

Pacemaker/ICD Irradiation Policies in Radiation Oncology.

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Abstract

A review of worldwide data shows that the sensitivity to ionizing radiation of pacemakers/implantable cardioverter defibrillators (ICD) has increased due to the introduction of high-density circuitry. Failures as low as 15 cGy have been reported. A prototype policy for megavoltage use has been developed with a new lower dose limit and a new data collection tool. New policies and interdepartmental discussions between radiation oncology and cardiology need to be fostered. An internet database should be used as a worldwide registry for reporting radiation and EMI interactions with pacemakers so further policy refinements can be made. Meanwhile, further experimental work is necessary by individual centres to acquire magnetic field strength values at accelerator isocentre to compare to pacemaker/ICD specifications.

Introduction

The utility of radiation therapy for the treatment of neoplastic disease combined with the significantly increased number of implanted pacemakers and defibrillators mandates an appreciation of the interaction between radiation and pacemakers concerning patient safety. Pacemaker failure due to ionising radiation has long been a recognised complication in the medical literature. [1, 2, 3]. In recent years implantable cardioverter defibrillators (ICDs) have been introduced which have on board RAM chips as well as other high-density integrated circuit devices. Because of these components, ICDs have greater sensitivity to ionising radiation than that of the ordinary pacemaker. Consequently, present radiation oncology protocols and safety measures for the irradiation of patients with cardiac devices must be updated.

As a prologue to protocol changes, the academic literature was reviewed. Additionally, the latest manufacturer's advice was examined. Based on this overview, we have written a prototype hospital protocol for the management of patients with ICD/pacemakers undergoing radiation therapy treatments. This protocol can be a starting point for discussions between the cardiology and radiation oncology departments at other institutions.

In addition to the effects of ionizing radiation on pacemaker/ICDs, electromagnetic interference from individual accelerators needs to be measured experimentally. With knowledge of the electric and magnetic field strengths at the accelerator's isocentre, the pacemaker/ICD manufacturer's tolerances can be acted upon. A sponsoring institution is needed to develop a voluntary database of pacemaker/ICD experience on the worldwide web. Non-cardiologists wishing a brief introduction to pacemaker/ICD technology should consult our Background Section.

Background

In 1903 Dr. Willem Einthoven of Holland published the details of a practical electrocardiogram that allowed a basic understanding of cardiac electrical conduction. Throughout the first half of the 20th Century, however, little could be done medically for cardiac conduction system disease. This changed with the introduction of artificial electronic pacemakers, and, while at first they were large, unreliable and difficult to implant, their potential to make a significant contribution was quickly appreciated. In 1959, the first fully implantable internal electronic pacemaker was used on a human. The first ICD was described in 1970, but not implanted into a human until 1980. Over the last decades pacemakers

and ICDs have become smaller, more sophisticated, more durable and safer to implant. An estimated 500,000 devices are implanted worldwide annually. Although over sixty companies currently manufacture cardiac pacemakers/ ICDs, Medtronic, Guidant, Biotronik, and St. Jude Medical currently dominate the market in the US.

Permanent pacemakers are indicated for several clinical reasons usually symptomatic bradycardia (slow heart rate) [4]. Once implanted, the pacemaker's battery lasts between two and fifteen years depending on the model and the frequency of use. Some patients are *pacemaker dependent* (i.e., without continuous or nearly continuous pacemaker activation, the patient would suffer life-threatening symptoms). Other patients are *pacemaker independent* meaning that the patient's escape rhythm is enough to sustain an adequate blood pressure.

ICDs are placed in patients with a risk of fatal ventricular arrhythmias. Defibrillators continuously monitor the cardiac rhythm and are often able to differentiate between potentially lethal tachycardias and otherwise benign atrial tachycardias. Using a programmable algorithm, the device uses rapid pacing in an attempt to terminate an arrhythmia or, as a last resort, will deliver a high electrical shock. While pacing is accomplished with minimal energy output (1 to 10 micro Joules) and no patient sensation, defibrillation uses up to 41 Joules, and can be quite painful for a patient who is awake. ICDs that are placed for primary or secondary prevention of cardiac sudden death often go many years without delivering a shock. All modern ICDs have pacemaker backup functions and many patients have combination devices for multiple cardiac issues.

There are several types of pacemakers and defibrillators all of which share common components. A generator (or "can") is a hermetically sealed canister housing the electronics and the battery. From the can, one or more leads are connected to the heart. The generator is usually implanted subcutaneously in the infraclavicular region above the pectoral muscles, although several other locations are used for both cosmetic and technical reasons. In the early years of defibrillator therapy (until about the mid-1990's), it was common for placement to be in the left upper quadrant of the abdomen. There are both endocardial (inside the heart) and epicardial (outside the heart) leads. Endocardial leads are by far the most common and are placed via a transvenous approach without the need for surgery.

The internal circuitry of a pacemaker is obviously complex and starts with DC-DC converters that multiply or divide the battery (usually Lithium) voltage to charge a capacitor. MOSFET devices do switch duty. A sense amplifier that includes gain amplifiers and frequency filters monitors cardiac depolarization to control timing. A telemetry circuit with an internal antenna communicates with an external programmer. This programmer can interrogate the pacemaker and adjust its setting. Also on board the pacemaker are a voltage/current reference circuit and a measurement circuit for battery capacity, lead resistance and analog to digital conversion.

Pacemakers are divided into single chamber (one lead, either into the right atria or ventricle), dual chamber (two leads, usually to the right atria and right ventricle) and biventricular pacemakers. Biventricular pacemakers allow for the simultaneous stimulation of both the left and right ventricles. One lead is placed in the right ventricle and the other from the right atrium and into the coronary sinus, which traverses the lateral wall of the left ventricle. Passive placement of the lead in the coronary sinus allows for stimulation of the left ventricle. Early defibrillators were attached only to large endocardial patches placed during an open chest procedure. Today, defibrillators have single leads placed into the right ventricle. Many manufactures have a variety of pacemakers with optional defibrillator capabilities for patients that require elements of both devices. ICDs have larger batteries and capacitors necessary to deliver higher energy shocks.

Regardless of the type of pacemaker (single or dual chamber), a standard system to describe the programmed characteristics of the device is employed. The four letter code system begins with the letter of the chamber being paced (A=atria, V=ventricle, D=dual or both, O=none), the second letter for the chamber being sensed, the third for the chamber that is inhibited. A fourth optional letter "R" is added if the pacemaker is rate responsive. Responsive pacemakers increase or decrease firing rates

based on a piezoelectric transducer that detects movement from either patient activity or respiration. This allows for a more natural increase in heart rate during the activities of daily living.

Literature Review

An extensive review by Marbach, *et al* [5] in 1994 formed the basis for the American Association of Physicists in Medicine (AAPM) guidelines for pacemaker irradiation. Their specific recommendations are:

- (1) "Pacemaker implanted patients should not be treated with a betatron.
- (2) Pacemakers should not be placed in the direct (unshielded) therapy beam. Some accelerator beams can cause transient malfunction.
- (3) The absorbed dose to be received by the pacemaker should be estimated before treatment. Estimation methods can be found in the literature.
- (4) If the total estimated dose to the pacemaker might exceed 2 Gy, the pacemaker function should be checked before 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 Gy and significant functional changes have been observed between 2 and 10 Gy, early changes in pacemaker parameters could signal a failure in the 2-10 Gy region.
- (5) Although transient malfunction from electromagnetic interference is unlikely from contemporary therapy accelerators and cobalt irradiators, the patient should be closely observed during the first
- (6) treatment with a linear accelerator and during subsequent treatments if magnetron or klystron misfiring (sparkling) occurs.
- (7) 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."

A review by Last in 1997 [6] describes the solid-state damage to pacemakers from ionizing radiation and reviews the literature on observed types of pacemaker failure. Additionally, he comments on electromagnetic interference and develops recommendations on the irradiation of pacemakers:

1. Confer with Cardiology on pacemaker dependence.
2. Assume a 2 Gy cumulative absorbed dose tolerance.
3. Keep, if possible, a 3 cm. margin from the radiation field edge.
4. Consider TLD or diode measurement on day one of radiation therapy.
5. Do low-level cardiac monitoring if < 2 Gy cumulative dose.
6. Do high-level monitoring if > 2 Gy or pacemaker-dependent patient.
7. If cumulative dose > 10 Gy, consider repositioning the pacemaker.

An experimental study by Mouton, *et al* [7] on pacemaker failure was released in 2002. Ninety-six various pacemakers were irradiated in a water phantom to high dose levels by 18 MV x-rays. Failure was observed at a cumulative dose of only 15 cGy for one pacemaker, at ≤ 100 cGy for two pacemakers and at ≤ 200 cGy for nine. A maximum dose rate of only 20 cGy/min is considered "safe". Thus, no pacemaker must ever be directly irradiated in a conventional radiotherapy setting (but see Tsekos, *et al* [8] for a counter-example with complex control measures). At conventional daily dose rates (2 Gy/min), **15% of the tested pacemakers had a clinically important failure**. Two clinical comments of note are made: stop therapy if the patient faints, and record an EKG during therapy for pacemaker-dependent patients.

Most recently, Hoecht, *et al* [9] reported that while in nine various ICDs tested, eight failed only after 50 Gy, one did fail at just 1% of this dose. They recommend regular monitoring of ICDs during the course of radiation therapy.

Manufacturer's Specifications and Guidelines

Guidant literature [10] states its **new** opinion that no level of cumulative radiation dose is “safe”. Curiously, they opine that the “random nature of radiation scatter” prevents meaningful laboratory testing of its products. They state that ICDs are 5 to 10 times more sensitive to radiation than pacemakers because of the use of RAM chips. As part of the on-board software of pacemakers and ICDs, bad memory locations can be detected and corrected up to a point. If the amount of memory alteration is too great however, the device will invoke its ROM-based operating mode (“Safety Mode”), which gives only basic pacing at a preset mode and rate or in the case of the ICD only basic shock-only tachy therapy and brady pacing at a fixed mode and rate.

Medtronic [11] lists specific, do-not-exceed, cumulative dosages for its eleven various models of ICD. Two models are at 5 Gy and nine at one Gy. For pacemakers, tests have revealed minor radiation damage as low as 5 Gy, and they recommend monitoring after each therapy session when this limit is reached. The possibility of replacement at the conclusion of the therapy course should be considered.

St. Jude Medical [12] states that its pacemakers (Programalith III[®], Phoenix[®], Paragon[®], Synchrony[®], Trilogy[®], Tempo[®], Affinity[®], Entity[®], Integrity[®] and Identity[®]) have been tested to 30 Gy cumulative dose without adverse effect. They echo Last [6] in their comments on patient management during therapy and note that a change in the capture or sensing threshold is a harbinger of trouble with the pulse generator.

The Biotronik [13] product information sheet states that pacemakers have functional disturbances at 20 Gy cumulative doses and less severe damage at 5 Gy. They indicate that the current consumption of the pacemaker may be an indirect assessment of radiation damage to circuit elements. If current consumption is > 15%, then radiation damage can be assumed. High current consumption also puts a pacemaker with a low battery at risk of having its voltage supply decrease below the minimum and stop.

Electromagnetic Interference

The effects of radiated electromagnetic interference (EMI) on cardiac pacemaker/ICD devices has been documented in the case of electronic article surveillance system for theft control, airport metal detectors and a wide variety of industrial (*e.g.*, arc welding) and medical devices (*e.g.*, electrocautery) [14].

Numerous investigators have seen transient changes in pacemaker function when a linear accelerator first ramps up to deliver radiation [15]. These EMI events are said to be clinically insignificant.

Mouton, *et al* [7] measured the magnetic field of their Saturne 3 accelerator (CGR MeV-General Electric) as a few μT with a low frequency variation over that of the earth's magnetic field. They advise that others may check on their own unit without a magnetometer by remotely observing a compass for strong swings. On two Siemens accelerators tested by one of the authors (KDS), a KD-2 model manufactured in 1993 and a Primus model manufactured in 2001, showed no compass deviation at isocentre with either 6 or 23 MeV x-ray production.

Siemens personnel [15] measured the magnetic field leakage at isocentre on a current model of their dual-beam accelerator. With their bending magnet at maximum current, they found $H_z = 2.5 \mu\text{T}$ and $H_x = H_y = 1 \mu\text{T}$. For comparison the earth's magnetic field is roughly $50 \mu\text{T}$.

Varian personnel [16] measured the magnetic field at isocentre for their Clinac 2100C and Clinac 23 EX with a large bend magnet current and large solenoid power supply current. Under their worst-case scenario, they had a reading of $50 \mu\text{T}$. There was a strong variation with gantry angle and values of $10 \mu\text{T}$ were typically seen.

The effect of a sparking or arcing Klystron or Magnetron should be investigated with respect to its EMI at isocentre. The magnetic field during this event should be measured. Such sparking may persist for many weeks before the element in question is replaced. It is advised not to treat pacemaker/ ICD patients with such equipment.

Brachytherapy

The calculated effect of intravascular brachytherapy (IVB) using either Ir-192 or Sr-90 on pacemaker/ICD functionality has been investigated by Abner, *et al* [17]. For typical cases the Sr-90 source train gave less than one cGy to the device while the Ir-192 source gave typically a 2.5 cGy dose (maximum of 7 cGy). While not explicitly studied by Abner, *et al* the dose rate for IVB is low compared to accelerator rates and does not itself present a problem. While some atypical geometry is always possible, thus yielding a cumulative dose of importance, no extraordinary precautions are seen necessary for IVB beyond possibly a CT study to confirm relative distances.

In the case of high dose rate (HDR) remote afterloading using a nominal 10 Ci (3.7×10^{11} Bq) Ir-192 source, cumulative doses in excess of 1 Gy are entirely possible for such conditions as oesophageal and lung CA. Irradiation to the breast using MammoSite technology [18, 19] is also potentially harmful. For a typical prescribed total dose of 34 Gy to 1 cm beyond the balloon surface, the cumulative dose approximately 15 cm from the source is 1 Gy. This distance is within the geometric possibility of a pacemaker/ICD position. Again, a CT study can investigate distances and appropriate precautions can be made.

Model Protocol

Given the information cited above and, in particular, concerned with ICD patients, a new departmental policy with lower threshold doses was implemented in July 2003 at St. Barnabas Medical Center, a large community hospital. That policy formed the basis for the model protocol below. It is hoped that many institutions can use this protocol as a point of departure for their own needs.

1. **The pacemaker/ICD shall not be placed in the direct beam. Double-exposure portal imaging shall not be performed.**
2. **A cardiologist shall evaluate the patient and interrogate the pacemaker/ICD before the start of radiation therapy. A written report shall be filed in the patient's radiation therapy chart. An estimation of the clinical consequences of pacemaker/ICD termination shall be made available to the treating radiation oncologist.**
3. **Before therapy, medical physics personnel shall estimate the dose to be received by the pacemaker/ICD based on the physician's prescription. A report shall be recorded in the patient chart. Equipment to treat complete pacemaker failure shall be readily available. A pacemaker magnet to reset pacemaker mode to VOO should be available.**
 - a. **If the estimated dose is < 100 Gy, the patient shall be carefully observed during treatment.**
 - b. **If the estimated dose ≥ 100 but < 500 cGy, or if the patient is pacemaker dependent or, has an ICD, the device shall be monitored during the first treatment by ECG telemetry. The pacemaker/ICD shall be interrogated by the cardiologist at mid-therapy and end of therapy.**
 - c. **If the estimated dose is ≥ 500 cGy or if the dose exceeds manufacturers restrictions, the patient shall not be treated without a full interdepartmental review.**
4. **Vital signs shall be obtained before and after the first treatment of all pacemaker/ICD cases. The Given Dose superior to the pacemaker/ICD shall be measured on the first day of treatment.**
5. **No patients with a pacemaker/ICD shall be treated on accelerators with an arcing magnetron or klystron.**
6. **The pacemaker/ICD database shall be updated at the end of therapy.**

The database contains demographics on both the patient and pacemaker/ICD with notes on treatment, Given Dose measurements and calculations.

Website

Since few radiation oncology centres are large enough to see a statistically significant number of pacemaker/ICD patients per year, a method to share data through the internet will appeal to many. Toward this end the authors are seeking an institutional sponsor for a website. At such a website one could leave data on successful and unsuccessful irradiations including model and conditions of treatment (no patient identification of course), or measurements of EMI at isocentre on various models of accelerators, or miscellaneous notes and comments. At periodic intervals registered and vetted members would be given a summary by email.

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