Comparison of Measured and Estimated Induced Voltage on Implanted Cardiac Leads due to MRI Gradient Magnetic Fields

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Introduction:

It would be beneficial to patients and their physicians alike if implanted cardiac pacemakers or defibrillators were labeled for use in MRI systems. Implanted cardiac rhythm management systems typically consist of an implantable pulse generator (IPG) or implantable cardioverter-defibrillator (ICD) connected to leads that are implanted intravenously into the heart. There are a number of different aspects of the MRI environment that may compromise the safety and reliability of these systems. One concern is the electric field induced in the patient's body by the pulsing of the scanner's gradient magnetic fields. This electric field will cause a voltage to be developed along the path(s) of the cardiac lead(s). This voltage may cause unintended cardiac stimulation, which could be hazardous to the patient if it were to occur at a high rate repetition that would emulate ventricular tachycardia and cause hemodynamic collapse. In order to evaluate the risk of unintended cardiac stimulation and other potential effects of voltage induced along the lead path, the amplitude of the induced voltage must be determined.

Methods:

In many aspects of medical device design, analysis is done using worst case values and conditions. If a device is shown to be safe under worst case conditions, it can then be considered safe within the environments it is intended for. This approach was taken for the analysis of the risks associated with gradient magnetic fields on an implantable device. In order to determine a worst case maximum value for the gradient-induced voltage along an implanted lead, a loop area method of approximation is used. The first step of the loop area approximation consists of artificially closing the lead path with a straight line from the lead tip to the IPG and determining an effective loop area for the lead path. The voltage induced on the lead can then be estimated by multiplying the magnitude of dB/dt orthogonal to the loop with the effective loop area, which is simply Faraday's law of induction.

In order to verify that the loop area approximation is reasonably accurate and can be used to find a worst case induced voltage, a series of measurements were made within an electrolyte filled phantom placed in an MRI scanner. A total of fifty, two dimensional lead paths (figure 1) were defined based on coronal x-rays of patients with ICDs or IPGs. Twenty five of the paths represent a device implant in the left pectoral region while the remaining twenty five paths represent a right pectoral device location. The lead paths were set up within the phantom and positioned in a region of high gradient field dB/dt oriented orthogonal to the plane of the lead path. The voltage induced between the electrode at the tip (distal end) of the cardiac lead and an IPG case connected to the proximal end of the lead was then measured along with the magnitude of dB/dt orthogonal to the two dimensional lead path. All internal IPG circuitry was disconnected from the lead to prevent it from affecting measurement results. The measured voltages and measured dB/dt were then used to evaluate the accuracy of values calculated using the loop area method.

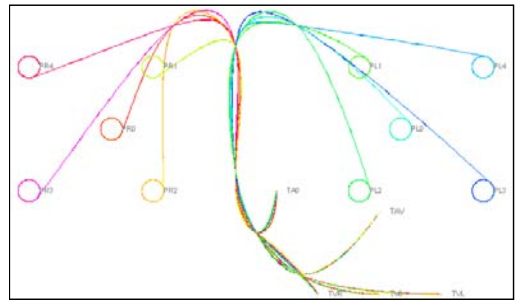

Figure 1. 50 Two-dimensional lead paths used for gradient induced voltage measurements.

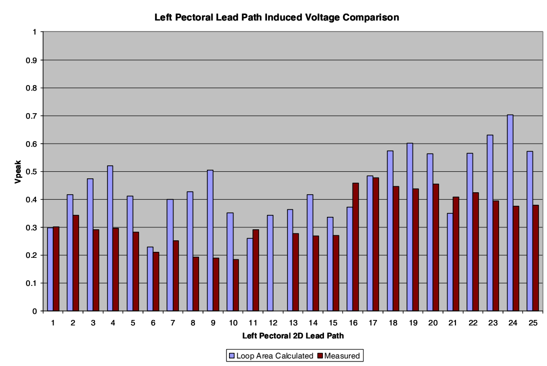

Figure 2. Left pectoral implant gradient induced voltages and loop area approximations.

Results / Conclusions:

Measurement results and the corresponding loop area approximations are presented in Figures 2 and 3. The measured results (in red) were made on a GE Echospeed scanner using a slice select gradient pulse from a coronal imaging sequence. The loop area approximation (in blue) is determined by multiplying the effective loop area with the dB/dt that was measured in the region of the lead path. Figure 2 provides the results for the left pectoral device location while Figure 3 provides the results for the right pectoral device location. In general, the lead paths for left pectoral device implants have larger effective loop areas and larger measured induced voltages, as can be seen by comparing Figures 2 and 3. In addition, it can be noted that the loop area approximation method results in a larger estimate of the induced voltage than what was physically measured for the majority of the lead paths. Most importantly, the maximum calculated value using the loop area method is approximately 47% larger than the maximum measured induced voltage. These results suggest that the loop area method provides a useful estimate of gradient induced lead voltage. They also suggest that induced lead voltages estimated using this method will result in a conservative assessment of potential effects upon implanted cardiac rhythm management systems by providing an over-estimate for the maximum gradient induced lead voltage. Based on these results, a worst case voltage can then be defined via the loop area approximation that can be used for purposes of device design and patient risk analysis.

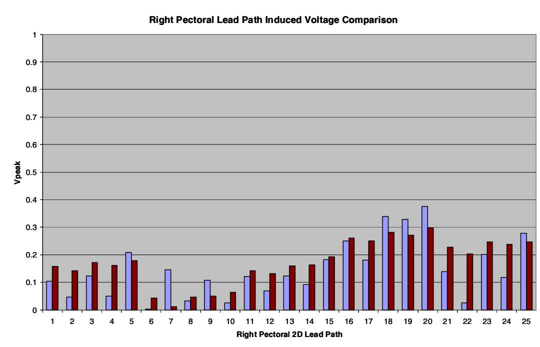

Figure 3. Right pectoral implant gradient induced voltages and loop area approximations.