Monitoring Patients With Implanted Cardiac Rhythm Devices Receiving Radiation Therapy

Marilyn I. Chavez, RN, BSN, MPH

Diagnosed in 2007 with chronic lymphocytic leukemia (CLL), S.B. was a 78-year-old man. Treatment consisted of a course of rituximab with stable blood counts. About two years after the initial diagnosis, S.B. presented with a moderately rapidly enlarging mass in his left-anterior shoulder. Biopsy of the mass revealed a Merkel cell carcinoma and, within a month, another mass was noted in his left axilla that was again positive for Merkel cell. S.B. underwent wide local excision with skin grafts. A restaging positron-emission tomography/computed tomography (PET/CT) scan was carried out to determine what treatment modality would best serve S.B.

S.B. had a significant history of cardiac disease that included coronary artery disease requiring coronary artery bypass graft. A former history of myocardial infarction and congestive heart failure predisposed S.B. to symptomatic bradycardia requiring implantable cardiac pacemaker (ICP), hypertension, and peripheral vascular disease.

S.B.'s CLL was stable at presentation, but had the potential for future clinical challenges. Despite S.B.'s age and medical history, he was active, walked one mile per day, lived alone, and was able to carry out activities of daily living in an independent manner. As defined by the Eastern Cooperative Oncology Group (ECOG), his performance status was rated as "1," which means he was restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (Oken et al., 1982).

Consultation between S.B.'s medical and radiation oncologists determined that he was not an optimal candidate for chemotherapy because of his comorbidities.

The PET/CT scans were negative for any distant metastasis. S.B.'s disease was limited to the left shoulder and axillary region and, therefore, definitive radiation therapy was determined to be the best option to eradicate his disease locally before it became widespread. The fact that his pacemaker was located in the left-upper chest wall just a few centimeters away from the original lesion was a matter of concern to the radiation therapist. During radiation CT planning and simulation, it was determined that the pacemaker was within the intended radiation field. Therefore, S.B. was scheduled to have his pacemaker explanted from the left chest and a new pacemaker reinserted in the right chest area away from the radiation field. After a two-week period of recovery, S.B. proceeded with his prescribed radiation therapy treatments.

Radiation Precautions

According to the American Heart Association (2009), the leading cause of death in the United States continues to be heart disease, with cancer running a close second. Therefore, a clinician in a radiation oncology setting quite likely will face challenges in treating a patient population with cancer and heart disease. Patients who have implanted cardiac devices, such as an ICP or a cardioverter defibrillator, present concerns because of the potential effect that ionizing radiation can have on the function and reliability of the devices. An estimated 500,000 patients in the United States will have implantable cardiac devices, with pacemakers implanted at a rate greater than 115,000 per year and defibrillators at 228 implants per million (Solan, Solan, Berdnarz, & Goodkin, 2004).

Significant breakthroughs have occurred in the technology and delivery of radiation as well as in the circuitry of newer cardiac implantable devices such as implantable cardioverter defibrillators and cardiac resynchronization therapy pacemakers. Manufacturers of implantable devices have improved technology to produce devices that have low current consumption, which prolongs generator lifespan while maintaining a small size for ease of implantation and patient comfort. However, the complementary metal oxide semiconductor circuits that are a part of these devices can be more susceptible to therapeutic radiation and electromagnetic interference (EMI) (Kapa et al., 2008; Medtronic USA, Inc., 2008; St. Jude Medical Technical Services, 2008).

Effects of Ionizing Radiation

The risk of radiation effects on the operation of cardiac rhythm devices rises with increasing cumulative exposure, but no exact threshold (i.e., safe dose) has been determined. Recommendations differ from manufacturer to manufacturer (Solan et al., 2004). The range has been as low as 2,000 cGy and as high as 15,000 cGy (St. Jude Medical Technical Services, 2008). Medtronic USA, Inc., (2008) has carried out research to establish a safe threshold, with internal tests conducted on their proprietary pacemakers revealing minor damage at accumulated radiation doses greater than 500 cGy. The potential negative effect on implanted devices can range from permanent damage (rare) to temporary loss of sensing, temporary device inhibition, loss of capture, rate changes, and device reset back to demand mode when the patient is device dependent—all of which are uncommon (Kapa et al., 2008; Medtronic USA, Inc.; St. Jude Medical Technical Services).

The most common documented effect is a temporary increased sensor rate that makes the device more sensitive to "noise" around it (e.g., EMI or microwave frequencies generated by power sources) and potentially delivering inappropriate therapy (e.g., delivering a shock when not indicated, causing asystole) (St. Jude Medical Technical Services, 2008). Direct exposure of implantable cardiac devices to radiation can damage the circuitry, which

can lead to device failure or malfunction. The effects of scatter radiation and EMI on the devices are not clear. Kapa et al. (2008) conducted an in vitro study on 20 devices that were not previously exposed to radiation, and the devices did not demonstrate any episode of device reset or changes in parameters. A retrospective review was done by the same group on 13 patients treated from 2002–2007. With device protection consisting of relocating the pacemaker or cardioverter defibrillator to prevent direct exposure to radiation, no negative outcomes were noted in post-treatment analysis.

Actual risks to implantable cardiac devices are difficult to determine because research data have been limited to implantable devices exposed to 6 millivolt (mv) beams. At a 6 mv dose, the principal components of scatter radiation are photons. If higher radiation levels are used (i.e., above 18 mv), neutrons play a role, and it remains unclear how neutrons could affect implantable devices (Kapa et al., 2008). Since the late 1990s, and even more so with newer models, the linear accelerator is the predominant radiation therapy equipment in use in most radiation treatment centers worldwide. It delivers radiation energy in packets called photons for deep-seated tumors and in electrons for skin lesions or superficial lymph nodes. The energy delivered ranges from 4–25 mv. Despite these more sophisticated radiation energy delivery systems, the risks to implantable devices remain the same (Hilderley, 1992; Thompson, 1996). Zweng, Schuster, Hawlicek, and Weber (2009) cited a life-threatening incident with pacemaker dysfunction during which the patient experienced hemodynamic collapse as a result of pacemaker-induced tachycardia. The implantable cardiac device was outside the radiation field and the estimated cumulative dosage of scatter radiation was only 0.11 cGy (lowest in vivo dose reported to date). It is not fully understood what induced this pacemaker malfunction, but the authors posited that it was most likely induced by EMI as opposed to scatter radiation.

Assessing the Risk of Radiation

Several strategies can be used to assess the potential impact therapeutic radiation can have on an implantable cardiac device (see Figure 1). Important variables range from patient status; device manufacturer guidelines; and the frequency, dose, and type of radiation prescribed. Standards of practice published by the Association of Physicists in Medicine (AAPM) Task Group 34 (Marback, Sontag, Van Dyk, & Wolbarst, 1994) and Solan et al. (2004) provide a thorough review of the literature that identifies guidelines based on descriptive research and surveys and outlines major manufacturer's safety precautions and practice patterns across radiation settings.

Guidelines for Radiation Therapy Treatment

Based on experimental studies, theoretical data, and recommendations from Medtronic USA, Inc. (2008), St. Jude's Medical Technical Services (2008), and Guidant Corporation Cardiac Rhythm Management Technical Services (2004), the following guidelines were developed and tailored for use at the Center for Radiation Therapy of Beverly Hills, a free-standing radiation oncology facility in California.

All pacemaker devices and implanted cardiac devices are to be interrogated prior to initiation of treatment, the first three days during the initial week of radiation treatment, and every other week until completion of treatment. The interrogations may be more frequent if the clinician deems it medically necessary. A change in the capture or sensing threshold may reflect an early issue with the pacing system, requiring changes or intervention. Pacemaker and device interrogation is done by a cardiologist or electrophysiologic study (EPS) technician. EPS evaluation is accomplished by placing a programmer over the implanted device that reads and summarizes device activity. This usually is performed in the physician's office or can be carried out by telephone (transtelephonic). Several pieces of data are retrieved during an interrogation, but what is pertinent to radiation oncology are battery life, any changes in original settings, any device activity (e.g., is the pacemaker turned off?), or indications the cardiovertor defibrillator has delivered a shock (Lee & Lee, 2002).

Figure 2 delineates what information is derived during a pacemaker or ICD interrogation. The first phase of interrogation is to identify the cardiac device being interrogated. This includes documentation of the device manufacturer, date of implantation, and recommended parameters. The second phase identifies the purpose and settings of the device (e.g., to recognize bradycardia, ventricular tachycardia, and ventricular fibrillation as actionable parameters) and what intervention the device should deliver (e.g., a cardiac pacing to initiate heart rate or a defibrillation shock). The third phase generates salient information for the radiation oncology staff to ensure patient safety. This portion of the report documents any detected cardiac events and corresponding cardiac device action, such as the exact time and date of occurrence. This information can be used as a baseline to determine if an association can be established if radiation therapy affects cardiac device function. An evaluation summary also is recorded to document cardiology or EPS technician assessment of interrogation findings (Lee & Lee, 2002).

Technical issues of an implanted device can be detected during an interrogation. However, during a radiation treatment session, regardless of indication, the radiation oncology team (radiation oncologist, RN, and radiation therapists) should always be vigilant of any concerning signs and symptoms—any change in vital signs

- Identify the type of device.
  - Many device manufacturers provide their own safety guidelines.
- Review the patient's medical history and specific cardiac indication for device implantation.
  - Is the patient pacemaker dependent?
  - Arrange a preradiation cardiac consultation.
- Evaluate the proximity of the implanted device to the radiation beam prior to initiation of treatment.
  - Could the device be deactivated or reset by ionizing radiation and, subsequently, deliver an inappropriate intervention?
  - Should the device be moved outside the radiation field?
- Determine the frequency of radiation fractionation and concurrent therapies that may increase exposure of the device to electromagnetic or scatter radiation.
- Document the type and energy level of the radiation beam.
  - At high energy levels, the effects of electromagnetic and scatter radiation cannot be predicted.
  - Monitor the patient with an implantable cardiac device during each radiation therapy treatment for adverse symptoms, such as change in vital signs, dizziness, palpitations, and chest pain.

Figure 1. Monitoring Risk Factors of Radiation Effects to Implantable Cardiac Devices

Note. Based on information from Marback et al., 1994; Solan et al., 2004.

(compared to baseline), patient reports of feeling light-headed or dizzy, palpitations, dyspnea, chest tightness, or pressure—because symptoms may be indicative of pacemaker or device malfunction.

Identifying before initiation of treatment whether the patient is pacemaker dependent or nondependent is important. For pacemaker-dependent patients, a consultation with the patient's cardiologist is of benefit because the generator battery may need to be changed if the device is close to its end of life. Pacemaker-dependent patients should have vital signs checked prior to the initiation of therapy for baseline readings, daily during treatment, and again after completion of treatment. A radiation dose-measuring device is applied over the pacemaker or ICD daily during the first week of treatment to ensure that the device is not likely to receive 500 accumulated cGy over the planned course of radiation. Therapeutic radiation can affect implanted cardiac devices because of repeated direct exposure or beam scatter. If the radiation beam is collimated (parallel rays) with well-defined edges, it typically can be directed to miss the device by at least one inch. Scatter radiation is small at distances of more than one inch from the beam. If this is not possible, it may be necessary to shield the pacemaker generator or surgically move it to an alternate location. Lead extenders also may be used to extend existing leads to a new implant location as lead extenders appear to be impervious to radiation interference. Even if the pacemaker or cardioverter defibrillator is moved to an alternate position or shielded, the pacemaker interrogation schedule should remain the same.

Nursing Implications

Extensive review of guidelines and recommendations from published articles and the three leading manufacturers of implantable cardiac devices (Medtronic, Guidant, and St. Jude Medical) demonstrated the lack of significant research data to support a universal set of guidelines or standard of practice related to radiation care of a patient with an implanted cardiac device. What is highlighted by the literature is the high probability of a potential adverse event and the necessity for clinicians to develop practice standards for their institution (Solan et al., 2004; Zweng et al., 2009). However, because of the random nature of the occurrence of these events, the degree of attention is minimal, at best, and practice patterns vary widely from no policy to differing schedules and monitoring methods. However, it is well established that the risk of radiation exposure to implanted cardiac devices can be life threatening (Solan et al.).

In an ambulatory or free-standing radiation facility, emergency resources are not always convenient or easily accessible, including the lack of a cardiologist in the facility or no EPS technician to carry out frequent interrogation of these devices. Without compromising patient safety, the monitoring of patients with cardiac implantable devices has to be accomplished without unduly taxing resources and personnel. For the author's setting, identification of the need for safety standards to ensure that this population of patients were properly assessed and monitored served as the impetus to develop an outpatient flow sheet to document patient status and serve as a communication tool for all caregivers involved in the patient's radiation treatment protocol. Incorporation of AAPM recommendations and pertinent literature provided the evidence-based standards of practice. The major goal of the flow sheet was to provide clinicians with guidelines to assess the frequency of device interrogation and what changes in programmed parameters necessitate alerting the supervising physician. After initial patient assessment according to cardiac device guidelines, the flow sheet is updated at each treatment session.

Phase I. Device and Lead Information
- Device model and serial number
- Date of pacemaker or cardioverter defibrillator implantation
- Cardiologist and contact information
- Cardiologist consult notes: diagnosis; indication for cardiac device implantation; and patient's underlying or native rhythm, which will indicate whether the patient is pacemaker dependent

Phase II. Status of Device Programming
- Programmed detection and programmed intervention set to be delivered
- Programmed parameters—high and low limits—of cardiac device (e.g., pacemaker programmed to initiate pacing mode if heart rate falls below 60 beats per minute)

Phase III. Telemetry of Adverse Effects
- Detection of event and therapy delivered
- Any mode switches resulting from any event
- Battery voltage or lead impedance
- Shocks delivered and aborted

Phase IV. Healthcare Team Findings
- Document patient status (e.g., vital signs, signs and symptoms).
- Document follow-up interventions.

Figure 2. Encapsulated Pacemaker or Cardioverter Defibrillator Interrogation Information

Note. Based on information from Lee & Lee, 2002.

Conclusion

Assuring patient safety with implanted devices during radiation therapy takes an interdisciplinary approach. A cardiology consultation is highly recommended if the patient is device dependent, and the patient should be monitored closely during and after treatment. This may include an initial electrocardiogram, a required baseline cardiac device interrogation, vital signs before and after each radiation treatment, and scheduled device interrogation during the course of radiation therapy. Follow-up cardiac evaluation at the completion of radiation treatment is highly recommended. Interdisciplinary staff, the radiation oncologist, nursing, and radiation therapists should collaborate to advocate for patient safety to ensure evidence-based practice guidelines incorporating AAPM recommendations and documented literature resources (Solan et al., 2004). The major discrepancies found between manufacturer recommendations and practice across settings increased awareness of the need for the author's free-standing radiation center to develop and initiate a policy and procedure to ensure safe practice and follow-up.

Marilyn I. Chavez, RN, BSN, MPH, is a nurse clinician at the Center for Radiation Therapy of Beverly Hills in California. No financial relationships to disclose. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the *Oncology Nursing Forum* or the Oncology Nursing Society. Chavez can be reached at chavezm@toweroncology.com, with copy to editor at ONFEditor@ons.org.

Digital Object Identifier: 10.1188/09.ONF.629-632

References

American Heart Association. (2009). Cardiovascular disease statistics. Retrieved April 13, 2009, from http://www.americanheart.org/presenter.jhtml.identifier=4478

Guidant Corporation Cardiac Rhythm Management Technical Services. (2004).

Impact of therapeutic radiation and Guidant ICD/CRT-D/CRT-P/pacing systems (pp. 1–6). St. Paul, MN: Author.
Hilderley, L.J. (1992). Radiation oncology: Historical background and principles of teletherapy. In K.H. Dow & L.J. Hilderley (Eds.), *Nursing care in radiation oncology* (p. 5). Philadelphia: Saunders.
Kapa, S., Fong, L., Blackwell, C.R., Herman, M.G., Schomberg, P.J., & Hayes, D.L. (2008). Effects of scatter radiation on ICD and CRT function. *Pacing and Clinical Electrophysiology [PACE], 31*(6), 727–732.
Lee, J., & Lee, P.C. (2002). Pacemaker and implantable cardiac defibrillator. In D.B. Cooke & L.A. Sheinis (Eds.), *Cardiology at a glance* (pp. 263–276). New York: McGraw-Hill.
Marback, J.R., Sontag, M.R., Van Dyk, J., & Wolbarst, A.B. (1994). Management of radiation oncology patients with implanted cardiac pacemakers. *Medical Physics, 21*(1), 85–90.
Medtronic USA, Inc. (2008). *Technical services: Radiation and pacemakers/ICD*. Minneapolis, MN: Author.
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., et al. (1982). Toxicity of response criteria of ECOG. *American Journal of Clinical Oncology, 5*(6), 649–655.
Solan, A., Solan, M., Berdnarz, G., & Goodkin, M. (2004). Treatment of patients with cardiac pacemakers and implantable devices during radiotherapy. *International Journal of Radiation Oncology Biology and Physics, 59*(3), 897–904.
St. Jude Medical Technical Services. (2008). *Effect of therapeutic radiation on St. Jude Medical implantable cardiac rhythm devices*. St. Paul, MN: Author.
Thompson, P. (1996). Orientation to radiation oncology. In C.M. Washington & D.T. Leaver (Eds.), *Introduction to radiation therapy* (p. 154). St. Louis, MO: Mosby.
Zweng, A., Schuster, R., Hawlicek, R., & Weber, H.S. (2009). Life-threatening pacemaker dysfunction associated with therapeutic radiation. *Angiology, 60*(4), 509–512.

Clinical Highlights: Patients With Implanted Devices Receiving Radiation

Definition

Implanted cardiac rhythm devices include implanted cardiac pacemakers and implantable cardioverter defibrillators. Radiation therapy is the delivery of a therapeutic dose of ionizing radiation to cause cancer cell death or shrink a tumor while minimizing injury to surrounding healthy tissue. Therapy is delivered with either curative or palliative intent (Hilderley, 1992). To ensure patient safety, implementing diagnostic precautions is necessary when treating patients with implanted cardiac devices with radiation therapy.

Pathophysiology and Contributing Factors

Indications for implanted cardiac pacemakers range from sinus node dysfunction with documented symptomatic bradycardia to complete heart block (Greenberger, Bernsten, Jones, & Velakaturi, 1998; Solan, Solan, Bednarz, & Goodkin, 2004). Symptoms of bradycardia may include syncope, cardiac arrest caused by sinus node dysfunction, or atrioventricular block. Automatic implanted cardioverter defibrillators are inserted to treat symptomatic ventricular tachycardia or ventricular fibrillation to prevent cardiac arrest in high-risk patients (Greenberger et al.; Solan et al.).

Risk Factors

Reports document potential damage to implantable cardiac devices and life-threatening events that may occur when implanted devices are exposed to electromagnetic interference or direct ionizing radiation (Solan et al., 2004).

Patient Management

Except for guidelines from the American Association of Physicists in Medicine (AAPM) Task Group 34, no uniform or documented standard of practice exist for radiation therapy departments to monitor the safety of patients with implanted cardiac devices.

Evidence-based practice points to the necessity of radiation therapy departments and personnel to develop and implement guidelines to minimize the risk of harm to patients with implantable cardiac devices. A consistent recommendation is that the device (i.e., pulse generator) should not have direct exposure within the radiation field and, if necessary, the device should be repositioned or a new device implanted outside the field prior to the initiation of radiation therapy (Solan et al., 2004). Treatment of these patients demands an interdisciplinary approach, including cardiology, radiation oncology, and nursing.

Implications for Nursing Practice

Initial assessment of the patient with an active cardiac device should include the following information: device model, manufacturer guidelines, and cardiology consultation to determine whether the patient is implant dependent or nondependent. If necessary, the device should be moved outside the intended radiation field or, if necessary, deactivated and a new device placed away from the radiation field.

Patients' vital signs should be observed by nurses before and after treatment. The pacemaker or device should be interrogated initially and at scheduled intervals while the patient is receiving radiation therapy. Developing a flow sheet can be very helpful to keep track of the information. The flow sheet can ensure timely patient monitoring and protection from harm. Nurses should identify and report any adverse event and communicate to the radiation team any changes in treatment strategy. In addition, nurses are responsible for providing adequate patient follow-up after termination of radiation therapy to ensure that the cardiologist has made full interrogation of the cardiac device following treatment.

References

Greenberger, N.J., Berntsen, M.S., Jones, D.K., & Velakaturi, V.N. (1998). *Handbook of differential diagnosis in internal medicine: Medical book of lists* (5th ed., pp. 3–44). St. Louis: Mosby.
Hilderley, L.J. (1992). Radiation oncology: Historical background and principles of teletherapy. In K.H. Dow & L.J. Hilderley (Eds.), *Nursing care in radiation oncology* (p. 5). Philadelphia: Saunders.
Solan, A., Solan, M., Bednarz, G., & Goodkin, M. (2004). Treatment of patients with cardiac pacemakers and implantable cardioverter-defibrillators during radiotherapy. *International Journal of Radiation Oncology Biology and Physics, 59*(3), 897–904.