

Clinical Concerns and Strategies in Radiation Oncology

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1. Introduction

The Chapter was constructed to offer the recommended tactics of clinical practice in radiation oncology, since pacemaker patients generally maintain their implanted pacemaker throughout their cancer treatment. Recent improvements to the functionality and stability of implantable pacemakers involve changes for greater battery power consumption efficiency as well as radiation hardened electrical circuits. Manufacturers have also pursued MRI-compatibility for these devices with some success. While such newer models of pacemakers are similar in construction to previously marketed devices, even for the recent MRI-compatible designs currently in clinical trials, there is increased interest now with regard to radiation therapy dose effects when a device is near or directly in the field of radiation. This manuscript provides the radiation safety precautions clinically incorporated for the management of patients having implantable pacemakers with a required need for radiation therapy. It provides guidance and current recommendations for the cardiac physician, radiation oncologist and medical physicist prior to and during radiation delivery.

The Chapter first details extensively the concepts of CT imaging, computerized treatment planning, and dose aim analysis with mock treatments. The later sections deal with current research observations from investigators concerned with the consequences of using different modalities of treatment and imaging for a patient having a pacemaker implanted. These sections include novel research on electronic device instability induced by x-rays, neutrons, and proton beams as well as radiation from radioactive material. The recent advancement of technology for magnetic resonance imaging and its limitations are also provided. This Chapter should provide a sound basis for comprehension of the complex nature of dealing with a patient having a pacemaker, while requiring continual treatment for cancer care after their implant. It is also a significant educational source for the detailed research on device interactions presented.

2. Radiation oncology methods

It is not a common occurrence for radiation oncologists to be referred a patient having a cardiac pacemaker implanted. At a clinic operating up to 60 patients per day with two radiation oncologists, only two patients may be referred to them for consultation in any

calendar year. However, when faced with the dilemma of how to treat such a patient, the radiation oncologist often finds one of their greatest challenges. Not only do they have to determine the best chances of survival for the patient given their type of disease, classification, staging, and current physiological status, but they also have to be aware of the possible harm to the stationary pacemaker when the prescribed amount of radiation is directed at the patient. Treatments most commonly performed for cancer patients involve radiation originating from external beam particle accelerators. Many of these machines are capable of emitting x-ray radiation in the clinical energy range of 6-18 MV and at dose-rates¹ of 6 Gy/min. Figure 1 shows a commonly used particle accelerator found in a Radiation Oncology Department.

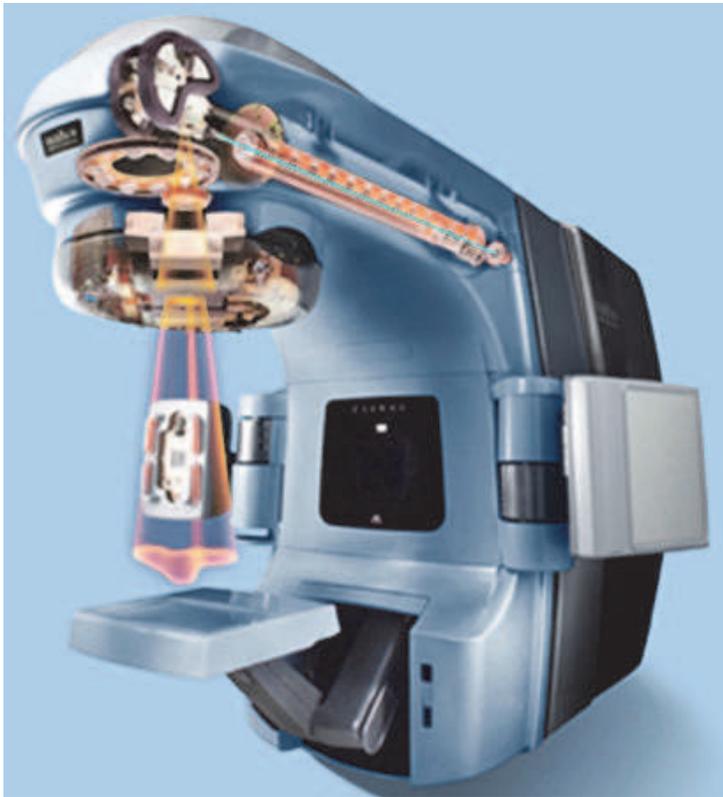


Fig. 1. Varian Medical Systems (Palo Alto, CA) Clinac® model Trilogy particle accelerator [Varian Medical Systems, Inc. - All rights reserved]

¹ The gray (Gy) is the International System of Units standard unit for absorbed dose, defined as the absorption of 1 Joule of ionizing radiation by 1 kilogram of matter (i.e. human tissue or water). It is equivalent to 100 cGy or 100 rads.

The radiation oncology community practice guidelines used when dealing with radiation safety issues for patients that have a pacemaker implanted are those published by the American Association of Physicists in Medicine (AAPM) through Task Group-45 (Marbach et al., 1994). Now seventeen years later, much of the electronics in pacemakers have been reengineered. Therefore, designs and mechanisms addressed in that literature are now outdated. While the newly formed AAPM Task Group-203² is actively researching to update and recreate a new guidance document, pacing specialists, radiation oncologists and medical physicists struggle to determine standards to these issues clinically. Even the effect of simple computerized tomography (CT) scanning on pacemakers is not well defined (Solan et al., 2004).

Nearly all radiation oncology treatments are performed in the accompaniment of a CT scan of the patient's anatomy. This is something that most cancer centers have within their department. Although the CT scan is not intended to diagnose the patient, the three-dimensional data may be utilized within planning computers to simulate the intended delivery of dose to the patient before they are actually treated with radiation. Such computers, referred to as treatment planning systems, contain radiation data measured by the medical physicist from the particle accelerator. By applying the radiation measurements at the various depths in water, and for the various beam aperture sizes that can be used, one may be able to visualize the distribution of dose overlay on the patient's CT scan. It is this preliminary dosimetric simulation that the radiation oncologist uses to determine the intended plan for treating the targeted cancer. The ability to predict the consequential dose distribution is important to assist in the predetermination of excessive doses to pacemakers as well.

There are two important issues concerning pacemakers in radiation oncology. First, does the treatment planning system model the dose to the pacemaker accurately? In general, incident radiation has three possible directional pathways to travel when directed at an object. It can pass directly through the device with some blocking affects (attenuation), it can bounce backward (back-scattering), or it can ricochet outward (side-scattering) from it. Research has proven that treatment planning systems underestimate all three of these interactions for metallic structures. Under the most standard geometry, the amount of radiation blocked by the pacemaker and scattered from it were determined to be less when calculated by computer then when measured with ionization detectors.

Specifically, for a selection of pacemaker generators investigated over a span of 2 years identically from Medtronic (Gossman, et al., 2010, 2011) (Adapta model ADDR01, Versa model VEDR01, Sensia model SEDR01, and Enpulse2 model E2DR01) as well as those from Boston Scientific (Gossman, 2011) (Altrua 60 EL model S606 and Altrua 60 model S603) attenuation results varied between computer and measurement up to a maximum disagreement of 5.3%. Actual measurements revealed attenuation ranges for all devices to be significant with respect to normal tissue at -6.4% to -15.9% at 6 MV and -5.2% to -9.4% at 18 MV respectively. Back-scattering and side-scattering were of the least consequence of the three. Back-scattering results were shown to range from 0.0-2.8% at 6 MV and 0.0-3.4% at 18 MV, whereas side-scattering ranged from 0.0-2.5% at 6 MV and 0.0-5.7% at 18 MV.

Electrode leads exhibit similar affects in altering the distribution of dose used therapeutically, although at less drastic levels. In these studies, marginally significant attenuation dose changes were observed only for electrode leads and connector ports, at less

² This author is a member of the American Association of Physicists in Medicine (AAPM) Task Group-203 on the Management of Radiotherapy Patients with Implanted Cardiac Pacemakers and Defibrillators.

than 3.1% for Boston Scientific (Gossman, 2011) devices (LD CV Acuity Spiral Up lead model 4593, Fineline II Sterox EZ lead model 4469, and Fineline II Sterox lead model 4457) and 3.8% for a Medtronic (Gossman et al., 2010, 2011) lead (Single wire lead model 5076-85CM) similarly. Scattering was determined to be negligible for either set of leads.

As a result of those publications, medical physicists have noted that the viability of computer modeling is heavily dependent upon the mathematical algorithms used. Still, the measured results forecast a concern as to the accuracy of computer approximations when electronics are included within the calculation matrix. This is true even when the pacemaker is not directly irradiated. Dose calculations compute dose throughout the anatomy of the patient regardless of whether or not the beam path projects through it. This leaves the radiation oncologist with no alternative recourse than to rely heavily on the medical physicist to best approximate treatment planning system results, while understanding from this published research that dosimetric results may be underestimated.

To enable treatment modeling on computer, the patient must first undergo a CT scan. These image data provide anatomical information specific to the patient in three dimensions. The CT is instrumental to be able to plan for the angle and size of the radiation beam prior to delivering radiation. Irradiation for imaging in this modality can result in pacemaker oversensing, although these effects are predominantly transient (McCollough et al., 2007; Yamaji et al., 2006). As explained in one group, benign problems are discovered when either there is a trigger for non-physiologic tracking that results in inappropriate rapid-paced ventricular rates, or perhaps when extra senses simulate an atrial arrhythmia that inducing a false detection and delivery of an unnecessary atrial antitachycardia pacing therapy. However, oversensing did cause inhibition of pacing in some tests. This delay is important if the heart resorts back to the same problematic functionality, putting them at risk for asystole. The researchers proved that dynamic CT scanning without table movement should not be employed. They further demonstrated that it is appropriate to consider situations in the future with other imaging modalities, in review of possible effects that may produce clinically important risks (White, 2008).

The material of the pacemaker can cause imaging limitations for the radiation oncologist using CT scans as well. Research has shown that the digitally reconstructed radiograph of a patient having a pacemaker implanted often contains artifacts which could lead to errant computer calculations if not corrected properly by a qualified medical physicist (Gossman 2010, 2011a, 2011b). These artifacts show up as non-uniform lines that obscure normal tissue anatomy. Closer analysis of these artifacts lead to marked observations that the Hounsfield units (HU) assigned by the convoluted reconstructor of the CT scanner at locations not containing the pacemaker actually have metallic values of upwards of 3000-8000 HU. At physical locations where no metallic pacemaker is present, normal tissues values in its immediate vicinity typically registers values more near to 0-250 HU. As these values are directly related to the density of the material, it is not appropriate to scan such a patient using the “normal HU range” which extends from -1000 HU (air) to 0 HU (water) and upward to +1000 HU (dense bone: 900 mg/cm³). Rather, it is recommended to use the “extended HU range” (Coolens & Childs, 2003) to account for these very high density metals. Incorrect HU scaling for locations around the pacemaker will happen no matter what. These must be corrected in the treatment planning process. Medical physicists refer to this process as contouring with Boolean operation. Planning system software used should have the capability of permitting manual reassignment of HU values as a solution. An example of this correction is shown in Figure 2.

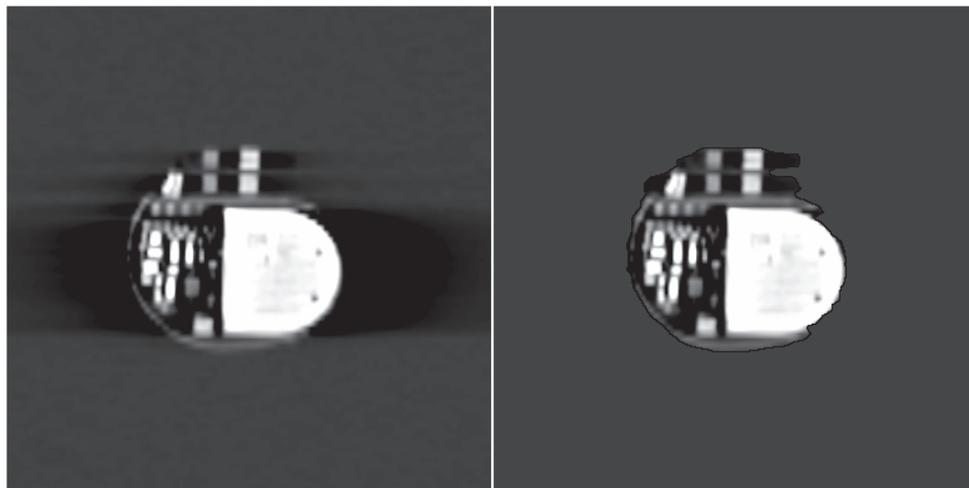


Fig. 2. General Electric (Fairfield, CT) CT scanner model LightSpeed RT® digital reconstructed radiograph in the coronal plane detailing a Medtronic ICP Adapta® model ADDR01 in water; (Left) with unavoidable artifact distortion and (Right) following appropriate manual Hounsfield unit correction

Treatment planning system dose calculations should also be conducted with care. Only the best algorithms should be employed to handle dose distributions around pacemakers and any other high density device (Gossman et al., 2009), such as electrode leads for that matter.

While some calculation algorithms provide only results assuming the entire patient is comprised of water density, this is not true for a real patient. Instead, the algorithm chosen by the medical physicist should be one which performs results with heterogeneity density correction throughout the entirety of the patient's anatomy. In this manner, as radiation passes through the body and hits the pacemaker, a more accurate depiction of dose will result from the computer having calculated consequential scattering and attenuation from it. Likewise, a more accurate dose will result when radiation passes through local organs which have their own unique density. As an aid to the radiation oncologist, where both algorithm tools are available, the medical physicist should provide results with the pacemaker's density computed as metal, and with it assigned as water as a second plan (Reft et al, 2003). Then, the differences between the two plans can illustrate for the radiation oncologist observable consequence of having the pacemaker in the calculated dose region. The treatment plan modeling described is exhibited in Figure 3.

The second issue concerning the irradiation of pacemakers in radiation oncology are the consequential malfunctions and damage that a device might incur if irradiated. In clinical practice pacemakers should be placed outside of the unshielded beam as recommended by the AAPM³ (1). It should be well understood that even though a radiation therapy beam aperture can be adjusted in shape to not aim radiation directly at the pacemaker, radiation

³ The AAPM is a scientific and medical organization with society membership affiliation to the American Institute of Physics. Publications include the scientific "Medical Physics Journal", technical reports, and symposium proceedings.

will also penetrate the shielding of the head of the particle accelerator that shapes the beam (transmission), resulting in imperceptible and possibly significant dose to the pacemaker.

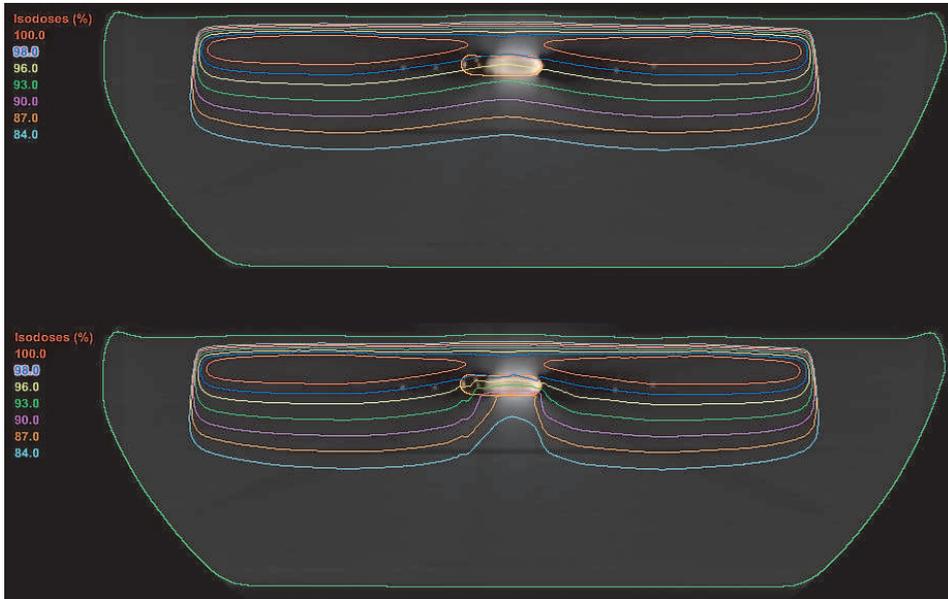


Fig. 3. Treatment plan dose distributions in the axial plane at 6 MV x-rays involving the Boston Scientific ICP Altrua® 60 EL model S606 in water; (Top) with no density correction and (Bottom) following appropriate heterogeneity correction

Some radiation will also scatter from the patient to the pacemaker as back-scatter and side-scatter. Under geometrical conditions where the pacemaker is out of the direct radiation beam although near a field edge, which is defined within the beam profile where the intensity falls-off laterally, as much as 80% of the intended dose to the target structure can be given. Even if the directed beam is adjusted to just barely keep the pacemaker out of the field, it can very easily absorb a significant amount of dose prescribed to a tumor that is not intended for the generator. The variation of dose across the irradiated field is shown in Figure 4. Inspecting the dose profile shape, one will notice that the relative dose within the beam is very symmetric in shape and flat. A closer inspection reveals that between the 80% and 20% relative dose, the intensity decreases dramatically away from the center of the radiation beam. This distal off-axis region on each side of the scan axis is called the penumbra. This is considered to be out of the ideal treatment intensity, since therapeutic dose is not well controlled in this region. Still further away from the penumbra, the dose continues to be present, although continually diminishing. This area constitutes the scattering of radiation outward, which resembles the aperture transmission as well as the scatter caused by the patient or phantom media. The plot provided is the definitive proof that a pacemaker can get a significant dose, even if it is not placed directly within the field intended to target the tumor. By definition, penumbral doses of up to 80% can be registered, while scattering doses can range of up to 20% as shown. Depending on how close the beam is to the pacemaker, there can be significant escalations in the absorbed dose to it.

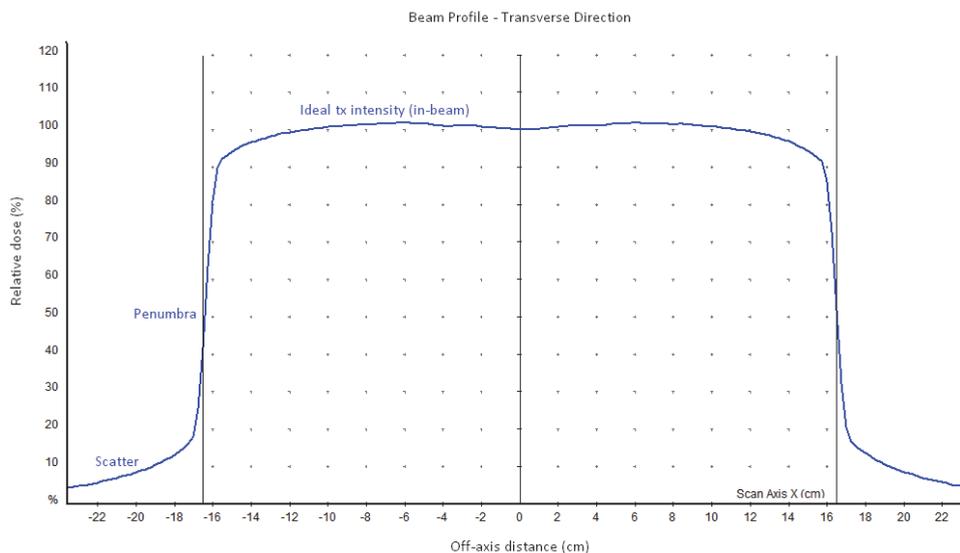


Fig. 4. Beam profile for a square aperture in water from 6 MV x-rays of the particle accelerator

With these facts, the medical physicist needs to pay close attention to the dose given to the pacemaker over the entire course of treatment.

As an example, let's consider an early stage non-small cell lung cancer prescribed to receive a low dose boost of 20 Gy over 10 fractional days of treatment. If we assume the pacemaker can only tolerate 2 Gy of radiation from the particle accelerator in accordance with the current guidelines of the AAPM (Marbach et al., 1994) and assume a single beam is assigned with a profile represented in Figure 4 with a plan for treatment such that the pacemaker is 2.0 cm away from the field, then theoretically we would see a scattered relative dose of nearly 11% possibly being absorbed by it. Each fractional dose prescribed to the tumor is scheduled to receive 2 Gy. Although 11% of this dose is small at only 0.22 Gy, the total dose after all 10 fractions yields a pacemaker total dose of 2.2 Gy. This is beyond the specified limit of 2 Gy. Therefore, the medical physicist will need to incorporate more beams with various oblique angles to avoid contribution of dose to the pacemaker.

A second example details the concern for an implantable cardioverter-defibrillator (ICD) similarly placed too close to the field as presented in Figure 5. It illustrates what is often experienced with pacemakers in this treatment planning process, similar to an ICP. Three beams are oriented at different angles to target a tumor in the example patient's right lung. The first beam is directed anterior at 180°. The second beam is directed to the tumor at a left anterior oblique angle of 250°. Then, the third beam is angled with a left posterior oblique angle of 310°. At 180° the AP beam passes through the generator. At 250° the LAO beam is directed such that the device is within the penumbra region of the beam. At 250° in this example, the LPO resulting geometry leaves the generator out of the field of radiation in the scatter region only. The beams-eye-view of each radiation field is shown in Figure 6 with the tumor and generator contoured for illustration. The proximity of the generator to the beam aperture is well observed in each example. Figure 7 provides the dosimetric results for the mock treatment in terms of a dose-volume histogram. Each scenario is analyzed in Table 1.

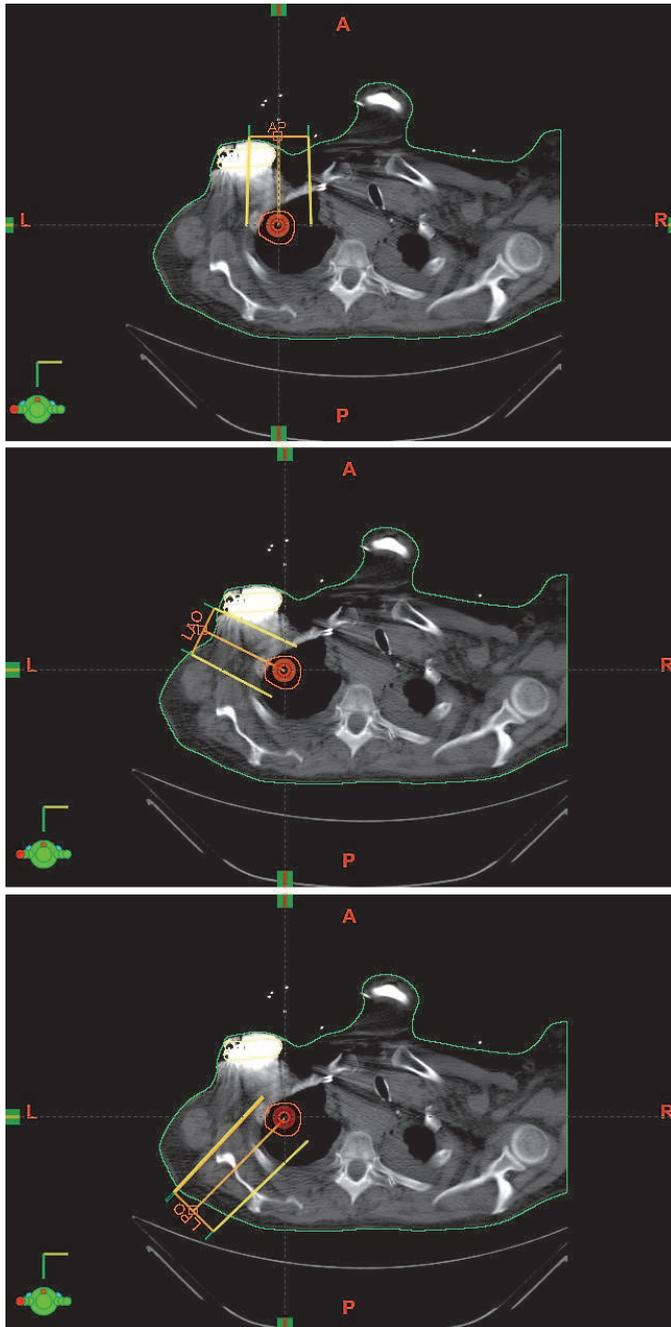


Fig. 5. Mock treatment projected beam paths in the axial view for a patient having the St. Jude Medical (St. Paul, MN) ICD Atlas® model V-242 implanted

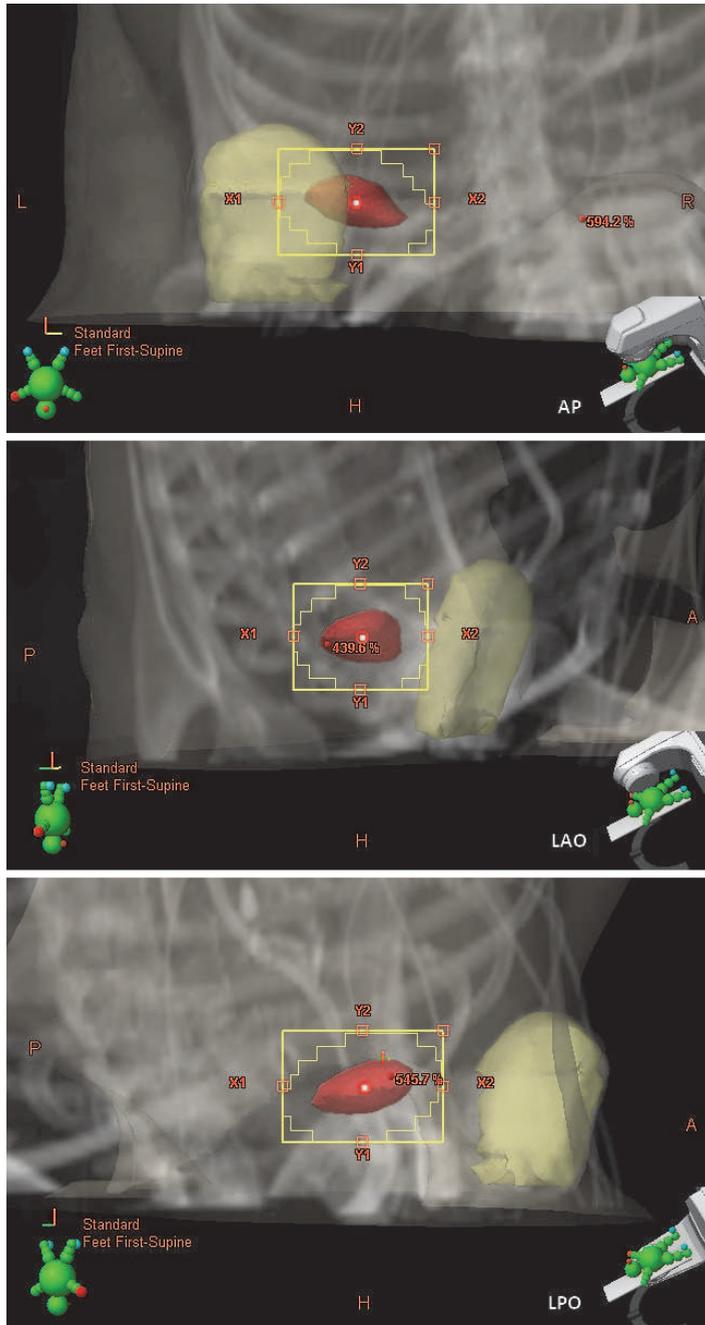


Fig. 6. Mock treatment beams-eye-views for a patient having the St. Jude Medical (St. Paul, MN) ICD Atlas® model V-242 implanted

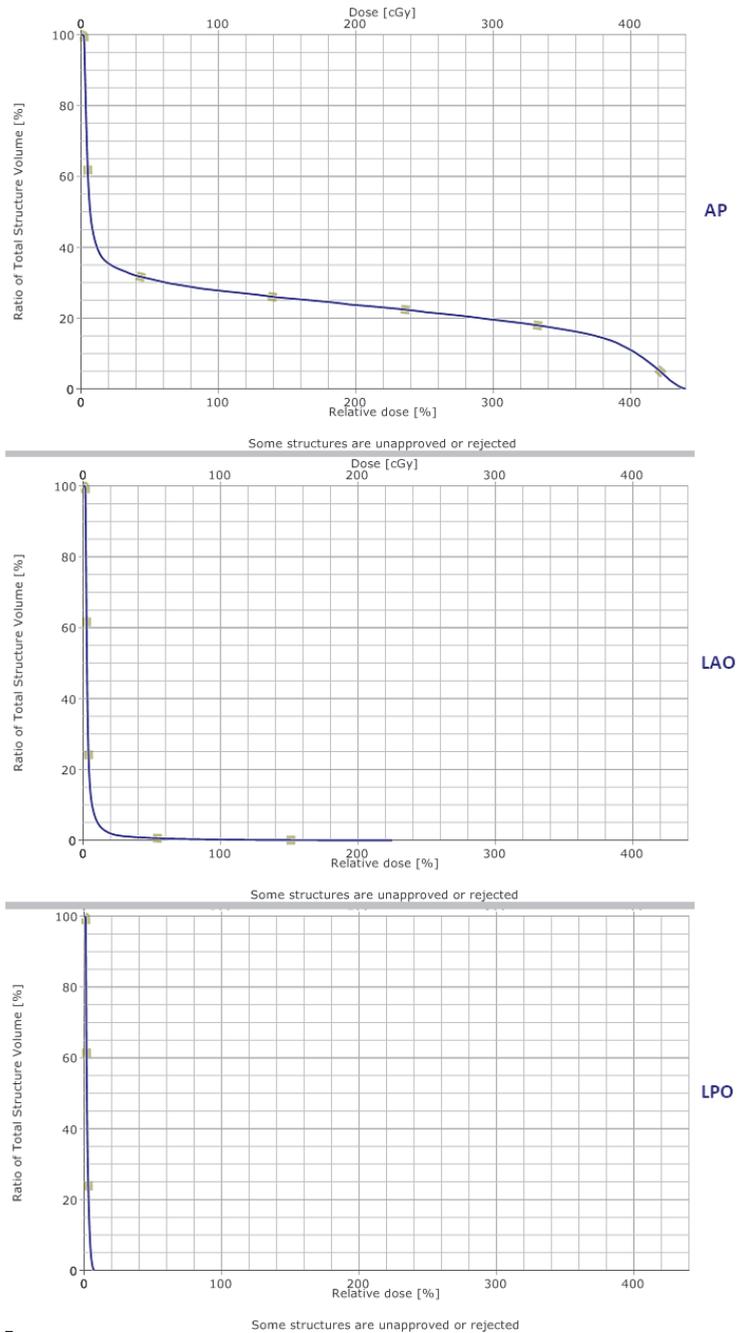


Fig. 7. Mock treatment dose-volume histogram resulting dose to the pacemaker for a patient having the St. Jude Medical (St. Paul, MN) ICD Atlas® model V-242 implanted

Beam Direction	Percentage ICD Volume	Percentage Dose Received	Maximum Percentage Dose on Entire Volume
AP	90%	3%	
	50%	7%	
	30%	60%	
	10%	405%	443%
LAO	90%	2%	
	50%	3%	
	30%	4%	
	10%	6%	225%
LPO	90%	1%	
	50%	2%	
	30%	3%	
	10%	4%	8%

Table 1. Dose-volume histogram results for the mock treatment detailing absorbed dose to the ICD from radiation

Looking at the maximum percentage dose absorbed by the generator for the example of a patient scheduled for 2 Gy in 10 fractions with an overall dose of 20 Gy, only the LPO beam yielded satisfactory results of dose to the generator, as it was in the scatter region outside of the direct radiation field and the penumbra. At a maximum dose of 8% of that 20 Gy prescription, the resulting dose to the electronics of the device is 1.6 Gy. This is the only beam arrangement that satisfies the 2 Gy recommendation. The medical physicist could benefit from the application of a variety of different beams at different angles. Using this approach, the dose absorbed to the device will be spread out over the entire surface rather than one directed device volume, resulting in less maximum percentage dose.

This is the definitive dilemma for the medical physicist and radiation oncologist. Some diseases may be best suited for a simple 2-field technique. An anterior-posterior opposed field technique is the likely tactic approached for a small lung tumor medially located. In this example with a patient lying supine on the treatment couch, an anterior-to-posterior beam aimed from the patient's chest to their back, and a posterior-to-anterior beam aimed through their back up through their chest may only be assigned. With the pacemaker having been implanted in the anterior chest wall of the patient, it then resides not only in the field of the entering anterior beam, but also in the field of the posterior field about to exit upward through the chest. These APPA beams are likely of little use now given the radiation tolerance limitations of the pacemaker as shown in the example.

Instead, oblique angles should be considered (Riley et al., 2004) as shown. The radiation oncologist will now have to concentrate their awareness of the limitations of dose to the pacemaker as well as the elevated doses that will now be incurred by all these other organs resultantly (Gullane, 1991), while insuring the pacemaker is considerably away from the radiation field edge.

The practice of irradiating pacemakers beyond levels recommended by society-based entities and manufacturers is discouraged. Many researchers have sought out to investigate the consequences of extensive irradiation to pacemakers in order to test their susceptibility to induced operation changes that is unwanted. For such testing, researchers often place the devices directly in the path of the beam. However, the approach is safely conducted when the generator is implanted into a phantom environment, thus removing concerns for patient radiation safety as well as needs for clinical trials. Further, with devices tested directly in the path of the beam, the total time for irradiation is much less than if it were placed out of the field, to arrive at the same cumulative dose for testing. Numerous issues were discovered by researchers. These will now be summarized here.

3. X-ray radiation

A large pacemaker study was performed (Mouton et al., 2002) incorporating a batch of 96 used pacemakers to test the influence of radiotherapy and the electromagnetic field. Several dose-rates (from 0.05 to 8 Gy/min) were used to yield pacemaker cumulative doses ranging from 6.2 Gy to 120 Gy. According to this group, approximately 15% of the irradiated pacemakers showed an important failure under 5 Gy. Below 2 Gy, the results indicated failure occurrences to drop by 9% although still present. There maintained the observance of important defects noted at cumulative doses of merely 0.15 Gy.

Later, a smaller study (Hurkmans et al., 2005) was initiated involving 19 new pacemakers having radiation delivered directly to each in fractional increments up to doses of 120 Gy while being monitored. Results for pacing pulse tests included 25% amplitude deviations in 5 devices, a complete loss of signal in 7 devices, and 30-50% pulse duration decreases. Pacing frequency tests revealed inhibitions during irradiation for 8 devices. Sensing thresholds changed more than 25% for 2 devices with no recovery. Telemetry capability was lost entirely for 3 devices. Battery problems were exhibited in 5 devices. Lead impedance changes were seen in nearly all devices. Finally, although 5 devices did not show any error, 7 lost output completely. With the exception of one device, which showed its point of failure at 20 Gy, all other devices could withstand a dose of 90 Gy or more before it reached a point of failure.

Devices differ in their susceptibility to radiation interference and damage (Yerra & Reddy, 2007). The effect on the device is cumulative, depending on the total dose to the device. There was no safe threshold observed in either study, validating the concerns of the AAPM (Marbach et al., 1994).

4. Electromagnetic interference

Forty-five irradiated patients implanted with a heart rhythm device was prospectively investigated in an 8 years span (Ferrara, 2010) to identify any relationship between the various types of devices with the electric and magnetic fields produced near the linear accelerator. An analysis of radiation damage to pacemakers, depending on the geometric and dosimetric characteristics of the radiation beams was carried out. There were no discovered problems with the devices due to the interaction with the electromagnetic fields. Acute (3 cases) and late (2 cases) cardiac events were observed only in 5 patients who underwent treatment, but with no dysfunction observed in any pacemaker for electromagnetic interference (EMI).

5. Neutron radiation

Neutrons are created in interactions involving high energy x-rays or high energy protons. Most proton beams can produce a knock-out neutron. However, neutrons can only be produced by x-ray beams operating above 8.04 MV. The flux of thermal neutrons created by an 18 MV x-ray beam of a radiotherapy linear accelerator has been observed to have caused a high rate of soft errors in integrated circuits that contain ^{10}B compounds (Wilkinson et al., 2005). These memory-loss effects can be removed entirely if 6 MV x-rays are used alternatively.

6. Proton radiation

Investigations on proton beam radiation therapy with implanted cardiac pacemaker function have been studied in at least one group (Oshiro et al., 2008). After a phantom study confirmed the safety of proton therapy in patients with cardiac pacemakers, 8 patients were treated using proton therapy to a total tumor dose of 33-77 Gy in dose fractions of 2.2-6.6 Gy. 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 proton therapy. The phantom study could not distinguish between proton dose and neutron scatter dose contributions on pacemaker generators. However, device functionality observances were well documented. In the study, changes in heart rate occurred in 2 patients. Proton therapy can result in pacemaker malfunctions that manifest as changes in pulse rate and pulse patterns. Minor malfunctions of implanted cardiac pacemakers occurred in 25% of patients receiving relatively high dose-rate proton therapy. Therefore, it was recommended that patients with cardiac pacemakers should be monitored by means of electrocardiogram during proton therapy.

7. Brachytherapy

Limited research can be found with regard to radiation induced effects on pacemakers from sealed source radioactive material. This is mainly due to the large variety of types and energies of radiation that is emitted by all the different radionuclides available. Heavier emissions, such as alpha particles, beta particles and electrons each have mass. Therefore, they have no ability to penetrate the metal casing of the pacemaker. However, gamma radiation may pass through the device entirely, depending on the energy of the photon being considered. Some brachytherapy sources emit kilovoltage photons, whereas others emit megavoltage energies. In general for electronics, the greater the mass and energy of the incident radiation, the greater the likelihood for it to interact with metallic components that affect pacemaker functionality.

The limited research involving brachytherapy sources are also due to their intensity of emission. The radioactivity of a source is dependent on the stability of the atom and the quantity of emissions per unit time increment when it decays. Most radiation oncology sources have relatively low activity concentrations. Consequently, radioactive material for human use generally does not deliver as high a dose-rate as a particle accelerator. Still, one such investigation was found (Abner et al., 2002). Intravascular brachytherapy has been used for more than 10 years to treat restenosis within the heart. The doses imparted

to a pacemaker from intraluminal brachytherapy sources was calculated to be less than 0.01 Gy for ^{89}Sr as compared to 0.74 Gy for ^{192}Ir , maximally. Both were deemed non-consequential by the investigators, since no patient induced side effects were noted in the clinical study.

8. Magnetic resonance imaging

The presence of a cardiac pacemaker had been a strict FDA (Ahmed & Shellock, 2001; U.S. FDA, 1988) contraindication for patients undergoing a magnetic resonance imaging (MRI) procedure for pacemaker dependent patients since 2000. According to estimates, 50-75 percent of patients worldwide with implanted cardiac devices are expected to need an MRI scan during the lifetime of their devices (Kalin & Stanton, 2005). Consequences with the use of non-FDA approved devices as determined in computer modeling, in vitro testing, animal in vivo studies and clinical trials include a considerable list of concerns (Kalin & Stanton, 2005; Bassen & Mendoza, 2009; Roguin et al, 2004). These include: thermal injury to the myocardium and endocardium from electrode radiofrequency absorption heating of the electrode tip causing thermal tissue damage locally. Other consequences include induced voltage in leads that couple with pacing electrodes to trigger unwanted stimulation or sustained tachycardia, electrical in-operation, conductivity of the pacemaker case, vibration of the device, and a static magnetic field forcing of translation or rotation of the device or lead.

Recently, the U.S. FDA (U.S. FDA, 2011) relaxed their position with the advancement of an MRI compatible pacemaker; the Medtronic model Revo MRI™. The device may only be used with the associated CapSureFix MRI™ SureScan leads that are FDA approved for use in the MRI environment. The pacemaker may only be prescribed for certain patients under specific conditions. This comes after a few years of experience with a similar device outside of the United States. The Medtronic model EnRhythm had been approved since 2009 in Europe and is the first pacing system approved for MRI acquisition anywhere (Kalin & Stanton, 2005).

9. Summary

The following are a summary of the recommendations for medical physicists and radiation oncologists to consider for implantable pacemakers and cardioverter defibrillators when continuing care for a patient having a pacemaker implanted in the treatment planning process.

Recommendations for treatment planning:

- i. Only conduct computed tomography scanning using the commissioned extended Hounsfield unit range when using these scans for computer modeled dose delivery simulation calculations.
- ii. Incorporate known implant device outer dimension information provided by the manufacturer in assisting manual contouring of the device in simulation software.
- iii. Remove all streaking artifacts local to the pacemaker implant device that may cause the resulting calculation to be inaccurate.
- iv. Position reference points for computer prescriptions away from all high density areas.

- v. Use algorithms for calculation that minimally have three dimensional convolution superposition capabilities for most accuracy in determining dose with high density implants.
- vi. Avoid directly aiming radiation through the pacemaker through the pacemaker and provide a considerable margin away from the field edge so that it is away from the penumbra region.
- vii. Facilitate both homogeneous and heterogeneous calculations while comparing the differences observed for a better understanding of the magnitude and direction of profile shifts in the isodose distribution.
- viii. Review published research on treatment planning system inaccuracies involving these devices.

Recommendations for treatment & imaging:

- i. Particulate radiation at low energies, such as those from brachytherapy sealed sources, generally cannot penetrate the casing of a pacemaker and will therefore likely not be of any considerable cause of device malfunction, unless they are adjacent to high dose-rate afterloader devices containing ^{192}Ir at high activity.
- ii. With proven consequences resulting with higher dose-rates for x-ray radiation, the smallest clinical dose-rate should be utilized.
- iii. X-ray radiations at 6 MV energy are preferred over higher energies, since lower nominal x-ray energies and those from radioactive material brachytherapy sources will avoid neutron production and their consequences.
- iv. Proton and neutron radiations have indicated the ability to induce malfunctions in similar to x-rays. Proton irradiation is known to create secondary neutrons, which can interact heavily with devices containing ^{10}B compounds. All such patients should be monitored with an electrocardiogram before and after treatment.
- v. EMI changes have yet to be verified in the research referenced.
- vi. Cumulative dose testing has shown no real absolute threshold for a safe dose to the pacemaker. However, the least dose possible should be considered strongly as the suitable plan for treatment. This is consistent with the ALARA standard; "As low as reasonably achievable."

Finally, consultation with the implanting pacing specialist, radiation oncologist and medical physicist should always be obtained for each patient, aside of the initial preparation for such cases, in an attempt to devise an in-house quality assurance protocol addressing timelines for assessing patient and device status during all imaging and radiation therapy procedures. As a general precaution for situations that arise beyond material presented here, it is strongly recommended that the clinician contact the manufacturer about the specific model in question, while referring to the most recent investigative research and updated formal guidance from the AAPM Task Group-203, which is now pending.

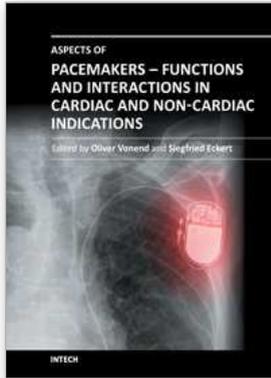
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Aspects of Pacemakers - Functions and Interactions in Cardiac and Non-Cardiac Indications

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Outstanding steps forward were made in the last decades in terms of identification of endogenous pacemakers and the exploration of their controllability. New “artificial” devices were developed and are now able to do much more than solely pacemaking of the heart. In this book different aspects of pacemaker “functions and interactions, in various organ systems were examined. In addition, various areas of application and the potential side effects and complications of the devices were discussed.

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