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Interference between active implanted medical devices and electromagnetic field emitting devices is rare but real: results of an incidence study in a population of physicians in France

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Short Title: implantable medical devices and EMF emitting sources

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Abstract

Background and objective: Assessing the behavior of active implanted medical devices in response to electromagnetic field (EMF) transmitters is a current issue of great importance. Given the multiplication telecommunication systems and our lack of knowledge as to the impact of electromagnetic effects, the present study investigated the reality of possible AIMD disturbance by electromagnetic fields by questioning health professionals.

Method: A self-administered postal questionnaire was sent to almost 5,000 physicians in 5 specialties: cardiology, endocrinology, ENT, urology and neurology. It collected data on the existence and annual number of incidents observed and the conditions under which they occurred, the EMF sources involved, and the means of managing the malfunctions.

Results: 1,188 physicians agreed to participate. 16% reported cases of implant failure, three-quarters of whom, mainly in cardiology, reported rates of at least 1 incident per year – amounting to more than 100 incidents per year in all. Severity appeared to be moderate (discomfort or transient symptoms), but frequently required resetting or, more rarely, replacing the device. Some serious incidents were, however, reported.

The sources implicated were basically of 2 types: electronic security systems (antitheft and airport gates) and medical electromagnetic radiation devices.

These incidents were poorly reported within the public health system, preventing follow-up and effective performance of alert and surveillance functions.

Conclusion: Although minor, the risk of interference between EMF sources and AIMDs is real and calls for vigilance. It particularly concerns antitheft and airport security gates, although other sources may also cause incidents.

Key Words: Active implanted medical devices, Medical survey, Adverse effects, Electromagnetic fields, Electromagnetic interference, Equipment failure, Postal questionnaire, Security systems, mobile phones .

Introduction

We live in an environment where there are increasing sources of electromagnetic fields (EMF) to which active implanted medical device (AIMD) bearers are exposed on a day-to-day basis. For frequencies in the 80 MHz to 1 GHz range, current regulations require all electrical devices not covered by dedicated standards to function in an environment with an EMF not exceeding 3 volts per meter. This safety level is, however, often raised for equipment considered to be critical: thus for medical life-support devices the immunity level is raised to 10 V/m between 0.8 and 2.5 GHz.

There have been 3 distinct types of study of EMF interference with AIMDs: in-vivo studies reproducing a real-life situation, in-vitro studies of AIMD immunity by simulation of the EMF conditions to which AIMDs are subject, and finally clinical studies. Of these, only the in-vitro studies using a phantom equivalent of biological tissue allow cross-study comparison of results.

The considerable increase in the use of radio frequencies in everyday life is increasingly exposing AIMD (pacemaker, internal neurostimulator, insulin pump, etc.) bearers to EMFs exceeding 3 V/m. The ubiquity of EMFs precludes avoidance of at-risk situations: a single exposure may be enough to disturb AIMD functioning, with harmful physiological impact on the bearer. There have been more and more studies over a number of years seeking to assess and describe such EMF-related risks ¹, mainly in cardiological (pacemakers and implantable automatic defibrillators (IAD)) and ENT (cochlear implants), which are the most widely used.

Situations in which the 3 V/m (not to mention 10 V/m) threshold is exceeded are rare but probable: e.g., security or antitheft gates or radiofrequency identification (RFID) readers, in presence of radio-telephones, particularly in confined spaces such as subways or elevators, or high-power transmitters; in medical practice, high exposure may also be involved in magnetic resonance imaging (MRI) or the use of an electric knife. It is technically possible that such exposure disturbs AIMDs, causing malfunction and thus transient or more serious problems for the bearer: burns, impact on brain tissue in contact with a neurostimulation electrode, uncontrolled discharge of insulin or other drugs, pacemaker crash, etc. ².

Although bearers are usually warned of such situations by their physicians and advised to make themselves known in them, it is not easy to be aware of all the possible sources of exposure they may encounter on a day to day basis so as to be able to avoid them. For this reason and given the increasing number of AIMD bearers, EMF-related disturbance is a current issue.

Individuals and associations have on several occasions expressed their worries to the French public authorities about incidents experienced by AIMD bearers exposed to radiofrequency fields, but the issue has not been reported to have been taken up by the health authorities and no real action has been taken, current regulations being considered sufficient for prevention purposes.

A certain number of cases having, however, come to our knowledge, we felt it necessary to investigate the reality of such incidents as testified to by physicians and assess the seriousness of the situation in terms of frequency, severity and circumstances so as to be able to provide the health authorities with precise data.

Methods

Study population: The study population comprised physicians dealing with AIMD bearers in 5 specialties: cardiology, endocrinology, neurology and neurosurgery, ENT and urology.

Data: A questionnaire, brief enough to be quickly completed, comprised 3 main rubrics:

- Preliminary: physician identification and medical activity (number of AIMDs and bearers followed) and complaints of AIMD failure associated with electrical interference during the year;
- Description of the complaint: type of AIMD, number of incidents per year, type of physiological or symptomatic disturbance, type of EMF source implicated, type of corrective action required, description of situation;
- Reporting of incidents.

Survey methodology (Two-step survey):

The first step comprised a postal self-administered questionnaire. Respondents were selected at random from a national database, from an estimated 18,000 relevant physicians. With an expected incident report rate of 3% and to obtain a data set for about 150 physicians reporting 1 to 3 incidents per physician per year, 5,000 physicians were contacted.

Having failed to obtain lists of physicians from the National Medical Order, we used a database derived from the Yellow Pages of the Phone Book. Randomization took account of population per specialty. To obtain a sufficient number of responses per specialty, questionnaires were sent to all listed endocrinologists (n=856), neurologists (n=616) and urologists (n=381), the numbers of which were relatively small, and to 25% of the cardiologists (n=1,717) and 35% of the ENT specialists (n=1,296). In all, 4,866 specialists were sent the questionnaire. A reminder was sent after 1 month, to maximize response.

The second step comprised a telephone survey of respondents having reported at least 1 incident, to allow more precise analysis of the incidents reported: precise devices involved, and circumstances of the incident.

Results were reported as frequency tables.

Results

For 120 physicians, envelopes were returned to sender by the Post as “unknown at this address”. 1,188 of the 4,866 physicians contacted replied (response rate: 25%). 333 wrote that they were not concerned by the survey as their practice did not involve following AIMD bearers. 137 of the 855 physicians concerned by the survey reported having observed at least 1 incident (figure 1).

Description of incidents

16% of respondents were aware of at least 1 incident resulting from interference between an AIMD and an EMF-emitting device. Proportionally, cardiologists and urologists were the most concerned (Table 1). Most physicians reporting an incident had observed less than 1 incident per year.

Pacemakers were the implants most frequently (>50%) concerned (Table 2).

Most incidents involved malfunction, resulting, for example, in abnormal stimulation (Table 3). Devices frequently went into fail-safe mode after the initial failure; in 12% of cases, there was total shut-down. Complete resetting was especially required for cardiological devices: for 70% of pacemakers and 56% of defibrillators.

Patient disturbance ranged from simple discomfort (40% of cases) to transient symptoms (39%); in 18% of cases, symptoms were serious enough to require emergency treatment. The kind of disturbance depended on the type of AIMD: insulin pumps, valves and neurostimulators gave rise to the most severe symptoms.

EMF devices implicated

The EMF sources most frequently implicated were store antitheft gates (21%), followed by electrosurgical knives (13%, despite real improvements that have been made and increasing physician awareness of and adherence to instructions for use) and airport security gates (10%) (Table 4). Cell-phones and Wi-Fi stations were involved in less than 10% of cases, and Digital Enhanced Cordless Telephone (DECT) base stations and microcells were very seldom implicated.

It was noteworthy that 8 of the 11 cochlear implant incidents involved telecommunication radiofrequency sources: 1 DECT handset, 2 DECT bases, 2 cell-phones, 1 microcell in a store, 1 Wi-Fi base, and 1 radio transmitter at very close proximity.

Half of the physicians concerned by the survey reported AIMD failure to at least 1 organization, mainly (77%) the manufacturer. French Health authorities (health product safety agency (AFSSAPS) or Ministry of Health, France) were contacted in only 2 out of 170 cases; the Order of Medicine was never contacted. The other 33 reports were made to the implanting physician.

Discussion

The frequency of AIMD incidents associated with EMFs was low (involving only 16% of physicians potentially concerned), but non-zero. Cardiologists and urologists were the specialists mainly involved. Severity was relatively low: three-quarters of incidents induced only transient physiological and/or symptomatic disturbance, with minor impact (discomfort or transient symptoms). However, 18% of incidents required treatment; incidents involving insulin pumps, valves and neurostimulators induced the most severe symptoms.

EMF sources were basically of 2 types: electronic security systems (store antitheft gates and airport security gates) and medical electromagnetic radiation devices (electric knives, radiation therapy, MRI scanners), although the incident-rates associated with the latter have decreased. Security equipment has been the focus of a few previous reports. Gimbel et al² reported 2 cases of failure (1 IAD and 1 pacemaker) induced by store security apparatus: the IAD bearer received 2 inappropriate shocks in 30 seconds just after passing through the gate, and the pacemaker bearer lost consciousness while in the gate until he was finally removed. Other studies^{3,4} showed that security system frequencies are sometimes close to cardiac device signals, and thus liable to induce failure. In contrast, in a large-scale in-vivo study in 2003⁵, 200 pacemaker and 148 IAD bearers were asked to cross an airport security gate at varying angles; continuous ECG recording assessed any change in stimulation. Results suggested that the apparatuses were harmless, with no cases of interference, heart problems or implant failure. The present findings contradict these results for a single security gate tested on an experimental protocol rather than in real-life situations which only an epidemiological study can assess.

A very large number of medical and surgical electromagnetic radiation devices are liable to disturb AIMD functioning. The potential risks associated with electric knives have been widely discussed^{6,7}, and it is now well known that they can adversely affect AIMD bearers; several means of reducing this interference have been suggested^{8,9}: e.g., using the electric knife in bipolar mode.

The literature on MRI machines is abundant: AIMDs seem to be very vulnerable to this diagnostic tool, which applies an intense magnetic field involving very high frequency emissions. Cochlear implants, for example, are liable to be displaced and their electronic system to be affected^{10,11}. The risk with cardiac devices is of inhibition or on the contrary of excessive stimulation during MRI examination^{12,13}. With neurostimulators, there is a proven risk of implant heating and dysfunction¹⁴. When AIMD bearers require radiation therapy, the risk of interference also appears to be serious. In 2006, Uiterwaal¹⁵ sought to determine the effect and associated risk of radiation therapy on IADs, and found systematic interference in all 11 devices subjected to ionizing radiation.

The initial controversy concerned mobile communication, given its soaring use. We found 8 incidents involving telephones, 5 involving Wi-Fi and 4 involving microcells: although few, they demonstrate that a risk exists and will cause more incidents as the sources multiply and grow closer together. Several studies in recent years have analyzed interactions between AIMDs and new communication technologies. Tandogan¹⁶ tested 43 IAD bearers, and found no impact of testing on IAD functioning. Jimenez¹⁷ surveyed 72 IAD bearers on adverse effects due to cell-phones, and found no clinically perceptible interference. In contrast, a multicenter study¹⁸ assessed analogic and digital phone impact on 980 pacemaker bearers: a series of tests revealed clinically significant effects in 6.6% of cases. Another study¹⁹ focused on cell-phone effects inside hospitals, where the need for restrictions is being questioned, and found that, although the incident rate has been reduced by improved electromagnetic compatibility in AIMDs, cases remain in which cell-phones impact medical equipment. Likewise, given the spread of portable music readers, recent studies have examined their impact on AIMDs and on cardiological implants in particular. In vitro²⁰ and in vivo studies^{21,22}, covering a wide range of AIMDs, assessed the EMF levels and impact of portable music readers and found no evidence of interference or effect on IAD or pacemaker function. In contrast, Thaker²³, in 2008, reported several cases of interference: they assessed the impact of EMFs emitted by 4 iPods on more than 100 pacemakers, implementing 2 test phases so as to ensure reproducibility; results pointed to a probable risk of interference between multimedia readers and pacemakers.

Electronic security systems and medical EMF sources are the most frequent causes of interference, but other sources may also be implicated. The present results notably include 4 cases in industrial settings: welding irons and arc welding; hitherto using such tools was strongly advised against in AIMD bearers but ongoing research is seeking to draw up safety measures to allow AIMD bearers to work without danger in industrial settings²⁴. In everyday life, on the other hand, identifying sources of interference is less straightforward, as many are hard to detect: for example, everyday objects such as jewelry or clothing increasingly use strong magnets which, despite their small size, may induce strong static magnetic fields. *In vitro* studies have determined the threshold of the electromagnetic fields beyond which IAD could be disrupted by a magnet: Ryf et al.²⁵, for example, assessed the maximum distance between IADs and magnets commonly used at home or at work at which magnetic malfunction is still observed. Wolber et al.²⁶ in a clinical study, placed different magnets of various power on the skin of patients with PM or DAI and found that all patients presented disturbance of the electrical parameters of the heart. Finally, Beinart²⁷ reported a case of electromagnetic interference between an IAD and the small magnetic press-studs of a jacket; this incident, similar to a case in the present study involving magnets in a hairdresser's gown, led to complete reprogramming of the implant.

Constantly developing, electromagnetic environments confront society with the question of their public health impact. The present study therefore sought to shed light on the relationship and underlying problems of certain EMF-exposed AIMDs.

The conclusions do not claim to give a precise account of the issue and in particular do not include any annual incident frequency as the survey was based on subjective reports. There were several study limitations: the response rate of 25% was good for a postal survey but made exact calculation difficult as it was not known whether physicians failed to respond because they had no AIMD bearers in their practice or because they did not wish to respond; this reporting bias likely led to underestimation of the real frequency of electromagnetic incidents. Memory bias in terms of frequency and date of incident doubtless led certain physicians to report some old cases, although

the study sought to analyze only recent cases thanks to information gleaned during the second telephone interview; and the difficulty for the physician to distinguish radiofrequency and low-frequency related incidents led to all reported incidents being included for analysis. Furthermore, physicians may not have adequately declared the consequences of compatibility incidents: for example, the total failure rate of 7% seems to be higher than expected²⁸.

In any event, the data collected here seem to us to confirm the reality of these incidents that the health authorities have not been in a position to assess, and to call for real vigilance. The means of monitoring and preventing AIMD failure need to be planned for: one approach could be risk management education by raising awareness and/or instituting mandatory training both for AIMD bearers as a whole and for the health professionals concerned by the issue. Other approaches, put forward by patient associations, include training for airport controllers and information posters concerning EMF values to be posted in such places as hospitals, industrial premises, etc. Finally, the occurrence of such incidents should encourage AIMD makers to develop ever more resistant designs.

Conclusion

The question of EMF impact on AIMDs is real, as is the associated health risk: several cases of implant failure were linked to low or high frequency electrical devices. The actual number of incidents was, however, small. Some EMF sources emerged as posing more risk than others: security equipment (antitheft and airport security gates) and certain medical devices involving electromagnetic radiation (e.g., electrosurgical knives). By reinforcing AIMD immunity, manufacturers could guard against an increase in the number of incidents. In most cases, incidents were momentary, although they could endanger the safety of certain patients. Reporting to health authorities appeared to be virtually non-existent; physicians may fail to report failures spontaneously, being faced by a very limited number of cases, of moreover limited severity.

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Table 1: Distribution of the 137 physicians reporting incidents (out of 855 respondents) according to number of incidents per year

Number of incidents per year	Cardiology	Endocrinology	Neurology	ENT	Urology	Total
	n	n	n	n	n	n
<1	75	13	7	7	6	108
1	10	0	0	2	3	15
2 -3	7	0	2	2	0	11
>3	2	0	0	0	1	3
Number of respondents	410	141	88	185	31	855
Total	94 (23%)	13 (9%)	9 (10%)	11 (6%)	10 (32%)	137 (16%)

Table 2: Distribution of incidents by type of implant

	Number of incidents*	
	n	%
Cardiological implant		
Pacemaker	90	58.1
Defibrillator	16	10.3
Neurological implant		
Valve	6	3.9
Stimulator	9	5.8
Urological implant		
Stimulator		
vesical/Modulator	11	7.1
ENT implant		
Cochlear implant	11	7.1
Endocrinological implant		
Insulin pump	12	7.7
Total	155	100

* for a given implant, several types of incident are possible

Table 3: Types of incident by type of implant

	Failure		Shut-down		Temporary stoppage with normal start-up		Other and NR*		Total
	n	%	n	%	n	%	n	%	n
Pacemaker	74	76.3	7	7.2	9	9.3	7	7.2	97
Defibrillator (IAD)	13	68.4	0	-	5	26.3	1	-	19
Valve	4	-	0	-	1	-	1	-	6
Stimulate	3	-	3	-	2	-	1	-	9
Vesicle stimulator/modulator	5	38.5	4	-	3	-	1	-	13
Cochlear implant	8	61.5	3	-	2	-	0	-	13
Insulin pump	4	-	4	-	1	-	1	-	13
Total	111	65.3	21	12.4	23	13.5	18	10.6	170

*NR: non-response

Percentages calculated only for n ≥5

Table 4: Type and frequency of implication of devices underlying AIMD failure

	Devices implicated	
	N*	%
Low frequency devices		
Household equipment	5	2.3
Other [†]	17	8.0
High (including radio-) frequency equipment		
Diathermal device	3	1.4
Electrosurgical knives	28	13.1
DECT at home/hospital or near base	9	4.2
Cell-phone. Ipod	8	3.8
Wi-Fi (computer or PDA/router/network access point or box)	5	2.3
Microwave oven	3	
Store antitheft gate	44	20.7
Airport security gate	21	9.9
Proximity to cell-phone relay	3	
Microcell (small relay antenna)	4	
Proximity to radio. TV transmitter	3	
MRI, scanner	9	4.2
Other [‡]	5	2.3
Low and high frequency devices		
Other [§]	7	3.3
X-ray devices		
Radiographic equipment	6	2.8

Unknown frequency

Other [¶]	3	
Remote control	1	
Do not know	29	13.6
Total	213	100

Percentages calculated only for n ≥5

* Physicians were not always able to identify a single device; some suspected 2 or more sources for a single incident – whence the number of sources exceeding the number of incidents.

† Physicians were not always able to distinguish radiofrequency and other frequency-range transmitters; sources were grouped together, without excluding non-radiofrequency sources, as the information seemed useful.

Other low-frequency devices: electrotherapy (2), electric train, power lines (2), electrified fence (2), hairdresser's gown button magnet, defective household equipment (2), car battery recharge, loud-speaker (3), electric transformer, weapons detector..

‡ Other high frequency devices: ski entry gate (2), surgical sterilizer (1), in-car IT equipment (2).

§ Other high- and low-frequency devices: welding iron, arc welder (3), induction hotplate.

¶ Other devices of unknown frequency: working environment, electrical equipment, electrical DIY equipment.

Figure 1: Breakdown of study population

