In Vivo Study of Electromagnetic Interference With Pacemakers Caused by Everyday Electric and Magnetic Fields

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In daily life and occupational environments, individuals generally encounter electric and magnetic fields (EMFs). They occur mainly with frequencies of 50 Hz/60 Hz, the worldwide power grid frequencies. Examples of EMF sources are power lines, household appliances, electric tools, entertainment electronics, and many different kinds of equipment at work. Electric fields are indicated in kilovolts per meter (kVm^{-1}); magnetic fields, in micro-Tesla (μT).

To date, there is no conclusive evidence for the extent to which sources of EMF may cause harmful electromagnetic interference (EMI) in patients with pacemakers or implantable cardioverter-defibrillators. Clinical guidelines on the perioperative management of patients with pacemakers/implantable cardioverter-defibrillators and review articles state that large clinical evaluations and robust scientific data are missing.[1,2]

An in vivo study from our group suggests that 50-Hz EMFs can disturb implantable cardioverter-defibrillator function in patients,[3] but no systematic evaluation has been performed on their effect on pacemaker function. Considering the different sensing algorithms of implantable cardioverter-defibrillators and pacemakers, 2 questions arise: Does exposure to daily life or occupational EMFs disturb regular pacemaker function? And to what level of EMFs are the wearers of pacemakers safe? Therefore, the present in vivo study (ClinicalTrials.gov identifier NCT01626261) sought to determine interference thresholds of pacemakers and to ascertain different conditions for EMI.

Of the 119 patients with pacemakers included in the study, unipolar leads were implanted in 5 patients (device types: 4 VVI, 1 AAI). The remaining 114 patients had bipolar leads with bipolar sensing (device types: 18 VVI, 3 AAI, 90 DDD, 3 cardiac resynchronization therapy pacemakers).

All patients gave written informed consent and were exposed to single and combined electric and magnetic 50-Hz EMFs with stepwise increasing field strengths until the first pacemaker sensing failure (ie, interference threshold) occurred or maximum field levels (30 kVm^{-1} and 2550 μT; German occupational limits) were reached. The first sensing failure was either inappropriate oversensing or undersensing resulting from constructive or destructive superposition of intracardiac signals and EMFs. Tests were conducted considering worst-case conditions (eg, whole-body exposure, maximal inspiration, sustained pacing). The interference thresholds were determined with pacemakers programmed to maximum sensitivity, nominal sensitivity, VVI mode, and DDD mode, if applicable.

The study was approved by the Ethics Committee at the RWTH Aachen University Faculty of Medicine. For a complete method description (worst-case conditions, test setup, and test procedure), please refer to our previous study[3] because patients with pacemakers were tested in the same manner.

The results in the following are differentiated between maximum and nominal sensitivity (depicted by "/").

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In patients with unipolar leads, EMI was provoked in all 5 pacemakers at both maximum and nominal sensitivity by 50-Hz EMF. The lowest interference thresholds were determined at 1 kVm^{-1}/9.6 kVm^{-1} in single electric fields, 40 μT/200 μT in single magnetic fields, and 1.1 kVm^{-1} +40 μT/3 kVm^{-1}+150 μT in combined EMFs.

In patients with bipolar leads, EMI occurred in only 71.9%/36.0% of 114 pacemakers within the tested limits. Ventricular EMI was observed in 32.4%/3.6% of 111 devices (VVI+DDD+cardiac resynchronization therapy pacemakers), and 72.9%/42.7% of 96 devices (AAI+DDD+cardiac resynchronization therapy pacemakers) showed atrial EMI. Ventricular EMI arose only at 9 pacemakers in DDD mode; in all other cases, in VVI mode. The atrial channel had generally lower interference thresholds than the ventricular channel; therefore, pacemakers were more susceptible when programmed to DDD mode. The lowest interference thresholds were 4.3 kVm^{-1}/11.9 kVm^{-1} in single electric fields, 130 μT/300 μT in single magnetic fields, and 2.5 kVm^{-1}+60 μT/5.2 kVm^{-1}+255 μT in combined EMFs.

Our study design, in combination with the large number of tested participants, allows conclusions about the safety of pacemaker patients in 50-/60-Hz EMF. In the Figure, the incidences of EMI in patients with bipolar leads are shown, and the risk of EMI can be assessed for different EMF sources or limit values. Considering, for example, hand drills, EMF emissions were reported with a maximum field strength of 13 kVm^{-1} and 2137 μT.[4] At these levels, EMI occurred in our study in 61%/16% (maximum/nominal sensitivity) of the pacemakers (Figure, C). Considering the US 50-Hz/60-Hz EMF limits for the general public at 5 kVm^{-1} and 904 μT (Institute of Electrical and Electronics Engineers Standard C95.6-2002; implies whole-body exposure, no coverage for persons with implants) in combined fields, 34%/4.4% (maximum/nominal sensitivity) of the pacemakers were disturbed. Thus, our study reveals that EMI may occur

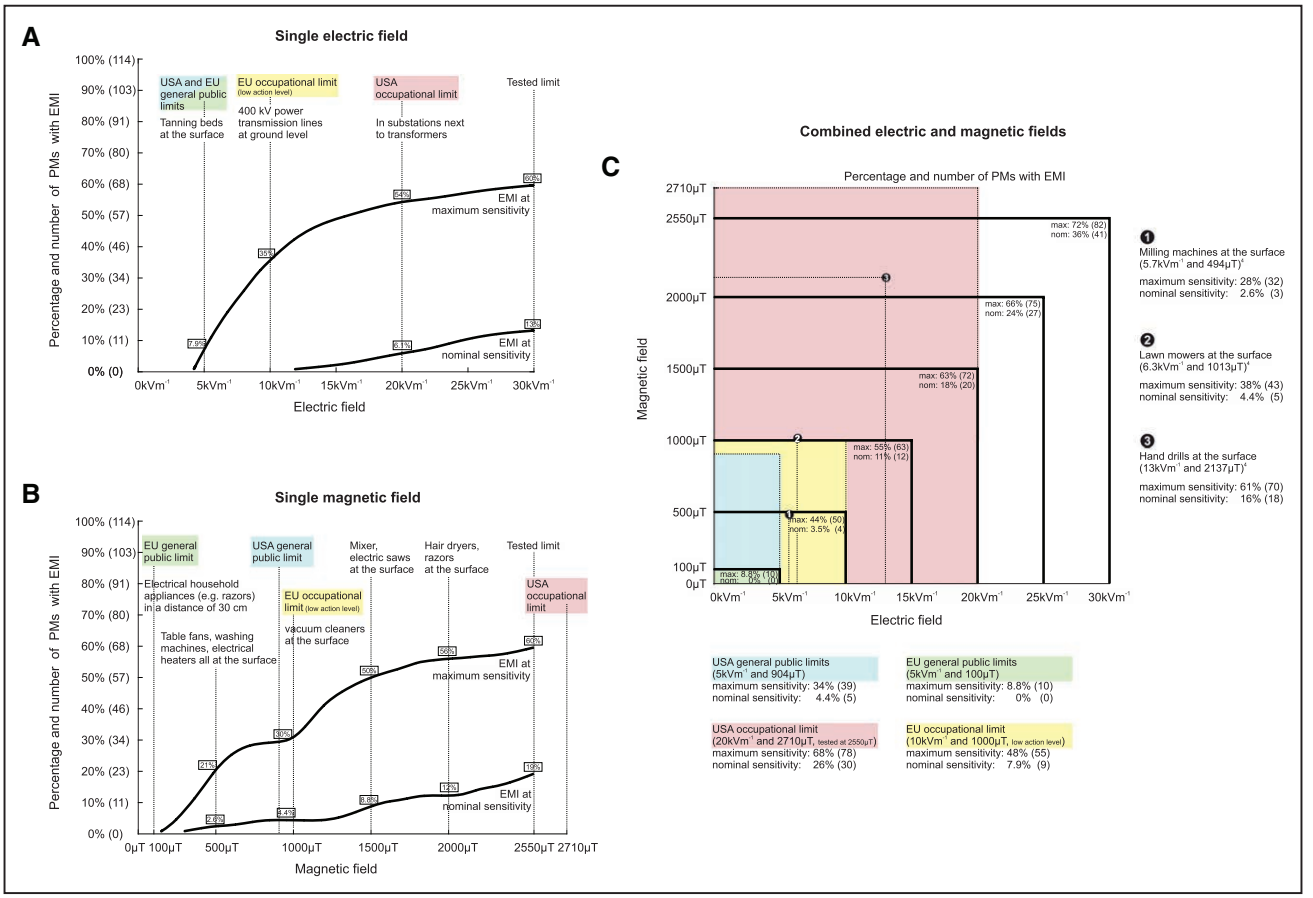

Figure. The incidences of electromagnetic interference (EMI) determined in our study in patients with bipolar leads at maximum and nominal sensitivity (max/nom) for single electric fields (A), single magnetic fields (B), and combined electric and magnetic fields (C) in percentages and in raw numbers.
Depicted are the additional percentages/raw numbers of EMI for electric and/or magnetic fields (EMFs) of power lines, different household appliances, electric tools, and EMF limit values (US limits are defined in Institute of Electrical and Electronics Engineers Standard C95.6-2002 for general public and occupational environment; European Union [EU] limits are defined in 1999/519/EC for the general public and in 2013/35/EU for occupational environment). The EMF levels are typical maximum values for the mentioned EMF sources but can vary in individual cases.

even under daily life exposure conditions. This study represents a worst-case appraisal.

Among the EMI effects, ventricular oversensing is the clinically most relevant problem, which may cause asystole in the case of pacing inhibition with symptoms such as palpitations, dizziness, or syncope in pacemaker-dependent patients. Further clinical consequences of EMI are described elsewhere.[2] To protect patients from EMI, adjusting pacemaker settings to a lower sensitivity, bipolar sensing, and keeping at a distance from EMF sources are effective measures. The field strength decreases at least by half if the distance is doubled. Further actions to reduce susceptibility (eg, programming to VVI mode and improved lead placement[5]) might be necessary in selected patients exposed to strong EMF in occupational environments.

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FOOTNOTES

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