Editorial

Can cardiac pacemakers and magnetic resonance imaging systems co-exist?

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Online publish-ahead-of-print 17 January 2005

This editorial refers to ‘In vivo heating of pacemaker leads during magnetic resonance imaging’† by R. Luechinger et al., on page 376

Background

One of the earliest lessons learned by physicians and technologists working in the field of magnetic resonance imaging (MRI) is that cardiac pacemakers represent a strict contraindication to performing an examination. However, there are multiple examples of implants and devices that previously were contraindicated for MRI and are now allowed within specific guidelines. These include neurostimulation systems, cochlear implants, a drug infusion pump, and a bone fusion stimulator.

Because of expanding clinical indications, both MR and pacemaker technology has steadily advanced. It is no surprise then that these two powerful technologies might clash. There has been a steady increase in the number of pacemakers implanted in the United States and worldwide. More than 900 000 pacemakers were implanted worldwide in 2003, and since 1999 implantation rates have increased 5–6% per year.

MR systems have been increasing in number as well. There are now ~15 000 MR systems worldwide, and 35 million MR studies performed yearly. MR is an important diagnostic tool in musculoskeletal, central nervous system, and oncological disorders. It is also rapidly expanding into the cardiovascular arena. Because of its varied clinical applications there are times when denying MR examinations to patients with a pacemaker may have a significant impact on public health. The patients may be subjected to a more invasive or less accurate test which may influence the quality of healthcare. A 1999 Japanese study found that 17% of patients with pacemakers were denied MRI in the previous year. Applying those numbers worldwide, the effect could influence the healthcare of over 1 million people.

Notably, harmful effects to patients have been documented. To date there have been 10 deaths attributed to MR and pacemaker interactions. However, the fatalities were poorly characterized and no electrocardiographic data were available. Importantly, no deaths have been reported during physician-supervised MRI procedures.

Current strategies

Strategies for safe MRI in patients with pacemakers differ around the world. Some investigators have suggested that the pacemaker be programmed sub-threshold or ‘off’. This would diminish, but not eliminate, the potential for the rare episode of ventricular fibrillation. Asynchronous programming is another strategy; however, this does not completely eliminate the potential for lethal ventricular arrhythmias either. Some investigators have even favoured explanting the pulse generator; however, this might be considered a greater risk than performing the MR examination. From a MR standpoint, limiting the exposure to radio frequency (RF) power by manipulating MR sequences is reasonable, as is scanning with the pulse generator outside the bore. However, employing the latter strategy may be impossible if clinical necessity dictates.

Previous studies

Multiple investigators have attempted to answer the question of whether an acceptable risk benefit ratio may exist with regard to pacemaker use in a MR system. Phantom and animal studies have shown multiple
potential problems including heating of the leads, an increase in the stimulation rate, asynchronous pacing, rapid pacing, reed switch inhibition, and induction of ventricular fibrillation. However, despite the value of these studies, their applicability to humans is not known. Case reports and retrospective studies in humans have reported rapid ventricular pacing and asynchronous pacing as well as normal pacemaker functioning, but these studies have little clinical applicability.

Within the last few years, there have been a number of prospective human studies at varying static magnetic field strengths over multiple anatomical regions examining the issue of MRI and pacemaker interactions and safety\(^5\text{-}\text{9}\). The results of these studies were that no patients were harmed. A small number of stimulation threshold changes were seen but were overcome by device adjustments after MRI. Of note is that none of these studies included pacemaker-dependent patients. To date there have also been at least 300 pacemaker patients who have safely undergone MRI. These data suggest that the presence of a cardiac pacemaker is not as detrimental as once thought.

However, a limitation to all of the previously reported in vivo studies is that heating could only be inferred from changes in lead impedances, and sensing and stimulation threshold changes. It was never measured directly. The study by Luechinger et al.\(^10\) in the present issue of the Journal makes an important contribution to the growing work in the field by examining heating directly in an in vivo swine model.

**Current study**

The investigators implanted pacemakers and the concomitant lead systems in nine pigs. Leads were placed in the right atrial appendage, right ventricular apex, and right ventricular outflow tract. To measure temperature, thermocouples were used in the leads instead of fiberoptic sensors. The first three animals were used to optimize the experiment and the last six pigs were used for the investigation. The pacing function was turned off and bipolar sensing in an ODO mode was used during MRI. Stimulation thresholds, pacing impedance, sensing measurements, and heating were measured for each animal. All except the first two animals underwent MRI 4 weeks after implantation. The first two animals underwent MRI immediately after pacemaker implantation. MRI was performed on a 1.5 T system in a worst-case scenario with whole body averaged specific absorption rates (SAR) reaching 3.8 W/kg.

The principle results were that significant heating was encountered along with significant changes in impedance and stimulation thresholds. However, at post-mortem examination, no histological damage from heating could be detected and troponin levels, drawn after MRI, were also not elevated. No pacemaker dysfunction occurred. One animal developed a tachycardia up to 240 beats per min during MRI that was self-terminated and consistently reproducible.

Examining the results, both the heating and threshold changes are somewhat concerning. The threshold changes are also larger than seen in the previous study on humans at 1.5 T.\(^7\) However, the authors do note that the pigs were scanned in a worst-case scenario with high SAR levels up to 3.8 W/kg. The United States Food and Drug Administration states that the maximum allowable whole-body averaged SAR is 4.0 W/kg for a time of \(\geq 15\) min. The previous study had SAR levels up to 2 W/kg. Therefore, limiting the exposure to RF power and keeping the SAR values \(\leq 2\) W/kg would be a reasonable approach in helping to achieve safety. This may become more important in the future with upgrades in MR hardware and software.

The present study also showed some puzzling results with respect to heating changes. Heating did not seem to correlate with stimulation threshold or impedance changes. Significant threshold changes were seen in

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Number of patients</th>
<th>Number of examinations</th>
<th>Field strength (T)</th>
<th>Results</th>
<th>Investigated region(s)</th>
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<tr>
<td>Sommer et al.</td>
<td>1998</td>
<td>18</td>
<td>18</td>
<td>0.5</td>
<td>Deactivation of reed switch</td>
<td>Head, neck, lumbar spine, thorax</td>
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<tr>
<td>Sommer et al.</td>
<td>2000</td>
<td>44</td>
<td>51</td>
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<td>No significant changes</td>
<td>Heart, brachial plexus, brain, knee, lumbar spine, pancreas, abdomen</td>
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<td>Valhaus et al.</td>
<td>2001</td>
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<td>34</td>
<td>0.5</td>
<td>Reversible battery voltage decreases; temporary deactivation of reed switch</td>
<td>Heart, arm, brain, liver, abdomen, pancreas, shoulder</td>
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<td>Schmiedel et al.</td>
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<td>48</td>
<td>58</td>
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<td>Martin et al.</td>
<td>2004</td>
<td>54</td>
<td>61</td>
<td>1.5</td>
<td>Stimulation threshold changes Minor patient symptoms Insignificant ECG changes</td>
<td>MRA of head, neck, abdomen, pelvis, and legs; MRI of brain, heart, lumbar and cervical spine, abdomen, chest, brachial plexus</td>
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MRA, magnetic resonance angiography.
leads with minimal heating, and minimal threshold changes were seen in leads with high heating. It may be possible, despite the authors’ contention to the contrary, that the thermocouple may have interfered with the heating measurements. Heating was also measured at one position, which was an acknowledged limitation of the study. The authors suggest that myocardial scar could act as an insulator and may account for the lack of correlation between heating and threshold changes. Taking this a step further, the scar could prevent heat leakage from the tip and may also have a dual role as myocardial protectant. But this does not explain the significant threshold changes seen in minimally heated leads. These questions remain unanswered by the current study.

Only the first animal, scanned with MRI immediately after pacemaker implantation, showed ECG abnormalities. A tachycardia was encountered up to 240 beats per min and was self-terminated once scanning was completed. This was reproducible at all scans greater than a SAR ≥1 W/kg. Since the pacemaker was programmed ODO, it would be almost impossible for pacing to be delivered by the pulse generator. This suggests that the phenomenon was caused by the MR system. It is possible that the explanation for this could lie at the lead–tissue interface. Perhaps the recent implantation sensitized the myocardium to stimulation. The geometry of the pacemaker system with respect to the animal may also pre-dispose the myocardium to stimulation. Regardless, this animal underwent MRI immediately after pacemaker implantation, which would be an unlikely scenario in clinical medicine.

Recommendations

So, does this study add to the literature favouring safe MRI in patients with pacemakers? I would answer, yes. Encouragingly, despite significant threshold and impedance changes and heating, no histological heating changes were seen. The significant changes may have been the result of aggressive MRI protocols. Therefore, using protocols that limit SAR levels, ideally below 2 W/kg, might be reasonable. Additional recommendations based on the literature would include: (i) document that a clinically necessary MR study is warranted in a patient with a pacemaker; (ii) obtain informed consent; (iii) have emergency equipment and Advanced Cardiac Life Support (ACLS)-trained personnel readily available; (iv) scan only non-pacemaker-dependent patients; (v) interrogate the pulse generator immediately before and after MRI and reprogram if necessary; (vi) disable the minute ventilation feature; (vii) maintain voice contact throughout the procedure and continuously monitor heart rhythm and rate. Pulse oximetry monitoring is not necessary but can be used concomitantly with rhythm monitoring to provide an additional level of safety; (viii) a physician adept in pacemaker programming needs to be present during the MRI; (ix) sub-threshold output programming is reasonable but has not been shown to be necessary if the above guidelines are followed; (x) scan modern pacemakers (manufactured after 2000).

Future studies

Future research could examine animal models with less aggressive MRI protocols, or compare less aggressive with more aggressive protocols, to see whether significant heating, stimulation threshold, and impedance changes occur. Future studies could also concentrate on pacemaker-dependent animals and humans to develop a safety protocol.

Conclusion

Over the last few years, the risk benefit ratio for patients with pacemakers undergoing MRI has shifted towards safety, if guidelines are followed. Therefore, the presence of a permanent pacemaker may no longer represent a strict contraindication to MRI.

References