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REPORT OF
TASK GROUP 34

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Reprinted from MEDICAL PHYSICS, Vol. 21, Issue 1, January 1994

July 1994

Published for the
American Association of Physicists in Medicine
by the American Institute of Physics

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International Standard Book Number: 1-56396-380-9
International Standard Serial Number: 0271-7344

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Published by the American Institute of Physics
500 Sunnyside Blvd., Woodbury, NY 11797

Printed in the United States of America

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

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(Received 12 May 1992; accepted for publication 4 October 1993)

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

I. INTRODUCTION

It is estimated that in 1986 more than 100 000 cardiac pacemaker implants were performed in the United States and that there were at least 500 000 pacemaker implanted patients.¹

Cardiac pacemakers are either extrinsically or intrinsically attached to the heart muscle (outside or inside the heart). If, during open heart surgery, it is determined that a patient requires pacing, the leads are attached to the heart at that time and the pacemaker is usually fitted into the patient's upper abdomen. If surgery is not required, then the pacemaker leads are intrinsically attached to the apex of the right ventricle by passing them through an opening in the subclavian vein. The pacemaker is then placed under the skin on top of either pectoral muscle, usually laterally near either axilla. On occasion, a pacemaker is located underneath a breast for cosmetic reasons.

In 1992, it is estimated that 168 000 new cases of lung cancer were diagnosed in the United States.² In addition, an estimated 180 000 new breast cancers were discovered as well.

As with most cancers, treatment of lung and breast tumors depends somewhat on the staging as well as the cell type of the disease and, to some extent, the condition of the individual patient. Therapy involves the use of surgery, radiation, or chemotherapy or, often, a combination of two or all three. However, in 1990, 47% of all cancers were at least partially managed with radiation therapy.³

Thus, it is safe to assume that over 150 000 new cancer patients a year in the United States could present for radiation to that part of the anatomy that could include an implanted cardiac pacemaker. Further, the majority of pacemaker implants are in older patients who now utilize

them for longer periods of time. Since cancer incidence increases with age, this further suggests that significant numbers of patients could present for therapy with pacemakers.

Task group 34 was formed by the Radiation Therapy Committee of the American Association of Physicists in Medicine in 1985 with the charge to determine the effects of radiation on implanted pacemakers in patients undergoing radiation therapy and to formulate a set of guidelines for the management of these patients. A preliminary guideline was formulated early and informally disseminated throughout the radiation oncology community.⁴

The interaction of a complex electronic cardiac pacemaker with the radiation environment encountered in the clinical radiation therapy setting is not a trivial one to predict. Many variables can have a profound effect on these interactions and particularly on the resulting behavior in the pacemaker. Thus, an optimum set of recommendations is difficult to determine based on available experimental and theoretical data. Since the potential risk to an individual patient is high, while the overall population risk is low, we are left to suggest precautions that will seem too conservative for some. The alternative is either a demand on pacemaker manufacturers to redesign their devices for a small percentage of patients or a recommendation that will prove too high a risk to these special patients we are addressing.

Cardiac pacemakers have found increasingly widespread use in the management of heart block and bradycardia since the early 1960s when synchronized pacemakers were developed. These so-called demand pacemakers stimulate the heart only when the heart itself does not function at the proper beating rate. Early devices utilized conventional bipolar transistors and, by comparison to to-

day's designs, relatively unsophisticated circuits. The development of integrated circuits, large-scale integrated circuits (LSI), and eventually very-large-scale integrated circuits (VLSI) was rapidly implemented by all pacemaker manufacturers. These devices, along with microcomputer technology, make today's pacemaker extremely sophisticated.

The contemporary cardiac pacemaker uses complimentary-metal-oxide silicon (CMOS) and other sensitive transistor devices in VLSI arrangements to result in very small (3-5 cm diam) units. These can be programmed to fit each individual's changing pacing needs, with self-contained batteries that can last for 10 yr or more.

The basic function of the pacemaker is to sense, through leads connected to the heart muscle, the electrical activity of the heart and, if necessary stimulate electrically, through those same leads, the heart into performing its normal pumping function. The sensitivity and response of the pacemaker can be adjusted to fit the individual's needs through computer programming. This is accomplished remotely by "talking" to the pacemaker through a simple radio-frequency transmitter using a special device placed near the patient's chest over the implanted pacemaker. The same device allows evaluation of the pacemaker function and the general condition of the patient's heart. This information is sometimes sent over a telephone connection to a physician's office by the patient.

II. POTENTIAL PACEMAKER MALFUNCTIONS

Failure of a pacemaker constitutes either not pacing the heart as required or pacing it erratically or inappropriately. Lack of pacing will occur if the electronics fail catastrophically. Erratic or inappropriate pacing can occur if the computer becomes deprogrammed due to selective damage to parts of the chips. If noise is coupled into the circuitry directly, or through the leads, the pacer might be improperly reprogrammed or may lose programming capability.

A. Transient interference

Transient interference of the pacemaker is largely due to erratic pacing caused by noise coupling into its circuits directly or through the heart leads.

Hermetic sealing of the circuitry with high conductivity metal cans has virtually eliminated direct coupling of electromagnetic noise into the circuits of contemporary pacemakers.⁵ The pacemaker leads, however, remain vulnerable to noise pickup and extensive efforts have gone into electronically filtering the pacemaker inputs to minimize this problem. Low-pass filtering is very effective for frequencies above 100 kHz, but below this frequency, especially in the 2-500 Hz region, elegant techniques are required to minimize problems from interference.

Most pacemakers contain magnetic relays that are used during external programming. Thus, moderate static or dynamic magnetic fields can induce improper pacing.

In all cases of transient interference, the pacemaker returns to normal operation once the source of interference is removed.

B. Permanent interference

Permanent interference can result in either total malfunction or permanent erratic behavior. If sources of electromagnetic interference cause the computer to be reprogrammed, the pacemaker will function improperly for that specific patient. The malfunction is permanent unless the device is reprogrammed correctly.

If the pacemaker is exposed to a sufficient dose of ionizing radiation, individual chip components will fail, causing various malfunctions. Minimal radiation damage can sometimes anneal out of these components and the device can return to apparent normal function, but in general, once a radiation damage-induced failure occurs, the pacemaker must be considered permanently damaged.^{6,7}

iii. EXPECTED ENVIRONMENT IN RADIATION THERAPY

The various sources of electromagnetic noise in a typical radiation oncology department include the following:

- (1) Motor noise from couch drive motors, air compressors, x-ray tube rotors, and cooling pumps.
- (2) Transformer noise from x-ray transformers and power supplies.
- (3) Microwave leakage from magnetrons, klystrons and waveguide assemblies, and low frequency (< 500 Hz) noise from beam pulse forming circuits.

Since no known regulation or guide exists for determining and/or controlling these environments, there is little quantitative information available on the levels of noise to be expected around these types of equipment. Treatment and simulator couches usually use dc motors for speed control at relatively low voltages and power levels and are usually located within metal frames that afford some shielding. Water pumps are usually in the main structure of the accelerator which also act as a shield, and are usually running continuously under constant load which at least eliminates turn on/off transient noise.

Transient noise from x-ray transformers could justify some concern if the transformer is located near the patient, as could the high speed rotor of a typical x-ray tube. Again, the authors have not found definitive measurements that can quantitatively support this.

Some measurements of the noise spectrum around linear accelerators have been made by Siemens Corporation on both their klystron and magnetron powered units.⁸ Their data show that worst case noise levels found around various parts of the accelerators were less than 9 mV/m and in the 60-200 kHz frequency band.

Ionizing radiation sources typically utilized in a radiation oncology department today consist of continuous beam gamma-ray and beta particle radioisotopes, conventional x-ray machines, and pulsed x-ray and electron beams from linear accelerators and betatrons. Some large departments also use cyclotron produced proton or neutron beams. All of these sources of ionizing radiation, except the diagnostic x-ray units, are capable of depositing high doses into relatively large absorber volumes. The linear accelerator beams (and cyclotron produced beams) have the ad-

ditional characteristic of being pulsed with typical dose pulses being about 5- μ s wide and occurring at pulse rates of 120-250/s.

IV. EXPECTED NOISE SENSITIVITY OF MODERN CARDIAC PACEMAKERS

No accepted standard of design against electromagnetic interference exists for pacemaker manufacturers. This is, in part, due to the fact that each pacemaker performs slightly different tasks and in different priority for each patient. The dominant heart problem of the patient as well as the specific electrical characteristics of his/her heart dictate which noise rejection approach is best. Fortunately, because of the limited bandwidth requirements for pacing signals, a very large part of the electromagnetic spectrum can be shielded with narrow band filtering. At frequencies above several hundred Hz, the pacemaker input leads rapidly become very insensitive to noise.^{5,9} Manufacturers have continually made every effort to make each pacemaker application as safe from extraneous noise as possible and, in fact, chose to encapsulate the pacer electronics in a sealed metal can for that reason. The largest noise source of concern has actually become the patient. Extraneous muscle potentials, especially from the pectoralis muscles since the pacer is usually implanted close by, can be similar to the heart muscle signals. A lot of design effort has gone into improved bipolar leads because they, over unipolar leads, very much reduce this problem. Early bipolar leads were not popular because they were physically too large. Bipolar pacing automatically improves overall noise sensitivity and with improved lead design it is expected that more and more bipolar pacing will be used in the future.

Interference from microwave ovens has always been a public concern, but one would expect the heavy filtering discussed above to eliminate this as a problem. Indeed, testing has shown that although the 60 Hz transformer used to power the microwave generator could cause interference, the microwaves themselves do not present a problem.⁵ Another good filter for microwave frequencies (> 1000 MHz) is the patient's body which, as a reasonably good conductor, shields the implanted pacemaker leads.

Although a specific design and/or testing standard for noise control has not been established for the pacemaker industry, much effort by the manufacturers allows for sound speculation on what interference problems might be expected. Noise sources above 100 kHz such as those from radio transmitters, microwave ovens, etc., should not present a problem. Devices that produce electromagnetic fields below 500 Hz, particularly 60 Hz motors, areas around high current contact closures involving 60 Hz power, and pumps, etc., can be, but are not necessarily hazardous. The potential for interference depends on the strength of the EM1 field. Any device that directly applies electrical currents to the patient, such as cautery, diathermy, or electronic pain management devices, should be used cautiously, since they are potentially a direct source of electrical interference for a pacemaker. In most cases, these procedures are not contraindicated, but the patient must be

closely monitored. If a pacemaker should malfunction from noise interference, it will return to normal operation once the noise is removed.

V. RADIATION DAMAGE SENSITIVITY OF MODERN CARDIAC PACEMAKERS

The potential problems caused by ionizing radiation damage to electronic components, especially semiconductor devices, has been exhaustively studied since the advent of nuclear power. The development of low power semiconductors (e.g., CMOS) for space instrumentation stimulated further studies on these devices in particular.¹⁰⁻⁶⁰

The earliest cardiac pacemakers (1960-1970) employed discrete component technology of which the transistor was the most radiation sensitive. Bipolar transistors have typical radiation tolerance of the order of 1000-10 000 gray.⁶¹ A number of early studies of pacemaker sensitivity have shown that they are certainly resistant to therapeutic radiation levels.⁶²⁻⁶⁶

In the early 1970s, manufacturers began using CMOS devices in pacemakers because of their low power consumption. These devices, because of a phenomenon known as hole trapping, have a reduced radiation resistance to the order of 100-1000 gray.⁶⁷ Other studies have shown that when CMOS devices are tightly packaged onto LSI and VLSI chips, the functional unit they comprise becomes even more sensitive to radiation damage.^{61,68,69} In one study⁶⁸ it was demonstrated how a CMOS S-bit processor failed as low as 10-20 gray when the individual CMOS chips were rated to have a radiation resistance of 1000 gray.

Reduced radiation resistance of pacemakers was reported as early as 1981^{66,70} and subsequently by several authors.⁷¹⁻⁷⁵ At least two studies^{73,6,7} have demonstrated that significant permanent damage can occur to a pacemaker after exposure to 10 Gy and that some minor changes in pacemaker function are noticed at doses as low as 2 gray.^{73,6} In addition, a number of case reports of patients undergoing radiation therapy and experiencing pacemaker failure at therapeutic doses have been reported.^{72,76-79}

The question of whether equivalent effects on circuits should be expected from equivalent doses of various ionizing radiation beams was addressed in the 1970s using a satellite experiment. Various CMOS devices were flown on the Explorer 55 satellite through the earth's radiation belts and the effects of the mixed proton, electron, and x-ray radiations compared to Cobalt-60 exposures made on the ground. The experiment elegantly concluded that the devices experienced the same radiation sensitivity under both conditions.^{80,81} Brucker⁸² in 1982 compared electrons, protons, and Cobalt-60 gamma rays on CMOS devices and showed that above 5-MeV electrons and Cobalt-60 gamma rays are equivalent. Some difference was seen with protons that suggests further study.

The effect of pulsed radiation on CMOS and other semiconductors has been studied extensively, but only at extremely high instantaneous dose rates (> 100 000 gray/s). A 1981 report⁶⁶ of transient effects of therapy radiation

beams on both CMOS and bipolar pacemakers demonstrated that accelerator beams can induce transient failure in CMOS circuits. This same effect was seen by one of the authors (but not reported) during studies in 1982. During these tests, a pacemaker was seen to revert to interference mode operation, indicating noise interference while in the photon beams of both AECL Therac 20 and Siemens KD8067 accelerators. This was not seen in the beam of an AECL Therac 6 machine. The effect was seen to occur only when the direct beam was striking the VLSI chip on the pacemaker and not when the chip was just outside the direct beam. This suggests that the effect is either dose rate and/or pulse frequency dependent. This effect merits further study, particularly since double-exposure portal imaging in radiation therapy exposes the pacemaker to the direct beam, which could possibly cause momentary transient interference.

VI. GENERAL DISCUSSION AND CONCLUSIONS

Published studies show that the radiation sensitivity of contemporary cardiac pacemakers vary, depending on the manufacturer and model.^{6,8,83,84} Since the problem of radiation exposure still affects relatively few (percentage-wise) pacemaker patients, it is unreasonable to propose that all pacemaker manufacturers radiation harden their devices. To do so would incur a significant expense that would eventually have to be passed on to all cardiac pacemaker patients. If necessary, a pacemaker can be moved to an area outside the radiation treatment volume in order to preclude failure from overexposure.

Since it is difficult to predict the exact sensitivity of any given make or model of pacemaker, they should all be considered to have the highest sensitivity demonstrated in the literature.

There is good evidence that transient interference from electromagnetic noise is not a problem around properly functioning contemporary radiation therapy equipment.^{85,8} Betatrons are an exception,⁶⁵ but are slowly being replaced with linear accelerators throughout the world. The compact proton cyclotron now under development needs to be evaluated to be sure the magnetic fields associated with it will not present a problem similar to the betatron. Also, the possible differences between protons and gamma rays in causing damage to circuits⁸² should be addressed.

There is some evidence that the EM1 produced, when high power magnetrons and klystrons used in linear accelerators misfire (spark), can be significant, albeit brief.⁸⁶ Until this phenomenon can be evaluated, extra caution is indicated when linear accelerators are malfunctioning in this way.

Transient interference from pulsed radiation beams (such as those from linear accelerators) needs further study. However, there is evidence that if the pacemaker is kept outside the machine collimated edge of the beam, then this will not be a problem.⁶

One reference⁸⁵ indicated that some pacemakers could be momentarily inhibited during turn on/off of certain linear accelerators, but notes that this would not be dangerous to the patient.

Since diagnostic ionizing radiation procedures usually result in absorbed doses much lower than 2 gray, they are not contraindicated for pacemaker implanted patients. Any concern regarding diagnostic x-ray procedures should focus on keeping the patient away from large transformers and high current ac motors rather than the ionizing radiation beam.

Magnetic resonance imaging should be totally avoided by pacemaker patients, not because of potential radiation damage, but because of magnetic field interference.⁶

Ionizing radiation damage to pacemaker components is cumulative.^{6,7} Total dose to pacer (from leakage and scatter radiation) should be estimated for each patient who undergoes radiation therapy. The patient's cardiologist should be advised of the treatment so that the pacemaker can be evaluated and its operation checked regularly.

Recent studies^{83,84} show that at least some newer models of pacemakers may tolerate therapeutically high absorbed doses and that this resistance to radiation damage may be predictable. Further studies are needed, however, to demonstrate that this predictability can be extended to all pacemakers presently in use.

Interference sensitivity from either EM1 or ionizing radiation damage most certainly varies between pacemakers and possibly between individual models. The testing required to check all combinations of models and environments would be prohibitive as would a requirement for radiation hardening all devices. The task group is thus left to make specific recommendations based on the most sensitive of available observations.

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.

ACKNOWLEDGMENTS

The authors wish to thank Michael Hardage of Ventritex Corporation whose contributions as an expert in pacemaker design and operation were substantial. Also, special thanks to Elaine Morgan and Casey Anderson for typing the manuscript.

^aThis work is unrelated to Dr. Wolbarst's duties at EPA and has not been reviewed by the agency. The views expressed do not necessarily represent the views of the agency or the United States Government.

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