Implantable cardioverter-defibrillators exposed to low frequency magnetic fields

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Abstract

This paper presents a numerical modeling study of electromagnetic interference (EMI) in implantable cardioverter-defibrillators (ICDs), exposed to low frequency magnetic fields. Initially, an analysis of the standards that consider interference in ICDs was performed, to determine the level of induced voltage that may occur when the device is exposed to such magnetic fields. A Helmholtz coil was used to generate a uniform magnetic field. The magnetic field exposure was performed for the frontal position (front to back).This position presents the worst case scenario. The induced electric fields and voltage were investigated in both a simple homogenous block (brick) and in an anatomical model (virtual phantom). The ICD's sensitivity parameters were adjusted to minimum values (e.g. 0.2 mV for ventricular detection). This maximum sensitivity corresponds experimentally to the worst-case EMI scenarios. The results showed that magnetic fields above 5000 µT were required for the ICD to possibly present a dysfunction in the homogenous block, while they were only 1400µT in the anatomical model. These results could be informative for any proposed standards concerning the safety of ICDs (CENELEC, INCIRP) for workers as well as for the general public.

1. Introduction

Low frequency magnetic fields are present in daily life. They can be radiated from high-voltage transmission lines, electronic article surveillance (EAS), induction tables and other public or domestic devices. ICDs may be subjected to interference from various external electromagnetic sources depending on the patient's environment. The interference threshold depends on many parameters, such as the type and configuration of the ICD and its leads, the field strength, the body posture and stature. It has been shown that unipolar pacemakers have a much lower immunity threshold than bipolar configurations. Dawson [1] [2] and Silny [3] have performed extensive research on interference in pacemakers (unipolar). Dawson reported that bipolar pacemakers are not susceptible to EMI [1]. However, a recent publication has shown, to the contrary, that there are dysfunctions in pacemakers, at low frequency [4]. The ICD implantation rate is steadily increasing. Unlike pacemakers, this kind of cardiac implant uses only bipolar detection. The effects of EMI on ICDs are unpredictable but, as for pacemakers, there could be inappropriate inhibition or triggering of pacing activity, asynchronous pacing, reprogramming or software resetting of the device, damage to internal circuitry, activation of anti-tachycardia pacing or worse, defibrillation shock [5]. Most of these effects are, however, reversible.

In this paper, a numerical method for calculation of induced voltage in both a simple (brick) and a realistic (virtual phantom) model of the human body is presented and used to compute the induced potential drop at bipolar ICD leads. Firstly, an ICD, inserted into a homogenous block model, was chosen for investigation. Secondly, the ICD was inserted into the anatomical model. In this study we consider a 50-Hz homogenous magnetic field, with a frontal orientation (front to back), as the source of exposure. The induced voltage was then investigated in both models.

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2. Methods

All simulations were performed using the Finite integral method (FIT), provided by the commercial software package CST. A metallic box (figure 1a), representing an ICD pulse generator, is inserted into a homogenous brick. The distance between the two bipolar electrodes (tip to ring) is set to 16 mm, the distance used by the majority of manufacturers. Secondly, (figure 1b) a body model is used. This model, derived from high resolution magnetic resonance images (MRI) of healthy volunteers, is described in detail elsewhere [6]. The model of an average male, 34 years old (1.77 m and 76 kg), has a realistic external shape and over 80 organs and major tissues are identified. The model consists of cubic voxels with 5-mm sides. Conductivities are allocated to each voxel that correspond to the associated tissue values. The ICD is inserted in the left pectoral subcutaneous fat layer of the model, consistent with approximate clinical placement. Leads follow representative intravenous (i.v.) or extra venous (e.v.) paths from the ICD generator to the ventricle. The same distance as above (16 mm) is used. The table below gives the electric conductivity of major ICD components. ICD's housing and the electrodes are made of titanium and the isolation of epoxy.

Table 1 Dielectric properties of ICD components

Components	*Conductivity(S/m)*	*Relative permittivity*
Generator	7.45 e^5	1
Electrodes	7.45 e^5	1
Leads	7.45 e^5	1
Insulation	0	3

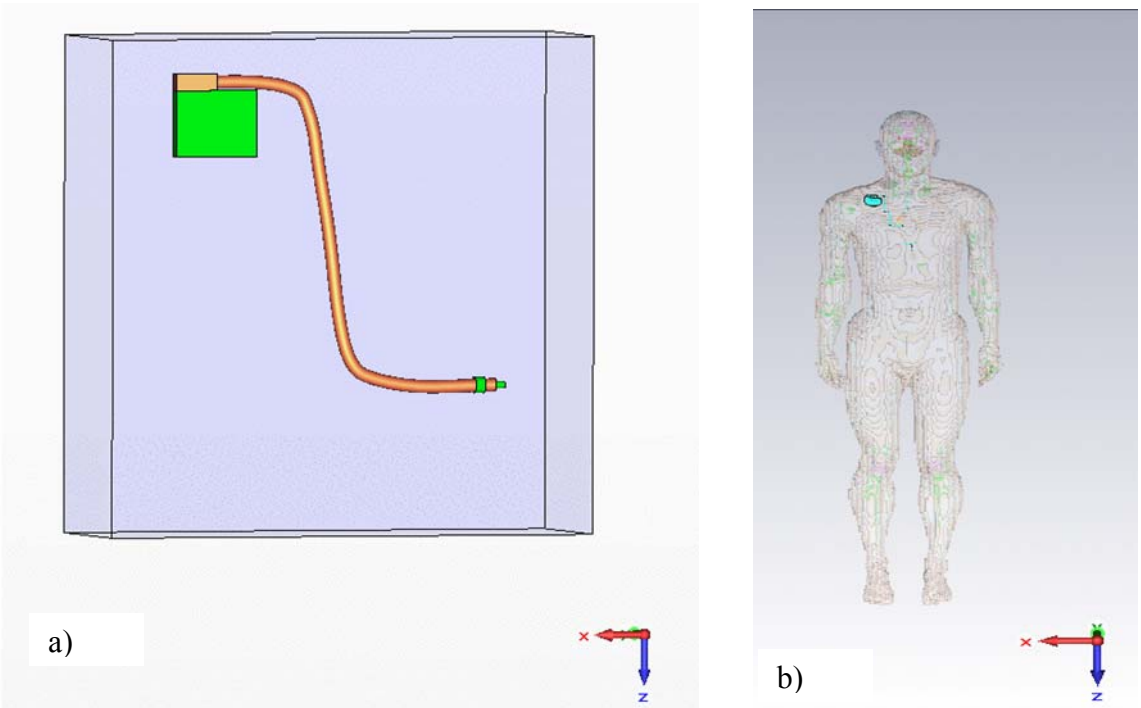

Figure 1 Models with inserted ICD: a) Homogenous block, b) Anatomical model

The evaluation of the induced voltage between the 2 electrodes is obtained by using the following equation:

$$U = \int_{Tip}^{Ring} \vec{E}.dl \tag{1}$$

3. Results

The ICDs were set to maximum sensitivity to experimentally reproduce the worst-case scenario of electromagnetic interference. It was found that a magnetic field strength of 700μT was required before the ICD could present a dysfunction in the homogenous brick model. In the anatomical model, a magnetic field of 1333μT was needed before the ICD could have a dysfunction. Figure 2 presents the distribution of the induced electric field in the anatomical model, where the ICD was implanted, while figure 3 displays how the induced electric field varied, upon changing the distance between the 2 electrodes. Figure 4 presents the induced voltage versus the medium, at the frequency of 50 Hz. This showed that the medium, where the ICD probe was inserted, was of great importance, specifically at the tip. For ICDs with a sensitivity value set of 0.6 mV (nominal value), the provocative exposure reached 4200 μT before the ICD could begin to show any dysfunction. In a previous study [8], our team presented *in vitro* results of ICD immunity testing, and no dysfunction was recorded for fields up to 4000 μT, supporting the results displayed here. The induced voltage was proportional to the frequency up to 5 MHz (limit of quasistatic validity), within an error of 7 %. The calculated induced voltage in the anatomical model was 0.15μV/μT. This value differed from the one calculated in the homogeneous brick by more than the half, which was due to the heterogeneity in the human body model. In the case of the homogenous brick model, the magnetic field strength was estimated of 700μT, while in the anatomical model, we estimated that, above a magnetic field strength of 1333μT, the ICD may show dysfunctions. This value was far greater, however, than limits given in the appropriate standard [9].

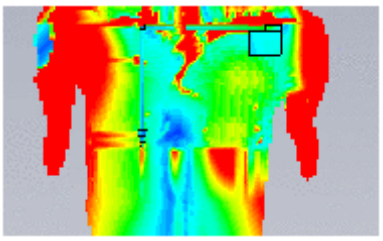

Figure 2 Distribution of induced electric field in the anatomical model with an inserted ICD

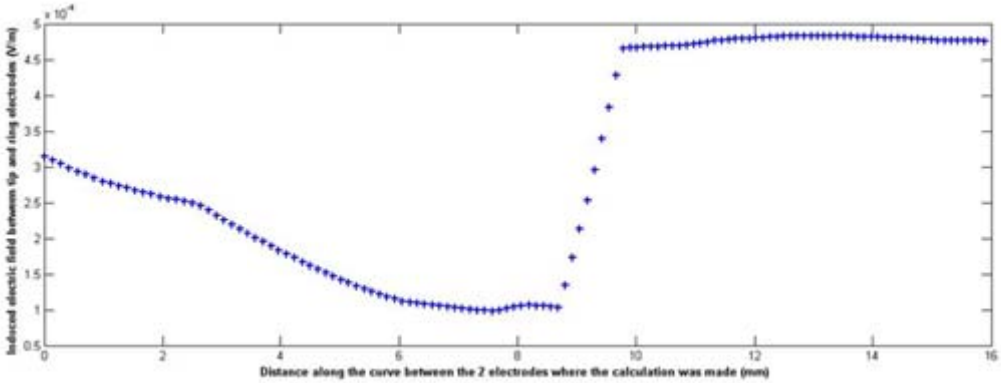

Figure 2 Variation of the induced electric field between the 2 electrodes

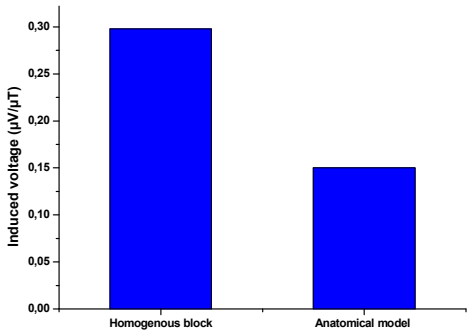

Figure 4 Variation of induced voltage versus the medium

4. Conclusion

In this paper, we presented a numerical study of the electromagnetic interference that could occur when implantable cardioverter-defibrillators (ICDs) were exposed to uniform magnetic fields and the theoretical methodology for the investigation of the induced voltage in ICDs. We found that the use of a detailed anatomical model was essential to investigate realistic induced voltages. This is particularly true for the electric properties of the organs that are of primary importance. No interference was found with magnetic field strengths less than 700µT. This value was very high compared to the usual limits given by many standards and recommendations. Other orientations of the field and types of inhomogeneous and modulated magnetic fields are currently under investigation.

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