Original Research

Pacemaker Lead Tip Heating in Abandoned and Pacemaker-Attached Leads at 1.5 Tesla MRI

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Purpose: To assess the risk of RF-induced heating in pacemaker-attached and abandoned leads using in vitro temperature measurements at 1.5 Tesla as a function of lead length.

Materials and Methods: Five custom lead lengths, 20–60 cm, were exposed to a uniform magnitude and phase radiofrequency electric field to examine the effect of lead length on pacemaker lead tip heating for pacemaker-attached and abandoned pacemaker leads.

Results: Abandoned and pacemaker-attached leads show resonant heating behavior and maximum heating occurs at different lead lengths due to the differences in termination conditions. For clinical lead lengths (40–60 cm) abandoned leads exhibited greater lead tip heating compared with pacemaker-attached leads.

Conclusion: Current recommendations for MRI pacemaker safety should highlight the possible increased risk for patients with abandoned leads as compared to pacemaker-attached leads.

Key Words: magnetic resonance imaging; medical device safety; pacemaker; RF-induced heating; abandoned leads
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MAGNETIC RESONANCE IMAGING (MRI) is an indispensable clinical tool for the diagnosis of disease and, in general, is considered a safe imaging modality when appropriate safety precautions are in place. The expanding diagnostic abilities of MRI in areas such as neurological, musculoskeletal, and cardiovascular imaging often makes MRI the diagnostic tool of choice (1). For a growing number of patients with implanted medical devices, including pacemakers, some patients are being precluded from diagnosis by MRI due to safety concerns about the interaction between the device and the static magnetic field (B_0), gradient magnetic field (dB/dt), and radiofrequency (RF or B_1) magnetic field used in MRI (2).

Since the first report of harmful interactions between MRI and pacemakers in 1983 there have been significant advances in pacemaker design (3). Pacemaker manufacturers have reduced the amount of ferromagnetic material, which has significantly reduced the risk of device displacement due to the static magnetic field (4). The risk of cardiac stimulation from currents induced by the gradient magnetic field has also been largely mitigated by the ability to program pacemakers to a nonsensing mode during an MRI procedure (5). Research into the risks of gradient-induced stimulation, however, is still on-going. Currently, for the newer generation of devices, the most substantial risk for patients with pacemakers arises from the RF field, which has been shown to cause pacemaker lead tip heating at the myocardial interface (6–8).

The RF field in MRI is a circularly polarized magnetic field that rotates at 64 MHz in 1.5 Tesla (T) MRI systems. The continual rotation of the RF magnetic field induces a concurrent RF electric field by Faraday's Law. The RF magnetic field is used to specifically excite hydrogen protons in the patient, isolating their signal for the creation of MR images. Although the RF electric field does not contribute directly to the formation of MR images, it does deposit energy in the subject, reported as the specific absorption rate (SAR), which is limited for patient safety by the FDA and IEC (9) (IEC 60601-2-33). The whole body SAR is limited to 4 W/kg. However, these regulations do not account for the presence of implanted medical devices, which can alter and may enhance energy deposition in tissue. For implanted devices such as pacemakers, the RF electric field inside the patient can couple to the pacemaker lead and causes induced currents in the pacing leads (10). For a 1.5T MRI, the RF electric field has a frequency of 64 MHz, which corresponds to a wavelength of 4.7 m in air and 0.52 m in water, neglecting the effects of conductivity which will decrease the wavelength with increasing conductivity (2). Clinically relevant pacemaker leads lengths range from 40 to 60 cm, making pacemaker leads particularly susceptible to RF-induced heating

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because of the comparable wavelength of the RF electric field in tissue and the pacemaker lead lengths used clinically.

As shown by Sung-min Park et al, the coupling of the RF electric field to the pacemaker lead is a governed by the amplitude and phase of the electric field along the lead, as well as the lead length (10). The resulting current induced in the pacemaker lead manifests as heating focused at the pacemaker lead tip, which is implanted in the cardiac tissue. The heating arises due to ohmic loss caused by the impedance mismatch that exists between the highly conductive metallic components of the pacemaker lead and the relatively low conductivity cardiac tissue (8). For pacemaker-attached leads, the resulting RF-induced heating has the potential to cause sufficient thermal damage to the myocardium, resulting in a loss of pacing capture of the cardiac tissue.

To examine RF-induced heating as a function of lead length, it is important to consider the how the electric field exposure varies as a function of lead length. The lead path is a crucial factor controlling RF-induced heating, because it determines the electric field exposure of the lead. Even for simple phantom geometries, there is a large spatial variation of the electric field throughout the phantom causing variations in both the phase and magnitude of the electric field. Recent studies have shown that the pacemaker lead path inside the commonly used ASTM head/torso phantom significantly impacts the magnitude of pacemaker lead tip heating (11–13). The dependence of pacemaker lead tip heating on the lead path, i.e., electric field exposure, is still not completely understood, therefore, it is difficult to devise testing scenarios that can be well-controlled scientifically as well as represent clinically relevant scenarios. In an attempt to standardize the electric field exposure as a function of lead length a cylindrical phantom was used to expose each lead to a uniform magnitude and phase electric field.

As the understanding of MRI–pacemaker interactions continues to mature, several recent publications have shown compelling evidence that MRI scanning of patients with pacemakers can be completed with no adverse effects to patient (5,14–16). There exists, however, a subpopulation of these patients with abandoned pacemakers leads whose safety risks at the time of MRI have been not addressed in these studies. Over the lifetime of the implant, pacemaker leads may be disconnected and replaced due to lead fracture, insulation breaks, dislodgement, or abnormalities in pacing or sensing (17–19). While these leads are no longer functional, they often remain in the patient due to the risks associated with lead extraction, including myocardial perforation (20). Abandoned leads are disconnected from the pacemaker, and in most cases a new lead is implanted and connected to the pacemaker, assuming the pacing role of the abandoned lead. The standardized pacemaker lead termination IS-1 connector of the abandoned lead is then covered with a plastic cap to electrically isolate the lead. In some cases the IS-1 connector remains uncapped and exposed to the surrounding bodily fluids. The plastic cap serves to electrically isolate the abandoned pacemaker lead and is intended to prohibit electrical excitation of the heart through the lead.

Although many researchers in the field acknowledge that abandoned leads present an unknown risk to patients (21), to date, there have been no publications that systematically compares the RF-induced heating of pacemaker-attached leads with abandoned pacemaker leads. As the medical community continues to pursue MRI scanning of patients with pacemakers, it has become increasingly necessary to assess the risk of abandoned pacing leads. The objective of this research was to assess the risk of RF-induced heating in pacemaker-attached and abandoned leads using in vitro temperature measurements at 1.5T. Due to many of the complex interactions associated with RF-induced heating measurements of pacemaker leads, a simplified electric field exposure can be used to standardize the measurement, allowing for the analysis of multiple lead lengths. This research summarizes RF-induced heating in pacemaker-attached leads and abandoned pacemaker leads, specifically exploring the effect of lead length in both connection scenarios.

MATERIALS AND METHODS

Cylindrical Phantom

A cylindrical phantom was used to create a uniform, magnitude and phase, electric field for a fixed radius lead path at the center plane of the cylinder. The nominally uniform magnitude and phase of the electric field can be verified by computer modeling of the RF electric field produced inside a cylindrical phantom using standard methodologies (22,23). The phantom design and lead path were chosen to standardize the electric field exposure for various lead lengths. There are limitations of using a simplified electric field exposure, however, it is the purpose of this research to create the foundation for a comparison between RF-induced heating of pacemaker-attached and abandoned leads. Further research must endeavor to assess the risk of abandoned leads once a more clinical testing environment has been established.

The cylindrical phantom had a 26-cm diameter and was placed inside the MRI such that the long-axis of the cylinder was perpendicular to the B0 field as shown in Figure 1A. The phantom was filled to a height of 10 cm with a polyacrylic acid (PAA) gel (8 g/L PAA, 1.4 g/L NaCl), with measured electrical conductivity 0.4 Siemens/meter. Each lead was placed along a 12-cm radius path along the inner circumference of the phantom, at a fixed height of 5 cm corresponding to the center plane of the phantom, shown in Figure 1B.

Pacing Leads and Termination Conditions

Pacemaker lead tip heating measurements were acquired for custom length 1688T St. Jude Medical (Sylmar CA, USA) active fixation bipolar pacing leads.

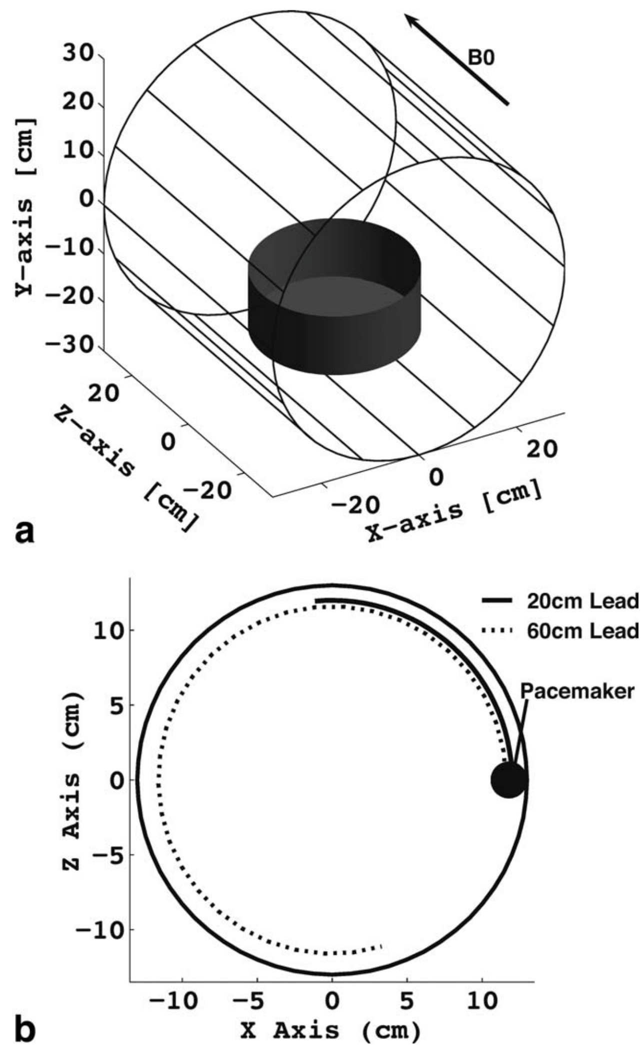

Figure 1. RF body coil and cylindrical phantom design. The cylindrical phantom with a diameter of 26 cm filled to a height of 10 cm with PAA solution was placed inside the MRI RF body coil as shown (A). The lead path for the 20-cm and 60-cm pacing leads are shown with a fixed 12-cm radius path in the XZ plane at a height of 5 cm (B).

The pacemaker lead length is an important variable because it determines the coupling between the RF electric field and the pacemaker lead. At the RF frequency of 64 MHz, the wavelength of the RF electric field is 52 cm in water, neglecting the effects of conductivity. To examine the effect of lead length, 20, 30, 40, 50, and 60 cm custom leads were used. This range of lead lengths includes the expected half-wavelength and full-wavelength of the RF electric field, approximately 26 and 52 cm, respectively. These lead lengths were also chosen to encompass clinical lead lengths, which range from 40 to 60 cm.

Pacemaker lead tip heating was evaluated using three different termination conditions: pacemaker-attached, abandoned-capped, and abandoned gel-exposed. The pacemaker-attached leads were connected to an Identity St. Jude Medical pacemaker (Sylmar, CA) at the IS-1 connector. For the abandoned-capped pacemaker leads, the IS-1 connector was covered with a silicone plastic cap. For the abandoned gel-exposed leads, the IS-1 connector was exposed to the PAA solution. With the IS-1 connector exposed to the PAA, this connection scenario simulates the possibility that the abandoned lead IS-1 connector is exposed to bodily fluids in the case where the pacemaker lead is not capped.

MRI Sequence and System

A balanced steady state free precession (bSSFP) sequence, which is commonly used in cardiovascular imaging applications, was used to induce pacemaker lead tip heating. The sequence parameters were as follows: echo time (TE) = 1.7 ms, repetition time (TR) = 3.4 ms, flip angle 40°, resolution 256 × 256, 60-s scan duration, and scanner reported whole body SAR 2.1 W/kg. All measurements were made on a 1.5T Avanto MRI (Siemens, PA) with a registered patient weight of 170 pounds. The RF body coil was used as both the RF transmitter and RF receiver.

Temperature Measurement

Temperature measurements were acquired continuously during the MRI scan using an STF Lumasense (Santa Clara, CA) fluroptic temperature probe. Temperature probe placement can significantly influence the absolute temperature measured for a given setup and is an important experimental concern as shown by Mattei et al (24). To assure repeatable probe placement the temperature probe was placed coaxially along the lead body and secured with rubber bands. The active sensing region of the temperature probe was placed approximately 1 mm above the pacemaker lead tip. To compare lead tip heating, the temperature increase was calculated for each acquisition by measuring the maximum temperature during the scan minus the baseline temperature taken before the start of the MR scan.

RESULTS

Pacemaker lead tip heating in the circular phantom for the 20, 30, 40, 50, and 60 cm leads is shown for the pacemaker-attached, abandoned-capped, and abandoned gel-exposed termination conditions in Figure 2. The pacemaker-attached lead exhibited maximum heating (11.6°) at a lead length of 20 cm and minimum heating (1.3°) at 60 cm, exhibiting decreasing heating with increasing lead length. The abandoned-capped lead exhibited maximum heating (29.9°) at a lead length of 60 cm and minimum (1.9°) heating at 20 cm, exhibiting increasing heating with decreasing lead length. The abandoned gel-exposed lead exhibited maximum heating (12.0°) at a lead length of 40 cm and minimum (2.2°) heating at 20 cm, exhibiting a peak heating response at 40 cm with decreased heating for both shorter and longer lead lengths. The most substantial difference in pacemaker lead tip heating occurred for a lead length of 60 cm, at which the pacemaker-attached lead heated 96%

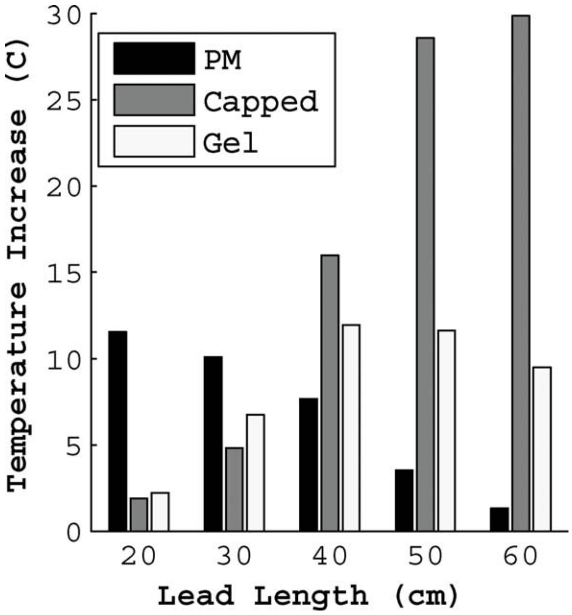

Figure 2. Pacemaker lead tip heating versus lead length and termination condition. The pacemaker lead tip heating in the circular phantom for the 20-, 30-, 40-, 50-, and 60-cm leads are shown, for the pacemaker-attached (PM), abandoned-capped (Capped), and abandoned gel-exposed (Gel) termination conditions.

less than the abandoned-capped lead and 86% less than the abandoned gel-exposed lead.

DISCUSSION

Our results have shown that pacemaker lead tip heating depends upon both the lead length and termination condition of the pacing lead. Whereas it is understood that the RF electric field couples with the pacemaker lead resulting in resonant behavior as a function of lead length, the idea that this coupling can also be affected by the pacemaker lead termination conditions is a new finding. To explain how the termination condition will affect the resonant behavior of the pacing lead, we can use some of the principles of RF antenna behavior, which is well understood in terms of transmission lines.

For a transmission line, a change in the termination condition will alter the transmitted and reflected signal based on the impedance mismatch of the transmission line and the termination condition. For transmission lines that correspond to half the wavelength of an applied RF signal, an electrical open termination will cause maximum voltage and minimum current at the termination point. For the same transmission line, an electric short termination will cause minimum voltage and maximum current at the termination point. For a given transmission line, the change between an open and short termination condition will cause a 90-degree phase shift of the standing wave (25). The termination condition, therefore, defines the standing wave that is able to form on a given transmission line and will dictate its resonant behavior in response to a given RF signal.

Theory of transmission lines has been applied to catheters with some success (26), however, it has not yet to be applied directly to pacemaker leads, due in part to their complex construction. For the purposes of this experiment, we will only draw analogies to the similar dependencies on termination condition exhibited by transmission line and pacemaker leads. For a lead attached to a pacemaker, the termination can be estimated as an electric short; the lead is shorted to the metal housing of the pacemaker and surrounding gel. Conversely, for a lead that is abandoned and capped, the termination can be represented as an electric open; the conductors of the lead are held in isolation by the silicone barrier. A lead that is abandoned and remains exposed to the termination does not fall into either of these strict categories, because the gel represents a termination condition in-between a true electrical short or open, depending on the electrical conductivity of the solution. The termination condition associated with a gel-exposed lead will depend on the conductivity of the gel. Applying these concepts, the changes in pacemaker lead tip heating as a function of lead length and termination condition can be interpreted.

By changing the termination condition of the lead from pacemaker-attached to abandoned-capped, the termination condition at the IS-1 connector is changing from a short circuit to an open circuit. For transmission lines, this change in termination condition causes a 90-degree phase shift in the standing wave. If we expect the same response from a pacemaker lead, then we would expect to see a change in the resonant condition as a function of lead length. For pacemaker-attached leads, the largest lead tip heating was seen for the 20 cm lead, whereas with this same lead length, the abandoned-capped termination exhibited minimal lead tip heating. The difference in the lead tip heating is caused solely by the change in the termination condition. The change in termination condition from pacemaker-attached to abandoned-capped shifts the resonant heating condition as a function of lead length. Ideally, the heating results would allow us to estimate the wavelength of the RF signal inside the pacing lead; however, other complex factors must also be taken into account. The exposure of the pacemaker lead in the MRI environment is dramatically different then most transmission line scenarios, because the electric field is applied simultaneously along the entire lead body rather than injected. Because of the long wavelength, the RF exposure from the MRI cannot be considered to be in the far field, therefore; models based on antenna theory are not directly applicable. Our experimental design was intended to lessen the variation in electric field exposure by using a circular phantom with uniform electric field; however, the dependence of lead tip heating on lead configuration is a complex issue that restricts researchers from being able to predict pacemaker lead tip heating behavior. There are many factors that contribute to lead tip heating that are not yet understood, thus necessitating more research to be undertaken in this area so that predictions of lead tip heating behavior can be made confidently.

These results indicate that finding the critical lead length for one termination condition does not suggest it is the lead length that will cause the greatest heating for any termination condition. In fact, our results have shown that the worst case heating for a pacemaker-attached lead, 20 cm, corresponds to the safest lead tip heating condition for an abandoned-capped lead. Thus, MRI pacemaker safety guidelines made under the assumption that the patient will have a pacemaker-attached lead should not be uniformly applied to patients with abandoned pacemaker leads. Specifically, we have shown that for clinical lead lengths, 40 to 60 cm, abandoned pacing leads exhibit more lead tip heating than pacemaker-attached leads for this testing scenario. Due to the limitations of this testing scenario, further research is advised to consider the risk of abandoned leads in more clinically relevant configurations before a consensus on the risk of scanning patients with abandoned pacemaker leads can be reached.

The number of patients with pacemakers undergoing MRI scanning will continue to increase as a consequence of recent publications, which have outlined safety precautions that enable safe scanning of patients with pacemakers in a monitored clinical environment (5,14–16). Although it is understood that this in vitro set-up is not directly comparable to results expected in patients, the large temperature increases of nearly 30°C emphasizes the hazardous potential for pacemaker lead tip heating, even if actual lead tip heating in patients was only a fraction of these temperatures. The implications of local thermal damage are still unknown. Thermal damage, however, could result in a change in pacing capture threshold, and more severe thermal damage could result in localized scar tissue forming an arrhythmic substrate that could further impair the cardiac function of the already at-risk population of patients with pacemakers. The pacing capture threshold has been used as the primary assessment tool in determining if permanent damage has been caused at the myocardial interface due to MRI exposure (27). The pacing capture threshold is measured by sending electrical pulses from the pacemaker and determining the ability of the pulse to induce myocardial activation. In abandoned leads, without a pacemaker attached, these measurements are not possible, therefore, physicians are unable to assess any damage caused by MRI exposure. The implant site of an abandoned lead is no longer required to sense pacing pulses, and, therefore, some may argue that there is little concern for damage caused by RF heating. However, thermal damage to the cardiac tissue could have long-term detrimental effects on cardiac function, the possibility of which cannot be ignored without further clinical research indicating safe limits for thermal exposure.

Although current safety recommendations have thus far prevented any known adverse effects for patients scanned with pacemakers, it remains unclear how close we are operating to the threshold for thermal damage. Therefore, it is necessary to remain cautious about any new patient exposure scenario, which could dramatically increase the expected lead tip heating, such as abandoned leads.

There will always be limitations of an in vitro test method, due to the inherent limitations of in vitro set-ups to incorporate the complexities of in vivo conditions. While in vivo testing is often considered the gold standard for temperature measurements in pacemaker lead tip heating studies, an in vivo set-up does not provide a controllable testing environment in which specific relationships and individual variables can be tested accurately. Uniform gel phantoms offer a stable testing environment, however, they cannot mimic the complex tissue structure of the human body, and, therefore, the RF electric fields inside a phantom cannot be directly compared with clinical conditions. For the purpose of this experiment, the use of the ASTM phantom was problematic due to the range of pacemaker lead lengths used. To create a controlled experiment with a more uniform electric field exposure along the lead's path (independent of lead length), a cylindrical phantom was a logical choice. In this study, each lead was placed along a uniform RF electric field, even though no such field is expected to be present in the human body. To accurately evaluate the risk of MRI scanning for patients with abandoned leads, further work should examine the electric field distribution in vivo, in comparison to the in vitro setups currently used so that lead configurations can be chosen to represent clinical scenarios. Patients with implanted pacemaker leads may be examined at a range of magnetic field strengths. Therefore, future research should also examine the length dependence of abandoned leads for $<$1.5T and 3T MRI systems. The results are expected to vary based on the different RF wavelengths associated with $<$1.5T and 3T MRI systems.

Another significant limitation of the study is the limited range of lead lengths used. Future investigation of lead lengths shorter than 20 cm and longer than 60 cm, despite not being of clinically relevant lengths, would be valuable since the current data indicates minima and maxima at these lengths. Additionally, the resonant lead lengths for the different termination scenarios may vary based on different lead configurations and on different lead constructions (28). The absolute temperature measurements could vary based on the size of the phantom and SAR of the MR sequence. These factors, however, are unlikely to affect relative temperature trends as a function of lead length. These results are, therefore, not a prediction of the magnitude of lead tip heating results expected for abandoned leads in vivo. Despite these limitations, these results can be used to inform clinicians that there may be additional risks in scanning patients with abandoned pacemaker leads.

In conclusion for a uniform electric field exposure, abandoned pacemaker leads, either capped or gel-exposed, exhibit greater lead tip heating than pacemaker-attached leads for clinical lead lengths (40 to 60 cm) at 1.5T. Both abandoned leads and pacemaker-attached leads show resonant heating behavior; however, maximum heating occurs at different lead lengths due to the differences in termination conditions. Patients with abandoned leads may be at a greater risk for RF-induced thermal damage due to

MRI exposure and risk assessment is complicated by the inability to fully monitor the affect of the MRI exposure for abandoned leads by measuring the pacing capture threshold. Additional work is needed to establish whether current safety recommendations for MRI scanning of patients with implanted pacemakers can be applied to the safe scanning of patients with abandoned pacemaker leads.

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