

New Comprehensive and Practical Guidelines for Managing Radiotherapy Patients with Cardiac Devices---TG203

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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 for RT procedures.
- Recommendations.

Pacemakers

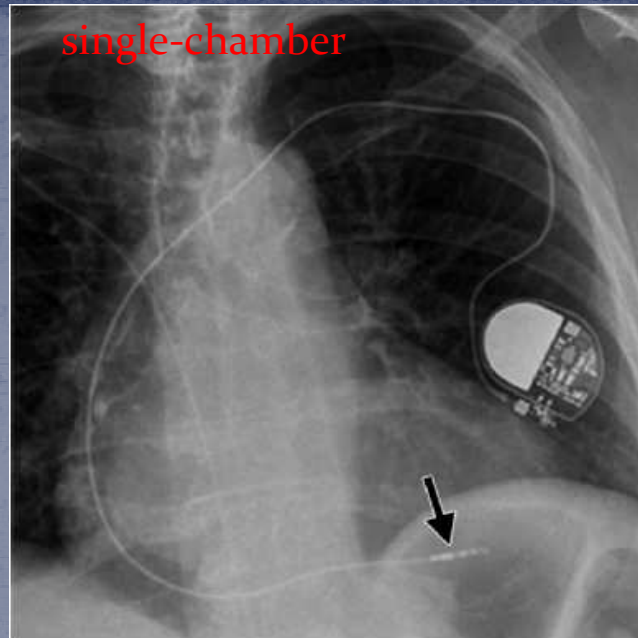
A mechanical pacemaker is an electronic device used to provide small electrical stimuli to cause cardiac contraction during periods of bradycardia, when the intrinsic electrical activity of the heart is inappropriately slow or absent (Fig 1). The natural pacemaker of the heart is the sinoatrial node, which is located in the wall of the right atrium near the superior vena cava–right atrial junction. When the normal electrical pathways are disrupted by intrinsic disease, the result is bradycardia and arrhythmias. Myocardial infarction, degenerative aging of the atrioventricular node, or degeneration of the conduction tissues can also disrupt these pathways.

Different types of pacemakers are placed depending on the cause of bradycardia (Fig 2). A single-chamber pacemaker has one lead that paces either the right ventricle or right atrium. Most commonly, this lead is placed in the apex of the right ventricle and is used to pace the heart when there is a problem with the conduction pathways (Fig 2a). Uncommonly, a single lead may be placed in the right atrium when an atrial dysrhythmia due to sinoatrial node dysfunction or an aberrant additional sinoatrial node pacemaker focus is present. In this case, the conduction tissues are normal; once the

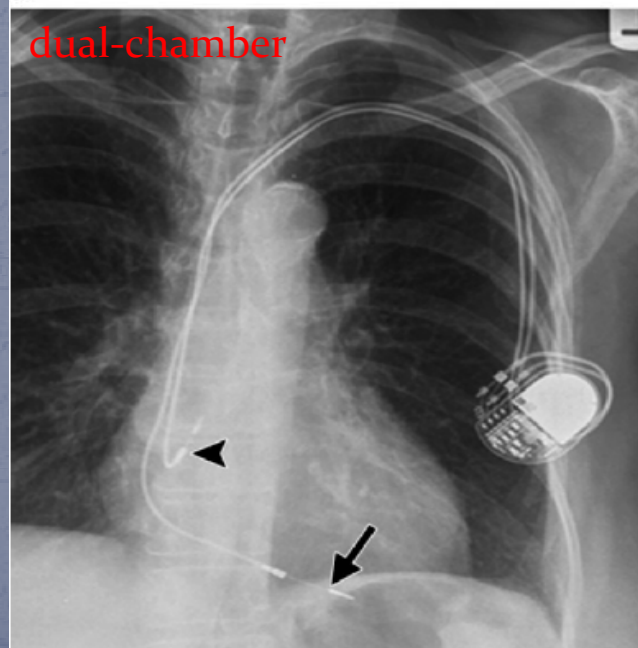
impulses are properly generated, they can travel unimpeded to the ventricles.

A dual-chamber pacemaker has two leads: one in the right atrium and one in the right ventricle (Fig 2b). This type of pacemaker helps coordinate signals to and contractions of the atria and ventricles.

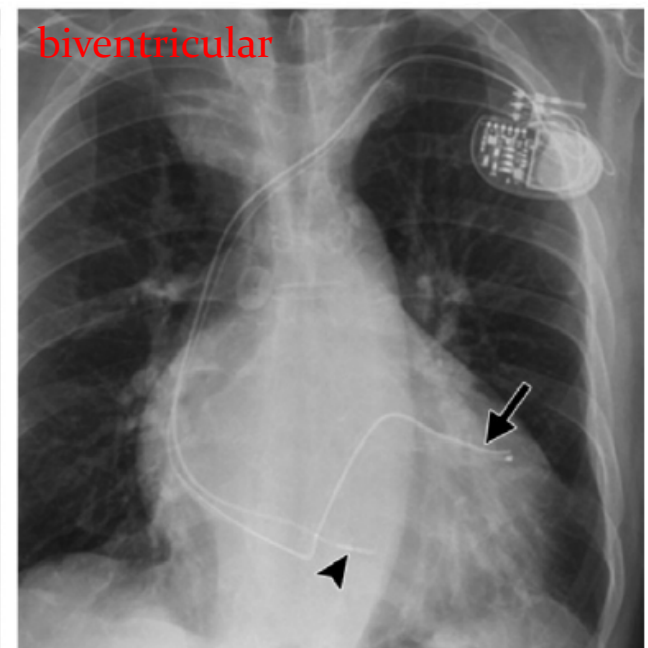
A biventricular pacemaker (aka a cardiac resynchronization therapy device) has at least one right ventricular lead and one left ventricular lead. It may have a right atrial lead as well. The left ventricular lead traverses the coronary sinus into a posterior or lateral cardiac vein (Fig 2c), allowing access to the lateral left ventricle wall for left ventricular pacing. Biventricular pacemakers stimulate simultaneous contraction of the left and right ventricles, resulting in a more efficient pumping action. These devices are commonly used when there is moderate to severe drug-refractory congestive heart failure with associated interventricular or intraventricular dyssynchrony; they are also used in cases where there is a weakened and enlarged heart.



a.



b.



c.

Figure 2. Three types of cardiac pacemakers. (a) Frontal chest radiograph shows a single-chamber pacemaker with a single lead in the right ventricle (arrow). (b) Frontal chest radiograph shows a dual-chamber pacemaker, which has leads in the right atrium (arrowhead) and right ventricle (arrow). (c) Frontal chest radiograph shows a biventricular pacemaker with one right ventricular lead (arrowhead) and one left ventricular lead (arrow). A biventricular pacemaker may also have a right atrial lead.

Figure 4. Normal radiographic appearance of an ICD. On a frontal chest radiograph, the shock coils of an ICD lead appear as sections of thickened metallic opacity that terminate in the regions of the superior vena cava and right ventricle.

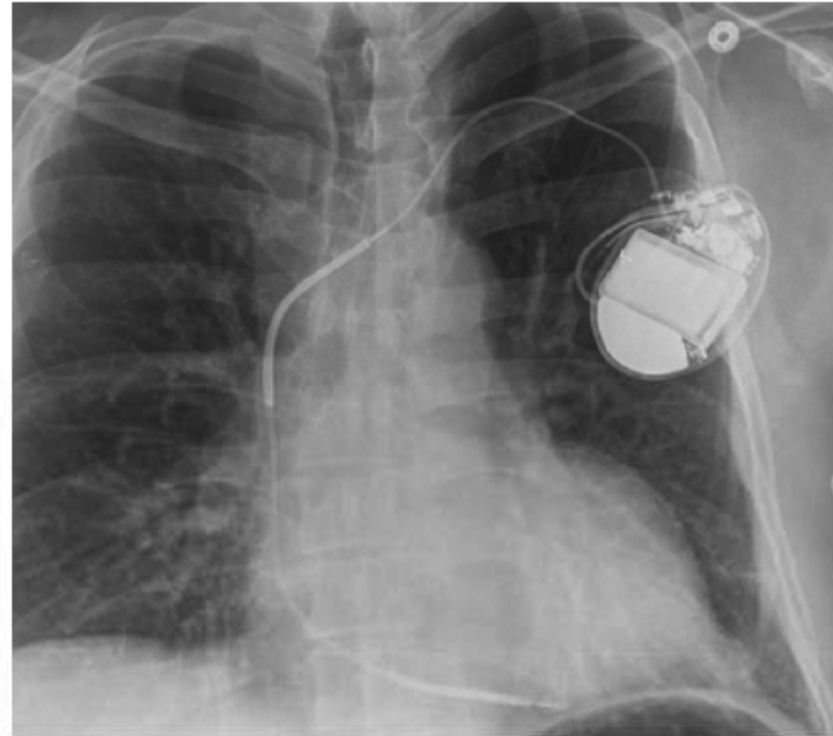
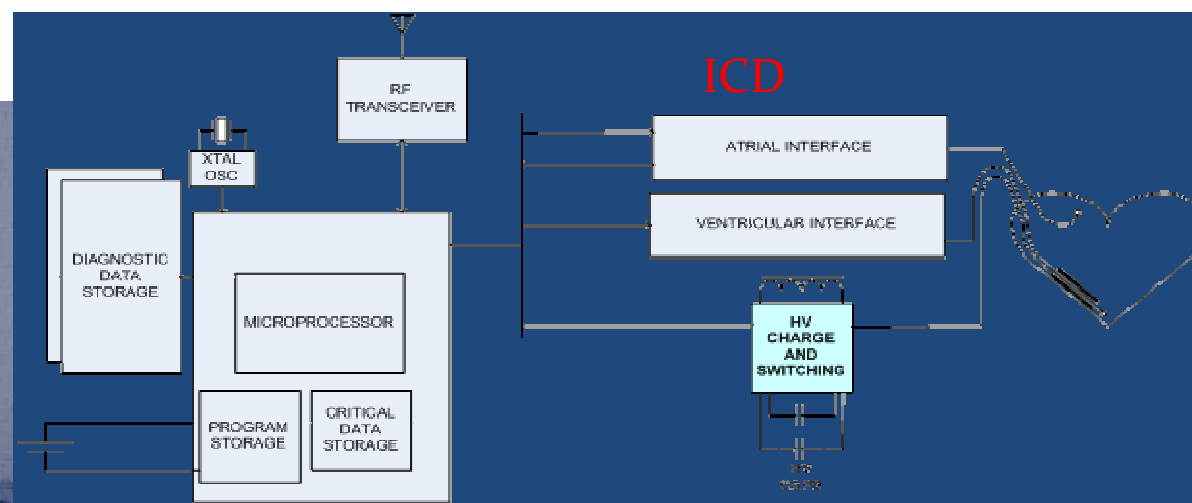




FIG. 3. [Top]: Five ICDs [Left to Right]: InSync Maximo model 7304, Concerto model C154DWK (VVE-DDDR), Entrust model D154ATG, Maximo DR model 7278, and Virtuoso model D154AWG; [Below]: four implantable pacemakers: Adapta model ADDR01, Versa model VEDR01, Sensia model SEDR01, and EnPulse2 model E2DR01.



TG₃₄: Management of Radiation Oncology Patients with Implanted Cardiac Pacemakers (1994)

Management of radiation oncology patients with implanted cardiac pacemakers: Report of AAPM Task Group No. 34

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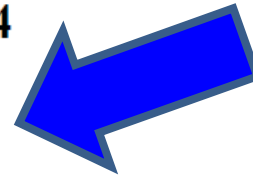
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Contemporary cardiac pacemakers can fail from radiation damage at doses as low as 10 gray and can exhibit functional changes at doses as low as 2 gray. A review and discussion of this potential problem is presented and a protocol is offered that suggests that radiation therapy patients with implanted pacemakers be planned so as to limit accumulated dose to the pacemaker to 2 gray. Although certain levels and types of electromagnetic interference can cause pacemaker malfunction, there is evidence that this is not a serious problem around most contemporary radiation therapy equipment.

Key words: radiation oncology, pacemakers, treatment protocol, complications



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.⁸⁷⁻⁹¹

(4) If the total estimated dose to the pacemaker might exceed 2 gray, the pacemaker function should be checked prior to therapy and possibly at the start of each following week of therapy. Since total and abrupt failure of pacemakers has been seen at cumulative doses between 10 and 30 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.⁶

(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.

Major issues with cardiac devices and radiotherapy equipment

- In spite of availability of TG-34 and other reports in literature, major discrepancies still exist among manufacturers' recommendations and wide variations exist among RT facilities regarding patient management and guidelines.
- Contradictory information exist: some devices have undergone deleterious effects at 0.15Gy (0.2Gy/min) while others have shown tolerance up to 20Gy or more dose?
- Interference with EM components, (partial) exposure to direct radiation, exposure to scattered radiation within the patient, other??

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.

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PHYSICS CONTRIBUTION

TREATMENT OF PATIENTS WITH CARDIAC PACEMAKERS AND IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS DURING RADIOTHERAPY

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Purpose: To define the practical clinical guidelines that can be implemented by busy radiation oncology departments to minimize the risk of harm to patients with implanted cardiac pacemaker (ICP) and implantable cardioverter-defibrillator (ICD) devices during radiotherapy.

Methods and Materials: A literature review was conducted to identify the mechanism of potential damage to ICPs and ICDs from exposure to electromagnetic interference and/or ionizing radiation and to assess the published evidence of such device malfunction or failure. Recommendations for patient management were obtained from three major manufacturers. Eighty-seven radiation oncology facilities across the United States and Canada were contacted to determine current practice patterns; 75 centers responded.

Results: The published documentation of potential life-threatening malfunction of ICP and ICD devices exposed to electromagnetic interference and ionizing radiation is considerable. However, major discrepancies exist among manufacturer recommendations and wide variations are present among radiation oncology facilities regarding patient management precautions.

Conclusion: Precautions are necessary to minimize the risk to patients with ICP and ICD devices during radiotherapy. Practical management guidelines are presented that can be readily adopted by any busy clinical radiation oncology practice. © 2004 Elsevier Inc.

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

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COMPLICATIONS OF TREATMENT

Radiotherapy to patients with artificial cardiac pacemakers

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KEYWORDS

Artificial pacemaker;
Implantable
defibrillators;
Radiotherapy;
Linear accelerators;
Electromagnetic Fields;
Radiation damage

Summary

Background: The in vitro studies show that the modern cardiac pacemakers utilising the complementary metal-oxide semi-conductor (CMOS) circuitry can be adversely affected by therapeutic radiation. However, the published clinical data are sparse regarding the safety of radiotherapy delivery to patients with artificial pacemakers. Despite the potential risk of life threatening complications, there are no national guidelines and most radiotherapy departments have no formal clinical risk management strategy in place. A literature review was performed to assess the risks involved in irradiating patients with pacemakers and to identify strategies, which minimise the risk of pacemaker malfunction. Recommendations for radiotherapy departments are made.

Conclusion: Modern multi-programmable pacemakers are very sensitive to therapeutic megavoltage irradiation. There is no safe radiation threshold for megavoltage radiation. The low energy kilovoltage X-rays used for radiotherapy simulation cause no pacemaker malfunction. Megavoltage radiation can be safely delivered to patients with cardiac pacemakers provided direct irradiation of pacemakers is avoided, adequate monitoring is done during and after irradiation, and the dose to the pacemaker generator is kept below 2 Gy. Close liaison with cardiologists and a pacemaker clinic is essential and radiotherapy departments should have protocols in place to identify and care for cancer patients with pacemakers.

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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

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PHYSICS CONTRIBUTION

INFLUENCE OF RADIOTHERAPY ON THE LATEST GENERATION OF IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

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Purpose: Radiotherapy can influence the functioning of pacemakers and implantable cardioverter-defibrillators (ICDs). ICDs offer the same functionality as pacemakers, but are also able to deliver a high-voltage shock to the heart if needed. Guidelines for radiotherapy treatment of patients with an implanted rhythm device have been published in 1994 by The American Association of Physicists in Medicine, and are based only on experience with pacemakers. Data on the influence of radiotherapy on ICDs are limited. The objective of our study is to determine the influence of radiotherapy on the latest generation of ICDs.

Methods and Materials: Eleven modern ICDs have been irradiated in our department. The irradiation was performed with a 6-MV photon beam. The given dose was fractionated up to a cumulative dose of 120 Gy. Two to 5 days passed between consecutive irradiations. Frequency, output, sensing, telemetry, and shock energy were monitored.

Results: Sensing interference by ionizing radiation on all ICDs has been demonstrated. For four ICDs, this would have caused the inappropriate delivery of a shock because of interference. At the end of the irradiation sessions, all devices had reached their point of failure. Complete loss of function was observed for four ICDs at dose levels between 0.5 Gy and 1.5 Gy.

Conclusions: The effect of radiation therapy on the newest generation of ICDs varies widely. If tachycardia monitoring and therapy are functional (programmed on) during irradiation, the ICD might inappropriately give antitachycardia therapy, often resulting in a shock. Although most ICDs did not fail below 80 Gy, some devices had already failed at doses below 1.5 Gy. Guidelines are formulated for the treatment of patients with an ICD.

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Cardioverter-defibrillator, Pacemaker, Radiotherapy, Radiation damage.

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Effects of Scatter Radiation on ICD and CRT Function

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Background: *Effects of direct radiation on implantable cardiac devices have been well studied. However, the effects of scatter radiation are not as clear. Recommendations on management of patients with implantable cardiac devices undergoing 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)*

Recent Review Articles



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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 review the experience of a large cancer center with radiotherapy (RT) patients bearing implantable cardiac defibrillators (ICDs) to propose some preliminary care guidelines as we learn more about the devices and their interaction with the therapeutic radiation environment.

Methods and Materials: We reviewed the experience of our center during a 5-year period at any of the five Memorial Sloan-Kettering Cancer Center sites. The number and dose detected from the device were recorded. During this time, a new management protocol was implemented for low energy beams (6 MV) and close proximity to the device. All patients received RT.

Results: During the study period, there was one event of the device to its initial factory setting. This patient had initially been treated with 6-MV photons.

Conclusion: Patients with ICDs are frequently in the RT department. We will continue to observe these patients in the radiation therapy department.

Implanted cardiac defibrillator

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 cell, 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

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Radiotherapy-induced

ble

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.

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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 review

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Conflicts of interest: None.

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Summary

The increasing human lifespan and development of technology over the last number of decades has seen an increase in the number of pacemaker and implantable cardioverter defibrillator (ICD) implantations worldwide. Given the number of risk factors common to both heart disease and cancer, it is not uncommon for several of these patients to present for radiation therapy treatment each year. A systematic review was conducted using online databases Medline and Scopus. Results were grouped into *in vitro* and *in vivo* studies. In 1994, the American Association of Physicists in Medicine (AAPM) defined guidelines for the management of these patients, which have since been adopted by many radiation oncology departments internationally. More recently, a number of studies have reported an increase in radiation sensitivity of these devices (encompassing the coiled metal leads and generator unit) due to the incorporation of complementary metal oxide semiconductor circuitry. Further avenues of device failure, such as the effect of dose rate and scatter radiation, have only more recently been investigated. There are also the unexplored avenues of electromagnetic interference on devices when incorporating newer treatment technologies such as respiratory gating and intensity modulated radiation therapy. It is suggested that each radiation oncology department employ a policy for the management of patients with ICDs and pacemakers, potentially based upon an updated national or international standard similar to that released by the AAPM in 1994.

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

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J. Radiat. Res., 52, 516–521 (2011)

Regular Paper

Radiation Therapy in Patients with Implanted Cardiac Pacemakers and Implantable Cardioverter Defibrillators: A Prospective Survey in Japan

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Radiotherapy/Pacemaker/ICD/Malfunction.

Patients with implanted cardiac pacemakers (ICPs) or implantable cardioverter defibrillators (ICDs) are increasing in number, and the incidence of treating these patients with radiation therapy also is increasing. Thus, a prospective survey was conducted of patients with these devices receiving radiation therapy. A prospective survey of patients with ICPs or ICDs treated with radiation therapy was conducted on methods of radiation therapy, status of ICP/ICD, and management of patients before, during, and after radiation therapy. After completion of radiation therapy, study participants were registered via mail, fax, or e-mail. Sixty-two patients from 29 institutions were registered from September 2006 to December 2008. Sixty patients had an ICP and 2 had an ICD. The total dose was estimated before radiation 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 dose did not exceed 478 cGy. Function of ICPs and ICDs was checked before radiation therapy in 38 patients (61%), after radiation therapy in 32 (52%), and both before and after radiation therapy in 29 (47%). ICP malfunction occurred in a 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.

Pacemaker Failure Due to Radiation Therapy

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KATZENBERG, C.A., ET AL.: *Pacemaker failure due to radiation therapy. Pacemaker malfunction occurred after a patient was given 3000-3600 rads to an area occupied by an A-V sequential pacemaker. Analysis of the removed generator showed that there was malfunction of the large scale integrated circuit and the type of damage was consistent with radiation-induced effects. The newer multiprogrammable units may be more sensitive to ionizing radiation than those previously available. (PACE, Vol. 5, March-April, 1982)*

pacemaker malfunction

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.

The Cardiac Pacemaker Patient

Might the Pacer be Directly Irradiated?

Alexander Tsekos, Felix Momm, Michael Brunner and Roland Guttenberger

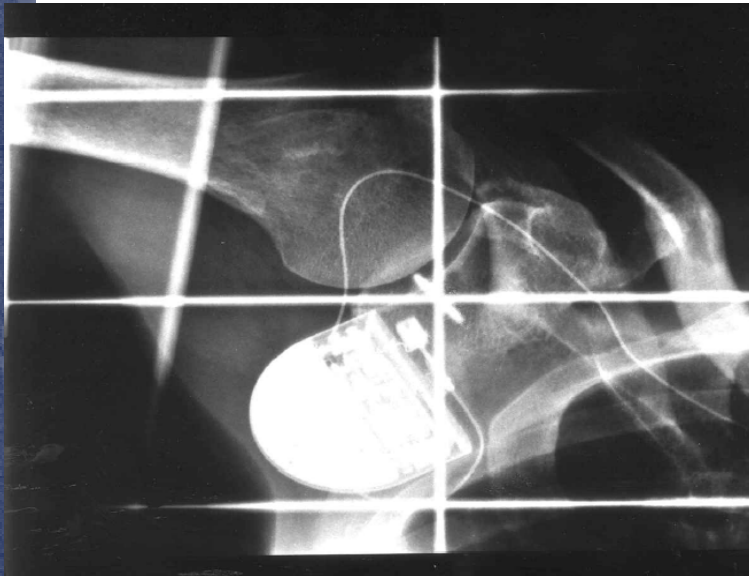
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Radiotherapy course. The patient received radiotherapy as an inpatient. Figure 1 shows the pacer in the treatment field. During each fraction we performed an ECG and observed the rhythm on a monitor outside. The cardiologist was with us during the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



Letter to the Editor

Defibrillator reset by radiotherapy

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Received 3 May 2007; accepted 30 June 2007
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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.

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The device first alarmed during his second course of radiotherapy (EBRT) to the pelvis using a four-field planned beam arrangement. The dose was 2 gray (Gy) per fraction with a total of 74 Gy in 37 fractions (74 Gy). Upon interrogation the device indicated that an ICD electrical reset had

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.

Life-Threatening Pacemaker Dysfunction Associated With Therapeutic Radiation: A Case Report

Andreas Zweng, MD, Reinhard Schuster, MD, Robert Hawlicek, MD, and Heinz Stefan Weber, MD, FESC, FACC

Reports about pacemaker (PM) dysfunction during irradiation (IR) are very rare, which is because of the extensive protective mechanisms that exist in these devices against electromagnetic interference (EMI). We report a case in which one of the most clinically relevant type of PM malfunctions, a runaway PM, occurred during radiation in a 76-year-old woman who was treated for inoperable esophageal cancer with a course of photon IR. The estimated IR dose of 0.11 Gy

was the lowest in vivo dose ever reported. So a direct radiation effect as cause for this malfunction appears to be improbable. It could be concluded that the PM dysfunction was most likely induced by EMI during radiotherapy. The real reason of the device's software failure remains unclear.

Keywords: pacemaker malfunction; therapeutic radiation; pacemaker-induced tachycardia

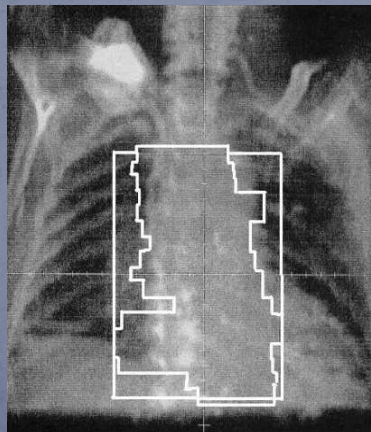


Figure 1. Simulation of the 2-field irradiation technique.

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

Haruko Hashii, MD,* Takayuki Hashimoto, MD,* Ayako Okawa, MD,* Koichi Shida, MP,* Tomonori Isobe, PhD,* Masahiro Hanmura, MP,† Tetsuo Nishimura, MD,† Kazutaka Aonuma, MD,† Takeji Sakae, PhD,* and Hideyuki Sakurai, MD*

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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.

Purpose: Radiation therapy for cancer may be required for patients with implantable cardiac devices. However, the influence of secondary neutrons or scattered irradiation from high-energy photons (≥ 10 MV) on implantable cardioverter-defibrillators (ICDs) is unclear. This study was performed to examine this issue in 2 ICD models.

Methods and Materials: ICDs were positioned around a water phantom under conditions simulating clinical radiation therapy. The ICDs were not irradiated directly. A control ICD was positioned 140 cm from the irradiation isocenter. Fractional irradiation was performed with 18-MV and 10-MV photon beams to give cumulative in-field doses of 600 Gy and 1600 Gy, respectively. Errors were checked after each fraction. Soft errors were defined as severe (change to safety back-up mode), moderate (memory interference, no changes in device parameters), and minor (slight memory change, undetectable by computer).

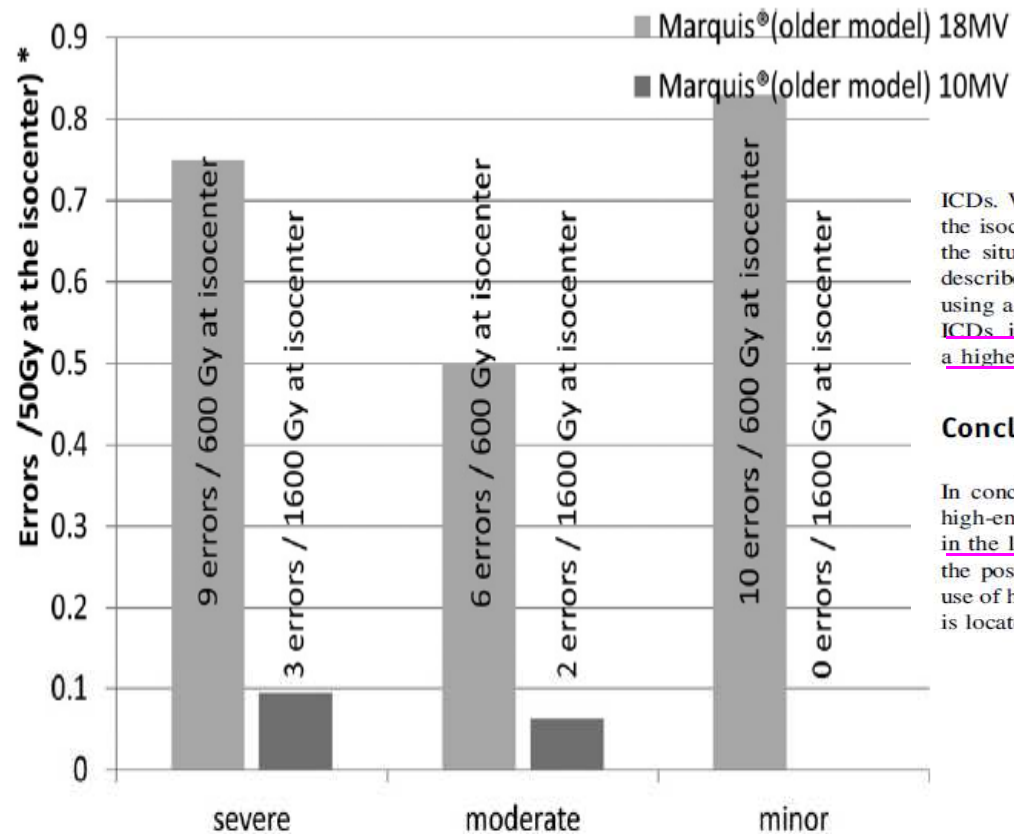
Results: Hard errors were not observed. For the older ICD model, the incidences of severe, moderate, and minor soft errors at 18 MV were 0.75, 0.5, and 0.83/50 Gy at the isocenter. The corresponding data for 10 MV were 0.094, 0.063, and 0.150 Gy. For the newer ICD model at 18 MV, these data were 0.083, 2.3, and 5.8/50 Gy. Moderate and minor errors occurred at 18 MV in control ICDs placed 140 cm from the isocenter. The error incidences were 0, 1, and 0/600 Gy at the isocenter for the newer model, and 0, 1, and 6/600Gy for the older model. At 10 MV, no errors occurred in control ICDs.

Conclusions: ICD errors occurred more frequently at 18 MV irradiation, which suggests that the errors were mainly caused by secondary neutrons. Soft errors of ICDs were observed with high energy photon beams, but most were not critical in the newer model. These errors may occur even when the device is far from the irradiation field. © 2013 Elsevier Inc.

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Conflict of interest notification: none of the authors report a financial conflict of interest regarding the work in the study.

Acknowledgment—The authors thank H. Fujimoto and K. Sunagawa from Medtronic Japan Co., Ltd., whose enormous support and information have helped us very much throughout the production of this study.



*The axis are scaled differently in figures 3 and 4.

Fig. 3. Comparison of the 2 irradiation energies, showing that 18-MV irradiation caused more frequent errors in the ICDs.

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



Europace (2013) 15, 60–65
doi:10.1093/europace/eus197

CLINICAL RESEARCH

Sudden death and ICDs

High incidence of implantable cardioverter defibrillator malfunctions during radiation therapy: neutrons as a probable cause of soft errors

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Received 12 December 2011; accepted after revision 25 May 2012; online publish-ahead-of-print 29 July 2012

Aims

To investigate the behaviour of the implantable cardioverter defibrillator (ICD) function during actual radiotherapy sessions.

Methods and results

Fifteen patients with an ICD underwent 17 radiation treatments for cancer [cumulative dose to the tumour was between 16 Gray (Gy) and 70 Gy; photon beams with maximum energies between 6 megaelectronvolt (MeV) and 18 MeV were employed]. During every session, the ICD was programmed to a monitoring mode to prevent inappropriate therapy delivery. Afterwards, the ICDs were interrogated to ensure proper function. Calculated radiation dose at the ICD site was <1 Gy in all patients. In 5 out of 17 radiation treatments (29%) the ICDs showed 6 malfunctions (35%). We noticed four disturbances in the memory data or device resets during radiation treatment and one case of inappropriate ventricular fibrillation detection due to external noise. In one case a late device data error was observed. All malfunctions occurred at 10 and 18 MeV beam energies.

Conclusion

Despite the fact that all recommended precautions were taken to minimize the damage to the ICDs during radiotherapy and the calculated dose to the ICDs was <1 Gy, in 29% of the treatments a malfunction occurred. We observed a possible correlation between the beam energy and the malfunctions. This correlation may be due to an interaction between neutrons produced in the head of the linear accelerator at beam energies ≥ 10 MeV, and boron-10 which is present in the integrated circuit.

Keywords

Radiotherapy • Implantable cardioverter defibrillator • Malfunctions • Neutrons • Reset

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	10	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)

Case reports of failures (neutrons, particles)

Runaway Pacemaker During High-Energy Neutron Radiation Therapy*

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Peter J. Kudenchuk, M.D.*

Runaway pacemaker occurred in a patient undergoing high-energy neutron radiation therapy despite adherence to published safety guidelines. The very low estimated dose of 0.9 Gy received by the pacemaker demonstrates the extreme sensitivity of integrated circuits to this new modality of radiation therapy.

(Chest 1994; 106:955-57)

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

PROTON BEAM THERAPY INTERFERENCE WITH IMPLANTED CARDIAC PACEMAKERS

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Purpose: To investigate the effect of proton beam therapy (PBT) on implanted cardiac pacemaker function.

Methods and Materials: After a phantom study confirmed the safety of PBT in patients with cardiac pacemakers, we treated 8 patients with implanted pacemakers using PBT to a total tumor dose of 33–77 gray equivalents (GyE) in dose fractions of 2.2–6.6 GyE. The combined total number of PBT sessions was 127. Although all pulse generators remained outside the treatment field, 4 patients had pacing leads in the radiation field. All patients were monitored by means of electrocardiogram during treatment, and pacemakers were routinely examined before and after PBT.

Results: The phantom study showed no effect of neutron scatter on pacemaker generators. In the study, changes in heart rate occurred three times (2.4%) in 2 patients. However, these patients remained completely asymptomatic throughout the PBT course.

Conclusions: PBT can result in pacemaker malfunctions that manifest as changes in pulse rate and pulse patterns. Therefore, patients with cardiac pacemakers should be monitored by means of electrocardiogram during PBT. © 2008 Elsevier Inc.

Cardiac pacemaker, Proton beam therapy, Neutron.

Case reports of failures in CT

Circ J 2006; 70: 190–197

Does High-Power Computed Tomography Scanning Equipment Affect the Operation of Pacemakers?

Table 1 Characteristics of the Patients With an Implanted Pacemaker

<i>Patient no.</i>	<i>Age (years)</i>	<i>Pacemaker mode</i>	<i>ECG pattern before CT</i>	<i>Malfunction during CT</i>
1	80	VVI	VP	Over-sensing
2	77	VVI	VP	None
3	78	VVI	VP	None
4	56	VVI	Own beats + VP	None
5	87	VDD	ASVP	Over-sensing
6	72	VDD	ASVP	Over-sensing
7	66	VDD	ASVP	Over-sensing
8	77	DDD	Own beats	None
9	65	DDD	APVS	Over-sensing
10	74	DDD	APVP	None
11	77	DDD	APVP	Over-sensing

CT, computed tomography; *VP*, ventricular pacing; *ASVP*, atrial sensing-ventricular pacing; *APVS*, atrial pacing-ventricular sensing.

PERFORMANCE

or after the exam.

Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices¹

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Andrew N. Primak, PhD
Wesley J. Clement, BSEE
John R. Buysman, PhD

Purpose: To prospectively measure the response of a variety of models of implantable cardiac rhythm management devices (ICRMDs) to the radiation delivered by computed tomography (CT), for both maximum and typical dose levels.

Materials and Methods: Twenty-one ICRMDs (13 pacemakers, eight cardioverter-defibrillators) manufactured by Medtronic (Minneapolis, Minn) were exposed to ionizing radiation from CT systems in both spiral and dynamic acquisition modes at maximum and typical dose levels. Devices were monitored during exposure to check for any operational abnormalities and were interrogated after exposure to check for any residual abnormalities. Total radiation dose and peak dose rate were measured, and the volume CT dose index was recorded.

Results: Oversensing was observed in 20 of 21 devices at maximum doses and in 17 of 20 devices at typical doses. Oversensing most often manifested as inhibition, although it occasionally manifested as tracking or safety pacing. Two devices inhibited for more than 4 seconds in spiral mode at clinical dose levels. Oversensing was transient and ceased as soon as the device stopped moving through the x-ray beam or the beam was turned off. The partial electrical reset (PER) safety feature was activated in two models, InSync 8040 and Thera DR. With the exception of PER, programming was not altered. Effects occurred only if the x-ray beam passed directly over the ICRMD.

Conclusion: CT irradiation at typical clinical doses results in oversensing of ICRMDs in the majority of devices tested, although the identified effects were predominantly transient.

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Heart and rhythm society consensus statement (2011)

The Heart Rhythm Society Expert Consensus Statement on the perioperative management of patients with implantable defibrillators, pacemakers and arrhythmia monitors: Facilities and patient management

The document was developed as a joint project with the American Society of Anesthesiologists (ASA), and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS)

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1. Preamble

- 1.1. Purpose
- 1.2. Consensus document definition
- 1.3. Appropriate use of this document

ABBREVIATIONS ICD = Implantable cardioverter defibrillator; EMI = Electromagnetic interference; CIED = Cardiac implantable electrical device; RF = Radio frequency; ECT = Electroconvulsive therapy; TUNA = Transurethral needle ablation; TURP = Transurethral resection of the prostate; TENS = Transcutaneous electrical nerve stimulation; CRT-P = Cardiac resynchronization therapy pacemaker; CRT-D = Cardiac resynchronization therapy defibrillator; CIED team = The physician, nurse, and technicians who care for the patient's CIED; Perioperative team = The anesthesiologist, surgeon, and/or other physicians and nurses associated with the procedure and the preparation for that procedure (Heart Rhythm 2011;xx:xxx)

^aRepresenting the American Society of Anesthesiologists.

[#]Representing the American College of Cardiology.

[!]Representing the American Heart Association.

^{##}Representing the Thoracic Surgery Society.

The document was endorsed by the Heart Rhythm Society on November 30, 2010, and endorsed by the American Heart Association on December 24, 2010. At the time of this print American College of Cardiology endorsement is pending. Address reprint requests to the Journal: Correspondence should be sent to: the Heart Rhythm Society, Attn: Sonja Olson (solson@hrsonline.org).

2. Introduction

- 2.1. Methods
- 2.2. Primary recommended approach

3. Problems that can occur during medical procedures

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New Task Group - AAPM TG 203

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

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- or -
You may save the address 2012.zTG203@mail.aapm.org to your local address book. This alias updates hourly from the AAPM Directory.

Charge Review published literature, evaluate all possible effects of therapeutic radiations on these devices, provide methods to clinically assess the do levels, provide an estimate of the risks for the various radiation associated lethal and non-lethal types of device failures, provide metho to manage patients with such devices and develop recommendations in order to minimize the damage during radiotherapy procedures.

Bylaws: Not Referenced. **Rules:** Not Referenced.

Approved Date(s) Start: 5/11/2010
End: 12/31/2011

Committee Keywords: TG203

- ⊕ [Board of Directors](#) [Status]
- ⊕ [Science Council](#) [Status]
- ⊕ [Therapy Physics](#) [Status]
 - ⊕ [Radiation Dosimetry & Treatment Planning SC](#) [Status]
 - ⊕ [Work Group on Radiation Dosimetry](#) [Status]

TG203 - Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators. [Status]
» [Active Task Group listing](#)

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 Wilkinson, Jeffrey D. 5/11/2010-12/31/2011 Consultant (non-voting)	

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

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
- HDR, breast, MammoSite[®]
- Other...

Peripheral Doses in Photon Beams

Peripheral dose from megavolt beams

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(Received 16 December 1982; accepted for publication 20 April 1983)

The peripheral dose (PD), defined as the dose outside of therapeutic radiation beams, has been investigated for ⁶⁰Co, 4-, 6-, and 10-MV x-ray machines. The measurements have been carried out down to dose levels of about 0.1% of the peak dose in the beam, since that dose level may be of clinical importance in some situations. The PD measurements for the various machines are qualitatively similar, which allows the identification of a simple basic data set which can characterize the PD for any particular machine. The PD has been separated into two components: in-phantom scatter dose and transmission (leakage) dose. Knowledge of the two components is important clinically when shielding is considered.

Key words: radiation dosimetry, scatter dose, megavolt beams

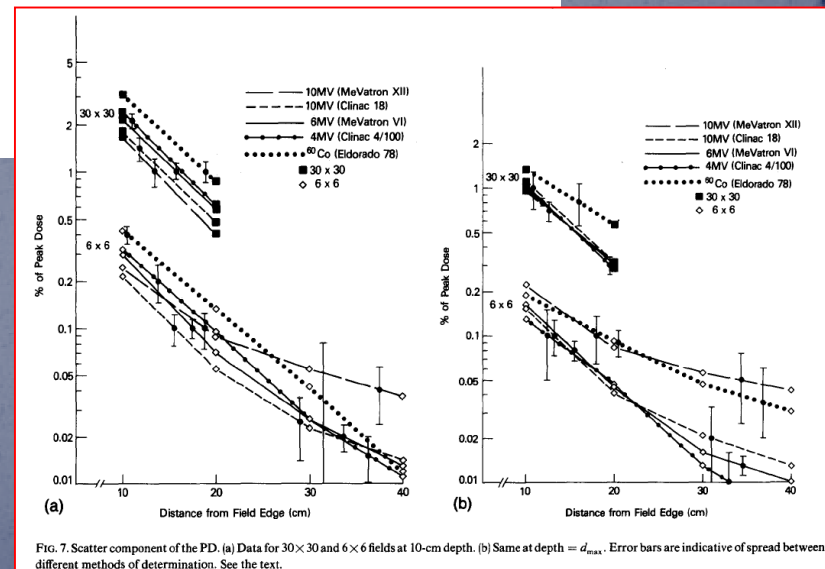


FIG. 7. Scatter component of the PD. (a) Data for 30 x 30 and 6 x 6 fields at 10-cm depth. (b) Same at depth = d_{max} . Error bars are indicative of spread between different methods of determination. See the text.

Dose Estimation: Photon out-of-filed

Fetal dose from radiotherapy with photon beams: Report of AAPM Radiation Therapy Committee Task Group No. 36

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(Received 2 June 1994; accepted for publication 20 October 1994)

Approximately 4000 women per year in the United States require radiotherapy during pregnancy. This report presents data and techniques that allow the medical physicist to estimate the radiation dose the fetus will receive and to reduce this dose with appropriate shielding. Out-of-beam data are presented for a variety of photon beams, including cobalt-60 gamma rays and x rays from 4 to 18 MV. Designs for simple and inexpensive to more complex and expensive types of shielding equipment are described. Clinical examples show that proper shielding can reduce the radiation dose to the fetus by 50%. In addition, a review of the biological aspects of irradiation enables estimates of the risks of lethality, growth retardation, mental retardation, malformation, sterility, cancer induction, and genetic defects to the fetus.

Key words: radiation therapy, fetus

1995



ELSEVIER

Radiotherapy and Oncology 58 (2001) 209–213

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THERAPEUTIC RADIOLOGY AND ONCOLOGY

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Peridose, a software program to calculate the dose outside the primary beam in radiation therapy

Peit-Hein van der Giessen

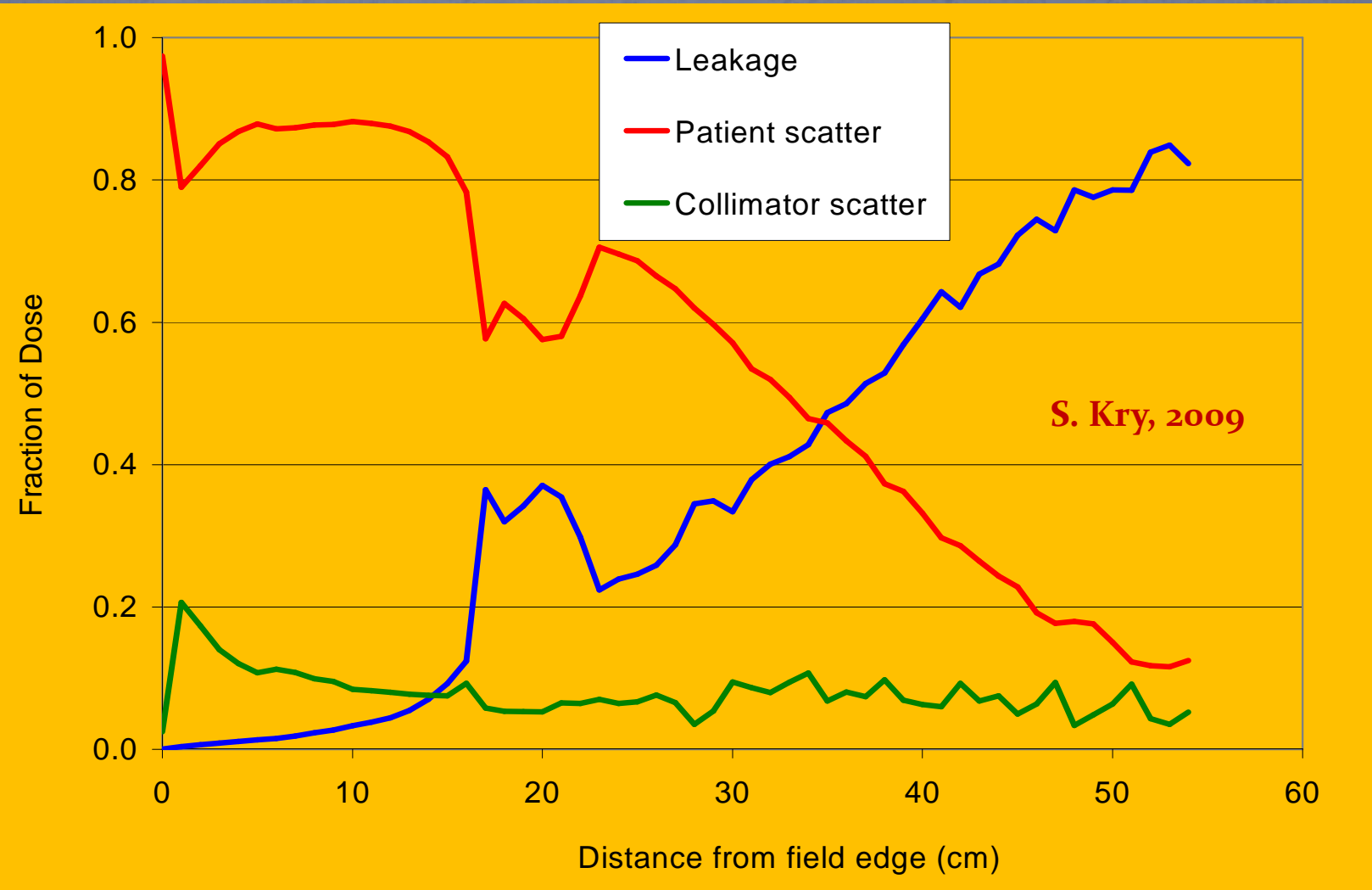
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Abstract

A software program, Peridose, is described to allow easy calculation of the peripheral dose (*PD*), the dose outside the target area. The calculation is based on published data from many authors, distinguishes between orthogonal and tangential beams and accounts for the use of wedges and shielding blocks. The separate contributions of leakage radiation and collimator scatter to the total *PD* are calculated too. © 2001 Elsevier Science Ireland Ltd. All rights reserved.

Keywords: Peripheral dose; Fetal dose; Radiation risks; Pregnancy and radiotherapy



S. Kry, 2009

Treatment planning-dose estimation

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Original Article

Radiation Therapy with Implanted Cardiac Pacemaker Devices: a Clinical and Dosimetric Analysis of Patients and Proposed Precautions

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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 .

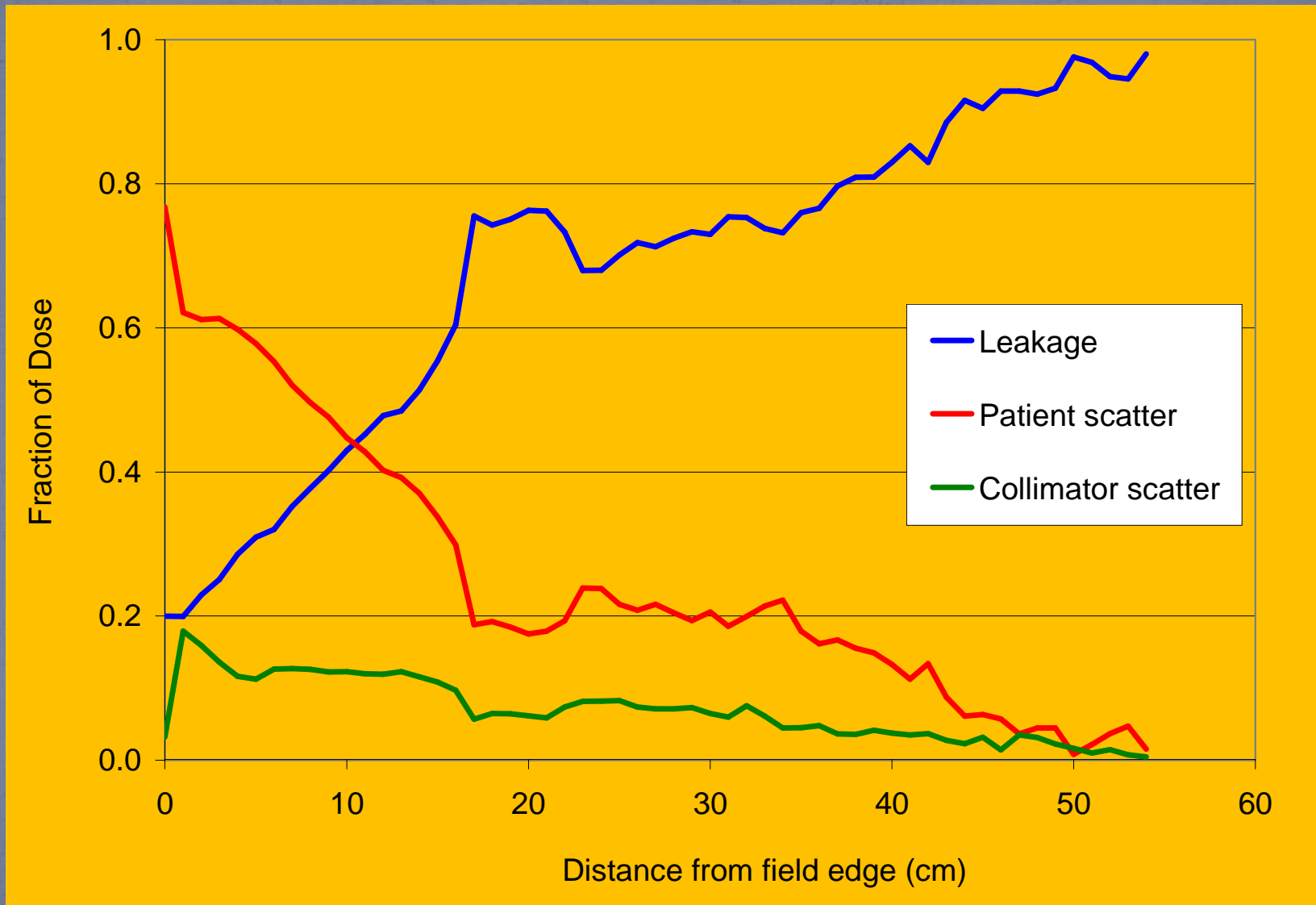
Always contour the pacemaker body, electrode and lead separately as an organ at risk

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.

What about IMRT?



S. Kry, 2009

Accuracy and sources of error of out-of field dose calculations by a commercial treatment planning system for intensity-modulated radiation therapy treatments

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V. CONCLUSIONS

In this study, we quantified the accuracy of out-of-field dose calculations by the Pinnacle treatment planning system for three IMRT treatment plans and found that the treatment planning system underestimated the out-of-field dose by an average of 50% at our measurement locations, with the degree of dose underestimation increasing with greater distance from the field edge. Locations relatively close to the treatment field (within 3-4 cm) could be associated with TPS-calculation errors in excess of 30%, while far from the field edge the error approaches 100%. Because a severe underestimation of out-of-field dose to an organ can lead to a severe underestimation of the risk of developing a secondary malignancy, as well as poor clinical decision-making for pregnant patients and patients with implantable electronic devices, TPS-reported peripheral doses should generally not be used in these cases. The source of these TPS errors appears to be underestimation of scattered radiation from collimators and other beam modifiers in the near field, as well as underestimation of leakage radiation and internal patient scatter at greater distances from the field edge.

by the Pinnacle TPS and Monte Carlo simulations (MC) plotted as a function of distance from the field edge (a), along with ratio of the two (b), for a 10×10 cm² open field.

field edge (the 50% isodose line) for the pediatric brain, lung, and breast IMRT treatment plans. Data from the study by Howell et al.⁽¹⁰⁾ with a simple mantle field and the Eclipse TPS is included for comparison.

What about SBRT and filter-free beams?

ORIGINALARBEIT

Flattening filter free beams in SBRT and IMRT: Dosimetric assessment of peripheral doses

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Conclusions: *Removing the flattening filter lead to reduced peripheral doses for advanced treatment techniques. The relative difference between peripheral doses of flattened and unflattened beams was more pronounced when the nominal beam energy was increased. Patients may benefit by decreased exposure of normal tissue to scattered dose outside the field.*

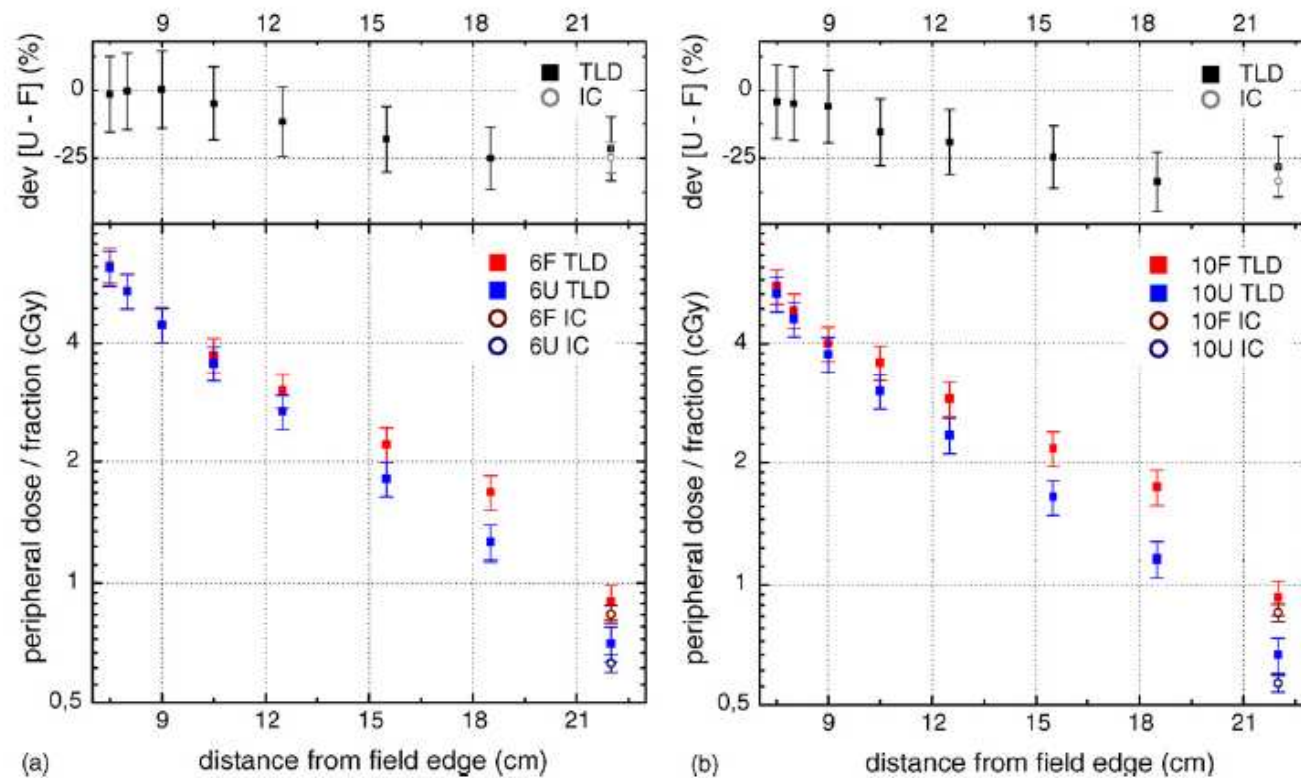
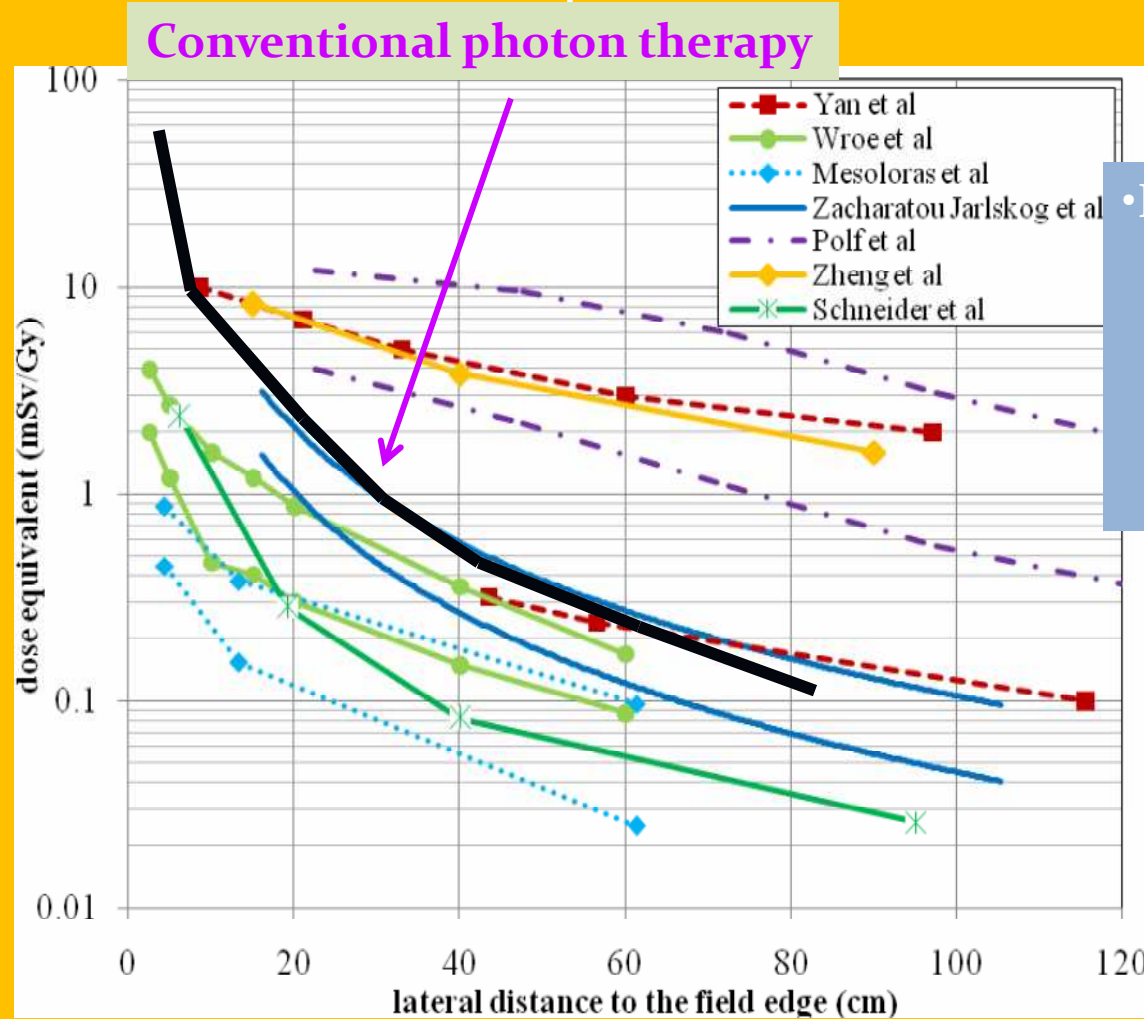


Figure 5. Results of peripheral dose measurements (in the isocentric plane) as a function of the distance from the field edge for the lung SBRT plans with a) 6 and b) 10 MV flattened and unflattened beams. The relative percentage reduction in peripheral dose (dev [U - F]) achieved by using FFF beams when compared to FF beams is indicated in gray in the top part of the figure.

Dose Estimation: Proton out-of-field dose

○ How much dose equivalent is there?



Xu, 2008, Phys Med Biol

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

RESEARCH

Open Access

Influence of secondary neutrons induced by proton radiotherapy for cancer patients with implantable cardioverter defibrillators

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Abstract

Background: Although proton radiotherapy is a promising new approach for cancer patients, functional interference is a concern for patients with implantable cardioverter defibrillators (ICDs). The purpose of this study was to clarify the influence of secondary neutrons induced by proton radiotherapy on ICDs.

Methods: The experimental set-up simulated proton radiotherapy for a patient with an ICD. Four new ICDs were placed 0.3 cm laterally and 3 cm distally outside the radiation field in order to evaluate the influence of secondary neutrons. The cumulative in-field radiation dose was 107 Gy over 10 sessions of irradiation with a dose rate of 2 Gy/min and a field size of 10 × 10 cm². After each radiation fraction, interference with the ICD by the therapy was analyzed by an ICD programmer. The dose distributions of secondary neutrons were estimated by Monte-Carlo simulation.

Results: The frequency of the power-on reset, the most serious soft error where the programmed pacing mode changes temporarily to a safety back-up mode, was 1 per approximately 50 Gy. The total number of soft errors logged in all devices was 29, which was a rate of 1 soft error per approximately 15 Gy. No permanent device malfunctions were detected. The calculated dose of secondary neutrons per 1 Gy proton dose in the phantom was approximately 1.3-8.9 mSv/Gy.

Conclusions: With the present experimental settings, the probability was approximately 1 power-on reset per 50 Gy, which was below the dose level (60-80 Gy) generally used in proton radiotherapy. Further quantitative analysis in various settings is needed to establish guidelines regarding proton radiotherapy for cancer patients with ICDs.

Keywords: Proton radiotherapy, Secondary neutrons, Implantable cardioverter defibrillator, Soft error, Monte-Carlo simulation

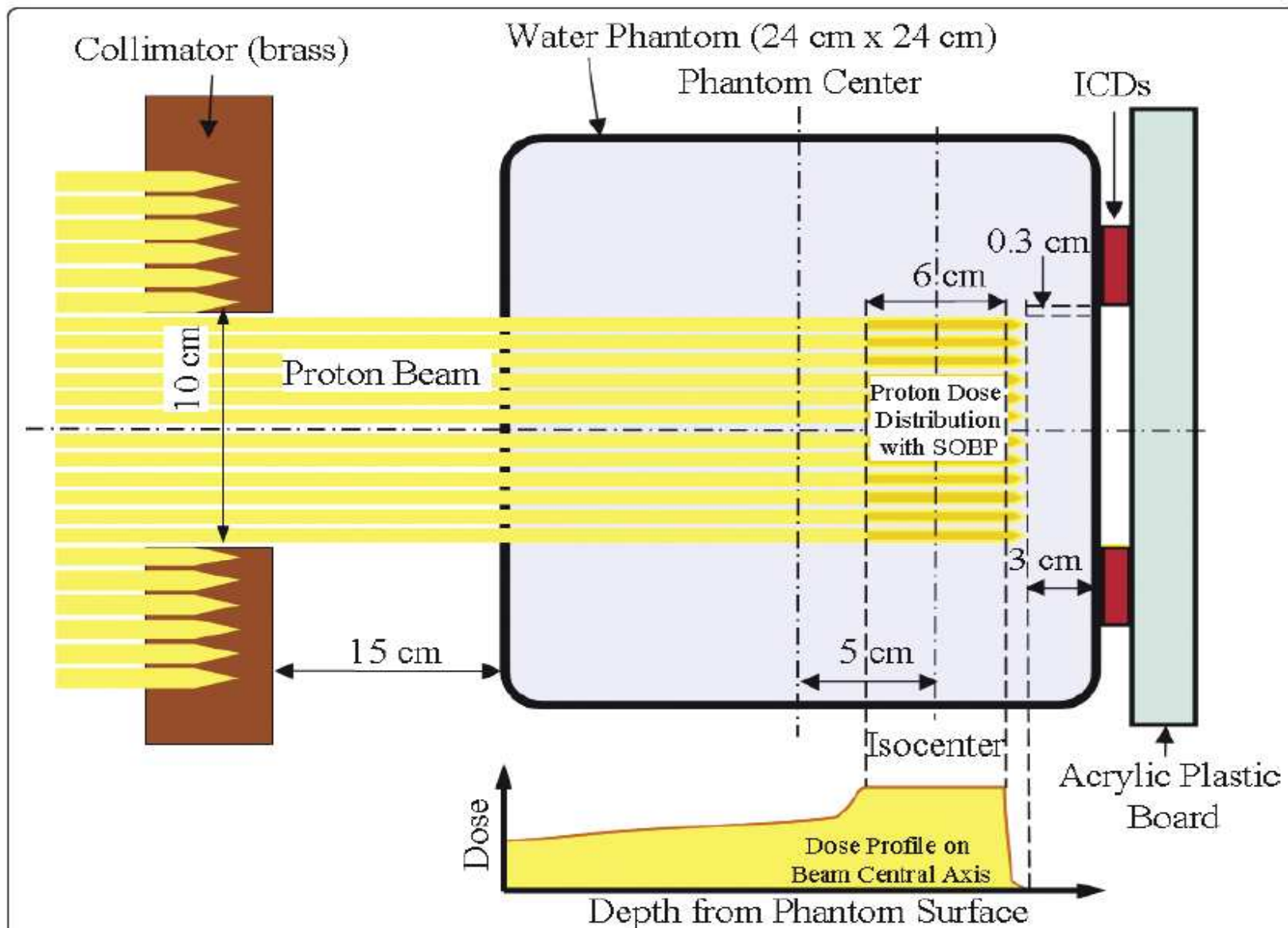


Figure 2 View of the experimental set-up of proton irradiation to the phantom with implantable cardioverter defibrillators (ICDs) on the central axis of the proton beam. Four ICDs were placed on the contralateral side of the phantom. Proton beams entered the water phantom laterally, and an acrylic plastic board was set behind the ICDs to provide backscatter conditions. Calculated spread-out Bragg peak (SOBP) curves in water and experimental values are included.

Pacemaker/implantable cardioverter–defibrillator dose in balloon high-dose-rate brachytherapy for breast cancer treatment

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ABSTRACT

PURPOSE: To retrospectively report pacemaker (PM)/implantable cardioverter–defibrillator (ICD) dose in balloon high-dose-rate (HDR) brachytherapy and provide distance–dose graph and table to approximately estimate the maximal device dose.

METHODS AND MATERIALS: For 3 patients (A, B, and C), PM/ICD was retrospectively contoured on planning computed tomography images and its maximal dose was extracted from a dose–volume histogram. The surface of 1 cm expansion from balloon was prescribed to 34 Gy and the inverse square law was dominant factor in dose calculation. Therefore, the maximal PM/ICD dose was approximately estimated from the distance–dose graph or table and compared with that of the treatment plan.

RESULTS: The minimal device–balloon surface distance was 10.9, 18.4, and 4.3 cm for patient A, B, and C, respectively. The maximal dose estimated from the proposed table/graph was 2.1 vs. 1.61 Gy for patient A, 0.87 vs. 0.49 Gy for patient B, and 8.9 vs. 9.14 Gy for patient C compared with that from the treatment plan.

CONCLUSIONS: Depending on the location of PM/ICD relative to the tumor bed, balloon HDR brachytherapy is feasible if the maximal dose is less than or equal to the dose limit. The proposed distance–dose graph and/or table enable to approximately predict the maximal device dose based on the measurement of minimal distance between lumpectomy and the device before balloon implantation for the suitability of balloon HDR brachytherapy. © 2012 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords:

Pacemaker; Defibrillator; Balloon HDR brachytherapy; MammoSite; Contura; Breast cancer

Table V.1. Estimated maximal dose (D_d)* to the device for typical distances from a spherical applicator's surface. (Table reproduced from [Ref. ##](#))

Balloon Vol. (cc)	35	50	70	90	110	125
Balloon Diam. (cm)	4.06	4.58	5.12	5.56	5.94	6.20
1 Gy	15.6	16.9	18.2	19.3	20.2	20.8
2 Gy	10.5	11.3	12.1	12.8	13.4	13.8
3 Gy	8.2	8.8	9.4	10.0	10.4	10.7
4 Gy	6.8	7.3	7.8	8.2	8.6	8.9
5 Gy	5.9	6.3	6.7	7.1	7.4	7.6

*Estimated dose to the device at distance, d from a spherical applicator is given by:

$$D_d = D_P \cdot \left(\frac{R_{balloon} + 1}{R_{balloon} + d} \right)^2$$

where D_P is 340 cGy at 1 cm from applicator surface and $R_{balloon}$ is the balloon radius. [##](#)

TG203
RECOMMENDATIONS

Recommended Dose Limits

The factors that are weighted in the proposed recommendation:

- CIED type and model.
- Cumulative dose, which might lead to permanent failures.
- Patient's pacing dependency.
- Dose rate, which might lead to mostly transient oversensing effects or reset type events.
- Neutron dose or high-LET radiation dose, which might cause SEUs.

Device Risk Levels

- LOW: < 2 Gy
- MEDIUM: 2-5 Gy
- HIGH: > 5 Gy

Device Risk Levels

If possible avoid:

- 1) photon $E > 10$ MV,
- 2) proton beams and
- 3) neutron beams

OTHERWISE

- HIGH: Secondary neutrons

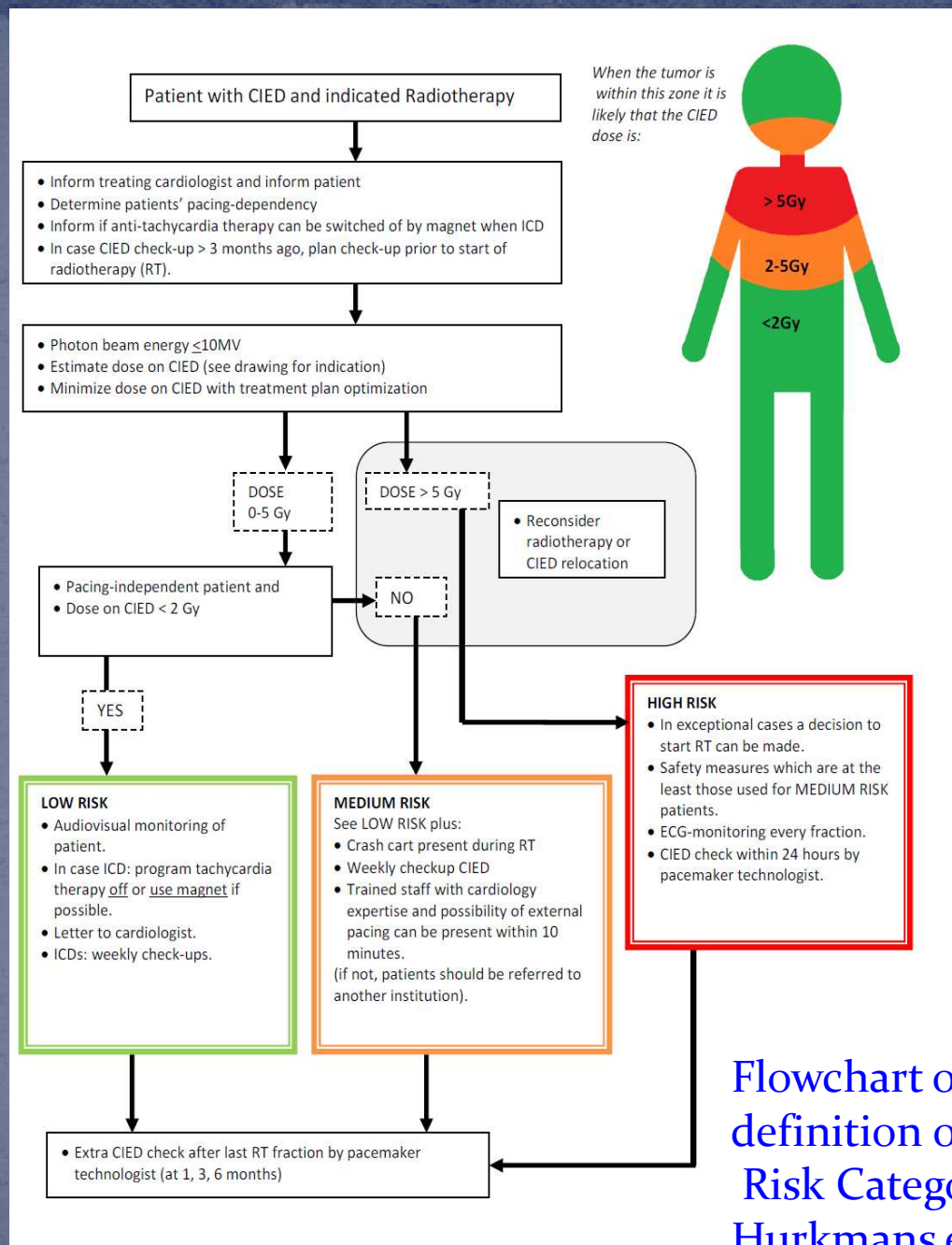
Pacing-Dependency

Patients with an inadequate or absent intrinsic heart rhythm, which turn symptomatic in case of a (sudden) failure of the CIED's pacing function. Symptoms can vary, but may include acute syncope, heart failure, arrhythmia, possibly leading the death. The incidence of pacing dependency is dependent on the definition and patient population, around 10%. Also patients with an ICD can be pacing-dependent. For patients with an ICP, pacemaker dependency can be categorized into three classes.

Class 1: Patients who display bradycardia-related symptoms that may result in an emergent situation or who have a history of these symptoms in the absence of device pacing (highly dependent). Class 2: Patients who are asymptomatic even with an intrinsic ventricular rate of less than 30 beats per minute (intermediately dependent). Class 3: Patients with an intrinsic ventricular rate in excess of 30 beats per minute and who have never experienced an emergent situation related to bradycardia (non-dependent). In clinical practice, it is already difficult to distinguish between class 1 and class 2&3.

Patient Risk Categories

Patient	Risk Category (Dose Region)		
	< 2 Gy	2-5 Gy	> 5 Gy
Pacing-independent	Low Risk	Medium Risk	High Risk
Pacing-dependent	Medium Risk	Medium Risk	High Risk



Flowchart or recommended guidelines, definition of patient Risk Categories (adapted and modified from Hurkmans et al. (2012))

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 6X photons used for treatment
 - Estimate dose/fraction
 - Verify proximity of treatment fields to device.
 - If edge of treatment area > 10 cm, then no further action necessary.
 - If edge of treatment area < 10 cm, then continue with checklist.
 - Add note to patient's chart to page to place in-vivo dosimeter prior to fraction #1
 - Verify/adjust imaging fields do not irradiate device.
 - If device is in imaging field, use kV imaging where possible.
 - If fields adjusted, add note in chart to indicate appropriate field size for imaging.
- **First day of treatment**
 - Place in-vivo dosimeter on CIED at closest approach to treatment field edge.
 - Verify imaging field does not irradiate CIED
 - Read dosimeter and generate summary of reading for physician.

	Low Risk (<2 Gy)	Medium Risk (2-5 Gy)	High Risk (>5 Gy)
Department	<p>-- resuscitation protocol</p> <p>--good consultancy agreement with cardiology / electrophysiology dept.</p>	<p>Low-Risk requirements</p> <p>+</p> <p>--Crash cart including ECG monitor and defibrillator (or AED) available at treatment unit.</p> <p>-- external pacemaker available.</p>	<p>Medium-Risk requirements</p> <p>+</p> <p>--ECG monitoring at every fraction.</p>
Staff	<p>--Radiation oncologist and clinical physicist available with sufficient knowledge in the management of patients with a CIED.</p> <p>- -Radiation therapy technologists should receive training so they can manage complications experienced by the CIED patient having radiation treatment.</p>	<p>Low Risk requirements</p> <p>+</p> <p>--cardiologist/CIED technologist should be available within 10 minutes, if needed.</p> <p>-- CIED technologist to check device weekly.</p>	<p>Medium Risk requirements</p> <p>+</p> <p>--trained staff examines ECG</p> <p>- -CIED technologist to check device before and after every fraction.</p>

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THANK YOU