MRI-Induced Heating on Patients with Implantable Cardioverter-Defibrillators and Pacemaker: Role of the Lead Structure

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Abstract

Magnetic Resonance Imaging (MRI) induced heating on patients with pacemaker (PM) or implantable cardioverter-defibrillator (ICD) can pose severe health risks. Experimental studies in this field have shown a great variability in results and revealed that several aspects can affect the amount of heating induced at the lead tip. The structural parameters of the lead are one of these. In this study we performed in-vitro temperature measurements of PM/ICD leads inside a human trunk simulator exposed to the RF field of a 1.5T MRI scanner. A total of 26 leads were tested (23 PM leads, 3 ICD leads) and the temperature increases induced by the RF field ranged from 2.1°C to 15.0°C. Significant heating was observed not only at the lead tip, but also at the ring (as high as 4.2°C), even if not in all the bipolar leads tested. Active-fix leads showed higher temperature increases than passive-fix ones (4.7°C versus 7.4°C).

1. Introduction

In the last decade, advances in device technology were the driving forces to study the interactions between Magnetic Resonance Imagining (MRI) and pacemaker (PM) and Implantable cardioverter-defibrillator (ICD) systems, both in in-vivo and in-vitro experiments. The results of these studies demonstrated that the devices in use today may be more resistant to changes in function during an MR examination. Data on 430 patients who underwent clinically driven MRI are now available [1-3]. No deaths have been reported in physician-supervised MR studies in which the patients were carefully monitored, and only minor effects in few cases were observed (minor changes in pacing threshold, the need for device reprogramming, possibly battery depletion). Despite this evidence, MRI for patients with such pacemakers remains controversial, it is not approved by the US Food and Drug Administration and it is only being performed in specialized centers. There are indeed a number of aspects that need further investigations and that do not allow, at the moment, to define general standard conditions to extend MRI also to patients with PMs or ICDs. In particular the radiofrequency (RF) induced heating in tissues with metal implants is a major concern since it can pose severe health risks. Experimental measurements of the temperature increase at the lead tip of PMs/ICDs during RF exposure show widely varying results, with value ranging from negligible degrees up to more than 60°C [4,5]. These studies focused only on the induced heating at the lead tip, whereas the temperature increase at the ring of bipolar leads is either considered negligible or even not mentioned. Thus, the state-of-the-art reveals that there are a large number of elements that has to be taken into account and that must be properly addressed. Previously published papers demonstrated how the implant geometry and location, as well as the position of the patient inside the RF coil, can significantly affect the amount of induced heating at the implant tip [5]. However, other elements have not been exhaustively considered yet, and thus need further investigations.

In this paper we focus on some macroscopic characteristics of the leads and on how they can affect the MRI-induced heating. In particular, the number of electrodes (unipolar and bipolar) and the tip fixing modality (passive and active). A total of 26 leads were tested.

2. Materials and methods

We performed temperature measurements inside a full-size RF coil (length 112 cm, inner diameter 60 cm) with 16 legs forming the classic birdcage configuration. Tuning capacitors are placed on each of the legs, resulting in a low-pass structure. This system is the same as those used in 1.5 T clinical systems. The coil was fed by a quadrature power divider so to produce a circularly polarized B1 fields. The birdcage coil was housed inside a metal cage which acts as an RF shield, and the exposure was realized by a RF amplifier that delivers up to 150 Watts at 64 MHz.

A human trunk simulator was used to host the PM/ICD leads. The simulator was designed according to the ASTM F2182-02a standard for testing of MRI heating of implants [6], and was filled with a saline solution composed of hydroethylcellulose gelling agent (HEC) and NaCl (conductivity = 0.6 Sm^{-1}; permittivity = 79 @ 64MHz). The amount chosen for the HEC (2% by weight) allowed implants to be placed in the gel, moved and replaced, but, at the same time, provided a barrier to rapid thermal convection. Figure 1a shows a picture of the RF coil and the human-shaped phantom.

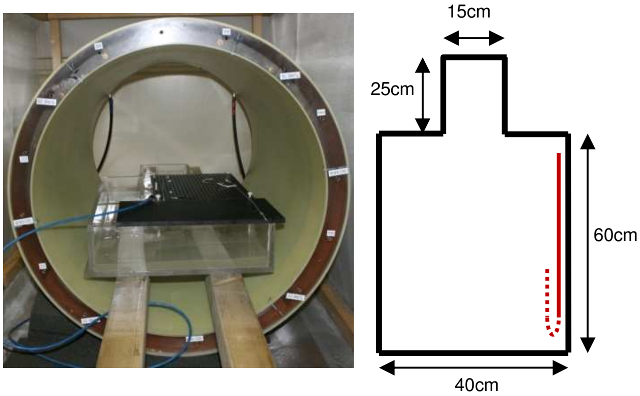

Figure 1. a) RF coil and human trunk simulator; b) sketch of the lead positioning inside the phantom

Temperature measurements were performed using a fluoroptic® thermometer (Luxtron model 3100) with four probes (SMM model). These plastic fiber probes (1 mm diameter) minimize perturbations to the RF fields. The Luxtron system was operated at 8 samples per second, with a resolution of 0.1°C. -. For passive fix leads, the terminal portion of the temperature probes were placed in transversal contact (i.e. the probe is perpendicular to the body of the lead-wire axis) with the lead tip: this contact configuration was demonstrated to minimize the measurements error associated to the physical dimensions of the probes [7]. For active fix leads, the temperature sensor was placed inside the helix tip of the lead.

Each PM/ICD lead was placed straight along one of the phantom's border for its entire length; when the total length of the lead exceeded the dimension of the phantom, the exceeding portion was bent back, always following the same linear path (Figure1b). Such configuration was chosen to provide easily repetitive and comparable measurements, and to maximize the amount of the RF-induced current along the lead.

The leads were not attached to any cardiac stimulator, and fixed on a 26x18 cm^2 PVC grid, that maintained a consistent separation distance between the leads and the phantom surface. It also allows a reliable positioning of the Luxon probes on the lead tip..

We tested 26 leads (23 PM leads and 3 ICD leads) of various length, diameter and structure, from 5 manufacturers (Biotronik, Medtronic, St. Jude, Medico, Sorin). The specific characteristics of the leads we tested are reported in Table 1.

Table 1. Structural properties of the leads tested

Lead #	*Polarity*	*Fixing type*	*Length (cm)*	*Tip surface (mm^2)*
1	Unipolar	passive	60	14.5
2	Unipolar	passive	60	5.7
3	Unipolar	passive	62	2.0
4	Bipolar	passive	62	3.4
5	Bipolar	passive	53	2.2
6	Bipolar	active	60	-
7	Bipolar	passive	62	3.4
8	Bipolar	passive	52	3.5
9	Bipolar	passive	58	3.5
10	Bipolar	active	46	-
11	Bipolar	passive	65	5.5
12	Bipolar	active	65	-
13	Bipolar	active	69	3.6
14	Bipolar	active	100	2.8
15	Unipolar	passive	103	5.8
16	Unipolar	passive	78	5.8
17	Bipolar	passive	78	5.8
18	Bipolar	passive	60	5
19	Unipolar	active	50	2.0
20	Bipolar	active	50	8
21	Bipolar	passive	62	4
22	Unipolar	active	62	-
23	Unipolar	passive	62	2.0
24	Bipolar	passive	52	6
25	Unipolar	passive	65	2.0
26	Bipolar	active	50	-

Before starting the tests, a calorimetric study was performed in order to set amplitude of the RF signal to produce inside the phantom a whole body specific absorption rate (SAR) of 1 Wkg^{-1}.

Each test had a length of 660 s: 60 s of temperature baseline recording (no RF exposure), 300 s of RF exposure, and 300 s of cooling phase. For each test, the induced temperature increase was calculated as the difference between the mean temperature at baseline, and the mean temperature in the last 5 second of the RF exposure. During all the tests, temperature was measured at the tip of the lead, and at the tip of a 20 cm-long straight metal wire, always in the in same position over the grid, which was kept as reference. The wire provided us with a mean to ensure the repeatability of the exposure conditions and of the measurement set-up. In addition, during all experiments the forward power delivered by the RF amplifier was constantly monitored by a power meter .

3. Results

Table 2 summarizes the results we obtained in terms of temperature increases measured at the lead tip and ring.

At the implant tip we observed widely varying results, ranging from 2.1°C, up to 15°C. Significant heating was also observed at most of the ring of bipolar leads: in this case, temperature increases ranged from 0.1°C (value comparable to the resolution of the fluoroptic® thermometer) up to 4.2°C.

Table 2. Temperature increases induced by the RF exposure at the lead tip and ring

#	*Lead Type*	*Tip dT (°C)*	*Ring dT (°C)*
1	unipolar - passive fixing	7.1	-
2	unipolar - passive fixing	7.8	-
3	unipolar - passive fixing	7.0	-
4	bipolar - passive fixing	5.6	0.6
5	bipolar - passive fixing	4.7	0.7
6	bipolar - active fixing	11.3	0.6
7	bipolar - passive fixing	7.2	0.4
8	bipolar - passive fixing	4.2	1.3
9	bipolar - passive fixing	4.8	0.6
10	bipolar - active fixing	14.4	1.4
11	bipolar - passive fixing	2.1	2.7
12	bipolar - active fixing	3.4	3.8
13	bipolar - active fixing	12.2	0.7
14	bipolar - active fixing	5.4	2.9
15	unipolar - passive fixing	4.9	-
16	unipolar - passive fixing	5.3	-
17	bipolar - passive fixing	6.8	0.5
18	bipolar - passive fixing	8.2	0.5
19	unipolar - active fixing	10.1	-
20	bipolar - active fixing	4.0	3.2
21	bipolar - passive fixing	6.8	0.1
22	unipolar - active fixing	3.4	-
23	unipolar - passive fixing	6.0	-
24	bipolar - passive fixing	2.4	4.2
25	unipolar - passive fixing	12.0	-
26	bipolar - active fixing	15.0	0.6

Figure 2 shows the bar plots of the temperature increases grouped by fixing modality. For bipolar leads, the temperature increase at the ring is also reported. It shall be noticed that the higher is the heating at the lead ring, the lower is the temperature increase at the tip. If we compared the temperature measurements at the lead tip for bipolar and unipolar leads, but considering only the bipolar leads where no significant heating occurred at the ring, we find that temperature increases of bipolar leads is generally higher than unipolar ones: the mean value (±s.d.) measured for the former is 9.2°C (±3.1°C), compared to 5.8°C (±1.7°C) of the latter.

A significant difference was observed between active and passive-fix leads. the mean value (±s.d.) of the temperature increase measured for the former was 7.4°C (±4.1°C), compared to 4.7°C (±1.8°C) of the latter.

On the other hand, the lead lengths and tip areas seem not to correlate, at least for the particular configuration tested, to the amount of induced heating.

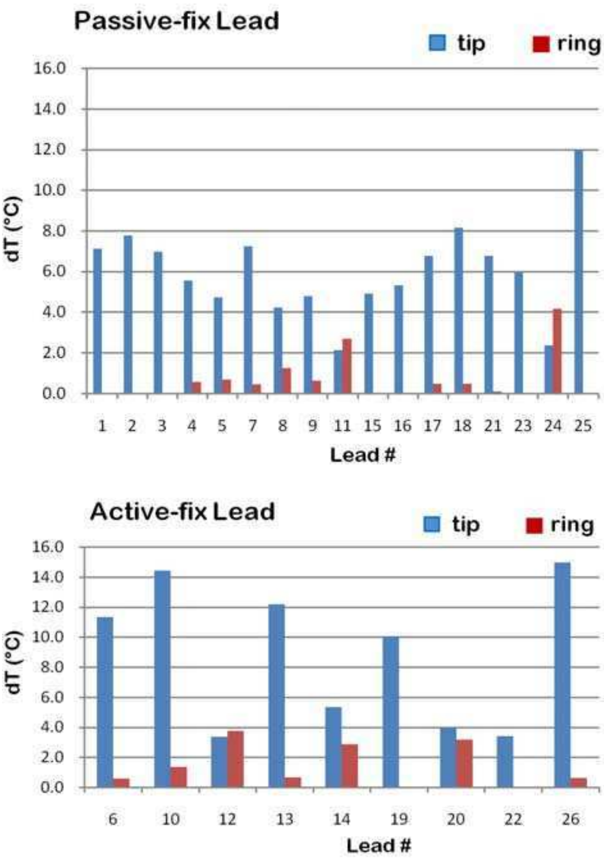

Figure 2. Temperature increases induced by the RF exposure at the tip and ring (only for bipolar leads) of passive-fix (upper panel) and active-fix leads (lower panel). Implant # refers to the first column of Table 2.

4. Discussion

Previous studies have shown that the MRI RF induced heating on metal structures is a very complex phenomenon, which involves a large number of variables [5]. It has been already demonstrated how the implant geometry (i.e. the path of the lead within the thorax and the location of the chassis in the pectoral regions) can affect the amount of induced heating at the tip. Little attention has instead been paid, so far, to the structural parameters of the leads.

The temperature measurements we performed on various types of PM/ICD leads revealed widely varying results, that cannot be justified by the minor differences in the implant geometry or lead path. Great care was paid to keep the leads always in the same position over the grid inside the phantom. In addition, the exposure and environmental conditions were monitored to guarantee reproducible results: the temperature increases measured at the tip of the reference wire were comparable for all measurements.

The parameters we investigated are the number of electrodes and the type of tip fixing. Most of the data reported in literature on the heating of implanted leads during MRI only focus on the temperature increase induced at the lead tip. The larger surface of the ring compared to the one of the tip implies a lower density for the deposited power and a consequent lower heating. This is the reason why temperature increase at the lead ring has always considered negligible compared to the one at the tip and often not even addressed. However, our data on bipolar leads show sensible temperature increases at the ring (>1°C) in the 41% of samples (7/17); in 3 cases the temperature increase measured at the ring was even higher than at the lead tip. An increase in the heating at the ring always correspond to a decrease in the heating at the tip. When no significant heating occurs at the ring, bipolar leads are generally associated to a higher temperature increase at the tip than unipolar ones. The different structure of the lead may produce a different coupling between the RF field and the metallic wires the lead is made up. In addition, the insulation sheath, which is generally thicker in bipolar leads so to increase the impedance towards the phantom for the current induced along the lead, may contribute to explain such differences.

Temperature increases measured for active tip fixing implants are higher than for passive implants. An active fixing is obtained by a thin metal helix which goes deep into the heart wall and works as an electrode. In this case, the smaller is the metal surface the current can flow out from, the higher is the power density and the induced heating. In addition, also the temperature probe positioning differs for the two types of lead: for active implants, the temperature sensor is inserted into the helix and it is in contact with the metal electrode for almost its entire length; for passive fix lead, the temperature probe is placed in transversal contact with the lead tip, causing a measurement error that has to be taken into account [7].

5. Conclusions

Structural parameters of PMs/ICDs leads are important elements that can significantly affect the heating induced by the RF field during MRI procedures. In particular, bipolar leads may produce tissue heating not only at their tip, but also along the ring surface. In addition, active tip fixing implant seems to be related to higher temperature increases than passive ones. However, other parameters, such as the number of wires and their arrangement inside the lead, steel need further investigations and do not allow to define general conditions to immediately extend MRI to patients with metal implants. At the moment, when a patient with a PM/ICD is supposed to undergo MRI examinations, preliminary studies on the particular implant characteristics are necessary in order to evaluate the risks/benefits and to plan the treatment minimizing the potential health hazards for the patient.

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