Understanding Risk of Cardiac Stimulation when Pacemaker Patients Undergo MRI Scanning

D. Manahan[1], J. Edmonson[1], B. Herberg[1], and A. Singal[1]
[1]Cardiac Rhythm Disease Management, Medtronic Inc., Minneapolis, MN, United States

Introduction:

The safety of MRI scanning for patients with implanted pacemakers (IPGs) and defibrillators (ICDs) is under debate. These devices are connected to insulated lead wires that terminate at electrodes implanted intravenously into the heart. One concern is associated with the time varying electric field induced in the patient's body by the pulsing of the scanner's gradient magnetic fields. This electric field will cause a time varying voltage difference to be developed between the cardiac electrodes and between cardiac electrodes and the case of the IPG or ICD. If the necessary conditions are present, this voltage can produce sufficient current flow through the electrodes in the heart to cause unintended cardiac stimulation (UCS) hazardous to the patient. The most significant device attribute affecting the risk of gradient induced UCS is the impedance of device circuitry connected to the lead wires and the conductive device case.

Analysis:

In order for the voltage induced between the electrodes in the heart and the case of the implanted device to cause UCS it must force a sufficiently large current through the cardiac electrodes. Figure 1 illustrates the paths for currents that flow as the result of gradient induced lead voltage for a simple dual chamber pacemaker with unipolar leads. V_{L1} and V_{L2} represent the gradient induced lead voltage. If the impedances the device presents between lead wires (Z_{12}) and between lead wires and the device case (Z_1, Z_2) are infinitely large, then no current can flow and cardiac stimulation can not occur. Conversely, if the device impedances are near zero, the flow of current will be limited only by the impedance of the tissue paths and may reach hazardous levels.

Methods:

All animal experiments were performed with approval and supervision of the Medtronic Animal Care Committee. An IPG case with the internal circuitry removed was implanted in an animal patient along with a lead wire implanted into the right ventricle (RV). A switch was connected so that the impedance between the proximal end of the lead wire and the device case (i.e. position of Z_1 or Z_2 in Figure 1) could be switched between open circuit and short circuit. The animal was placed in a clinical 1.5 T MRI scanner such that the approximate center of the pacemaker and lead path was located 35 cm from isocenter, where the rate of change for the vertical (y) gradient coil was measured to be approximately 25 T/s. The RF transmit power was the minimum programmable value. The animal was monitored using pulse oximetry and ECG. The in-vivo gradient induced lead voltage, pulse ox, and ECG were recorded. The stimulation threshold for the implanted lead was measured prior to MRI exposure.

Result:

With the gradients operating and the switch in the open position, the animal's cardiac rhythm was unaffected. The switch was then closed while the gradients continued to operate. The change in cardiac rate following switch closure confirmed the occurrence of gradient induced cardiac stimulation. When scan parameters were adjusted to cause stimulation at 300 beats per minute the pulse ox monitor indicated a loss of hemo-dynamic function. Representative portions of the ECG and pulse ox monitoring strips recorded during this test are shown in Figure 2.

Conclusion:

Susceptibility of pacemaker and defibrillator systems to gradient induced cardiac stimulation may vary widely dependent upon circuitry design, including the value of EMI filter capacitors. Gradient induced lead voltage will vary widely depending upon patient dB/dt exposure. Safety must be evaluated for each device design based on expected dB/dt exposure.

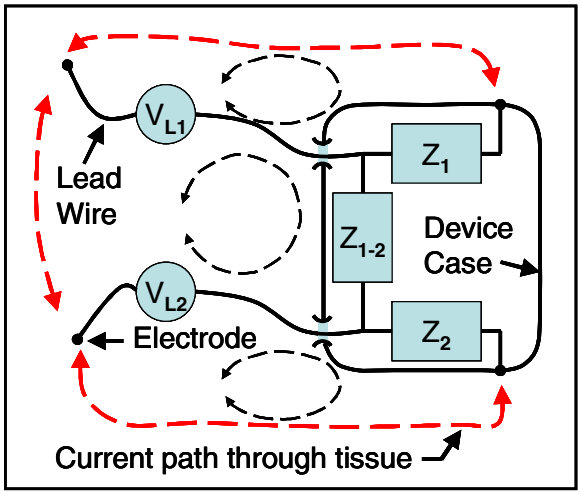

Figure 1. Representation of possible gradient induced current paths for a dual chamber pacemaker with unipolar lead wires.

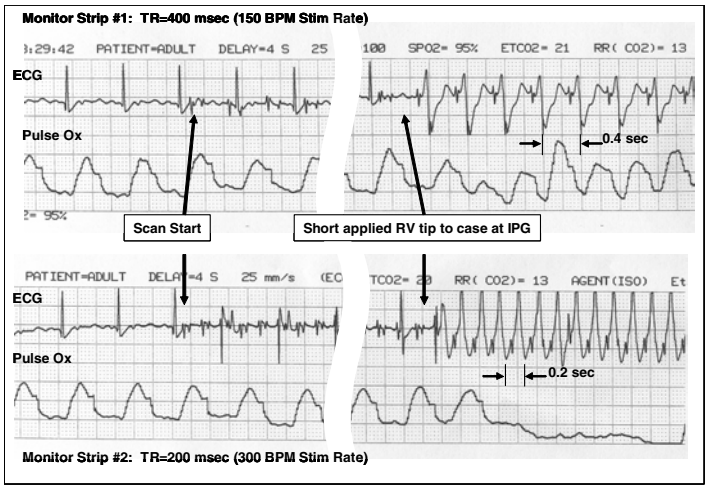

Figure 2. Monitoring strips collected during animal test conducted to demonstrate gradient induced cardiac stimulation.