Currents induced by fast movements inside the MRI room may cause inhibition in an implanted pacemaker

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Abstract— **The static magnetic field generated by MRI systems is highly non-homogenous and rapidly decreases when moving away from the bore of the scanner. Consequently, the movement around the MRI scanner is equivalent to an exposure to a time-varying magnetic field at very low frequency (few Hz). If people with an implanted pacemaker (PM) enter the MRI room, fast movements may thus induce voltages on the loop formed by the PM lead, with the potential to modify the correct behavior of the stimulator. In this study, we performed in-vitro measurements on a human-shaped phantom, equipped with an implantable PM and with a current sensor, able to monitor the activity of the PM while moving the phantom in the MRI room.**

Fast rotational movements in close proximity of the bore of the scanner caused the inappropriate inhibition of the PM, programmed in VVI modality, maximum sensitivity, unipolar sensing and pacing. The inhibition occurred for a variation of the magnetic field of about 3 T/s.

These findings demonstrate that great care must be paid when extending PM MRI compatibility from patients to healthcare personnel, since the safety procedures and the MRI-conditional PM programming (e.g. asynchronous stimulation or bipolar sensing) used for patients cannot be applied.

I. Introduction

The presence of a permanent pacemaker (PM) has always been a relative contraindication for the performance of magnetic resonance imaging (MRI). In recent years, position statements from the European Society of Cardiology and the American Heart Association have suggested that with careful programming and supervision, MRI assessments may be performed in selected patients with non-conditional devices, when the same clinical benefits cannot be obtained with other diagnostic techniques [1,2]. In addition, the introduction of MRI conditional PM have enable more patients to undergo routine MRI assessment without risk of morbidity or device malfunction [3]. Thus, the enhancements in PM technology and the improved understanding of the interactions between device components and the electromagnetic fields generated by MRI scanners have finally release the restrictions for PM bearer to access the MRI environment. The electromagnetic fields used in MRI can interact with the implanted PM in several ways, posing hazards comprising: erratic and inappropriate device functioning, thermal damage to the heart tissue, high rate pacing and over- and under-sensing due to the induced current on leads [4]. One possible way of interaction is the induced voltage at the PM input during the movement of the PM implant inside the static magnetic field generated by the MRI scanner. Indeed, the movement inside a non-homogenous static magnetic field is equivalent to an exposure to a time-varying magnetic field at very low frequency (few Hz), and can be considered an instance of electromagnetic induction, per Faraday's law. The induced voltage on the conductive loop formed by the PM lead will vary as a function of the loop area, the spatial gradient of the magnetic field around the scanner and of the movement speed, and may cause inappropriate reactions of the device. MRI scanners typically used in clinical practice generates a static magnetic field of 1.5 T or 3T. In both cases, the highest value of magnetic field is limited to the bore of the scanner, and decreases rapidly when moving away from the scanner. At 1 m from the bore of the scanner, the magnetic field reaches value hardly higher than 500 mT, and further decreases under the threshold of 0.5 mT at distances > 4m.

Differently from the RF and the gradient fields that are activated only during the execution of the MRI scan, the static magnetic field is always present and all the people who enter and move inside the MRI room experience the effects of its non-homogenous spatial distribution.

The potential hazards caused by the movement inside the static magnetic field is not a major issue for the patient, whose movement speed in the MRI room can be easily limited and controlled by applying specific safety procedures. On the other hand, such procedures cannot be always applied also for the health-care personnel that operate inside the MRI room. In addition, whereas for patients undergoing MRI, the PM can be programmed immediately before the scanning and only for the duration of the examination in specific modality, that prevents erroneous sensing and interferences, it cannot be the case for health-care personnel.

In order to evaluate the effects of the movement inside the static magnetic field of an MRI scanner, we performed in-vitro measurements on a human-shaped phantom, equipped with an implantable PM and with a current sensor, able to

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monitor the activity of the PM while moving the phantom in the MRI room.

II. METHODS AND MATERIALS

A. The human-shaped phantom

The human-shaped phantom was designed and built at the Dept. of Technology and Health of the National Institute of Health in Rome. It consists of a transparent PVC phantom that reproduces the trunk and the thighs of a 75 kg male, with an internal volume of about 50 liter (Figure 1a). In order to move the phantom inside the MRI room, the bottom of the phantom was fixed over a plastic stand provided with wheels, which allows both translational and rotational motions. All the metallic components were removed to ensures the compatibility with the MRI environment. In order to simulate the dielectric properties of the human body in the low frequency range, the tissue-weighted mean electrical conductivity have been calculated from the database of the Italian National Research Council at 10 Hz (http://niremf.ifac.cnr.it/tissprop/). The torso simulator was then filled with a saline solution with the resulting electrical conductivity of 0.3 S/m. The PM, the lead and the current sensor were fixed over a PVC grid (20x38 cm^2) placed inside the phantom, and the lead path was arranged to form a loop with an equivalent area of 225 cm^2 (Figure 1b).

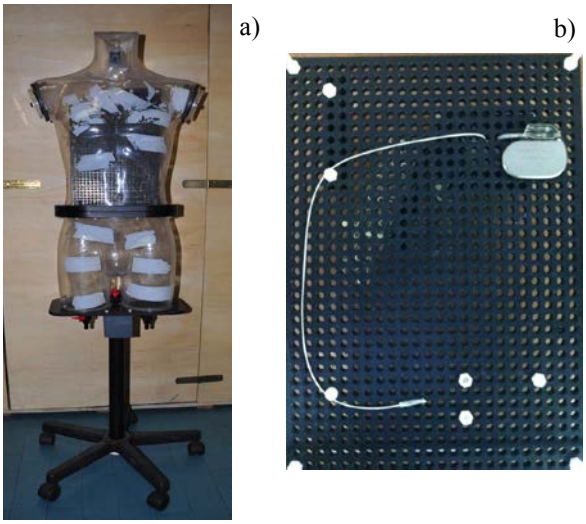

Figure 1. Human-shaped phantom (a) hosting the PM, the lead and the current sensor (b – on the backside on the grid).

B. The PM programming and the current sensor

A PM with endocardial electrograms (IEGM) recording was used. The possibility to record the IEGM gives us important information on the actual signal seen by the PM at its input stage during the test. The PM was programmed in the VVI modality at the maximum sensitivity allowed by the device (1 mV), with unipolar sensing and unipolar pacing. The worst-case conditions in terms of possible interferences induced at the input of the PM were thus adopted. A bipolar, passive-fixing, 62-cm long lead was attached to the PM.

In order to constantly monitor the PM activity during the movements around the MRI scanner, a custom-made current sensor was placed between the PM input and the IS-1 connector of the PM lead. By monitoring the current delivered by the stimulator, we were able to verify the correct behavior of the PM while moving inside the MRI chamber.

The sensor was designed and built at the Dept. of Technology and Health of the National Institute of Health and it is based on an optically coupled system that allowed the recording of the PM activity from a standard laptop placed outside the MRI room. The system is described in details in a previous published paper [5].

C. Measurement procedure

Measurements were performed at the Bambino Gesù Children's Hospital, IRCCS, in Rome, on a 3 T whole-body scanner (Magnetom Skyra 3T, Siemens, Germany). Before testing the PM implant, preliminary measurements were performed to identify the motion schemes of the human-shaped phantom leading to the highest variation of the magnetic field (dB/dt). Both translational and rotational motions in close proximity to the scanner were considered. During the movement, the magnetic field variation was monitored using a three-axis Hall magnetometer (THM-1176, Metrolab Instrument SA, Switzerland) placed over the sternum of the human-shaped phantom and operating at a sample frequency of 10 Hz. The maximum dB/dt was recorded for rotational movements performed next the scanner bore. During the test, the human shaped phantom was thus first moved from the entrance of the MRI room toward the patient bed and then towards the bore of the scanner. Once placed as close as possible to the bore, rapid rotational movements were performed, before moving the phantom away, outside the MRI room.
The magnetic field probe was used also together with the PM implant placed inside the human-shaped phantom. The signal form the probe was synchronized to the signal of the PM activity recorded from the current sensor: in this way, we were able to relate any degradation of PM performances to a specific value of dB/dt experienced by the human-shaped phantom.

III. RESULTS

Figure 2 summarizes the results of the test: the magnetic field variation measured by the magnetic field probe (Figure2c) shows that the initial increase of the magnetic field, corresponding to the movement of the human-shaped phantom towards the bore of the scanner, does not cause any degradation of the PM performances (Figure 2b). Then the graph shows two intervals where rapid rotational movements were performed in close proximity to the scanner bore: the complete inhibition of the PM was observed. At the end of the two intervals, the pacing activity of the PM is immediately restored, even when the phantom was still rotating at a lower speed (end of interval #2).

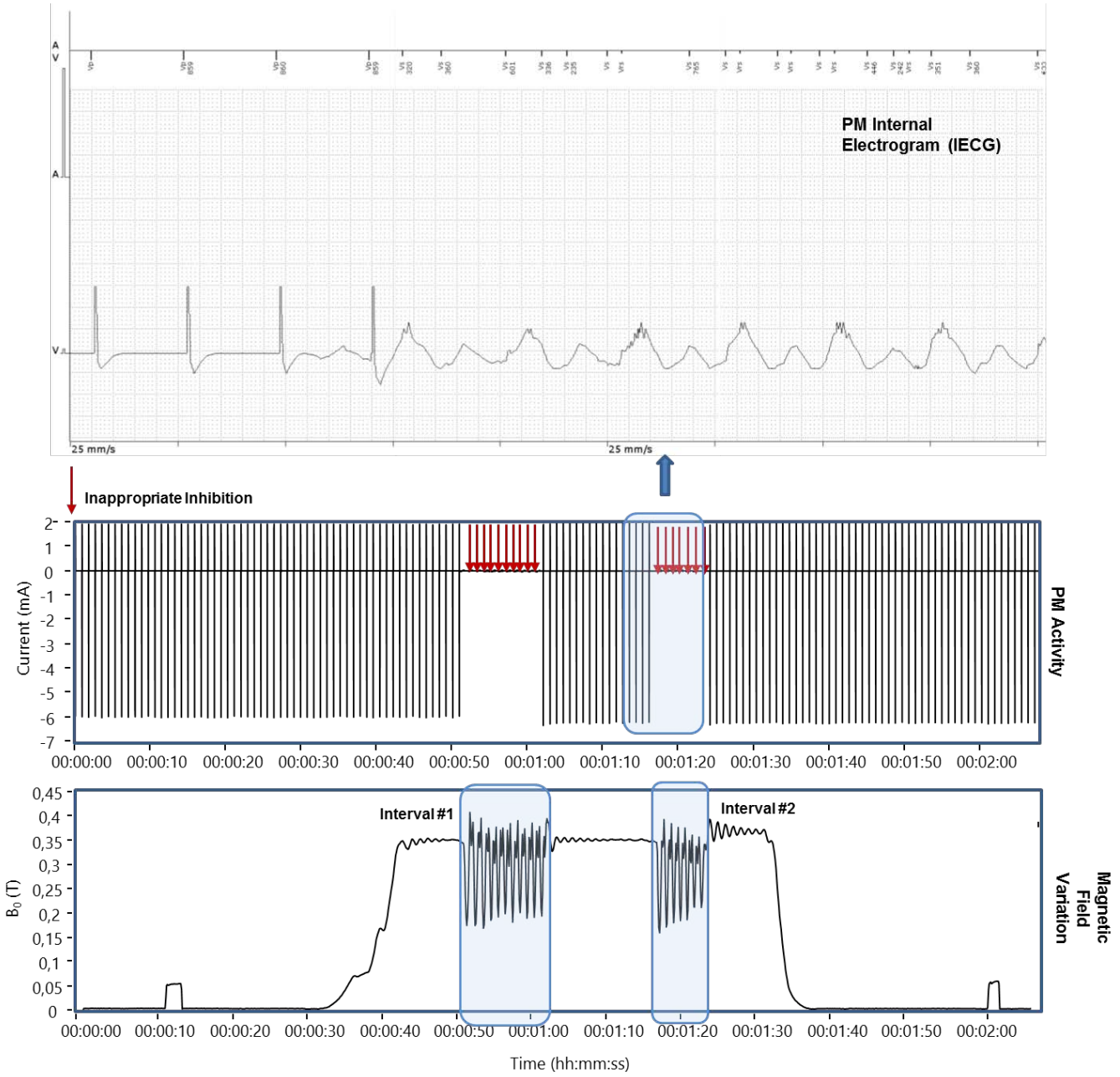

Figure 2. Inappropriate inhibition of the PM pacing activity during movements in the MRI room. The PM activity (b) is synchronized to the magnetic field variation recorded with the magnetic field probe (c). The detail reported in the upper panel (a) is the endocardial electrogram (IECG) of the PM.

The effect of the movements of the human-shaped phantom inside the magnetic field of the MRI scanner is highlighted in the IEGM recording of the PM (Figure 2a): the movement induced a voltage at the input of the PM that is interpreted as physiological activity and caused the inhibition of the pacing activity.

IV. DISCUSSION

The magnetic field trace reported in Figure 2c is expressed in terms of field intensity measured along the three axes. However, only the components perpendicular to the plane of the implant actually contributes to the induced voltage at the PM input. Figure 3 shows such component (upper panel) and its derivative in time (lower panel). If we assume that the field measured by the magnetic probe, located at the center of the loop formed by the PM lead, is uniform all over the loop, we can have an estimation of the induced voltage (EMF), by simplifying the Faraday-Neumann-Lenz law as follows:

$$EMF_{\max} = \max\left(\frac{\Delta B_z}{\Delta t}\right) \cdot S \qquad (1)$$

Where $\Delta B_z/\Delta t$ is the discrete derivative in time of the magnetic field component B_z perpendicular to the plane on the PM implant. Given the sampling period of the magnetic probe ($\Delta t = 0.1$ s) and the area of the lead loop ($S=225cm^2$), equation (1) leads to an estimation of the induced voltage of about 80 mV, for a maximum $\Delta B_z/\Delta t$ of about 3T/s. Notably, this value cannot be compared with the programmed sensitivity threshold of the PM, since it is calculated for stimuli having much higher frequency components than the low-frequency voltage signal induced by the movement of the human-shaped phantom inside the magnetic field of the MRI scanner.

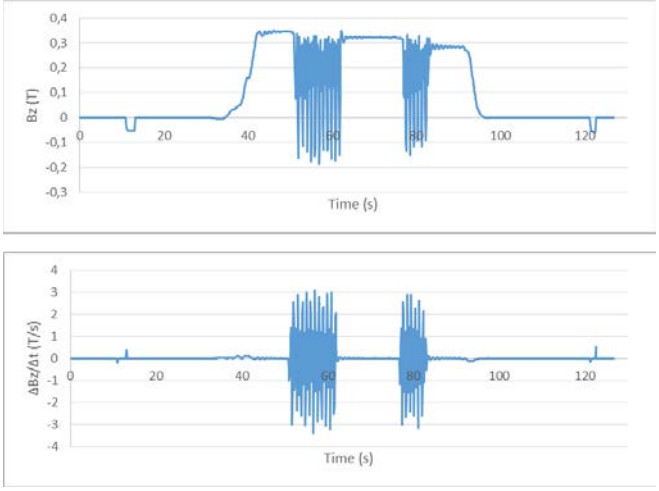

Figure 3. Variation of the magnetic field component perpendicular to the plane of the PM implant during the movement of the human-shaped phantom in the MRI room (upper panel) and its derivative in time (lower panel).

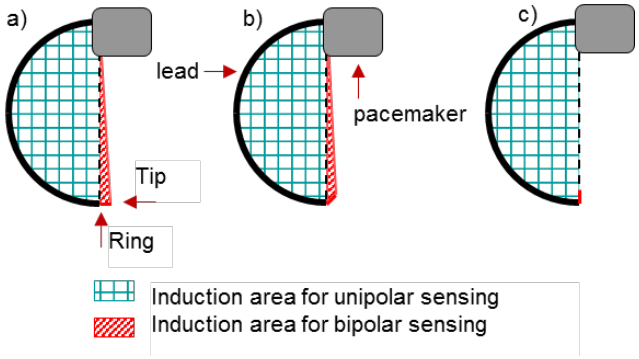

Figure 4. Schematic representation of magnetic induction area for bipolar and unipolar sensing configuration, as a function of the lead tip orientation

Equation (1) also reveals that a major role is played by the area of the loop formed by the PM, its lead and the saline solution of the phantom. Besides the lead path, the induction area of the loop can be also modified by changing the programming parameter of the PM. In particular, when the PM is programmed in bipolar sensing, the area of the loop, which determinates the induced voltage at the PM input, is reduced of a factor of 20 compared to the unipolar sensing, given the same path for the PM lead (figure 4.). In unipolar sensing the PM measures the voltage generated between the distal electrode of the lead (tip) and its case, whereas in bipolar sensing, the voltage is measured between the distal and the proximal electrode (ring) of the lead, which are commonly located few cm apart each other. Indeed, the same movements, which caused the inappropriate inhibition of the PM in unipolar sensing, did not affect the PM performances if programmed in bipolar sensing.

The experimental setup and testing procedure adopted in this study can be further exploited to test more PM implants as well as MRI environments, in order to increase the significance of the findings and to provide the basis for the definition of safety criteria for workers with PM implants moving inside an MRI room.

V. Conclusion

Fast movements inside the MRI room may cause the degradation of the basic performances of an implantable PM. Inappropriate inhibition of the pacing activity was observed for rapid rotational movements performed in close proximity to the scanner bore. Whereas it is relatively easy to control and limit the movements of a patient undergoing MRI, it is much more complex for health-care personnel who is working inside the MRI room. These findings demonstrate that great care must be paid when extending PM MRI compatibility from patients to healthcare personnel, since the safety procedures and the MRI-conditional PM programming (e.g. asynchronous stimulation or bipolar sensing) used for patients cannot be applied.

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