REVIEW

# Interference in Implanted Cardiac Devices, Part II

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## Medical Sources of Electromagnetic Interference (EMI)

Patients with implanted cardiac devices (generally of advanced age and with severe cardiovascular disease) often require diagnostic and therapeutic procedures that involve strong sources of EMI. It should be emphasized that with appropriate planning most of these procedures can be performed safely. Consultation regarding exposure to EMI in the medical environment constitutes a frequent clinical practice issue for physicians and nurses caring for patients with pacemakers and implantable cardioverter defibrillators (ICDs). The routine use of prepocedural checklists to identify patients with implanted cardiac devices in advance is strongly recommended.<sup>1</sup> Likewise, all institutions (especially those with dedicated staff and clinics) should have written policies regarding evaluation and management of patients before, during, and after procedures involving sources of EMI. Continuous education of patients and colleagues in other specialties and avoidance of improvisation will go a long way in preventing bad outcomes and reducing legal liability.

## **Magnetic Resonance Imaging (MRI)**

MRI has many advantages compared to X raybased diagnostic techniques, including its nonionizing nature and the ability to discriminate different soft tissues without contrast media. In properly operating MRI systems, the hazards associated with direct interactions between their electromagnetic fields and the body are negligible. However, deleterious interactions between these fields and implanted cardiac devices can occur. The Food and Drug Administration (FDA) database contains several reports of deaths in pacemaker patients during or immediately after MRI.<sup>2</sup> These reports are poorly characterized in terms of type of pacemaker and programming, patients' pacemaker dependency, field strength of the MRI unit, imaging sequence, and cardiac rhythm at the time of the patient's demise. The risk of serious adverse events and the existence of reasonable alternative imaging modalities have been obstacles to performance of large scale systematic studies of MRI in patients with an implantable device. At most institutions, the presence of an implantable device has constituted an absolute contraindication to MRI, precluding a substantial and growing number of patients from the advantages of this imaging modality. In a survey of 1,567 Japanese pacemaker patients, 17% stated that they presented conditions for which MRI would have been recommended if the device had not been present.<sup>3</sup>

Three types of electromagnetic fields are present in the MRI environment: an "always on" static magnetic field (with its spatial gradient), a rapidly changing magnetic gradient field, and a radiofrequency field (Table I). The last two are pulsed during imaging.<sup>4</sup> Exposure to the static magnetic field (0.2–2 T at the center of the magnet bore with current systems) occurs on entry into the MRI suite. This results in activation of the reed switch with asynchronous pacing in pacemakers and suspension of tachyarrhythmia detection in most ICDs. Paradoxically, when the MRI static field is perpendicular to the reed switch axis (i.e., patient inside the gantry of the scanner), the reed switch may not be activated and demand pacing (as programmed) may persist.<sup>5</sup> Even prolonged exposure to static magnetic fields (10 hours to 1.5 T) does not result in permanent damage to the reed switch, telemetric coils, or pacemaker software.<sup>6</sup> The static magnetic field can also impart translational and rotational (torque) forces to a generator containing sufficient ferromagnetic material that could result in pain and tissue damage. A magnetic force exists only if the magnetic field changes from place to place. Therefore, no magnetic force is measured at the isocenter of the magnet, but it increases rapidly towards the portal of the scanner. However, magnetic torque is highest

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Table I.
Potential Effects of Magnetic Resonance Imaging on
Implanted Cardiac Devices

- 1. Static magnetic field
  - a. Reed switch closure
- b. Generator displacement
- 2. Radiofrequency field
  - a. Alterations of pacing rate (inhibition or triggering)b. Spurious tachyarrhythmia detection
  - c. Heating
  - d. Electrical reset
- 3. Time-varying magnetic gradient field
- a. Induction voltage (resulting in pacing)
  - b. Heating
  - c. Reed switch closure

at the isocenter of the magnet. Shellock et al.<sup>7</sup> exposed seven pacemakers and seven ICDs to a 0.2-T extremity MRI system and found that the magnetic field attraction was relatively minor for all devices. Luechinger et al.<sup>8</sup> exposed 31 pacemakers (15 dual chamber and 16 single chamber) from eight manufacturers and 13 ICDs from four manufacturers to the static magnetic field of a 1.5-T MRI scanner while measuring magnetic force and acceleration measurements quantitatively and torque qualitatively. For pacemakers, the measured magnetic force was in the range of 0.05–3.60 N. Pacemakers released after 1995 had lower magnetic force values than older devices, with a measured acceleration lower than the gravity of the earth (< 9.81 N/kg). Likewise, the torque levels were significantly reduced in newer generation pacemakers ( $\leq 2$  from a scale of 6). ICDs, except for the more current GEM II 7273 (Medtronic Inc., Minneapolis, MN, USA), showed higher force (1.03-5.85 N), acceleration (9.5-34.2 N/kg), and torque (5–6 of 6) levels. The authors concluded that modern pacemakers present no safety risk with respect to magnetic force and torque induced by the static magnetic field of a 1.5-T MRI scanner. On the contrary, ICDs, despite considerable reduction in size and weight, may still pose problems due to strong magnetic force and torque. The effects of the magnetic fields of 1.5-T MRI on other contemporaneous ICDs have not been reported. The metallic parts of the leads are usually composed of MP35N. This alloy of nickel, cobalt, chromium, and molvbdenum is nonferromagnetic; therefore, there is no concern that such leads will move or dislodge due to magnetic attraction.9

The radiofrequency fields can induce EMI in the device circuitry with resulting inhibition or rapid pacing. Several mechanisms for rapid pacing have been proposed. Rapid pacing up to the upper track limit can occur in dual chamber devices if EMI is sensed in the atrial channel. Inhibition and tracking are avoided by programming asynchronous modes.<sup>10</sup> "Runaway" pacing syn-chronized to the radiofrequency pulses (attributed to interference with pacemaker electronics) is the most severe potential complication. Rates up to 300 beats/min have been observed in animal studies.<sup>11</sup> In addition, the time-varying magnetic fields pulsed during imaging can induce voltage in leads (up to 20 V in unipolar leads; much less in bipolar leads) that can pace the heart or interfere with sensing. This could occur with the device in the OOO mode or programmed to deliver subthreshold pulses.<sup>12</sup> The radiofrequency field in an MRI scanner has sufficient energy to cause local heating of long conductive wires, like pacemaker leads, which could damage the adjacent myocardial tissue. Such thermal changes could result in increased thresholds, myocardial perforation, or scar tissue formation and subsequent arrhythmogenesis. In animal studies testing transesophageal pacing, MRI induced lead heating resulted in tissue necrosis.<sup>13</sup> Bench studies have investigated the heating effects of MRI on endocardial pacemaker leads.<sup>14–16</sup> Increases in lead tip temperature of up to 10–20°C were common, depending on the lead model, the duration and type of the imaging sequence, and testing conditions. In one study, the changes were similar when the leads were isolated or connected to pulse generators,<sup>15</sup> whereas in the other the effect was greatly attenuated when leads were attached to the generator.<sup>14</sup> For bipolar leads connected to a pacemaker and submerged in saline (the scenario that most closely resembles clinical conditions), the mean increase in lead tip temperature was 2.2°C (maximum observed 8.9°C) with a 1.5-T machine.<sup>14</sup> Another study with a 0.5-T system found mean electrode maximum temperature raises of 1.8°C when used energies similar to those used clinically.<sup>16</sup> In vitro, heating was less (especially when the lead was away from the field isocenter) when imaging with a send/receive coil than with a receive-only coil.<sup>17</sup> The cooling effect of circulating blood should also attenuate the rise in temperature. The clinical significance of electrode heating is unknown. The limited available data do not suggest an increase in pacing thresholds after imaging. MRI has not been shown to reprogram or permanently damage pacemakers or ICDs. A single Reveal (Medtronic Inc.) implantable loop recorder exposed in vitro to a 1.5-T MRI scanner developed a nonreversible error.<sup>18</sup>

The body structure to be scanned also influences the risk of interactions. With MRI of the brain or an extremity, the device in the thorax is exposed to a weaker radiofrequency field. For example, in the bench study by Shellock et al.,<sup>7</sup> the 0.2-T extremity MRI system did not alter the function of any device. They concluded that clinical use of these units (i.e., with the patient's thorax outside the magnet bore) should be safe in patients with implanted cardiac devices. However, during brain scanning the generator will be at the entry of the scanner and subject to a higher translational magnetic force. Cardiac MRI would expose the implanted systems to the highest magnetic and radiofrequency fields.

Despite the risks, some investigators have performed carefully planned in vivo studies in an attempt to provide guidelines for safe MRI in device patients. Gimbel et al.<sup>19</sup> described safe performance of MRI in five patients with permanent pacemakers. Unfortunately, the authors did not use consistent safety strategies and studied only Pacesetter (Siemens Pacesetter, Inc., Sylmar, CA, USA) devices. A 2-second pause of uncertain mechanism was observed in the only pacemaker dependent patient (programmed in DOO mode). Valhaus et al.<sup>5</sup> performed 34 varied MRI examinations (including brain, neck, heart, abdomen, and extremities) with a 0.5-T superconducting system in 32 patients with permanent pacemakers from different manufacturers. All pacemakers had been implanted for > 3 months and no patient was pacemaker dependent. Their protocol included reprogramming of the pacemaker to an asynchronous mode (AOO, VOO, or DOO) at a rate above the intrinsic one. Pacing and sensing thresholds, lead impedance, and battery voltage were measured before the MRI, immediately after, and 3 months thereafter. The response of the reed switch with the patient inside the gantry of the scanner was also carefully documented. No instance of rapid pacing was seen. Lead impedance and pacing and sensing thresholds did not change. Battery voltage decreased immediately after MRI and recovered at 3 months. Battery current and impedance tended to increase. The projected longevity did not change after MRI. Programmed data and the ability to interrogate, program, or use telemetry were not affected. In almost half of the patients temporary deactivation of the reed switch (activated when entering the MRI suite) occurred when positioned in the gantry of the scanner at the center of the magnetic field. The authors concluded that MRI at 0.5 T is feasible in selected pacemaker patients and that it does not affect the devices irreversibly. Coman et al.<sup>20</sup> reported preliminary results of clinically indicated 25 MRI examinations at 1.5 T in 24 unselected patients with pacemakers. No specific programming was followed. They observed one instance of pacing inhibition. Minor changes in capture threshold were common after the scan. Overall, 11% of the leads

required a change in output to accommodate the altered threshold.

In view of the potential for catastrophic complications, the presence of a pacemaker should still be considered a *prima fascie* contraindication for MRI. Although recent evidence suggests that with appropriate planning, selected patients could undergo MRI without excessive risk,<sup>4</sup> it should be noted that obtaining detailed, informed consent from the patient and performance of the procedure under a research protocol approved by the local human research or ethics committee may not eliminate physician and institutional liability if a complication occurs. Therefore, alternative imaging techniques should always be considered first. The following recommendations should be followed if MRI is deemed indispensable for patient care. In nondependent patients, programming of the pacemaker to the OOO mode (when available) or to subthreshold output will avoid most interactions. It is important to note that rapid pacing secondary to induction voltage is still possible in this mode. Alternatively, the pacemaker could be programmed asynchronously to override the intrinsic rate.<sup>5</sup> Pacemaker dependent patients should be reprogrammed to asynchronous mode. Low field strengths ( $\leq 0.5$  T) should be preferred. The patient must be monitored using electrocardiography (ECG), pulse oxymetry, and direct voice contact during the scan. Imaging should be started with graded scanning sequences (single slice, low resolution) and then eventually progress to more conventional sequences. Sequences with a high absorption rate (e.g., turbo spin-echo) are more likely to induce EMI and lead heating and should be avoided if possible. There is little information on ICDs and MRI. This combination should only be explored under investigational circumstances. Tachyarrhythmia detection should be disabled.

#### Neurostimulators

Spinal cord stimulation has been used to treat peripheral vascular disease, intractable pain, and refractory angina pectoris. The few published reports on concomitant use of implanted cardiac devices and spinal cord stimulators have highlighted the importance of testing to avoid interactions.<sup>21</sup> Pacing inhibition or spurious tachyarrhythmia detection can occur secondary to oversensing of the spinal cord stimulator output. Bipolar spinal cord stimulation and bipolar pacemaker or ICD sensing minimize the risk of interaction.<sup>22</sup> Testing at the highest tolerated spinal stimulator output and at different frequencies should be performed. Inhibition can be output dependent, while noise reversion can be frequency dependent.<sup>23</sup>

Other implantable neurostimulators are being

introduced in clinical practice, including those for Parkinson's disease, epilepsy, fecal incontinence, and neurogenic bladder. There is little data on the compatibility between these devices and pacemakers or ICDs. Testing protocols should explore the possibility of interference before patient discharge, and the devices programmed accordingly. Tavernier et al.<sup>24</sup> reported a patient with severe Parkinson's disease and two separate neurostimulators connected to quadripolar electrodes in the subthalamic nuclei who received an ICD. An "integrated bipolar" lead was used, and there was no oversensing of the neurostimulator signals even at maximum output in unipolar configuration. Maximum energy (34 J) shocks reproducibly reset both neurostimulators (in right and left prepectoral pockets) to the off mode. Obwegeser et al.<sup>25</sup> implanted an ICD with a "dedicated bipolar" lead in a patient with essential tremor and a deep brain stimulator implanted into the left ventral intermediate nucleus of thalamus. Testing during implantation did not disclose interactions. However, shocks > 20 J were not tested. It should be noted that the programmer wand for Medtronic neurostimulators contains a magnet that will close the reed switch of a pacemaker or ICD if moved close to the pocket.

## **Peripheral Nerve Stimulators**

Peripheral nerve stimulators are used to assess the extent of neuromuscular blockade intraoperatively or in the intensive care unit<sup>26</sup> and to localize nerves for blocks. O'Flaherty et al.<sup>27</sup> reported a case of reproducible inhibition of a unipolar right-sided VVI pacemaker during intraoperative left facial nerve stimulation with the standard train-of-four mode at 2 Hz. It should be noted that frequencies < 4 Hz (240 beats/min) are unlikely to invoke the noise reversion mode in most pacemakers. Further studies are needed to assess the risks presented by this source of EMI. Diagnostic nerve conduction studies with needle electrodes introduced at or distal to elbows or knees appear safe in pacemaker patients.<sup>28</sup>

## Transcutaneous Electric Nerve Stimulation (TENS)

TENS is a popular method for the relief of acute and chronic musculoskeletal pain. A TENS unit consists of electrodes placed on the skin and connected to a generator that applies 20  $\mu$ s rectangular pulses of up to 60 mA at a frequency of 20–110 Hz. Output and frequency are adjusted to provide maximum pain relief. Erikson et al.<sup>29</sup> reported inhibition by TENS in four patients with nonprogrammable unipolar pacemakers. In two patients with unipolar pacemakers, inhibition by a TENS machine could be eliminated by increas-

ing the sensing threshold (in one case to 5 mV).<sup>30</sup> In a study of the effects of TENS (four sites, 51 patients with 20 different pacemaker models), there were no instances of interference, inhibition, or reprogramming.<sup>31</sup> It appears that TENS can be used safely in patients with modern implanted bipolar pacemakers and in patients with unipolar pacemakers if sensitivity is reduced. It has been recommended that TENS electrodes not be placed parallel to the lead vector.

There is much less experience with the use of TENS in patients with ICDs. Several well-documented cases of spurious shocks triggered by TENS application in patients with a variety of lead configurations and sensing algorithms have been published.<sup>32–34</sup> ICDs constitute a relative contraindication to TENS therapy. If TENS is deemed indispensable, provocative testing should be performed with the ICD in the "monitor-only" mode.<sup>32</sup> Ambulatory TENS therapy should be allowed only in the absence of interactions during testing.

## **Percutaneous Coronary Intervention**

Rizk et al.<sup>35</sup> described a patient who received a spurious ICD discharge secondary to oversensing while a Teflon-coated coronary guidewire was in place in a diagonal branch close to the defibrillator lead. No right heart catheters were present, and other causes of oversensing were carefully ruled out. It was suggested that the guidewire picked up EMI present in the catheterization laboratory and delivered it to the proximity of the defibrillator lead. Until more information is gathered, it appears prudent to disable tachyarrhythmia detection while the heart is being instrumented for interventional procedures.

## Electrosurgery

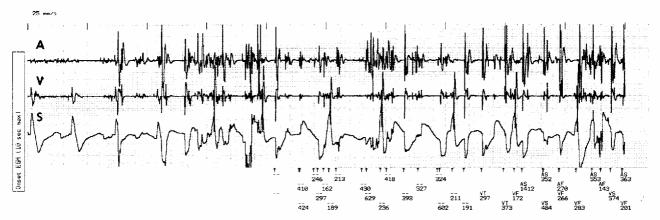
Several electrosurgical techniques can generate EMI. At times, the nomenclature of these techniques is confusing to the nonsurgeon. In Europe, the term surgical diathermy is often used to describe electrosurgical techniques, while in the United States, (short-wave) diathermy refers to the therapeutic application of current directly to the skin and is used for musculoskeletal ailments. Short-wave diathermy should be avoided in patients with implanted devices.<sup>36</sup>

Some techniques are used in general surgery, while others find their most frequent use in dermatologic surgery.<sup>37</sup> Although the term *electrocautery* is often used when referring to electrosurgery, in its strict sense electrocautery describes a technique that promotes hemostasis by heating a metal instrument. As no current is passed in the body, there is little or no risk of EMI. Battery operated, "pencil" electrocauteries are often used during pacemaker implantation. Electrofulgura-

tion and electrodessication are monoterminal techniques that destroy only superficial tissues. They are used mostly in dermatological surgery. Because there is no dispersive ground electrode, little current is generated in the body away from the lesion being treated. The most common electrosurgery modalities, electrocoagulation and electrosection (electrocutting), involve passing current through tissue. Coagulation and cutting use high voltage, low amperage current with high frequency radio wave oscillations 100,000 Hz. Co*agulation* is achieved with short bursts of current and uses lower energy levels than the cutting mode. The short intermittent bursts produce heat within the tissue to control bleeding by thermally sealing the end of a blood vessel. *Cutting* current is continuous and creates high temperatures, causing cell explosion and evaporation. Coagulation and cutting current is usually delivered in a monopolar configuration. Current begins at the active electrode located on the surgical instrument and after traveling through the body it returns to the electrosurgical generator through a dispersing ground pad. Cutting current is more likely to cause interference than coagulation current.<sup>38</sup> In true bipolar electrocoagulation, the current flow is localized across the two poles of an instrument (e.g., coagulation forceps). Because there is little flow of current outside of the surgical site and less power is used, EMI is unlikely to occur. However, it is useful only for delicate surgical procedures and small vessels. Monopolar and bipolar configurations are used during therapeutic endoscopic procedures (e.g., polypectomy, bleeding vessel cauterization).<sup>39</sup> Alternative surgical tools that will not produce EMI include the Shaw scalpel<sup>40</sup> (Oximetrix, Inc., Mountain View, CA, USA), laser scalpels,<sup>41,42</sup> and ultrasound scalpels (Harmonic Scalpel, Ultracision, Inc, Smithfield, RI, USA).<sup>43</sup> A microwave thermotherapeutic device have been introduced in clinical practice for transurethral ablation of benign prostatic hyperplasia. Extensive in vitro testing suggests that this device does not interact with pacemakers or ICDs.<sup>44</sup>

During electrosurgery in monopolar modes, the electric current spreads out and penetrates the entire body of the patient. This stray current may be interpreted by an implanted device as an intracardiac signal. Pacing inhibition, pacing triggering, automatic mode switching, noise reversion, or spurious tachyarrhythmia detection<sup>45</sup> can occur, depending on the type of device, the programmed settings, the duration of EMI, and the channel in which the current is oversensed. Although some investigators have suggested that electrosurgery is safe in patients with activated ICDs,<sup>46</sup> the risk of spurious tachyarrhythmia detection is clearly present (Fig. 1). Electrosurgery can also induce sensor mediated pacing at the upper rate limit in minute ventilation pacemakers.<sup>47,48</sup>

Other types of interaction are more common during electrosurgery than with other sources of EMI.<sup>49</sup> With older technology, up to 21% of pace-makers reverted to the power on reset mode. In a recent prospective study of 45 patients undergoing electrosurgery, electric reset occurred only in 7%.<sup>50</sup> Reset is more common when the surgical wound is closer to the pacemaker pocket.<sup>51</sup> A bipolar configuration is not protective.



**Figure 1.** Spurious ventricular fibrillation detection due to electrosurgical equipment. Stored atrial (A), ventricular (V), and shocking lead (S) electrogram in a patient with a Ventak AV III (Cardiac Pacemakers, Inc., St. Paul, MN, USA) who underwent placement of a Hickman catheter contralateral to the implantable cardioverter defibrillator pocket. Nonphysiological signals are seen in both sensing channels. Tachyarrhythmia therapy had been disabled prior to surgery. The atrial sensitivity was nominal; the ventricular sensitivity was programmed to "less." The device logged in seven detections during the surgical procedure.

Myocardial electrical burns may occur when there is conductivity between the pacing electrode and the indifferent (return) electrode of the electrosurgical unit. This may be facilitated by a pacing electrode with a small surface area and a higher current density. Furthermore, protective circuitry (i.e., zener diodes, thyristors) that shunt current away from the device may also contribute to the development of myocardial burns. Elevation in pacing thresholds can occur, although exit block has not been documented. More severe damage (and even ventricular fibrillation) can occur if the dispersive electrode is disconnected from the circuit, as the pacing electrode becomes the active electrode in the cautery circuit and can directly deliver current to the heart.<sup>52</sup> Irreversible generator failure due to damage to the internal circuitry can occur, especially when applying current close to the device pocket. Permanent loss of output or runaway syndrome<sup>53</sup> can be life threatening. Voltage control oscillator lockout has been identified as a mechanism of sudden output failure after electrosurgery current.<sup>54,55</sup> Irreversible loss of output has been reported after an initial application of electrocoagulation current far away from the pacemaker system (e.g., during hip replacement).<sup>56</sup> Although late recovery of function can occur,<sup>55</sup> the device should not be trusted after initial failure.

Several reviews describe the optimal management of patients with implanted devices undergoing electrosurgery (Table II).<sup>57,58</sup> Short notice and scarcity of specialized personnel make compliance with such guidelines difficult, even in the large hospital with a well-staffed pacemaker clinic. Ideally, the patient should be seen before surgery to determine pacemaker dependency and to document pacing and sensing thresholds. In patients with dual chamber generators that revert to single chamber pacing under electric reset, it may be valuable to observe the hemodynamic tolerance to the reset mode. In general, rate response and tachyarrhythmia detection should be disabled just before surgery. In patients who are not pacemaker dependent, it is best not to change the programmed mode. Pacemaker dependent patients should be reprogrammed to an asynchronous mode (DOO, VOO, AOO, according to the device) above the intrinsic rate. The VVT mode with a long refractory period can be useful in selected instances. It should be noted that asynchronous pacing modes are not available in many ICDs. It is preferable to program the pulse generator preoperatively to an asynchronous mode rather than doing it by application of the magnet. With some older pacemakers, application of the magnet allowed inappropriate random reprogramming by the radiofrequency current.<sup>59</sup> Taping the magnet

to the pacemaker pocket is still useful in emergency situations in which there is no time for reprogramming. It should be remembered, however, that magnet application suspends detection but does not trigger asynchronous pacing in ICDs. The Smartmagnet (Medtronic Inc.) 9322 has been designed to safely suspend tachyarrhythmia detection by Medtronic ICDs during surgical procedures without the need for reprogramming.<sup>60</sup> The battery-operated device contains a magnet, a radiofrequency transmitter, and light-emitting diodes. A green diode remains lit as long as the magnet is properly placed, indicating that tachyarrhythmia detection and therapy are suspended. Its use could facilitate the management of nonpacemaker dependent ICD patients undergoing procedures that can produce EMI.

Communication with the operating room personnel, including nurses, anesthesiologists, and surgeons is important. Electrocautery distorts the ECG and it may be impossible to determine if pacemaker inhibition occurs. Arterial pressure monitoring may be invaluable in this situation. The grounding (dispersive) plate or pad should be placed as close as possible to the operating site and as far away as possible from the pulse generator and lead(s), so that the electrical pathway between the electrosurgical probe and the ground is directed away from the pacing system. For example, during transurethral resection of the prostate, the grounding pad should be on the buttocks or lower leg. Good contact of the pad is mandatory, because with poor contact the pulse generator becomes the anode for the applied current. The patient's body should not come in contact with any grounded electrical device that might provide an alternate pathway for current flow. Proper grounding of all electronic equipment used near the patient is essential.

The monopolar probe should not be used within 15 cm of the pulse generator or lead. Cutting and coagulation time should be as short as possible with the lowest feasible energy level. If electrosurgery causes inhibition of an implanted pacemaker, it should be used in short bursts so as to produce only 1–2 dropped beats at a time. If there is no underlying rhythm, only brief applications (< 1 s) should be used, followed by 5- to 10second periods free from current to allow resumption of rhythm and normal hemodynamics. Ideally, a trained physician and the corresponding programmer should be available within the hospital whenever a patient with an implanted device undergoes electrosurgery. Since damage of the pacing system may occur, the capability of instituting emergency pacing must be present. An external transcutaneous pulse generator (and defibrillator) should be available. In case of inadvertent

#### Table II.

#### Management of Patients with Implanted Devices Undergoing Electrosurgery

#### Preoperative

- Consider alternative tools (knife and ligatures, ultrasonic scalpel, laser scalpel)
- · Identify device and determine "reset" mode
- Check device (programming, telemetry, thresholds, battery status)
- · Develop a contingency plan in case arrhythmias or device malfunction occurs during the procedure

#### In the Operating Room

- Disable tachyarrhythmia therapies
- Deactivate rate responsive features
- If the patient is pacemaker dependent, reprogram device to asynchronous or triggered (with long refractory period) mode. Remember that asynchronous pacing is not available in many ICDs. In these cases:
- Decrease the maximum sensitivity
- If available, program the noise reversion mode to asynchronous
- · Preapply external transthoracic pacing system
- · Consider insertion of separate transvenous pacing wire
- Monitor peripheral pulse or oximeter (ECG is obscured by artifact)
- Position the ground pad to keep the active-to-dispersive current pathways as far as possible and perpendicular from the pulse generator-to-electrode pathway. The current should flow away from the pulse generator
- · Use true electrocautery or bipolar electrocoagulation whenever possible
- · Limit cutting current to short bursts interrupted by pauses of at least 10 seconds
- · Use the lowest effective cutting or coagulation power output
- · Do not use cautery near device
- Reprogram if reset mode hemodynamically unfavorable
- · Use magnet with caution (may permit inadvertent reprogramming in some older devices)

#### Postoperative

- · Reactivate ICD tachyarrhythmia therapy as soon as possible
- Check device (programming, telemetry, thresholds, battery status)
- · Reprogram if necessary
- · Replace generator if circuit damage documented
- Replace lead(s) if pacing threshold too high

ECG = electrocardiogram; ICD = implantable cardioverter defibrillator.

reprogramming that is not hemodynamically tolerated, the pulse generator must be reprogrammed as soon as possible. Magnet application can be attempted as an interim measure (the magnet rate usually varies from 60 to 100 beats/min) but is unlikely to help in these cases.

A damaged pulse generator should be removed and replaced expeditiously, especially if runaway syndrome occurs. All devices must be carefully tested after the operation because reprogramming may be inapparent, especially if the spontaneous rhythm is faster than the lower rate of the pulse generator. Ideally, testing should be performed immediately after the operation and repeated 24 to 48 hours later. Endocardial burns should be suspected if the capture and sensing thresholds have increased. Follow-up is then required until stability can be demonstrated. Occasionally, a rise in threshold may require placement of a new pacing lead or, rarely, a high output pulse generator.

As more surgical procedures are performed outside the hospital (in physicians' offices or freestanding ambulatory surgery centers) these recommendations become difficult to implement. Although industry-employed allied professionals often participate in the perioperative management of device patients in those settings, current guidelines suggest that they should perform technical support tasks only with an appropriately trained

and experienced physician in close proximity (i.e., accessible to attend to the patient within a few minutes).<sup>61</sup> It is not clear what precautionary practices are standard in the community. A recent survey of 166 cutaneous surgeons<sup>62</sup> (mostly involved in electrosurgery of epitheliomas in the office setting), revealed that, although many had encountered instances of EMI with pacemakers or ICDs, few routinely checked or reprogrammed devices before or after surgery. The types of interference reported were skipped beats (8 patients), reprogramming of a pacemaker (6 patients), ICD firing (4 patients), asystole (3 patients), bradycardia (2 patients), and premature pacemaker battery depletion (1 patient). The estimated overall incidence of complications was low (0.8 cases/100 years of surgical practice). Precautions exercised by most dermatologists included use of short bursts of less than 5 seconds, use of minimal power, and avoiding use around the pacemaker or ICD. Bipolar forceps were used by 19% of respondents and were not associated with any incidences of interference.

It is necessary to gather more clinical evidence regarding the incidence and severity of EMI with current implantable devices and different electrosurgical techniques and operations. It is likely that current "blanket" recommendations will need to be revised to accommodate different degrees of risk and allow efficient, cost-effective, high quality perioperative management of patients with implanted devices.

## **Direct Current Cardioversion and Defibrillation**

Direct current (DC) external cardioversion/ defibrillation with paddles (or disposable electrodes) can apply several thousand volts and tens of amperes of current to implantable device systems.<sup>63</sup> Of all sources of EMI, this represents the highest amount of energy delivered in the vicinity of these devices, and have the potential to damage the pulse generator and the myocardial tissue in contact with the lead(s). Current devices incorporate elements (zener diodes, thyristors) to protect the pacing output circuitry and sensing amplifiers by shunting excess energy away from the device. The zener diode behaves as a short circuit as soon as the voltage exceeds a certain value, like 10–15 V, substantially above the output voltage of the pulse generator. Other, less common circuit designs can also limit the current flowing down the lead, but at the expense of inhibiting pacing output during the reception of large voltage.<sup>64</sup> The behavior of the Telectronics Meta 1254 (Engelwood, CO, USA) pacemaker during radiofrequency ablation (see next section) highlights some limitations of this approach. At times, the backup (reset) mode is activated by the countershock. However,

if the protection mechanism is overwhelmed by high energy input, permanent pulse generator circuitry damage may ensue. In addition, capacitive coupling or shunting in the pacemaker circuit may induce currents in pacemaker or defibrillator leads sufficient to cause thermal damage (burn) to the electrode to tissue interface and result in chronic threshold elevation.<sup>65,66</sup> In dual chamber pacemakers, cardioversion energy may be preferentially shunted to the ventricular lead.<sup>67</sup>

The risk of damage to the implanted device depends on the amount of energy applied, the characteristics of the device and lead, and the distance between the paddles or pads and the pulse generator and lead(s). In elective situations, the minimum energy likely to be successful should be delivered. External cardioversion<sup>68</sup> or defibrillation<sup>69</sup> with a biphasic waveform is more efficient (i.e., requires less energy) than the conventional damped sine wave monophasic shocks and should be preferred in patients with implanted devices. It should be noted that unipolar pacing systems are more susceptible to damage than bipolar systems. Whenever possible, an anterior-posterior configuration of the shocking electrodes should be used, as it maximizes the distance between the source and the implanted generator. If an anteroapical position must be used, the electrodes should be at least 10 cm from the pulse generator. However, this may be impossible with devices implanted in a right pectoral pocket, as the anterior paddle will lie directly on top of it. Transient elevations in capture thresholds are common following direct current shocks and should be anticipated. The threshold rise is usually temporary, lasting up to a few minutes, but occasionally it may remain elevated permanently and necessitate lead replacement. Pre- and postprocedural interrogation and testing for proper function should follow external DC shocks in all implantable devices (Table III).

Internal cardioversion is at times attempted in patients who fail external cardioversion of atrial fibrillation. There is limited published experience with this procedure in pacemaker patients. There were no instances of pacemaker malfunction in seven patients who underwent internal cardioversion of atrial fibrillation with electrodes in the right atrium and the coronary sinus or left pulmonary artery with biphasic shocks up to 20 J.<sup>70</sup> However, when high energy endocavitary shocks were used for ablation purposes, pacemaker failure was common.<sup>71</sup>

The availability of dual chamber rate responsive ICDs has greatly reduced the need for separate pacemakers and ICD systems. Among the many possible interactions when using separate devices, electric reset of the pacemaker by a defibril-

#### Table III.

Management of Patients with Implanted Devices Undergoing External Cardioversion or Defibrillation

## **Before Procedure**

- In patients with implantable cardioverter defibrillators, consider internal cardioversion via the device with commanded shock
- · Have pacemaker programmer available in the room
- Determine (if possible) degree of pacemaker dependency
- · Have transcutaneous external pacemaker available
- Use self-adhesive patches or paddles in an antero posterior configuration
- Keep patches or paddles as far from generator and lead(s) as possible
- Use lowest possible energy for cardioversion or defibrillation
- If available, use a biphasic waveform

## After Procedure

- Repeat determination of pacing and sensing thresholds immediately, and 24 hours later
- · Consider monitoring for 24 hours

lator shock was common.<sup>72</sup> To avoid the potential interference with ventricular fibrillation detection by unipolar pacing pulses, only pacemakers that reset to the bipolar mode should be used in conjunction with ICDs. Limited experience suggests that automatic internal defibrillator shocks do not interfere with the function of the dedicated cardiomyostimulator used in patients with dynamic cardiomyoplasty.<sup>73</sup>

## **Radiofrequency Catheter Ablation**

Radiofrequency catheter ablation is first line therapy for a variety of supraventricular and ventricular arrhythmias. The interaction between radiofrequency current and implantable devices has been studied most thoroughly during palliative ablation of the atrioventricular junction for drug refractory atrial fibrillation. There is also considerable clinical experience with the ablation of monomorphic ventricular tachycardia in patients with ICDs.<sup>74</sup>

Radiofrequency current (delivered as an unmodulated sine wave at 500–1,000 kHz) is an intense source of pulsed interference that interacts unpredictably with implanted devices. Energy delivery may result in asynchronous pacing, rapid tracking, spurious tachyarrhythmia detection, and electrical reset. Different interactions may be seen (in the same patient) during consecutive energy applications. Most of the interactions are transient and terminate with cessation of energy delivery.<sup>75</sup>

Animal and clinical studies have examined the incidence, mechanisms, and risk factors for these interactions. Chin et al.<sup>76</sup> studied 19 pulse generators implanted in 12 dogs. They found that interactions depended on the proximity of current application to the pacing leads. Interactions were frequent at 1 cm and absent at > 4 cm. The most dangerous interaction was "runaway" pacing with possible induction of ventricular fibrillation. In a tissue bath model, Dick et al.<sup>77</sup> investigated the effects of radiofrequency current (55 W; tip temperature 65°C–70°C) applied to four different pacing or defibrillation leads. Photographic and microscopic examination after energy delivery revealed no damage to the target lead. There was no malfunction of the attached pulse generators. The magnitude of induced current measured at the target tip lead was inversely proportional to the distance. Significant current was detected only when the ablation catheter was less than 1 cm from the target lead tip.

The clinical incidence of acute interaction between radiofrequency current application and permanent pacemakers has ranged widely. The incidence and severity of interference depends in part on the protective circuits of the implanted device. For example, the Telectronics Meta DDDR 1254 pacemaker presented a unique response to radiofrequency energy delivery.<sup>78</sup> When current was applied at the same time as the pacing pulse, the pacemaker output switched open to protect the circuitry. No pacing output was emitted until radiofrequency energy delivery ceased, although the event markers indicated normal pulse delivery. The combined incidence of acute pacemaker malfunction during radiofrequency current application in three relatively large series including a total of 125 patients with assorted pacemakers was 44%.<sup>78-81</sup> The most common interaction was asynchronous pacing due to noise reversion, followed by oversensing resulting in refractory period extension and "functional undersensing," pacemaker inhibition, or antitachycardia pacing in special pacemakers. Electrical reset, radiofrequency induced pacemaker tachycardia, erratic behavior, and transient loss of capture were less frequent. In contrast, Proclemer et al.<sup>82</sup> did not observe transient or permanent pacemaker dysfunction in 70 consecutive patients with Medtronic Thera I and Kappa single and dual chamber pacemakers with unipolar leads who underwent atrioventricular (AV) junction ablation. The pacemakers were implanted prior to radiofrequency ablation in a single session procedure and were transiently programmed to VVI mode at a rate of 30 beats/min.

The long-term effects of radiofrequency application on permanent pacing systems have been less well studied. Exit block (possibly due to scar at the lead to tissue interface), lead damage, and chronic generator malfunction (requiring replacement) have been reported.<sup>75,81,83</sup> In the multicenter report of Ellenbogen et al.<sup>78</sup> and the series by Proclemer et al.,<sup>82</sup> changes in lead impedances and pacing and sensing thresholds did not appear clinically significant. In a study of 72 patients with a preexistent pacemaker (n = 59) or defibrillator (n = 13) leads undergoing AV junction ablation, Burke et al.<sup>84</sup> observed a significant increase in pacing thresholds that was present immediately after ablation and became more marked 24 hours later. A twofold increase in pacing threshold was much more likely to occur in patients with defibrillator leads. Two of the ICD patients (15%) and two of the pacemaker patients (3%) presented a progressive rise in pacing threshold requiring lead revision. The mechanism of the increased vulnerability of the ICD leads was not clear.

Following a few simple precautions can minimize adverse outcomes. Complete pacemaker inhibition is dangerous in patients without an escape rhythm during ablation of the atrioventricular junction. It is prudent to always insert a temporary transvenous pacemaker (programmed to a high output and, if necessary, to an asynchronous mode) to avoid asystole. The preexistent unit should not be trusted to provide backup pacing because loss of output or capture can occur despite programming an asynchronous mode. The risk of pacemaker runaway may be reduced by programming the device OOO or to subthreshold outputs.<sup>76</sup> Rate responsiveness should be disabled. Pacing at the upper rate limit may occur when minute ventilation pacemakers that measure transthoracic impedance misinterpret radiofrequency current.<sup>85</sup> Tachyarrhythmia detection should be disabled in patients with ICDs to prevent spurious therapies. Attempts should be made to perform ablation as far as possible from the pacing leads. In some instances, a left-sided approach to ablation of the AV junction should be considered. Patients with previously implanted pacemaker or ICD systems should be followed closely after radiofrequency catheter ablation.

## Lithotripsy

Acoustic radiation, from extracorporeal shock wave lithotripsy (ESWL) machines, provides a noninvasive means to disintegrate renal, ureteral, gallbladder, and biliary calculi. With the original device (Dornier HM3, Kennesaw, GA, USA), the patient lies in a water bath, and multiple (~ 1,500) hydraulic shocks are generated from an underwater 20-kV spark gap and focused on the calculi by an ellipsoid metal reflector. The shock wave can produce ventricular extrasystoles, so it is synchronized to the R wave. Implanted devices could be subject to electric interference from the spark gap and mechanical damage from the hydraulic shock wave. Newer units (e.g., Dornier Compact Delta) use an enclosed water cushion for shock wave coupling. Other units use electromagnetic (e.g., Lithostar Plus Siemens AG, Erlanger, Germany) or piezoelectric (e.g., Piezolith 2500, Richard Wolf GmbH, Knittlingen, Germany) shock wave generators.<sup>86</sup> Most information regarding interactions with implanted cardiac devices has been collected with the Dornier HM3 unit.

Several investigators have studied the effect of ESWL on pacemakers in vitro.<sup>87–89</sup> Pacemaker output was not inhibited by properly synchronous shocks, but asynchronous shocks caused inhibition in unipolar and bipolar devices. During AV sequential pacing, a shock inappropriately synchronized to the atrial pacing pulse is often sensed by the ventricular channel, with the potential to cause inhibition of the ventricular output. Intermittent reversion to magnet mode can occur because of transient closure of the reed switch from the high energy vibration. Other responses noted during in vitro testing include an increase in pacing rate secondary to tracking of EMI in the atrial channel, noise reversion, spurious tachyarrhythmia detection,<sup>90</sup> and malfunction of the reed switch. Activity-sensing pacemakers increased their pacing rate to the upper pacing rate within 1 minute of the shock. ESWL caused no physical damage to the hermetic seal or the internal components of the pacemakers tested, except that when an activity-sensing pacemaker was placed at the focal point of the ESWL, the piezoelectric crystals shattered.<sup>89</sup> In vitro testing of two ICDs with a new generation lithotripter did not disclose adverse interactions (even when the generator was placed within the focus of the lithotripter), provided the shockwaves were applied synchronized to the R wave.<sup>91</sup>

There is limited clinical experience with the use of ESWL in patients with pacemakers or ICDs. Drach et al.<sup>92</sup> reported only four mild complications in a worldwide series of 131 pacemaker patients. One device exhibited power-on-reset, one patient developed irregular heart rhythm if more than 22 kV was used, one device exhibited intermittent asynchronous operation, and one a 10-beat/min increase in pacing rate with several extrasystoles. Albers et al.<sup>93</sup> did not observe detrimental interactions in 20 pacemaker patients undergoing ESWL for urinary tract calculi. Safe ESWL has been reported in a patient with an abdominal contralateral early model ICD shielded with polyestyrene foam<sup>94</sup> and in a patient with an

unshielded tiered-therapy ICD ipsilateral to the renal stone.<sup>95</sup> In a third patient with an Intermedics (Angelton, TX, USA) abdominal ICD near elective replacement time, contralateral ESWL triggered the elective replacement indicator.<sup>95</sup> It appears that ESWL is safe to use with implantable antiarrhythmic devices as long as the device and target are at least 6 cm apart. Activity-sensing rate adaptive devices implanted in the thorax can undergo lithotripsy safely, but the procedure should be avoided if the device is located in the abdomen. Synchronization of the shocks to the R wave is crucial. Activity sensors and tachyarrhythmia detection should be temporarily disabled in all cases. Reprogramming dual chamber pacemakers to VVI or VOO (if the patient is pacemaker dependent)<sup>96</sup> is safe, and will avoid ventricular inhibition due to shocks synchronized to the atrial output, irregular pacing rate, tracking of induced supraventricular tachycardia, or triggering of the ventricular output by EMI. In patients with AV sequential pacing (DDD or DDI) who cannot tolerate loss of AV synchrony during the procedure, enabling of safety pacing (or extending the postatrial pacing ventricular blanking when safety pacing is not available) should prevent ventricular inhibition. Safety pacing will result in a short AV interval that should not be detrimental. Careful followup should be performed over the next several months to ensure appropriate function of the reed switch. In patients with abdominal ICDs, full electrophysiological testing to confirm satisfactory detection and therapy of induced tachyarrhythmias may be warranted.

## Radiotherapy

Radiotherapy can induce different responses in implanted devices. EMI produced by the radiotherapy machine can result in pacing inhibition, tracking, noise reversion, or inappropriate ICD discharges. Usually, the effects are mild and observed only while the machine is switched on or off.<sup>97</sup> Interference may be more severe with betatrons<sup>98</sup> or with linear accelerators that misfire (spark).

More important is the risk of permanent generator damage due to ionizing radiation.<sup>99</sup> Although early pacemakers were not susceptible, newer devices incorporating complementary metal oxide semiconductor-integrated (CMOS) technology, may incur cumulative damage during radiation therapy.<sup>100</sup> Ionizing therapeutic radiation acts on the silicone and silicone oxide insulators within the semiconductors. Radiation may be sufficiently intense to cause complete failure or random damage to circuit components. Intense radiation may alter transistor parameters or create electrical shorts that result in premature battery

depletion. Failure may also involve changes in sensitivity, amplitude or pulse width, loss of telemetry, output failure, or runaway rates. Because the damage to the circuit is random and the radiation dose cumulative from one therapeutic exposure to the next, no specific prediction rela-tive to dose can be made. Last<sup>101</sup> has presented a comprehensive review of in vitro studies assessing the effects of ionizing radiation on pacemakers and ICDs. It should be remembered that total therapeutic radiation doses may be as high as 70 Gy (7,000 rad) given over several weeks. In studies that have used conventional (i.e., fractionated) dosage regimens, minor pacemaker malfunction has been reported with doses as low as 2 Gy, but no significant failure has been observed with doses less than 10 Gy. Changes in sensing and telemetry functions and pulse width often occur first. Total loss of output has resulted from doses of 16–300 Gy. The degree of susceptibility may be inversely proportional to the oxide thickness. Rodriguez et al.<sup>102</sup> found that more current devices with the thinner 3-µm CMOS technology were less sensitive than the older ones with 5 or 8  $\mu$ m CMOS circuits. Although one study reported no ICD failures at doses lower than 50 Gy, charge times increased dramatically. The available evidence does not suggest differences in risk of pace-

## Table IV.

#### Management of Patients with Implanted Devices Undergoing Radiotherapy

- · Avoid betatron
- Evaluate device and pacemaker dependency prior to therapy
- Plan radiotherapy to minimize total dose (including scatter) received by generator:
  - Avoid direct irradiation
  - Maximize shielding and distance of pulse generator from radiation beam
  - Consider moving the pulse generator away from the field if the estimated dose is  $> 10 \ {\rm Gy}$
- Institute appropriate level of monitoring:
  - If estimated dose < 2 Gy and patient not pacemaker dependent clinical monitoring suffices
  - If estimated dose > 2 Gy or patient pacemaker dependent high level monitoring is necessary
    - Continuous electrocardiogram monitoring during treatments
    - Have staff competent in advanced cardiac life support nearby
    - Check device function after each therapy session and regularly for several weeks thereafter
- Consider generator replacement at the earliest evidence of circuitry damage

maker damage for the different available types of therapeutic radiation. Diagnostic radiology procedures pose no immediate or cumulative effects on pulse generators.

Radiation oncology centers should have protocols for patients with implantable antiarrhythmic devices (Table IV).<sup>103</sup> Shielding and oblique fields may reduce the dose received by the device. This is particularly important in patients undergoing radiation for thoracic or chest wall malignant disease. If the pacemaker is within the field of radiation (e.g., in patients with carcinoma of the breast), there may be no alternative but to remove

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the device and reimplant it away from the area to be radiated. In many cases, the device can be relocated in an ipsilateral abdominal pocket and the preexistent leads reused with the aid of extenders. If the pulse generator is not in the field radiation, it should nevertheless be shielded to prevent damage. It is essential that patients with implanted devices undergoing radiation therapy be monitored closely during the course of the treatment and for a few weeks thereafter. Although some pacing changes may resolve in hours to days, the longterm reliability of the pulse generator is uncertain<sup>99</sup> and should always be replaced.

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