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ORIGINAL ARTICLE

Implantable cardioverter defibrillator and 50-Hz electric and magnetic fields exposure in the workplace

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Abstract
Purpose The operation of implantable cardioverter defibrillators (ICD) can be disrupted by exposure to electromagnetic fields (EMF). In the workplace, some workers can be exposed to EMF higher than in daily life. We present an approach aimed at assessing fitness for work in this type of situation, based on in situ case studies in the absence of clinical and in vivo studies.
Methods A risk assessment protocol was developed to measure the 50-Hz electric and magnetic fields in the various places where the worker is likely to be present. These measures are taken in the worker's presence, while monitoring the ICD operation.
Results All cases of implanted ICD workers in EDF, the French electricity company (around 130,000 employees), and potentially exposed to high electric and/or magnetic fields, between 2004 and 2009 are presented. These three cases involved different work circumstances, with exposure to 50-Hz electric and/or magnetic fields. No interference of the ICD was observed.
Conclusions This information provides the basis for the occupational physician to make a decision about fitness for work. This procedure can be extended to other medical implants and to electromagnetic fields frequencies other than 50-Hz.

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Introduction and objectives

In 2007, around 7,000 patients in France received an implantable cardioverter defibrillator (ICD), and this figure is in constant increase. It is known that cardiac pacemakers are implanted mainly in people older than 50 years, and for workers at this age, occupational physicians tend to recommend a change in job or work station, when that is possible, or early retirement. However, the situation is very different for patients with ICD, who are younger and want to be able to continue to use their training and experience in their competences.

Electromagnetic fields can disturb the operation of active medical implants. Several studies on pacemakers suggest that there is no interference risk for 50/60-Hz electric and magnetic fields at usual daily fields levels (Butrous et al. 1983; Toivoinen et al. 1991; Scholten and Silny 2001; Dawson et al. 2002; Irnich 2002). Less is known, however, about the risks of interference in the workplace, where field levels may be higher. To our knowledge, no large-scale study has examined device-wearers workers exposed to electric and magnetic fields. One case of worker with a pacemaker was studied at the hospital with a controlled 50-Hz magnetic field level up to 500 μT, without any interference reaction of the pacemaker (Beerlage and Lagendijk 2009).

Generally, the sensitivity of cardiac implants to electromagnetic interference depends on several factors, the most important of which are the settings of the probe (unipolar, between an electrode and the case, or bipolar, between two electrodes on the lead at the heart) and the detection sensi-

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tivity (the greater the sensitivity, the more susceptible the instrument may be to interference). Another factor is the way the probe has been implanted, which influences the coupling factor between the external electric and/or magnetic field and the ICD.

It is important to note that in order to comply with European directive 2004/40/CE, the employer must assess the EMF exposure, but also take into account the existing risks for people with active implants (European Community Council 2004).

ICDs are designed to sense and automatically treat rapid heart rate episodes: tachycardia and ventricular fibrillation. They also have a pacing function. ICDs necessarily use bipolar sensing, which considerably reduces the risk of interference.

Interference in ICDs may create two different situations: the ICD may incorrectly sense rapid cardiac activity and thus deliver an inappropriate shock, or the interference may disturb the sensing of a real arrhythmia and thus fail to treat it, leading to a vital risk.

By internally recording diagnostic information and electrocardiogram data, cardiac implants make it possible to refine settings, adjust treatment, and identify interference, where relevant. These data help greatly to determine the appropriate procedures after analysis of the workplace.

Contrary to the literature about pacemakers, the one on ICDs contains little information about cases of interference. Besides incidents of direct electrification, the cases in the literature concern disruption of ICDs by electronic anti-theft systems (Mathew et al. 1997; Gwechenberger et al. 2006; Gimbel and Cox 2007). In vitro studies at the Nancy Electronic Instrument Laboratory used a protocol based on dummy cardiac signals to simulate exposure to magnetic field during ICD operation, tested in an electromagnetic phantom simulating biological tissue (Marchal et al. 1989). Two different studies were conducted to see if the magnetic field led to false-positive sensing of ventricular fibrillation or tachycardia), expressed by an inappropriate shock, or if it inhibited detection of a true arrhythmia, and thus prevented the necessary treatment. These studies showed that the equipment tested could be defective in the case of conducted disturbances (direct contact with the phantom), but not in a radiated magnetic field, even for field amplitudes up to 1,000 μT at 50-Hz (Schmitt et al. 2005; Nadi 2008; Katrib et al. 2009). Nonetheless, only four models of ICD were tested.

A precautionary procedure is therefore recommended for risk assessment of an implanted worker.

This article describes a method for assisting the occupational physician's determination of fitness for work for people with ICD, based on multidisciplinary observations. The objective is not to determine whether a specific electric or magnetic field strength is compatible with this or that ICD, but rather to propose a method for assessing the risk incurred by specific employees in their daily work, in order to provide a basis for the occupational physician's decision.

Methods

To assess the risk of electromagnetic interference of ICD in the workplace, several people should be involved:

1. the worker's cardiologist, present with emergency cardio-pulmonary reanimation equipment
2. a representative of the implant manufacturer, present with telemetry equipment that can immediately analyze the implant's behavior
3. a technical team qualified to measure EMF
4. the occupational physician (if any)
5. the worker with the implant (who must be informed about the risk of electromagnetic interference and provide a written informed consent)

This cooperative procedure may seem complex, but the main difficulty is to bring together the whole team. In fact, the procedure is simultaneously simple to perform and precise in its objectives (Magne et al. 2007).

First, the technical team perform fields measurements to map the field throughout the workplace and classify the areas to which the worker is liable to be assigned, from the places where the field is lowest to the places where it is highest. We used an EFA-3 (Narda) or ESM-100 (Maschek) for field measurements.

The measurements are then taken again in the worker's presence, in the order of increasing exposure. For this second stage, the implant wearer is also equipped with a magnetic field recorder (EMDEX II, Enertech-USA) to verify his personal exposure. Simultaneously, the implant is analyzed by the manufacturer's remote testing system. This telemetric recordings shows whether the implant *sees* the electric and/or magnetic field and if so, if it interprets it as a cardiac signal. Obviously, all participants must consent to this protocol, before any investigation.

The ICD is not deactivated during the measurements: if treatment is deactivated, the patient will not be treated if the device senses ventricular fibrillation; if sensing is deactivated, the device will no longer detect arrhythmia and therefore will not treat it.

We therefore decided to leave both treatment and detection activated, but to use the telemetry programming head for the ICD implant to record and continuously print out the ECG and endocardial electrograms in bipolar and *far-field* (pseudounipolar) modes. We therefore have an exact real-time view of what the device detects. During the application of the programming head, the device detects all events with a period greater than 110 ms but does not interpret the

type of arrhythmia detected and thus does not deliver any treatment. Two particular situations may then occur:

- The device detects true ventricular fibrillation (confirmed by ECG and endocardial electrogram). The immediate withdrawal of the programming head switches the ICD into its automatic treatment mode and emits a shock after the capacitor charging time;
- The device detects interference (confirmed by the ECG and endocardial electrogram). The programming head is let close to the ICD and the patient moves away from the interference source until no further interference is detected.

An external defibrillator must be present as a safety measure, in case interference damages the device.

Results

This procedure has been conducted for all implanted ICD workers who may undergo high and frequent exposures to 50-Hz electric and/or magnetic fields in EDF between 2004 and 2009, that is three times in a company with approximately 130,000 employees. Each time, while the question was the same—that is, whether a specific worker with an ICD was fit to work at a specific workplace—the response was different, because of the circumstances and the difficulties of bringing all participants together.

First case

Mr. P, 50 years old, is a maintenance technician in four hydroelectric production units. Since 2004, he has had a *Medtronic* ICD. All the participants involved were able to meet, and the magnetic fields of his workplace were measured. The electric field was not measured: the maximum level at this workplace was in a 63 kV substation, where the electric field is less than 3 kV/m (Magne et al. 2009), and therefore compliant with public exposure (CENELEC 2010). The maximum magnetic field measured at the ICD case was 650 μT (Table 1). No dysfunction was recorded (Fig. 1a, b). The final telemetric verification showed that no event capable of confusing the detection systems was recorded. Analysis of his work station showed that there was no risk of ICD dysfunction. Following this personalized study, he was declared fit and was able to return to his job in the hydroelectric plants. In the four following years, no incident has been reported.

Second case

Mr. B, 29 years old, is employed by a service provider in a nuclear power plant where he is responsible for maintenance of the fire alarms. In 2005, he was implanted with a *Saint Jude* ICD. The occupational physician of the nuclear power plant, in coordination with the subcontractor's occupational physician, proposed a study of magnetic field exposure all around the plant. Electric fields measurements were not necessary because Mr. B did not access to areas with electric fields higher than 3 kV/m. Because Mr. B's cardiologist did not want to expose his patient to this potentially dangerous situation, a control subject, a colleague of Mr. B's, who did not have an ICD, volunteered for the magnetic field mapping, performing the same tasks. In this case, the manufacturer's presence with telemetry was unnecessary. The maximum magnetic field was 180 μT (Table 2) This study allowed us to determine areas where the magnetic field did not exceed the values usually encountered in the environment (a limit of 10 μT was chosen), in which Mr. B could work without any problem (Fig. 2). The occupational physician declared him fit to work within this limited areas. To go further, it would have been necessary to monitor the ICD in the area where the field exceeded 10 μT. This did not

Table 1 Measurements of magnetic field and control of ICD's first case

Place	Distance	Magnetic field at ICD position (μT)	ICD control
Office—computer	Operating position	0.5	Normal
63 kV substation—bus bars isolating switch—St Lary	Operating position	2.3	
63 kV substation—outside—St Lary	At grid contact	11	
Bulbe group control room—St Lary	Ambient	5–10	
Bulbe group control room—St Lary	At control cabinet contact	90	Normal
Machinery room—alternator—St Lary	Contact	150	Normal
Machinery room—alternator oil control—St Lary	Operating position	2.5	
Cable gallery—St Lary	Middle of the way at 1 m of the ground	220	Normal
Cable gallery—Maison-Blanche	At cables contact	650 (maximum value measured)	Normal

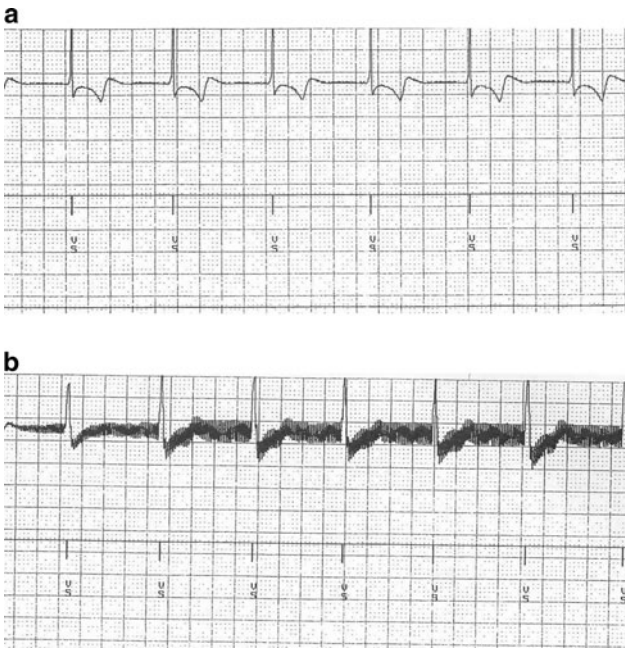

Fig. 1 **a** Measurement at maximal exposure (bipolar mode), **b** Measurement at maximal exposure (pseudo-unipolar mode)

Table 2 Measurements of magnetic field for the second case

Place	Distance	Magnetic field (μT)
Office	Ambient	0–0.02
Cable gallery	Contact	10–20
Electric cabinet 6.6 kV	Contact	50–150
Heat exchanger	Ambient	10–50
Heat exchanger	Contact	180
Cables 6.6 kV, transformers or alimentation of motors	Contact	10–100

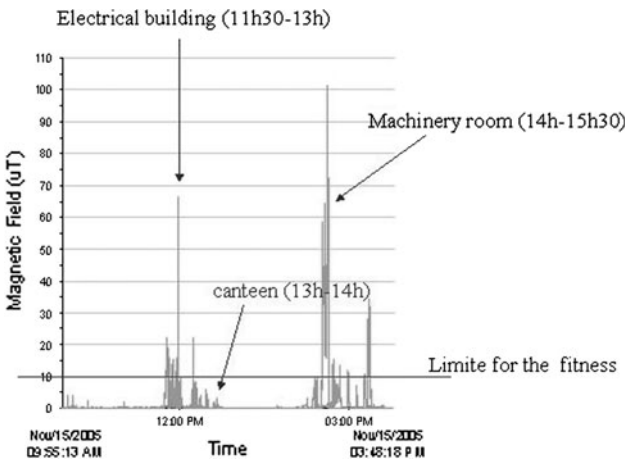

Fig. 2 Personal magnetic field record for the second case

Table 3 Measurements of electric and magnetic fields for the third case

Position	B (μT)	E (kV/m)
Inside relaying building	20.4	0.01
Under 400 kV lines (1,700 A)	20.2	5.7
Under 400 kV departure	65.2	12.2
400 kV switch control cabinet	44.3	4.8
Switch in 225 kV substation	23	3
Crossing of isolating switch	76.8	12

take place because in the meantime, Mr. B changed of jobs' location.

Third case

In 2004, Mr. D, 33 years of age, had a *Medtronic* ICD implanted programmed in bipolar mode with a 0.3 mV sensibility.

A change of jobs assigned him to work in a 225/400 kV transformer electric substation in 2005. A measurement day was organized with the worker, occupational physician, and manufacturer. The cardiologist was supposed to be present but had a last-minute emergency. Nonetheless, the occupational physician, trained in cardio-pulmonary reanimation, chose to conduct the study. The maximum magnetic field measured was 76.8 μT and the maximum electric field was 12.2 kV in the 400 kV substation (Table 3), and it did not disrupt the ICD. Following this particular risk study, the employee was declared fit for the job, but he still was in 2007 in sick leave.

Discussion

Another possible method to assess interference risk would be to do a provocative study. This should be done in a controlled environment, i.e., with a specific exposure system, delivering a predefined field, in value and direction. For magnetic field, this can be done with Helmholtz coils, which generates an horizontal field. For electric field, it is more complex because this implies to have high voltage source in hospital which is not possible for electric safety reasons, so a solution is to simulate the current induced in the body by a vertical electric field (Joosten et al. 2009).

The field can be increased up to a level where interference occurs. This approach seems safe, but it must be noticed that in the workplace, the situation is not the same. The orientation of the field is not unique because the field is three-dimensional. For example, in a high voltage substation, the electric field is not vertically oriented because of the presence of metallic structures. Moreover, the worker is

moving, and so the orientation between worker and field changes. We therefore think that in situ measurements with the implanted workers at his workplace are the best representation of potential situations of interferences.

The provocative study allows also to test the influence of the sensitivity settings, for example, the most sensitive one, but it is not necessary in our methods since the setting of the ICD workers is fixed by the cardiologist for his daily life. If the setting of the ICD is changed, the assessment has to be done again.

This method can assess the worse case exposure scenario, when some conditions are met.

- The people measuring the field must be able to determine where the field will be maximum. Experience of such measurement and a priori knowledge of the field repartition in similar workplaces is required.
- The configuration of the workplace must insure maximum exposure (i.e., maximum power or maximum current). If not possible, the real exposure conditions have to be noted.
- At the point of maximum exposure, the implanted worker has to move around, in order to explore all foreseeable orientations between the field and the implant.

This method does not allow to assess the safety factor between the worse case exposure scenario and the interference field level, but some experimental in vitro data indicate that there are no dysfunctions for ICD in 50/60-Hz magnetic fields below 1,000 μT (Katrib et al. 2010 submitted).

This procedure can be used regardless of the type of active implant or frequency of electromagnetic fields encountered in the workplace. For example, pacemakers are another type of cardiac implant, more frequent and better known. There are several publications on the topic including both in vitro and in vivo studies (Toivoinen et al. 1991; Silny 2003). Two of them, in real exposure conditions, examined the operation of different types of recent pacemakers in more than 300 patients exposed to a 50-Hz magnetic field (Trigano et al. 2005; Souques et al. 2007). The study by Trigano et al. found that at a maximum intensity of 100 μT, the devices switched intermittently to reversion mode[1] or inhibited stimulation in three cases among the 100 pacemakers with unipolar programming. The NOAEL (no observed adverse effect level) was 45 μT, higher than the values usually seen in the environment and in most occupational exposure. No level of interference disturbed the pacing function of any of the pacemakers in bipolar mode.

Even in the workplace, though, exposures to fields exceeding 45 μT are rare, and those exceeding 100 μT even rarer. Moreover, most pacemakers in France use bipolar sensing. The unipolar mode is found mainly in the oldest models, and thus in older people less likely to still be working. Looking at Table 4, which summarizes appropriate procedures for defining fitness for work of pacemaker wearers in the presence of 50-Hz magnetic fields, we see that the situation is clear for most situations, once the magnetic field level at the work places is known.

Table 4 Procedures for defining fitness for work of workers with cardiac pacemakers and exposed to 50-Hz magnetic fields

Magnetic field (μT)	Cardiac pacemaker in unipolar mode	Cardiac pacemaker in bipolar mode
<45	Fit	Fit
≤100	Study of work station	Fit
>100	Study of work station	Study of work station

This method permits the construction of a database that progressively lists the possible situations of exposure levels encountered in industry and the causal associations between different cardiac implants, settings, and interactions (if any).

It has to be noted that this method gives an assessment of the ICD interference for a specific implanted worker in a specific workplace. The results of the assessment cannot be transposed to other implanted workers or to other exposure conditions. For example, if the worker changes of job or ICD, the assessment has to be done again.

Conclusion

Today, accurate methods allow to study the exposure conditions of workers with active medical implants. These measurements help to decide whether they can keep their job or whether the job has to be modified to be safe and appropriate. The advantage of individualized studies is that they inform and reassure the occupational physician, the patient, the cardiologist, and the employer.

These three cases show the interest of measuring the real electric and/or magnetic field and telemetrically verifying the cardiac implant at the same time in the various premises, an employee is likely to work, to assess the risks of interference with the 50-Hz electric and/or magnetic fields. The advantage of individualized studies is that they inform and reassure the occupational physician, the patient, the cardiologist, and the employer. Safety no longer requires choosing an arbitrary determination of unfitness for work or of the systematic demotion of the worker.

This procedure can be used regardless of the type of active implant or frequency of electromagnetic fields encountered in the workplace. It would be useful to

[1] A safety mode designed in case of pacemaker inhibition, due for example to interference.

systematize such approach and thus construct an operational database for occupational physicians and cardiologists.

Note: In all cases, when electromagnetic interference is suspected, the first step is to move the person away from the field source.

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Conflict of interest The authors declare that they have no conflict of interest.

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