is easy for SSD treatments, but for isocentric techniques the user has to calculate the dose at d_{max} from the dose at isocentre. For non-coplanar, non-orthogonal beams, the program should be used with caution

Contribution of beam number 1 (left anterior oblique) Peripheral Dose: 1.8 cGy Leakage and External Scatter: 5.9 cGy

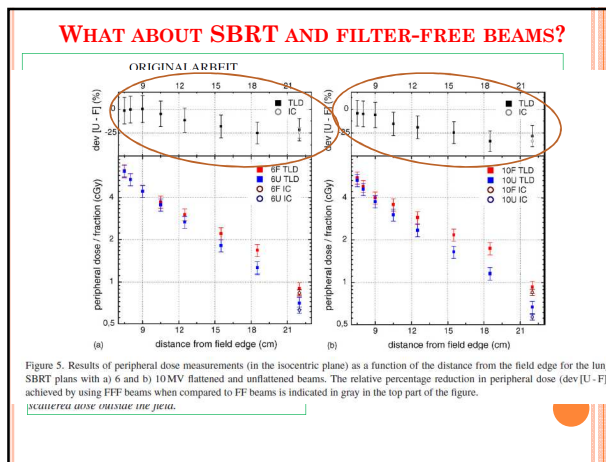
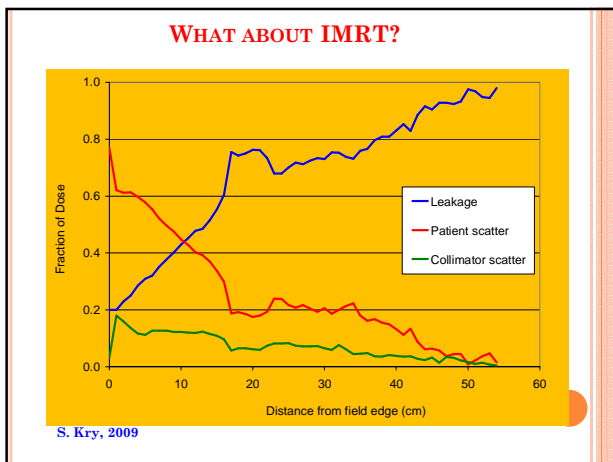
Contribution of beam number 2 (right lateral) Peripheral Dose: 12.4 cGy Leakage and External Scatter: 9.8 cGy

Fig. 2. Print of the results of the 2-beam calculation for which the input is shown in Fig. 1.

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 ESTIMATION: PROTON OUT-OF-FILED DOSE

How much dose equivalent is there?

Conventional photon therapy

Variations in beam

- Photons:
 - More dose near treatment field
 - Comparable dose beyond 10-20 cm from field edge
- Size and material of phantom, manufacturer of accelerator
- Challenges in Dosimetry
 - Lack of high energy response
 - Unique machines

Xu, 2008, *Phys Med Biol*


Courtesy of S. Kry

- ### CHECK LIST FOR PATIENT MANAGEMENT
- Initial Consultation**
 - CIED alert added to patient's chart
 - Copy of CIED card made and filed in patient's chart
 - Appointment with Cardiac Electrophysiology (EP) scheduled
 - Simulation Check**
 - Patient was evaluated by EP to verify dependence on device
 - Verify CIED alert added to patient's chart
 - Verify treatment planning directive completed by physician
 - Note added to planning directive to only use 6X photons and avoid wedges where possible
 - Contact vendor for dose limit recommendations

- **Planning check**
 - Verify only *CV* ablates used for treatment
- **Dose to pacemaker > 2 Gy (?)**
 - Inform Rad-Onc physician
 - Contact EP to inform them of dose and discuss monitoring strategy
 - Move device
 - Adjust monitoring frequency
 - Schedule EP follow on-set for all treatment fractions
 - No monitoring necessary
- Verify imaging field does not irradiate CIED
- Read dosimeter and generate summary of reading for physician

ACKNOWLEDGEMENT

- **This is a collective effort of members of TG203**
- **2012 AAPM Scientific Planning Committee and Program Directors.**



THANK YOU

