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Review

Implantable devices in the electromagnetic environment

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ABSTRACT

In the last few years we are witnessing a dramatic increase in the number of CIEDs implanted. At the same time new emitters are constantly entering the marketplace and more and more medical procedures are based on electromagnetic fields as well. Therefore, the topic of the interaction of CIEDs with the EMI is a real, actual and challenging one. In the non-medical environment several types of devices may be intentional or non-intentional sources of EMI. Most of the studies reported in literature focused on mobile phones, metal detectors, as well as on headphones or digital players, but many other instruments and tools may generate electromagnetic fields. In the medical environment most of the attention is paid to MRI and recently new PM and MRI conditional ICDs have been developed and launched in the market, but the risk of interaction is present also with ionizing radiation, electrical nerve stimulation and electrosurgery. Pacemaker/ICD manufacturers are incorporating state of the art technology to make implantable devices less susceptible to EMI. However, patients and emitter manufacturers should be aware that limitations exist and that there is not complete immunity to EMI.

Contents

Abbreviations: CIEDs, cardiovascular implantable electronic devices; SCD, sudden cardiac death; ICDs, implantable cardioverter defibrillators; CRT, cardiac resynchronization therapy; PM, pacemakers; EMI, electromagnetic interference; GSM, Global system comunication; RF, radio-frequency; MRI, magnetic resonance imaging; AEDs, automatic external defibrillators; HF, high-frequency; DFTT, defibrillation threshold testing; CMOS, metal oxide semiconductors; TENS, Transcutaneous electrical nerve stimulation

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1. Introduction

Since their introduction, at the end of fifties, cardiovascular implantable devices (CIEDs) have widely expanded in number and in their functions [1,2]. The dramatic increase in the number of CIEDs implanted in the last decade is mainly due to the aging of population and to the expanding indications for both primary prevention of sudden cardiac death (SCD) and non-pharmacological treatment of heart failure, following a huge prevalence, indeed, of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy devices (CRT-D/P) implants. On the basis of Eucomed data, 395,000 pacemakers (PM) and 62,000 ICDs were implanted in European countries, included in the Eucomed survey, during 2009. But as several countries are missing in the survey, real data of total implantation rate in European Community in 2009 reached the number of almost 500,000 PM and more than 71,000 ICDs [3,4]. If we look at data coming from a worldwide survey, more than 1 million PM and 300,000 ICDs were implanted only in the 2009 all over the globe [5], with an annual increase of CIEDs implants which is still today around 5% [6]. Besides such a huge increase of the number of patients wearing CIEDs, we are witness of a wide and unstoppable proliferation of technology generating electromagnetic signals. Thus, more and more tools and instruments for everyday use can create electromagnetic interference (EMI) potentially able to interact with CIEDs' normal functioning.

We should remind that human safety exposure standards for transmitters are actually based upon average power and biological effects (such as tissue heating). As a result, emitters are allowed to produce pulsed signals with peak power that greatly exceeds limits compatible with implantable device susceptibility. Furthermore, new indications for treatment with CIEDs results in younger patients returning to industrial worksites. Therefore, today as yesterday, EMI still represents a real challenge to PM and ICD manufacturers. Such a challenge takes place both in a medical environment as in a non-medical one and physicians caring for patients with CIEDs should be aware of potential sources of EMI and of appropriate management strategies, in both these scenarios.

1.1. Minimizing the effects of EMI

The potential effect of an electromagnetic field on an implantable device depends on the type of the device (single/dual chamber, PM, ICD, old/new generation, unipolar/bipolar lead) and on the type of electromagnetic source. The clinical impact of the interaction depends, instead, mainly on patient characteristics (PM dependent/non-dependent patient) [7].

The first and more important response to this emerging problem came, already since the 1980s, from the manufacturers who improved leads and devices safety and performance, significantly reducing the influence of electromagnetic exposure on the correct function of PM and ICDs. Modern pacing systems have evolved in various ways to decrease susceptibility to potential EMI. First very handy and thinner bipolar leads were developed so that, right now, all over the world, bipolar leads represent the current standard, thus reducing the "antenna" effect and the oversensing phenomenon of external electo-magnetic signals. Afterwards industries produced more and more protected devices, with hermetically sealed titanium shield housing or stainless steel cases surrounding circuitries specially designed with "bandpass filters", to filter out signals outside the narrow range of cardiac depolarization frequencies (10–50 Hz). Active bandpass filters have some important features: they are physically very small; they are only effective for very small amplitude signals; moreover they are limited to relatively low frequencies and can create very sharp filter edges to discriminate biological signals. Furthermore signals within the cardiac depolarization frequency range are amplified in order to not reduce sensing capability. Finally several specific algorithms, able to discriminate true intracardiac signals and noises, have been developed. Noise sampling periods, for instance, may further reduce the risk of inappropriate inhibition or triggering due to environmental signals. Signals detected during the ventricular refractory period, for example, are regarded as noise. Furthermore, in the presence of a strong EMI, pulse generator often reverts to a fixed backup rate, avoiding deactivation. In certain conditions, in fact, conversion to asynchronous pacing is a clinically acceptable alternative to inhibition.

Therefore, the risk of life-threatening arrhythmias, due to asynchronous ventricular pacing during a vulnerable period, is a quite uncommon event. The newest generations of devices are equipped also with "feed-through filters" (Fig. 1) to enhance insulation of cardiac devices, especially from high-frequency noise in the kilohertz, megahertz and gigahertz range (Fig. 2).

Although new technology trends are aimed towards developing smaller and long lasting devices, manufacturers also need to follow some design constraints on PM and ICD. For example small size is highly desirable by patients and physicians for comfort and appearance; however, it limits the size and number of components and limits the capability to control EMI indeed. At the same time, the power used to mitigate EMI reduces the life or increases the battery size of the device. Therefore, interference control often competes with newer features of CIEDs and needs to deal, for example, with the increased need for memory and data recovery, with the device-based and lead-based sensors for monitoring and algorithm control, with the new high frequency (RF) telemetry ($>$ 400 MHz) and finally with an increasing complexity of implanted lead wire systems.

In conclusion, even though the technology for protection and insulation of CIEDs has been so much improved, adverse events related to EMI in CIEDs patients may still occur and both patients and doctors must be aware of them and take the correct and adequate precautions and preventive measures in every risky situation. In addition emitter manufacturers should be encouraged to read the pacemaker and ICD EMC standards and work with the pacemaker/ICD industry in order to design their devices to avoid pacemaker/ICD bandpass.

1.2. The potential effects of EMI on devices' function

The protection given by the algorithms, available on the latest generations of devices, depends on the duration of EMI sourcing. A prolonged sensing of EMI will start one of the protection

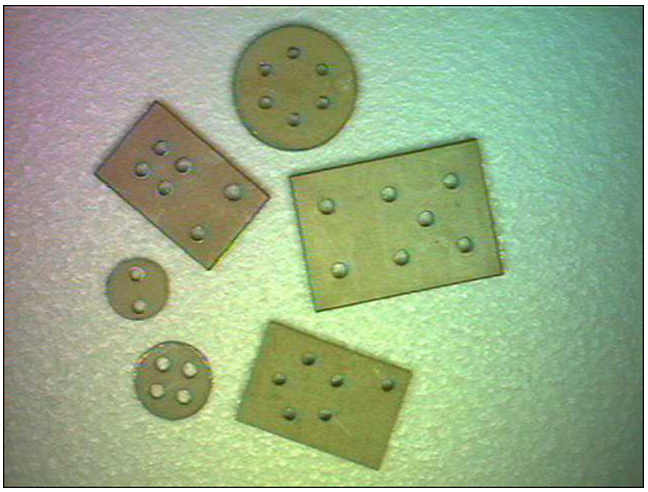

Fig. 1. Integrated feedthrough filters.

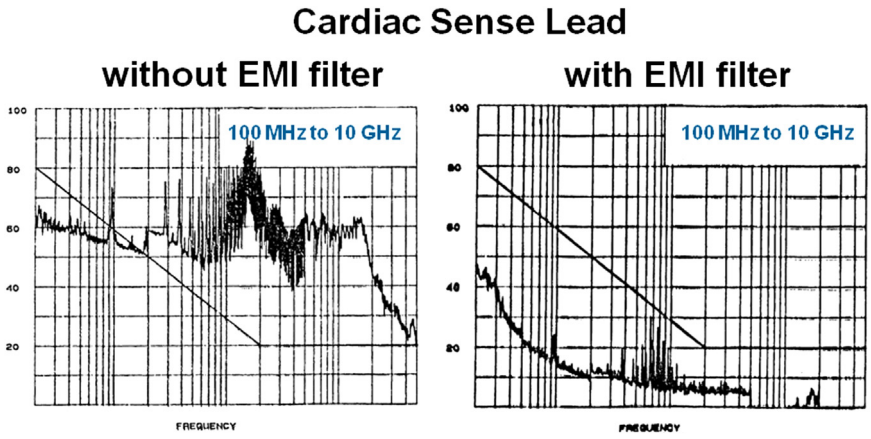

Fig. 2. Example of passive EMI filter performance.

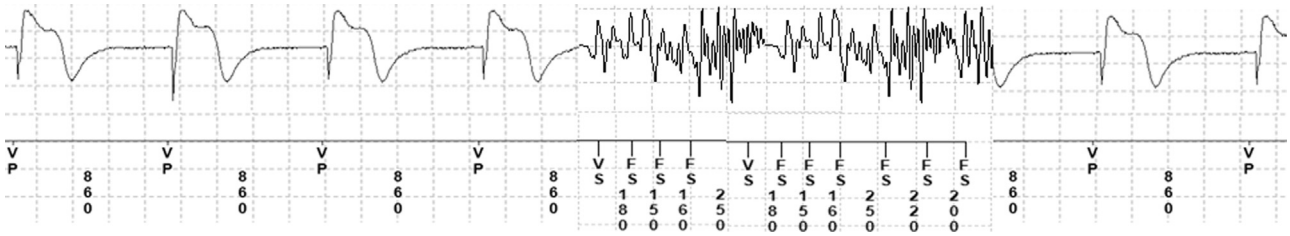

Fig. 3. Asystole in PM-dependent patient induced by EMI oversensing.

Table 1
Potential pacemaker response to EMI.

- Sensing/pacing inhibition.
- Noise reversion to asynchronous pacing.
- Tracking, for dual chamber devices.
- Rate changes within programmed rate limits, for rate adaptive devices.
- Activation of the reed switch (asynchronous pacing).
- Extreme case, but very unlikely: microprocessor reset.

algorithms, if activated, while an intermittent sensing of EMI could delay their activation. In case the algorithms does not work appropriately, because of deactivation or intermittent sensing, EMI could be sensed as an intrinsic ventricular activity driving to an oversensing event and inhibition of pacing, which in a pacemaker-dependent patient could result in a dangerous asystole (Fig. 3) (Table 1). If the oversensing related to EMI should be in the ventricular channel of an ICD, an erroneous detection of ventricular tachycardia or fibrillation could be present leading to an inappropriate ICD therapy (Figs. 4 and 5) (Table 2). The response to EMI-induced oversensing in the atrial channel of PM and ICDs may be inhibition of atrial pacing, if the device is programmed in AAI or DDD modes, or fast ventricular pacing (at the maximum tracking rate) if the device is programmed to initiate atrio-ventrocular interval (AV) in response to atrial signals (DDD or VDD modes). Furthermore if the automatic mode switch algorithms are activated, they may be initiated by the atrial oversensing, changing pacing modality from DDD to DDI (Fig. 6).

In case of a prolonged exposure to a strong electromagnetic field, devices may also identify it as EMI and switch in the "power-on reset" mode which is a safety mode available for most of the devices. Another possible response of CIEDs to EMI may be the activation of the magnet response, which is different for each manufacturer but in the majority of cases results in asynchronous pacing for PM and turning off tachycardia therapies in ICDs. Besides the specific algorithms, which equip the modern devices in order to protect CIEDs function from deleterious effects of EMI, it is also very important to know the correct and complete information of the patients concerning the potential sources of EMI and the related risks to them. Patients wearing CIEDs should be aware of avoiding EMI sources or at least limiting as more as possible the exposure, maintaining the largest distance and the shortest time as possible. Such a simple but essential caution may be the most important action against EMI related risks for CIEDs patients, especially outside of the hospital, for the non-medical sources of EMI.

1.3. Potential sources of EMI

Our world is more and more a technological one. Modern age is the age of electronics and digital innovation and just in the last 20 years a plenty of electronic instruments, tools, devices and machines of every kind and for every need have spread out invading our daily lives. Following this unstoppable "electronic tsunami", new powerful emitters and electromagnetic sources exploded as well, and this phenomenon is not limited in specific professional and industrial environments but most of all regards our private lives. Even though common household appliances, such as microwaves ovens, televisions or computers, do not interact with CIEDs, we still deal with plenty of potential EMI sources in most of our daily actions. Furthermore more and more medical procedures are based on electromagnetic fields, such as radio-frequency (RF) ablation, magnetic resonance imaging (MRI), lithotripsy, diathermy, harmonic scalpels and devices used in-home or public as automatic external defibrillators (AEDs), bone growth stimulators, etc. Emitters may be intentional, as cell phones, or unintentional, for example electric shavers (Table 3). The main factors concerning emitters that we have to consider are

– frequency of the emitter;
– modulation up to several hundred Hz;
– power;
– proximity to the patient;
– duration of exposure;
– coupling factors.

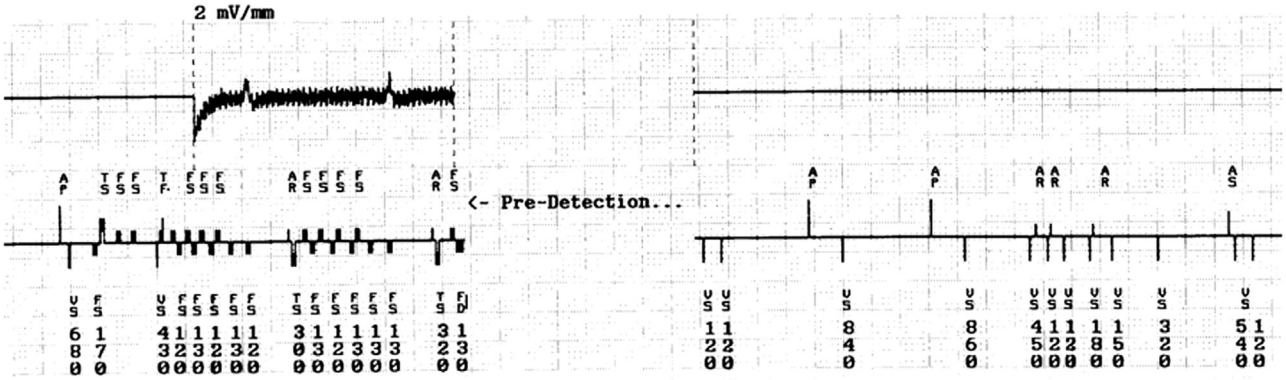

Fig. 4. Inappropriate detection of VF in ICD patient due to EMI.

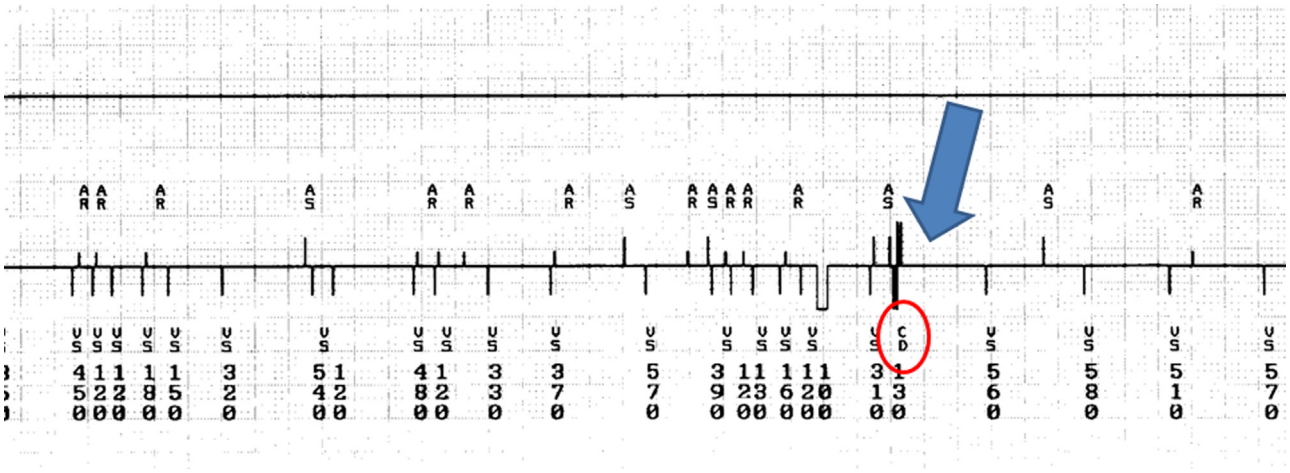

Fig. 5. Inappropriate shock delivery in ICD patient due to EMI.

Table 2
Potential ICD response to EMI.

- Oversensing that manifests itself as: inhibition (missed pacing beats), and potential inappropriate delivery of therapy.
- Tracking, for dual chamber devices.
- Undersensing an arrhythmia.
- Current induced into the lead system, that can trigger an arrhythmia.
- Reed switch activation (suspends detection).
- Extreme case, but very unlikely: microprocessor reset.

Non-medical environment

2.1. Mobile phones

Since the first years of their massive introduction among the population, researchers studied the potential interaction of mobile phones with CIEDs. First reports in vitro and in vivo showed various effects of electromagnetic field by cellular phones on CIEDs, ranging from oversensing and inhibition of pacing, ventricular tracking to high rate or switch to asynchronous pacing [8,9].

Since the first studies it was clear that GSM (Global system Comunication), using frequencies between 900 and 2100 MHz, higher power and digital signals, was able to arise most EMI interferences with CIEDs compared to the analogical signals, at 800 MHz frequency, used in Unites States [8].

As GSM covers actually more than 80% of the network market, following these findings, CIEDs' manufacturers equipped new generation devices with special filters reducing significantly the risk of interactions between CIEDs and mobile phones. In a in vivo study, enrolling 679 patients wearing new generation pacemakers, it was shown that when bipolar leads were used and a nominal sensitivity value was programmed, interactions between PM and mobile phones were recorded only in the 0.3% of patients. Furthermore authors observed that interferences were present only during the ringing phase, when the mobile phone was placed less than 10 cm from the generator. Finally a higher rate of interactions was recorded in the ventricular channel, even if this finding was probably due to the larger number of ventricular leads compared to atrial ones in the population studied, due to single chamber VVI devices [10].

Also concerning the interactions between ICDs and mobile phones, investigators found that no significant interactions with ICDs was provoked by the use of cell phones, even when the cell phone overlaid the device [11]. Only a loss of telemetry during communication between the ICD and the programming head was reported when cell phone was close to the ICD [12].

Looking at the results of all the studies performed to establish the safety of using mobile phones in the presence of CIEDs, we can summarize that the incidence of interference is very low and limited to the case the telephone is placed directly over the pacemaker itself. Finally, even in case of recorded electromagnetic interaction, no clinically significant events were ever reported [13]. So we can conclude that the use of mobile phones is safe for patients wearing CIEDs and is enough for the physicians to

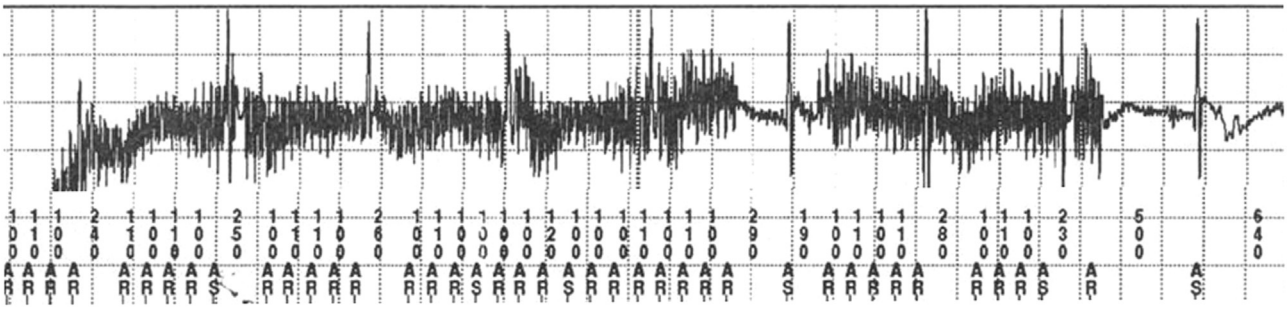

Fig. 6. In presence of a very high electric field the PM senses it and wrongly detects an atrial arrhythmia.

Table 3
Potential sources of EMI.

- Cellular telephones.
- Digital music players.
- Portable headphones and neodymium magnets.
- Electronic article surveillance (EAS) systems.
- Metal detectors.
- Tasers.
- Slot Machines.
- Power lines and equipment that generate electric and magnetic fields at 60 and 50 Hz.
- Medical procedures: electrocautery, lithotripsy, diathermy, external defibrillation, MRI

recommend to use the ear contralateral to the implantation side and to avoid to keep cell phone in the pocket just in front of the generator [14].

2.2. Digital music players

Due to their increasing utilization, the interaction between digital music players and CIEDs have been widely evaluated in the last years. Thaker et al. studied 54 patients exposed for 1 min to different types of iPod, for a total number of 162 tests, both in the presence of the telemetry wand and without the wand. The authors reported telemetry interference in the 36.4% of tests but no evidence of direct interference after the telemetry wand was removed [15]. Similar findings have been reported by Chiu et al. [16], who showed telemetry interference with the devices' programmer, in 16% of 67 patients exposed to digital music players but, again, no changes in CIEDs function. We can conclude, indeed, that digital music players do not affect pacemakers and implantable cardioverter-defibrillators function, but can cause only interference with interrogation telemetry [17].

2.3. Portable headphones and neodymium magnets.

Opposite findings have been reported when evaluating portable headphones, as most of them use neodymium which is a powerful magnetic substance. It has been showed that, when portable headphones are within 3 cm of the CIEDs, they can produce EMI and directly interact with the devices [18]. The strength of the magnetic field, in fact, decreases as the distance from the magnets increases. Another factor conditioning the potential interference is the size of the magnets, so that the in-ear headphones, using very small magnets, do not interact with the devices. The same neodymium magnets are used commonly in jewelry and clothing as claps and few reports of unexpected erratic behavior of implantable cardioverter-defibrillator related to the magnetic field generated by them have been published in literature [19,20].

In summary portable headphones are generally safe for patients wearing CIEDs, but it should be anyway recommended to them to keep the headphones far from the pulse generator.

2.4. Metal detectors.

Another common potential source of interference with CIEDs are the metal detectors. The main application for metal detectors is the security one, especially in the airports security check points. Many studies in the last decade evaluated the interaction between CIEDs and the magnetic field provided by metal detectors, especially by the walk-through type, which have considerably higher magnetic-field strength than the handheld ones [21].

Kolb et al. [22] studied 348 consecutive patients (200 pacemakers and 148 ICDs) underwent a short exposure time, into the magnetic field of an airport metal detector. A majority of the pacemakers were dual-chamber ($n=140$), although investigators also examined patients with single-chamber and biventricular devices. Among the ICDs, two thirds of the devices were single-chamber, 46 were dual-chamber, and four were cardiac resynchronization devices. Investigators set up a standard metal detector in their clinic and then studied the patients as they came in for routine checks of their ICDs and pacemakers. Testing a worst-case scenario in which patients would be forced to spend an excessive amount of time within the airport metal detector, investigators asked patients to remain 20 s within the security gate. There were no clinically relevant outcomes reported in any of the pacemaker patients tested. The electrical field from the airport metal detector did not result in any cases of atrial or ventricular oversensing, loss of capture, pacing disturbances, or spontaneous reprogramming in any of the pacemaker devices examined. In patients with an ICD, the metal detector did not result in any inappropriate detection of ventricular arrhythmias, spontaneous reprogramming of the ICD, or temporary suspension of the device. With no adverse episodes reported, investigators conclude that, considering a period of just a few seconds within the electromagnetic field for routine airport security controls, clinically relevant interactions with pacemakers or ICDs seem to be unlikely.

More recently Jilek et al. [23], studied a population of 209 pacemaker patients and 179 ICD recipients of different models. The authors used two models of metal handheld detectors, programmed at the maximal sensitivity, swiping them directly over the cardiac apex and the can for more than 30 s (much longer than conventional screening time, indeed). Nor changes of programming or pacing and sensing abnormality neither other unexpected malfunction of the devices has been reported in any patient. Following these clear findings, the most recent Transportation Security Administration recommendations advise, but not require, patients wearing CIEDs to alert security personnel concerning the implanted device. Even if metal detectors, both walk-through and hand-held ones, do not cause any interference with the functioning of the CIEDs, they recognize the ferrous

components of them, which can trigger the detector alarm. In this case a pat-down or hand search by the security officers will be required.

2.5. Electronic surveillance devices

Since several years electronic antitheft surveillance devices are present in almost all stores and shops. Few reports of inappropriate ICD shocks due to interactions with security systems in public and commercial environment have been reported in literature [24–26]. A crucial issue for the potential interaction with CIEDs seems to be, again, the time of exposure. In a study enrolling 170 patients with ICDs, exposed to 3 different surveillance systems, the authors did not report any interaction when the exposure time was as low as 15 seconds, but when exposure was as long as 2 minutes and the ICD within 6 in. of the gate, EMI, potentially able to drive inappropriate therapy of the ICD, has been recorded [26]. In the same study also 25 ICD recipients were evaluated following the same protocol and no abnormal response of any ICD with any of the security systems has been reported [27].

Acousto-magnetic security systems pulse a magnetic field able to detect tags at great distances and therefore have a higher risk of interaction with CIEDs. Among 50 pacemakers patients exposed to such systems in a single center study, in 48 patients it was possible to record interference, including asynchronous pacing, atrial oversensing and fast ventricular pacing, ventricular oversensing and pacing inhibition. These interactions were more frequent as the devices remained exposed longer to the security systems and were responsible for specific symptoms in some of the patients but only while patients were within the magnetic field [28]. Similar conclusions come from the results of a retrospective observational study including 336 patients wearing ICDs during a 16 years follow-up, without any report of inappropriate shock due to electronic article surveillance systems exposure [29].

In conclusion, even if the risk of effective interaction of CIEDs with surveillance systems is extremely low, patients wearing implantable devices should avoid to tarry inside or be close to the security gates, in public and commercial environment.

2.6. Other non-medical sources

Besides these more frequent EMI sources we described above, other less common potential causes of electromagnetic fields are present in the non-medical environment. Few case reports about the effects of Tasers' use in CIEDs patients are published in literature [30,31]. Tasers are weapons, used by police officers in many countries, that shoots tethered probes able to deliver short pulses of current with a peak voltage up to 1500 V. In one case ICD sensed the pulses of current delivered by the taser as ventricular fibrillation, charged the capacitors but did not deliver the shock due to interruption of the current flow [32].

Also slot machines have been reported to be responsible for inappropriate ICD shocks due to EMI in 4 patients playing the slots [33].

Furthermore, for many other electronic tools, reports of interactions with CIEDs are not available; this does not mean that there is no risk of interaction at all. Thus many manufacturers of household tools, for example, provide general recommendations for patients wearing CIEDs so as to keep as greater distance as possible from the tool motor and the pulse generator. Moreover newer and newer electronic tools, potentially able to interact with CIEDs, are continuously launched in the market; therefore it is a must for physicians to always consider the risk of EMI and to give appropriate recommendations to their PMK/ICDs patients.

3. Medical environment

3.1. MRI in CIEDs patients

Magnetic resonance imaging (MRI) is the imaging modality of choice in many clinical situations as a result of its ability to provide an excellent soft tissue contrast without radiation or the use of iodinated contrast media. The worldwide use of both MRI and CIEDs has increased significantly in the last years and a significant number of device-implanted patients likely will need an MRI over the course of the lifetime of their device.

Traditionally, MRI has been contraindicated in patients with cardiac pacemakers or ICD because of the potentially life-threatening interactions between the magnetic fields or the high-frequency (HF) pulses and the respective device. For this reason, in recent years attention has turned to devices that are specifically designed to be safe in the MRI. Previous experience and initial data suggest that this technology is safe and may allow pacemaker patients to undergo MRI [34–38] and in early 2011, the US Food and Drug Administration approved the first cardiac pacemaker designed to be used safely during MRI examinations. Although some studies demonstrated that, given appropriate precautions, MRI can be safely performed in ICD patients, the presence of an ICD is still considered a strong contraindication for MRI [39,40], and most ICD patients are denied from MRI.

There are several risks of performing MRI in CIEDs patients, which are different from those caused by other EMI sources. During MRI, in fact, static magnetic, magnetic pulsating gradient and radio-frequency fields generate strong forces which might interfere with the normal pacing function and have the potential to induce several hazardous effects.

The interactions of MRI with CIEDs can be classified as follows according to physical interactions and effects on the device or/patient:

(a) Static magnetic field
- The patient is subjected to an intense magnetic field that could produce mechanical forces on ferromagnetic components, causing mechanical or functional disorder of the device.
- Unpredictable magnetic sensor activation, reed-switching closure, drive to an inhibition of stimulation, or to a reversion of programming asynchronously.
- Changes in electrocardiograms.

(b) Modulated Radio Frequency (RF) Field
- Heating of cardiac tissue adjacent to lead electrodes: a current flow through the lead could result in overheating and thermal damage of cardiac tissue adjacent to lead electrodes which can cause changes in sensing and threshold values or myocardial perforation.
- Possible induction of life-threatening arrhythmias (very rare).
- Pacemaker reprogramming or reset.
- RF interactions with the device (over- and under-sensing).

(c) Gradient Magnetic Field
- Possible induction of life-threatening arrhythmias (unlikely in bipolar mode).
- Induced voltages on leads cause over- and under-sensing.

(d) Combined Field Effects
- Alteration of device function because of EMI.
- Mechanical forces (vibration).
- Electronic reset of device.
- Damage to pacemaker/ICD and/or leads.

These potentially harmful effects have been mainly identified in older pacing technology. During the last decade, a number of

small studies have asserted that MRI scans (at 0.5 T and 1.5 T) can be safely performed in patients with implanted pacemakers in carefully selected clinical circumstances when appropriate strategies are used [41–44]. Although distinctly different, PM and ICDs share similar electronic components and thus, to some extent, their response to the electromagnetic interference (EMI) might be similar. However, ICDs have more complex technology than pacemakers and have larger capacitors and batteries. As a result, the magnetic forces are greater, and they are theoretically more prone to electromagnetic and mechanical interference. In addition, in comparison with PM patients ICD patients have a higher-risk profile; therefore safety issues in imaging of ICD patients are more complex.

In recent years, there have been small to modestly sized human studies that have reported on the relative safety of MR examination in the setting of ICD patients [44–47]. These cases demonstrated a favorable risk to benefit ratio using tailored MRI scanning, pre- and post-scan reprogramming and monitoring during scanning. Nevertheless we should recall that a limited number of MRI scans have been reported on ICD patients in the medical literature. Such a controversy concerning safety of scanning patients with such devices cannot be settled just because a few ICD patients have safely undergone MRI. There is a need for safe MRI conditional ICD, which is both real and urgent. It is important to quote Professor Gimbel's editorial comment [48] on the study of Martin et al. [42] "…We believe strongly that device manufacturers must design their implantables as MR-compatible "from the ground up" rather than depend on a series of intrepid patients and physicians engaged in post-manufacturing experiments. Patients and the implanting community should expect nothing less than devices that are MR-safe by design, not by chance.". Of note, Biotronik has recently developed an ICD compatible with MRI, which has just been market-released in Europe. However, there are no published studies with this new currently available system. Although this system does not allow MRI scans of the chest, the technology is unquestionably developing fast and some current technical limitations are already being resolved.

3.2. Special precautions during MRI in ICD patients

There are some important issues to be considered about potential interactions of MRI scan with ICDs (Table 4). The exam should be performed only in experienced centers with close cooperation between the radiologists and electrophysiologists and, to minimize radiofrequency-related lead heating, specific absorption rate should not exceed the value of 2 W/kg [49]. Devices should be reprogrammed pre-MRI to avoid competitive pacing and potential pro-arrhythmia with deactivation of therapy delivery. In particular, the ICD should be reprogrammed to VVI pacing with the lowest possible lower rate limit and an asynchronous mode should be selected in pacemaker-dependent patients. Since reed switch closure is not reliable during MRI scans [50], deactivation of therapy delivery should be performed before the exam to minimize the risk of inappropriate therapy delivery. Another important interaction is an electrical reset leading to an unintended reprogramming of the ICD with reactivation of ventricular tachyarrhythmia therapy options. This can lead to inappropriate shocks during MRI scans. We also recommend the availability of full resuscitation facilities and continuous monitoring of ECG and pulse oximetry during the MRI exam. A complete ICD check is required immediately after MRI to evaluate and ensure the integrity of the entire ICD system. To exclude potential late effects, we also recommend to check again the integrity of the system 5–6 weeks after MRI,

Controversies exist with regard to the utility of defibrillation threshold testing (DFTT) to ensure integrity of the ICD system after MRI. Correct sensing of ventricular signals during VF may indicate that significant myocardial damage at the lead tip or damage to the ICD lead and the ICD device is unlikely. Levine et al., on behalf of the American Heart Association, recommends DFTT post-MRI [40]. In contrast, the European Society of Cardiology does not support the routine use of DFTT/DSMT post-MRI believing the risk attributed to DFTT/DSMT may outweigh any potential benefit [39]. More recently the results of a study on 38 patients undergoing MRI suggest that routine DFTT/DSMT post-MRI may not be necessary [47]. Our opinion is that in the presence of any modification of ICD electrical parameters post-MRI, the DFTT should be mandatory; other patients should be considered on a case-by-case basis

Table 4
Special precautions during MRI in ICD patients.

Pre-MRI
Complete ICD check
Deactivation of therapy delivery
VVI pacing with the lowest possible lower rate limit
Asynchronous pacing in pacemaker-dependent patients
During MRI
Presence of an electrophysiologist
Continuous monitoring of ECG and pulse oximetry
Limitation of specific absorption rate values
Post-MRI
Complete ICD check and reprogramming
Consider DFT to ensure integrity of the ICD system.
ICD follow-up 5–6 weeks after MRI

3.3. Electrocautery devices for surgical procedures

High frequency signals generated by electrocautery may interfere with implanted ICD devices. Electrocautery is often used to minimize blood loss during surgery and to ablate tissue. The probe used to perform electrocautery generates a high frequency electrical current that may result in oversensing, independent of unipolar or bipolar coagulation mode that is used. This oversensing leads to a pacemaker inhibition or false detection of ventricular tachyarrhythmias (Fig. 7) resulting in inappropriate shock therapy [51]. For this reason, the use of electrocautery is contraindicated when the automatic tachycardia response of the patient's ICD is enabled.

Due to these potentially harmful effects, there are some important precautions to consider whenever electrocautery is used with ICD patients. Device should be reprogrammed before surgery with deactivation of therapy delivery and an asynchronous mode should be selected in pacemaker-dependent patients. This detection of ICDs may be temporarily inactivated placing a magnet over the device; this suspends tachyarrhythmia detection and response as long as the magnet is held in place over the device. The patients should be closely monitored during the intervention, using short and intermittent bursts at the lowest feasible energy levels, avoiding direct contact between the electrocautery probe and the ICD system. We also recommend the use of a bipolar electrocautery system whenever possible [52], with the ground plate positioned as far as possible from the implanted system. Of note, electrocautery used in the direct vicinity of an ICD could potentially damage the device; therefore, in these cases, post-procedural ICD check may be considered to evaluate the integrity of the ICD system.

3.4. Potential interactions with radiation therapy

Many sources of ionizing radiation are capable of interfering with an implanted device, including those used for the treatment

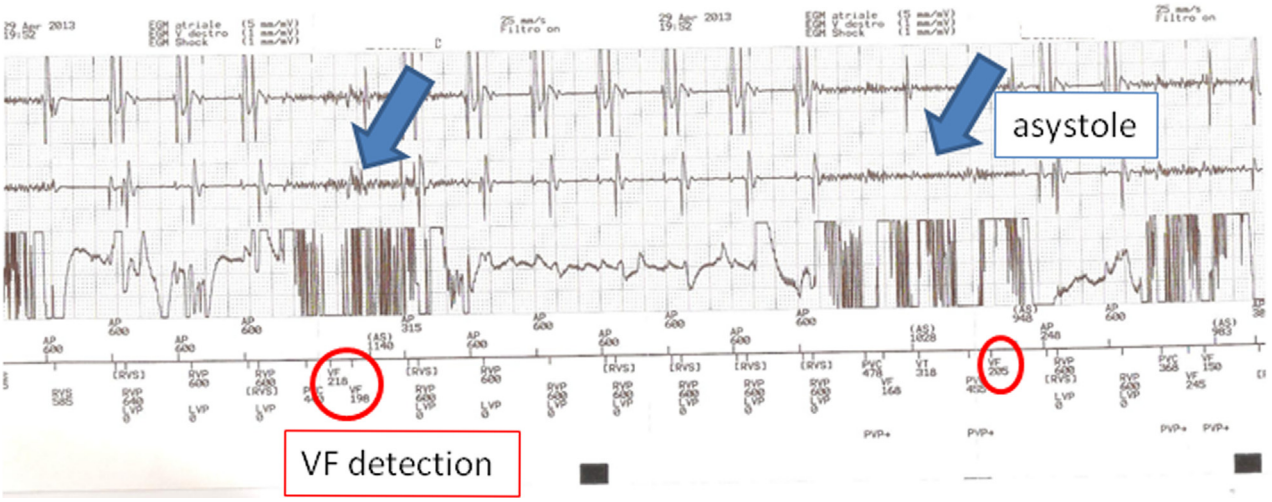

Fig. 7. EMI during electrosurgery in a CRT-D/PM-dependent patient leading to both, pacing inhibition with asystole and erroneous VF detection.

of cancer, such as radioactive cobalt, linear accelerators, radioactive seeds, and betatrons. Diagnostic radiation generally does not have any significant adverse effect on ICDs. On the other hand, ionizing radiation may adversely affect ICDs through electromagnetic interference or through its effects on the devices' metal oxide semiconductors (CMOS) components [53]. Severe malfunctions have been reported in ICDs exposed to radiations. In particular, radiation adversely alters CMOS technology and the mechanism of failure is unpredictable, since any part of the semiconductor can be damaged. Current approaches to treatment of ICD patients as well as recommendations given by the manufacturers of these devices differ considerably [54]. Reports in the literature include damage from radiation doses as low as 10 Gy; therefore direct ICDs radiation at therapeutic levels should be strictly avoided and accumulated doses should generally not be allowed to exceed 5 Gy. Of note, a complete ICD check is required in short periods during and after radiation, to evaluate and ensure the integrity of the entire ICD system.

3.5. *Electrical nerve stimulation*

Transcutaneous electrical nerve stimulation (TENS) and spinal cord stimulators may result in inappropriate inhibition or false tachyarrhythmia detection resulting in ICD shocks. Few ICD malfunctions have been reported in literature. TENS is commonly used for the relief of acute and chronic musculoskeletal pain. TENS units should be avoided in the proximity of the ICD system. In the situation of pacemaker-dependent ICD patients TENS is not recommended except in cases with a strong clinical indication and in which the benefits clearly outweigh the risks. There are a few reports that have suggested that, with proper precautions, bipolar spinal cord stimulators can be used safely in ICD patients [55,56]. Individual testing is recommended to exclude that spinal cord stimulation does not cause pacemaker inhibition or problems with sensing during ventricular fibrillation.

4. Conclusions

In the last years we are witnessing a dramatic increase in the number of CIEDs implanted. At the same time new emitters are constantly entering the marketplace and more and more medical procedures are based on electromagnetic fields as well. Therefore, the topic of the interaction of CIEDs with the EMI is a real, actual and challenging one. Pacemaker/ICD manufacturers are incorporating state of the art technology to make implantable devices less susceptible to EMI. However, patients and emitter manufacturers should be aware that limitations exist and that there is not complete immunity to EMI. The pacemaker industry is working with regulatory bodies and emitter manufacturers to educate patients and physicians and develop appropriate warnings, when required. But Pacemaker and ICD manufacturers cannot solve all EMI issues alone, labeling and customer education is required.

Conflicts of interest

Professor Massimo Santini: researcher for Medtronic, Boston Scientific, St. Jude Medical, Biotronik, Sanofi.

Consultant or speaker for Medtronic, MSD, Astra Zeneca.

Doctor Santini and Doctor Forleo received lecture fees (minor) from St. Jude Medical.

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