Interference between mobile phones and pacemakers: a look inside

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Summary. In this study we analyzed the problem of electromagnetic interference (EMI) between mobile telephones and cardiac pacemakers (PM), by looking at the mechanisms by which the radiated radio frequency (RF) GSM signal may affect the pacemaker function. From a literature review on this topic, we noticed that older pacemakers had a higher rate of being affected by mobile phones when compared to newer ones. This is probably due to the fact that new generation of PM are more protected against electromagnetic field, being equipped with RF feedthrough filters incorporated to the internal PM circuitry. In some experiments conducted by our group, we found that modulated RF signals are somehow demodulated by the PM internal non-linear circuit elements, if no feedthrough assembly is incorporated inside the PM. Such demodulation phenomenon poses a critical problem because digital cellular phones use extremely low-frequency modulation (as low as 2 Hz), that can be mistaken for normal heartbeat. The feedthrough assembly seems instead to prevents the RF signals from accessing the PM enclosure, thus attenuating EMI signals over a broad range of frequencies.

Key words: electromagnetic fields, artificial pacemaker, cellular phone.

Riassunto (Interferenza tra telefoni cellulari e pacemaker: uno sguardo all'interno). In questo studio ci siamo occupati del problema dell'interferenza elettromagnetica tra telefoni mobili e pacemaker cardiaci analizzando i meccanismi con i quali il segnale GSM interferisce con il funzionamento del pacemaker. Dall'analisi della letteratura su questo argomento, si nota come i pacemaker più vecchi hanno un incidenza più alta di interferenza con i telefoni cellulari rispetto a quelli più nuovi. Questo è probabilmente dovuto al fatto che i pacemaker di nuova generazione sono più protetti verso il campo elettromagnetico, essendo equipaggiati con filtri a radiofrequenza (RF) passanti incorporati nel circuito interno del pacemaker. In alcuni esperimenti condotti dal nostro gruppo, abbiamo riscontrato che i segnali a radiofrequenza modulati sono in qualche modo demodulati dai circuiti interni non lineari del pacemaker, se il sistema di filtraggio passante non è incorporato all'interno del pacemaker. Questo fenomeno di demodulazione pone un problema critico perché i telefoni cellulari usano modulazioni a frequenze estremamente basse (fino a 2 Hz), che possono essere erroneamente interpretate come il battito cardiaco. Il sistema di filtraggio passante sembra invece evitare che i segnali RF entrino nell'interno del pacemaker, attenuando i segnali di interferenza elettromagnetica in un vasto campo di frequenze.

Parole chiave: campi elettromagnetici, pacemaker artificiale, telefono cellulare.

INTRODUCTION

Any interference on devices such as pacemakers (PM) and defibrillators (ICD) may have serious consequences for the patient. The earliest generation of cardiac PM did not have the sensing function. Later, PM could sense spontaneous beats and synchronize with them provoking pacing or inhibition. Besides the beneficial effects of the introduction of the sensing function, it also created the potential for inappropriate inhibition of stimuli during pacing when electromagnetic interference (EMI) was mistaken for spontaneous cardiac depolarization. For dual-chamber pacing, EMI sensed in the atrium could trigger inappropriate stimuli in the ventricle, generating palpitations or even tachycardia. The most frequent effects of EMI on PM and ICD are inappropriate inhibition or triggering of stimulation, reversion to asynchronous pacing and spurious tachyarrhytmia detection, and, less frequently, reprogramming of operating parameters. Each of these anomalies is temporary, occurring only while the interference is present.

Patients with PM and ICD live a rather normal life, thus these devices may be exposed to a large number of EMI sources. In daily life patients can interact with cellular phones, electronic article surveillance devices, metal detectors, home appliances (microwave oven, electric razor), high speed train.

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At work patients can stay close to high voltage power lines, transformers, welders, electronic motors, induction furnaces, degaussing coils. In medical environment devices as magnetic resonance scanners, electrosurgical units, defibrillators, neurostimulators, TENS units, radio frequency (RF) catheter ablators, therapeutic diathermy devices could be used on a patient.

To date, Medline search for "interference pacemaker" gives a total of 418 references since 1957. If the search is restricted to the interference caused by telephones, the references become 39 since 1995, about 10 years later the introduction of cellular telephones. Nine of these references concern national studies mainly performed in Europe and in Asia. The others are publications in peer reviewed international journals and concern both *in vivo* and *in vitro* studies conducted on large population and using similar methodologies. Actually, the topic of EMI between mobile phones and PM was recognized in 1994, and since then, prompted several investigations [1-13].

For the scope of this paper, we analyzed the problem of EMI between digital mobile telephones and cardiac PM, by looking at the mechanisms by which the radiated RF GSM signal may affect the PM function.

Interference with cardiac *PM* by cellular telephones

EMI to PM from mobile phones has been investigated both *in vivo* and *in vitro* by several groups (*Table 1*) [1-13]. The majority of these studies systematically evaluated the PM and ICD models on the market, describing the adverse effects observed and indicating the incidence of EMI. Most of them also suggested a safe separation distance.

Table 1 Overview of the in vivo and in vitro studies about EMI of cellular telephones with cardiac pacemakers

| Authors | Year of publication | Type of experiments | Number of pacemakers tested | Number of pacemaker models tested | Resu Incidence of interference per patients | Its Incidence of interference per test |
|--------------------------------|---------------------|----------------------|-----------------------------------|---|--|--|
| Barbaro <i>et al.</i> [1] | 1995 | In vivo | 101 | 43 | 26% overall EM interference 10% pulse inhibition 20% ventricular trigger 8% EMI asynchronous pacing | |
| Naegeli <i>et al.</i> [2] | 1996 | In vivo | 39 | 6 | 18% overall EM interference | 3.9% EM interference 2.8% atrial triggering 2.8% ventricular inhibition 5.6% pacemaker inhibition |
| Irnich <i>et al.</i> [3] | 1996 | In vitro | | 231 | 31% for C-net 34% for D-net 0% for E-net | |
| Carrillo <i>et al.</i> [4] | 1996 | In vitro /In vivo | 65 | 4 manufacturers | | 31% overall EM interference 0% for PMs with EMI filter |
| Chen <i>et al.</i> [5] | 1996 | In vivo | 29 | 9 | 28% overall | |
| Nowak <i>et al.</i> [6] | 1996 | In vivo | 31 | 3 | 0% | 0% |
| Wilke A et al. [8] | 1996 | In vivo | 50 | | 4% | |
| Hayes <i>et al.</i> [7] | 1997 | In vivo | 980 | > 6 manufacturers | | 20% overall 14.2% atrial interference 7.3% asynchronous pacing 6.3% ventricular inhibition |
| Ruggera <i>et al.</i> [9] | 1997 | In vitro | 30 | 30 models 7 manufacturers | 37% overall | |
| Altamura <i>et al.</i> [10] | 1997 | In vivo | 200 | 18 | 21.5% overall 18% inhibition 5.4 % asynchronous mode 9.4% triggering | |
| Elshershari <i>et al.</i> [11] | 2002 | In vivo | 95 | 6 manufacturers | 1% (PM implanted transvenously in a subcutaneous pocket) | |
| Tandogan <i>et al.</i> [12] | 2005 | In vivo | 679 | | 5.5% overall | |
| Trigano <i>et al.</i> [13] | 2005 | In vivo | 158 | > 50 models 7 manufacturers | | 1.5% overall |



The great variability of the findings in the existing literature reflects the complexity of the study design to assess mobile phone interaction with PM. This complexity is attributable to a number of factors such as the rapid evolution of PM and mobile phone technologies, the characteristics of the phone antenna, device implantation and programming, electrode configuration, distance between the device and the radiation source etc. The results obtained so far have shown interference to occur when the phone is very close (less than 5 cm) to the implantable device connection to the cardiac leads (i.e., the PM "header"). Thus it can be concluded that with certain combinations of PM, cellular telephones, patients, and telephone-use habits, EMI can create anomalous PM behaviour with potential clinical consequences.

The number of PM tested in these studies varied from about 30 [6, 9] up to almost 1000 [7]. Until 1997, the reported incidence of EM interference varied form 20% to 30%; the last investigations showed a drastic reduction of EMI incidence to 1-5% [11-13] (*Figure 1*).

Irnich *et al.* [13] demonstrated that older PM had a higher rate of being affected by mobile phones when compared to newer ones. Tandogan *et al.* made a comparison as to the age of the PM and showed that the rate of being affected significantly increased by age [13]. New generation of PM are reported to be more protected against electromagnetic field, being equipped with RF feedthrough filters incorporated to the circuitry.

In the *in vivo* investigation involving the major number of PM patients (almost 1000), Hayes and coauthors found that PM models without a feedthrough filter had a higher incidence of interference than those with a feed-through filter [7]. Such results are consistent with those found by Carrillo *et al.* on 65 patients [4] and more recently by Trigano *et al.* on 158 patients [12]. Trigano *et al.* found effects of EMI in 4 PM models from a single manufacturers, all implanted before year 2000 and lacking the electromagnetic filters included in more recent devices [12].

The introduction of the feed-through assembly has significantly improved PM immunity [15], giving *a posteriori* evidence that the physical interaction occurs at the lead conductors.

Few studies have investigated the mechanisms through which electromagnetic fields interact with PM. It has been demonstrated that the susceptibility of PM to various sources of EMI depend on the circuitry design. PM have a titanium case acting both as an electromagnetic shield and a barrier against body fluids. Platinum lead wires come out of the case through hermetic terminals and connect with the heart. It is largely believed that the physical interaction between mobile phones and PM is due to the electric coupling with the lead conductors inside the silicon head of the PM, which can act as an antenna and conduct undesirable RF carrier signals to the electronic circuits inside the PM [15, 16]. Most implantable PM employ EMI low pass filters designed with chip or substrate mounted capacitors which should decouple and shield these signals. Such a solution turned out to be inadequate to guarantee a high level of immunity to high-frequency sources such as GSM mobile phones [16]. The incorporation of RF feedthrough filters to the electronical circuit of the PM can strongly reduce EMI from digital cellular telephones.

Feed-through assembly

State-of-the-art PM are protected by input filters, the feedthrough assembly. A feedthrough assembly used to suppress and decouple undesired interference or noise transmission along a terminal pin consists of a coaxial feedthrough filter capacitor. Typically, it comprises a so-called discoidal capacitor similar to a ceramic monolith. Two sets of electrode plates are embedded in spaced relation within an insulate substrate. One set of the electrode plates is electrically connected at an inner diameter surface of the discoidal structure to the conductive terminal pin utilized to pass the desired electrical signal. The second set of electrode plates is coupled at an outer diameter surface of the discoidal capacitor to a cylindrical ferrule of conductive material, which is in turn connected to the conductive housing of the electronic instrument.

The discoidal capacitor permits passage of relatively low frequency electrical signals along the terminal pin, while shunting and shielding undesired interference signals of typically high frequency to the conductive housing.

As a result, the filter capacitor and terminal pin assembly prevents the RF signals from accessing the PM enclosure, thus attenuating EMI signals over a broad range of frequencies.

It is generally mounted onto the hermetic terminal of the PM and thus acts electrically as a continuous part of the electromagnetic titanium shield (PM housing).

We have recently investigated the mechanisms through which the GSM signal affects the PM function by measuring the signal at the output of the sensing amplifier of PM with various configurations of low pass filters and exposed to modulated and non-modulated RF signals [17], as explained in the next paragraph.

Evaluation of EMI from inside the PM

Our group investigated the mechanisms of EMI between mobile phones and PM using a modified version of a commercial PM [17]: it had an electronic connection with the output of the sensing amplifier, just before the comparator circuit that detects any spontaneous activity of the heart. We used three modified versions of the same PM in order to have an electrical connection to the output of the sensing amplifier: one uses a block capacitor which shortcircuits high frequency signals (33nF, resonance frequency at about 20-30 MHz); another one uses a ceramic feedthrough capacitor (4.99nF, resonance frequency at about 2 GHz), consisting of a hermetically sealed mechanism that connects the electronics inside the PM to the connection block outside [17]; the third one uses both.

To avoid any spurious interference from the extra electrical connection, the PM were placed inside an aluminium box. The output of the amplifier buffered by an instrumentation amplifier was connected to an acquisition board through BNC connectors and shielded cables. This configuration guaranteed that only the silicon connection head of the PM and the lead connectors were exposed to RF radiation. A standard catheter was connected to the PM and the catheter was immersed in a 0.9% saline solution in a plexiglass box. All the connections were shielded with aluminium foil.

The noise level was computed on-line by estimat-

ing the power spectral density of the signal at the output of the sensing amplifier. The spectral estimation was obtained by averaged periodogram o without windowing or zero-padding. Fifty spectra of PM signal tracks between two consecutive PM spikes were averaged. In order to have the largest possible number of samples between two consecutive spikes, the PM frequency stimulation was set to the lowest value (30 bpm).

All PM were programmed with the same parameters. For each PM, the output of the sensing amplifier was monitored under 4 conditions: no signal delivered to the catheter and no electromagnetic field applied (baseline noise); white noise signal delivered to the catheter, in the presence and absence of non-modulated RF signals (at 900 and 1800 MHz); no signal delivered to the catheter and exposure to GSM signals (at 900 and 1800 MHz). Details on the experimental setup can be found in [17].



Fig. 2 | *Root mean square at the output of the sensing amplifier in mV for the 3 PM for exposure to all the modulating signals at 900 and 1800 MHz.*

We found that the exposure to RF signals does not alter the response of the PM sensing amplifier: the root mean square of the baseline noise (no signal delivered to the catheter and no electromagnetic field applied) at the output of the PM sensing amplifier was 3.99 mV for the PM with the block capacitor only, 4.04 mV for the PM with the ceramic feedthrough capacitor, and 3.45 mV for the PM having both capacitors. The hypothesis that the saturation and/or non-linear operation of the PM sensing amplifier could be responsible for EMI phenomena does not appear to be consistent with our findings.

The radiated RF fields (non-modulated, 900 MHz and 1800 MHz) did not alter the root mean square of the output of the sensing amplifier of any of the PMs when a white noise was applied to the chloridesilver square plates of the plexiglas box that hosted the catheter.

The spectral density of the output of the sensing amplifier for the PM equipped with the block capacitor only always shows a clear spectral peak at the frequency of the amplitude modulated radiation, indicating an underlying demodulation effect. In order to compare the results of the three PM at the various modulation frequencies and carriers, we computed the total power from the raw spectral data. *Figure 1* shows the root mean square at the output of the sensing amplifier in mV for the 3 PM for exposure to all the modulating signals at 900 and 1800 MHz. Note that the PM equipped with the block capacitor and the ceramic feedthrough showed no effect at 1800 MHz and minimal demodulation phenomena at 900 MHz.

DISCUSSION

Ideally, every possible combination of cellular phone model and PM model should be *in vitro* tested to assess the type and degree of interference to be expected. The number of possible combinations, however, being the product of the number of PM models and the number of cellular phone models, is too large to make this challenge practicable. Instead, PM manufacturers should be encouraged to include appropriate filters in new pulse-generator designs. Specific changes in the design of PM, such as the inclusion of feed-through filters, may limit electromagnetic interference, as was seen in several studies [4, 12, 18, 19] and as has been demonstrated by our investigation [17].

When we exposed the PM equipped only with the block capacitor to modulated RF signals, demodulation products were present at the output of the sensing amplifier. This finding corroborates the hypothesis that the PM functioning can be affected by a RF signal through its modulating components, which may fall within the PM passband and reach the input of the comparator. Once the RF signal is inside the PM case, substrate mounted block capacitors do not succeed in short-circuiting such signal and it is somehow demodulated by PM internal non-linear circuit elements. The PM equipped with the ceramic feedthrough capacitor only showed demodulation products slightly higher than the baseline noise. When both capacitors are installed, the total spectral powers of the output of the sensing amplifier exposed to modulated RF signals are as low as the baseline noise. Thus, the combination of both filters provides an effective attenuation of RF signals, and prevents demodulation phenomena.

The GSM signal utilizes low-frequency RF digital modulation. When exposed to a base-station GSM signal, a 217 Hz component (used by European GSM) appeared at the output of the input stage of the PM equipped with only the block capacitor. We observed demodulation products also at lower frequencies (below 10 Hz), although no specific harmonic components appeared. PM equipped with the feedthrough capacitor did not show demodulation products. These findings demonstrate that RF carriers with digital modulations may originate low-frequency demodulation products in the PM if these carriers are not adequately attenuated by the PM RF filters. Such low-frequency components fall within the typical PM passband; they can be erroneously detected as heart electrical activity and may interfere with the normal PM functions. This finding is consistent with, and can explain, the higher sensitivity of PM to EMI from digital phones than from analog ones, as reported by our and other research groups.

Studies aimed at investigating the mechanisms causing EMI to PM could be useful to prevent EMI effects generated by the large number of electromagnetic sources a PM patient can interact with. Understanding of the path of the electromagnetic signal throughout the PM circuits could improve the PM filtering design.

Since, to date, most PM models have the possibility to record intracardiac electrograms, investigations aimed at understanding the interference mechanisms from inside the PM could be performed easily and on a larger number of cardiac implantable devices.

It is important to note that the likelihood of clinically important symptoms caused by cellular telephone interference with PM operation depends on several aspects: the characteristics of the telephone in terms of the power of the transmitted signals and the use of analogue or digital technology, the pacing mode and implant configuration, the orientation of the telephone respect to the PM electrodes and the patient's underlying heart rhythm. Indeed, PMdependent patients are at greatest risk from the effects of EMI. However, the patients implanted with PM with inadequate filtering systems should be advised.

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