PROTECTION OF PACEMAKER WEARERS: EFFECTS OF MAGNETIC FIELDS ON THE OPERATION OF IMPLANTED CARDIAC PACEMAKERS

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INTRODUCTION

Between 30,000 and 40,000 cardiac pacemakers are implanted in France each year; two thirds go to patients younger than 80 years, most of whom are working and involved in all types of activities of daily living. The operation of these pacemakers can be disturbed by all sorts of electromagnetic fields, which are increasing in number with technological development in the areas of electricity and telecommunications (1-6), including the magnetic fields near electric transport or distribution lines or substation (50-60 Hz frequency) and the use of household induction cooktops with frequencies of 20 - 50 kHz.

In vitro experiments, in particular, have shown the risk of interference (3). These observations contrast with the rarity with which pacemakers settings are modified during check-ups and the equal rarity of patients' reports of symptoms when they go near such fields. Several factors may explain this difference: the briefness of the exposure may cause only temporary modifications; only some settings or configurations may be sensitive to these fields; some models may be more sensitive than others, or the combination of "implantation, pacemaker, and leads" may react differently in vitro and in vivo.

Although some clinical cases of symptomatic disturbances have been reported, there are few studies on the subject, and these are several years old; moreover, they have mainly studied electric fields (4-6): only one, conducted by Toivonen in 1991 (7), measured the magnetic field.

But cardiac pacemaker technology changes very quickly, and no systematic study has reproduced the conditions of magnetic field exposure with the current generation of cardiac pacemakers.

The aim of this study was to assess the changes in the behavior of cardiac pacemakers exposed to 50 and 60 Hz magnetic fields generated by industrial current and 20 to 50 kHz magnetic fields generated by a household in a booming period - the induction cooktop - and to study the incidence of these changes in a population of subjects with implanted pacemakers. This will enable us to give patients advices about dealing with electric transport lines and facilities and with induction cooktops and to advise manufacturers about the risks involved.

EXPOSURE SYSTEM

All of the equipment was installed in a room in the Cardiology Department reserved throughout the study for these experiments; each specific test also included the programmer for that patient's pacemaker.

Industrial magnetic field frequencies (50 and 60 Hz)

To reproduce the magnetic fields, an exposure apparatus was built, made of two rectangular coils 1.40 m high by 1.20 m wide, placed 80 cm apart so that a person could walk between them (figure 1). The variation of the current inside the coils enabled us to vary the field intensity from 0 to 50 µT. The device worked at two frequencies, 50 and 60 Hz, corresponding, respectively, to those of the European and North American power supply networks. We were able to measure and record the induction levels applied to the system with an integrated sensor. The measurement apparatus also included a tri-axial environmental sensor placed at 2.3 meter to axis of the portal.

The system was managed by a personal computer via a programmable power supply, with a driver based on "Labview" software. All the programmed and measured values were recorded in a data file for subsequent use.

The current induced density at chest level was calculated at 0.43 mA/m^2 for a 50 µT 50 Hz magnetic field, that is, 20 times less than the guideline upper limit of 10 mA/m^2 set by WHO organisation for 50 Hz. The electric field between the coils, on the other hand, was very low, on the order of 0.1 V/m.

Figue 1 : Industrial magnetic field exposure apparatus

The induction cooktop

The induction cooktop was a commercially available third-generation or IX3 model, 2.8kW, and operating at frequencies between 20 kHz and 50 kHz (figure 2). The magnetic field decreases with distance around such an appliance. The magnetic field in the area of an adult's thorax remained below European recommendations (5 A/m, or 6.25 µT for the frequencies used). Accordingly, the maximum current induced at hand level was calculated at 18 mA/m2 (IRPA/IRNIC limit at 50kHz: 200 mA/m2), and at chest level, from 0.18 to 0.36 mA/m2, that is, 50 to 100 times less than this limit value.

RECORDING SYSTEM

ECG monitoring was continuous, either by telemetry (ODAM), or by long cables attached to an ECG amplifier. Signals were continuously sent both to an oscilloscope screen and to a magnetic recorder, with a paper recording at each phase of the study. Particular attention was paid to minimizing interference, especially where the signal passed through wires. Low frequency signals were induced when the patient moved, causing the cables to move; this was prevented by fixing the electrodes and the cable pins onto the patient's chest and by limiting the length of the cables, which were fixed to the ceiling.

Figure 2 : The induction cooktop

METHODOLOGY

Nine manufacturers sell pacemakers in France (Biotronik, CPI, ELA, Intermedics, Medtronic, Pacesetter, Telectronic, Sorin, and Vitatron). They offer many models, of various ages and complexity. This was a pilot study, so it was arbitrarily decided to use models implanted only within the past year, and, to the extent possible, to use the most complex equipment -- dual-chamber, switchable polarity models.

The study included 60 subjects with currently implanted cardiac pacemakers of every brand sold in France. All tests were conducted, first at the usual settings of the pacemaker, chosen by the cardiologist, that we can regard as "medically correct", and then set to the maximum sensitivity allowed by the device.

The subjects' electrocardiograms will be monitored continuously, by telemetry and paper recording, from the time the exposure system is switched on until it is turned off.

For the 50 and 60 Hz frequencies, pacemaker operation was tested with the subject in three different positions relative to the exposure system: passing through the equipment, walking normally, in a forward direction, at 0 or 50 μT; passing through, walking normally, but in a sideways or profile position, at 0 or 50 μT, and standing immobile between the coils at 0 or 50 μT, arms along the body. If the pacemaker responded to this intensity, the cut-off point of detection was measured by progressively decreasing the field, by 5 μT to 5 μT, and then, if necessary, by 1 μT until 0 μT.

For the induction frequencies, a pot filled with water was placed on the cooktop, and recordings made in the following conditions: a patient was stationed near the cooktop, without touching it, then he or she placed one hand on the pot (a small pot on the largest burner), and finally stirred the contents with the other hand. These positions were held with the power set to 0 (control situation), then to the maximum on the front burner (12) , then in sequence mode at 4 on the front burner, and finally, at maximum on both the front and back burners (10-10).

The sequence of exposure for each site was random, directed by a technician and unknown to the cardiologist. The tracings were analyzed in real time, with the physician unaware to the intensity of the patient's exposure. A second look was made by another cardiologist, after the tests.

ASSESSMENT CRITERIA

Three types of dysfunctioning might be observed:

- inappropriate pacing (atrial or ventricular) while the pacemaker is inhibited,
- inappropriate inhibition (atrial or ventricular) while the pacemaker is pacing,
- deprogramming of the pacemaker.

PATIENT RECRUITMENT

Adult subjects older than 18 years and younger than 85 years, autonomous, not pacemaker-dependent, who had neither an escape rhythm higher than 50/mn after a pause of less than 1.2 second in case of inhibition nor any exclusion criteria, were followed in the Cardiology Department.

Are excluded: subjects in a precarious cardiovascular condition, subjects with a prosthesis other than a pacemaker, subjects with a serious disease, such as epilepsy or liver, respiratory, or renal failure.

RESULTS

The population comprised 60 patients, 27 women and 33 men, aged from 20 to 80 years (mean 60 ±13 years), who had received implants for paroxysmal atrioventricular block (18), sinus dysfunction, with or without atrial rhythm disease (26), carotid sinus hypersensitivity (8), or for hemodynamic reasons (8).

Nine brands of pacemakers were included in the study, with between 1 and 13 models per brand (Table A), all dual-chamber. At the time of the tests, 27 were pacing atrium and ventricles (ApVp), 15 were atrial sensing and ventricular pacing (AsVp), 15 were inhibited,

only sensing atrium and ventricles (AsVs), and 1 was pacing atrium and sensing the ventricles (ApVs). Finally two paced in ventricular mode (Vp) due to atrial fibrillation (fallback mode). Because of technical problems with the generators, only 58 pacemakers were tested in 50 and 60 Hz fields, and 57 near the induction cooktop.

Brand	N° Subj	AsVs	AsVp	ApVp	ApVs	Vp
Biotronik	6	1	1	4	0	
CPI	9	1	4	3	0	1
ELA	9	2	2	3	1	1
Intermedics	3	1		2		
Medtronic	10	6	2	2		
Pacesetter	11	2	3	6		
Sorin	4	1	1	2		
Telectronic	1			1		
Vitatron	5	1	1	3		
Total	60	15	15	27	1	2

Table A: Type and setting of included pacemakers

Baseline settings

None of the baseline settings of any of the pacemakers was disturbed by either the 50 Hz and 60 Hz fields or the induction cooktop. The atrial and ventricular leads were bipolar, except in 6 patients who had either unipolar leads, or leads set to unipolar. Depending on the model, atrial sensitivity was set to between 0.25 and 1.2 mV, with a mean of 0.66±0.24 mV. The ventricular sensitivity was set at between 1 and 7 mV, with a mean of 2.7±0.9 mV. In particular, pacing did not revert to asynchronous when the spontaneous rhythm was inhibiting the device, no acceleration was caused by inappropriate sensing by the atrial lead, and the device was not deprogrammed.

Unipolar mode, maximum sensitivity

The highest atrial sensitivity ranged from 0.1 to 1mV, according to the model, with a mean of 0.47±0.16 mV, and the maximum ventricular sensitivity from 0.5 to 2 mV, with a mean of 0.95 ±0.33 mV. The maximum setting was limited by the pacemaker automatic inhibition.

Neither at 50 Hz and 60 Hz fields nor with the induction cooktop did we observe any deprogramming of the standard adjustment nor any runaway device. One device (Biotronik) shifted out of its special program (hysteresis research) during the tests with the induction cooktop, but it maintained its standard program, and the event could not be repeated despite further testing.

The only anomalies observed were pacing irregularities in 10 cases with the 50 Hz and 60 Hz fields (Table B). Analysis of the tracings enabled us to identify the mechanism of these irregularities -- but it was never inhibition of the pacemaker:

Seven cases involved interference by the dual-chamber pacemaker with the device responding as planned by the manufacturer -- shifting into asynchronous mode or fallback into mode VVI.

In 3 cases atrial lead sensing caused a ventricular response, simulating atrial extrasystole, and in one case the pacemaker recycled at the preceding T wave.

Pt	Brand	Model	Field	A sens	V sens	??	size	Loops	side	AN??
60	Biotronik	Actros D	60F	0.1	1	AsVp	163	1	R	REPLI-VVI
10	Biotronik	Actros DR	50P-60P	1	0.5	ApVp	168	1	R	Interf-DOO
1	CPI	Vigor 950	50S-60S	1	0.5	ApVp	165	2	R	Vs/T
14	CPI	Vigor 950	60P	0.25	0.5	AsVp	163	2	L	Interf-DOO
29	CPI	Vigor 950	50P 60P	0.5	1.5	AsVp	182	2	L	REPLI-VVI
41	CPI	Discovery DR	60S	0.15	1	Vs	178	1	R	Interf-DOO
47	CPI	Pulsar 972	60P	0.15	1	AsVp	160	1	R	ESA*
53	CPI	Vigor 950	P10/10C	0.25	1	AsVp	161	2	R	Interf-VVI
13	ELA	7034 chorum	50P	0.4	1.2	AsVs	173	1	R	ESA
21	Medtronic	TheraDR 7962i	60P	0.5	1	AsVp	158	2	L	Interf-DDI
20	Telectronic	MetaDDDR 1254	60P	0.5	2	ApVp	175	1	R	ESA

Table B: Anomalies observed with 50 Hz or 60 Hz magnetic fields
F: Forward, P: Profile, S: Standing, 50: 50 Hz, 60: 60 Hz.

For those devices that reacted the most, sensitivity could be programmed to detect lowest potentials. We note that 6 of 9 CPI devices (with a atrial sensitivity that went down to 0.15 mV) and 2 of 4 Biotroniks (with an atrial sensitivity that reached 0.1 mV) were sensitive to the magnetic field. In contrast, only one of 10 Medtronic and 1 of 9 ELA devices reacted. The one and only Telectronic device could not be considered representative, and no products of the other 4 other manufacturers reached such low values.

On the other hand, the type of lead, the side of implantation and the number of loops around the casing had no effect. The size of the subject did not matter; detection could occur

with very large subjects, whose pacemaker was above the portal and not occur for smaller subjects.

Toivonen (7) is the only author who examined the magnetic as well as the electric field, in vivo. Like the other studies, it found that the bipolar mode was less sensitive than the unipolar mode and that programming maximum sensitivity in unipolar devices was risky. He found no anomalies for fields from 48 to 90 μT, with normal sensitivity, while the same fields disturbed the pacemaker's functioning when it was set to unipolar mode high sensitivity. In Toivonen's study, all the pacemakers were located on the right. This raised the question of whether devices on the left might be even more sensitive, because of their longer leads. In our study, they were not.

To our knowledge no study has examined the frequencies of induction (20 to 50 kHz). Our results show, as did Toivonen's experiments, the innocuousness of such fields as long as the pacemaker remains set to normal values. Disturbances are recorded only for extreme sensitivity values in unipolar mode on the ventricular electrode -- a medically erroneous setting. Moreover, unlike the older experiments, these studies found that the disturbances had no negative consequences, since they involved neither inhibition nor acceleration, but only a temporary reversion to an asynchronous mode; they are not life-threatening.

We did not, however, observe the prolonged inhibition described for models from the 1980s. This is probably explained by the fact that current devices are better protected against interference, whether it involves the filter component at circuit entry or software methods for sensing interference.

These data show, first of all, the need for in vivo studies, because cardiac pacemakers appear to be more sensitive to electromagnetic fields in vitro than when implanted in the body.

The data also confirm the danger of sensing in unipolar mode, which increased sensitivity to interference. This accords with the general ideas of cardiac pacing and with our experience. Finally, our results also show the diversity of possible pacemaker responses.

We note, in particular, that ventricular sensitivity at the level that permits these inhibitions in the in vivo studies is too high for the potentials recorded in this cavity: the default ventricular sensitivity of pacemakers is always greater than 2 mV, as in our series. More sensitive settings would only be used in error, either when the ventricular lead is inserted or during programming. It was, by the way, necessary in our study to verify that inhibitions were indeed due to the magnetic field and not to inappropriate sensing of the paced complex or of contractions of the pectoralis major, or even to the crosstalk made possible by these unusual settings.

We should also note that the fields emitted were not sufficiently intense to directly disturb the microprocessor circuits.

The limitations of this study are clear -- the limited number of patients, which prevents the detection of a possibly random interference effect. However, we intend to continue the study with a similar experimental protocole on a larger number of patients.

CONCLUSION

Our series show that it is only at very high sensitivity settings and in unipolar mode that pacemaker functioning may be affected, with, as the only consequence, the spontaneously

reversible switch to a fallback mode planned by the manufacturer when interference is sensed. Such high sensitivity should not be used with ventricular leads. This study also shows the variety of the reactions of devices from various manufacturers. It also shows the need to continue systematic in vivo tests for new generations of pacemakers.

IN PRACTICE

1- The 20 to 50 kHz magnetic fields produced by the current generation of induction cooktops do not affect pacemakers.

2- The 50 and 60 Hz magnetic fields can be sensed as interference by pacemakers and can lead a device to switch temporarily to the safety mode planned by the manufacturer.

3- These influences are detectable only for some unipolar configurations, with very sensitive detection thresholds , and only for some patients and some models.

4- It basically involves brief switches to asynchronous mode. They have no clinical consequences -- making them different from the phenomena observed in earlier publications. With the protocol we used, we observed neither acceleration nor deprogramming.

5- Using bipolar leads or, if a unipolar lead is preferred, taking precautions to avoid the highest levels of sensitivity, makes it possible to avoid all interference problems.

The advice to give pacemaker patients must be cautious and in fact depends on each situation. The absence of any serious events in our series, which corresponds to the extreme rarity of reported incidents, suggests that patients can be reassured. Only pacemaker-dependent subjects with unipolar ventricular leads attached to a pacemaker sensitive to ventricular potentials less than 2 mV should have their pacemaker reactions tested in different magnetic fields. This advice should be made known to cardiologists, who are responsible for the settings of their patients' pacemakers.

PERSPECTIVES

Until then, this sensitivity to magnetic fields had been studied essentially in vitro; according to the manufacturers' internal data, it varies from between 200 and 1000 µTesla. This led the ACGIH (8) to suggest a minimum exposure value of 100 µT

These results encouraged us to continue in vivo investigations of the fields associated with the transport and distribution of electricity, with more types of pacemakers and more subjects. The pilot study results also indicate that we can safely include in the present study volunteers dependent on their pacemakers, a group excluded from the previous study.

This new study is a multi-centre study aimed at evaluating the behaviour of implanted pacemakers in the presence of a magnetic field of 50 Hz of 100 µT (100 µT is the value retained at this frequency in European recommendation 1999/519/EC, dated 12/07/99 concerning public exposure to electromagnetic fields. It will provide the Council of the European Union with data on which to base exposure limits for persons wearing implanted active prostheses (pacemakers account for the majority of these), who are currently excluded from the recommendation.

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