Electromagnetic immunity of infusion pumps to GSM mobile phones: a systematic review

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Summary. Electromagnetic interference with life-sustaining medical care devices has been reported by various groups. Previous studies have demonstrated that volumetric and syringe pumps are susceptible to false alarm buzzing and blocking, when exposed to various electromagnetic sources. The risk of electromagnetic interference depends on several factors such as the phone-emitted power, distance and carrier frequency, phone model and antenna type. The main recommendations and the relevant harmonized standard are also reported and discussed. From the data available in literature emerges that, for distances lower than 1 m there is a non negligible risk of electromagnetic interferences, although significant differences exists in the reported minimum distances. Interference effects clinically relevant for the patients are rare. No permanent damage to the pumps has been ever reported, although in several cases intervention of personnel is required to resume normal operation.

Key words: electromagnetic interference, infusion pumps, cellular phone, risk reduction behaviour.

Riassunto *(Immunità elettromagnetica di pompe ad infusione a telefoni cellulari GSM: un'analisi sistematica della letteratura)*. Interferenze elettromagnetiche su dispositivi medici sono state descritte da vari gruppi. Studi pubblicati hanno dimostrato che le pompe a infusione e le pompe siringa sono suscettibili a falsi allarmi e interruzioni dell'erogazione, se esposte a varie sorgenti di campi elettromagnetici. Questo studio è quello di analizzare i dati pubblicati in letteratura relativamente al rischio di interferenze elettromagnetiche dovute a telefoni cellulari GSM su pompe ad infusione e pompe siringa. Le principali raccomandazioni per limitare i rischi associati e la normativa internazionale di riferimento sono inoltre riportate e discusse. Dall'analisi della letteratura disponibile emerge un rischio non trascurabile di interferenze elettromagnetiche, quando le pompe ad infusione sono esposte a telefoni GSM a distanze inferiori al metro, anche se significative differenze esistono relativamente alle distanze minime osservate. Non esistono dati relativamente a danni permanenti alle pompe, anche se in molti casi dopo interferenza è necessario un intervento manuale sulla pompa per ripristinarne il corretto funzionamento.

Parole chiave: interferenze elettromagnetiche, pompe ad infusione, telefono cellulare, comportamento di riduzione del rischio.

INTRODUCTION

Problems with electromagnetic compatibility (EMC) of medical devices have been known for some time in hospitals. Research groups, manufacturers, and governmental and non-governmental agencies have reported incidents related to electromagnetic interference (EMI) to medical devices. Some of them had life-threatening consequences, others could have had, others can be considered just a nuisance. From 1979 to 1993 the Food and Drug Administration (FDA) received more than one hundred reports related to EMI. These reports prompted the need for an increased attention to medical device electromagnetic compatibility by users, manufactures, and standard organizations. There are several motivations behind the increasing researches and efforts in this field: deaths and severe injuries have occurred due to EMI on life-supporting medical devices; the ambient electromagnetic environment continues to intensify (*e.g.*, mobile phones, wireless local area networks, paging system); use of higher carrier frequencies the medical devices have not been tested for; increase in electronic sensors, actuators, and microprocessors based medical devices (*e.g.*, ventilators and infusion pumps); increased number of patients with electrical active implanted devices (pacemaker and cardioverter/defibrillator); widespread of new EM sources such as anti-theft systems and metal detectors, due to the increased need for security in public areas and buildings.

Interestingly, most of the reported incidents before 1993 involved EMI originated from other sources (*e.g.*, electrosurgical units, other medical devices, power line interferences). In the report of Silberberg, 3% of the reports involved mobile phones and 6% hand-held transceivers. It should be observed that

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in 1993 the usage of mobile phones was much less prevalent than today. The large number of different medical devices, the peculiarity of some of them (*e.g.*, implantable *vs* non-implantable or diagnostic *vs* therapeutic), and the gravity of the potential consequences in case of EMI make difficult to treat this matter in a unique way. The wide number of potential sources of interference and their associated mechanism (*e.g.*, conducted *vs* radiated) make the problem even more complex. These differences are also reflected in the international standard on EMC for medical devices. According to these standards, three groups of devices may be considered: electrical active implantable devices (*e.g.*, pacemakers, implanted defibrillators, nerve stimulators); life-support devices (*e.g.*, ventilators, external defibrillators, electrosurgical units, infusion pumps, monitors); non life-support devices (*e.g.*, ECG, EEG, ultrasound scanner, MRI, CT-SCAN).

Since the early studies of FDA, various groups have reported problems attributed to EMI from mobile phones with medical devices such as ventilators, external defibrillators, wheelchairs, monitors and infusion pumps [1-8]. Prompted by these reports, recommendations to restrict the use of mobile phones in critical areas of hospitals have been issued. These recommendations include either the definition of a separation distance or the total banning of mobile phones from intensive care areas and surgical theatres, if not from the entire hospital. In view of the lack of evidence reported in other studies [2, 4], the above mentioned restrictions have been criticized [9, 10]. Since most of the reported EMI with medical devices occur only under worst-case conditions (*i.e.* maximum emitted power and/or very short distances), and because in several cases the clinical consequence might be not significant, the debate whether mobile phones pose a real risk is still open [12].

In this review we addressed the EMI problem of infusion pumps. The reason for focusing on this type of devices are various. First, as mentioned before, a large number of parameters are involved in the EMI problems with medical devices., making a unique approach difficult; volumetric pumps and syringe pumps are commonly used in hospitals both in non-critical (wards) and critical areas (*e.g.*, intensive care, surgical theatres, first aid departments). Recently, their use at patient's home has gain popularity; in some cases, a malfunction of such devices may pose a significant risk for the patient.

Evidence of cellphone EMI with infusion pumps were observed and documented by [1, 6, 8, 11] while no effects were observed by Turcotte and Witters [2]. According to Klein and Djaiani [13], infusion pumps are particularly prone to EMI. In 2005, Hahm *et al.*, documented the case of an acute Epinephrine poisoning due to cellular phone interference with an infusion pump [14]. In a previous study our group carried out an experimental investigations on EMI to infusion and syringe pumps exposed to 900 Mhz and 1800 Mhz GSM phones [15]. A systematic review, focused on mobile phones and technologies used in Australia can be found in [16].

METHODS

The major databases were searched (Medline and Science Citation Index) using the key words "mobile phones", "cellular phones" and "equipment" or "medical devices". From a first list of papers, the research was then refined searching for cited authors and papers.

Studies were considered eligible if published in peer-reviewed journal in English and if included testing of infusion and syringe pumps against electromagnetic interference from mobile phones.

In the published studies, several differences in the methodology used to investigate the EMI problem do exist, and it makes difficult a perform a meta-analysis of the published data. In addition, the different standards of mobile phones adopted worldwide likely contribute to the heterogeneity of the studies and of the reported effects. Thus, we did not attempt to draw conclusions, but reported the conclusions of each author.

RESULTS

Table 1 summarizes the main findings of our review. We found 6 studies which included GSM mobile phones and infusion pumps among the devices investigated. The percentage of devices susceptible to various kind of EMI ranged from 0% to 58%. Some of the studies investigated a very limited number of pumps, thus an underestimation of the rate of susceptibility may be occurred. In all the studies the maximum distances between the mobile phones and the devices were always relatively short (< 0.5 m). There were only two cases of documented changes in the delivery rates [1, 14]. In all the other cases the effect of the EMI consisted in buzzing, alarm sound, changes in the displayed information and pump stopping.

DISCUSSION AND CONCLUSIONS

Several studies have investigated the susceptibility of medical devices to EMI from mobile phones. As far as infusion pumps are concerned, the percentage of devices susceptible to various kind of EMI ranged from 0% to 58%, indicating real significant differences in the findings of the various groups. Differences exist among the papers, especially regarding the testing protocol, the mobile phones technology, the handset model and the number of pump tested.

Two main international standards are currently applied for evaluating EM compatibility of medical devices [17, 18]. The IEC-EN-60601-1-2:2003 establishes the minimum immunity levels, as well as the methods for conformity assessment. This standard is mainly intended for manufactures and notify bodies, as it requires specialized facilities (*e.g.*, anechoic chambers, radio frequency - RF - signal generators, power meters) and trained personnel. In

Table 1 | *Papers investigating the electromagnetic interference (EMI) of GSM phones with infusion pumps*

First author Year	Number of model tested	Incidence of EMI	Maximum distance (cm)	Notes	Author's conclusions
Medical Device Agency 1997 [1]	59	32 (54%)	100	EMI source included: analog and digital phones, 2-ways radios, and LAN	Mobile communication equipment does present a real risk for medical devices Restrict use of mobile phones in critical areas.
Irnich 1999 [3]	66	28 (42%)	n.a.	Results obtained grouping drop-controlled, volume-controlled and syringe pumps	Medical device must be made resistant to mobile phones 1 m minimum distance recommended Replace of device with more than 50 cm interference distance
Robinson 1997 [11]	1	0 (0%)	-	Immunity up to 40V/m	Suggested safe distance of 1.2 m
Hanada 2000 [6]	6	0 0%	-	EMI source: PHS phones (max 80 mW power)	No interference with PHS phones (the power is ten times lower than GSM)
Morissey 2002 [8]	9	2 (22%)	25	Infusion, perfusion and feeding pumps	To mitigate EMI, reduce the emitted power by providing good coverage in the hospitals. Identify most sensitive devices.
Calcagnini 2006 [15]	12	7 (58%)	30 (900 MHz) 30 (1800 MHz)	EMI probability as a function of emitted power also calculated	Limit the emitted power of GSM using in-building repeaters

n.a.: information not available.

addition, infusion and syringe pumps must comply with the particular harmonized standard EN 60601-2-24:1998 [19], which requires an immunity level of 10 V/m, in the frequency range 80-2500 MHz.

The ANSI C63.18 is a technical guide developed to aid clinical and biomedical engineers in assessing the immunity of medical devices to radiated electromagnetic fields from portable RF transmitters. According to this guideline, medical devices can be tested in the hospital, and RF transmitters can be selected among commercial equipment used in the health facilities. Recently, the ANSI C63.18 has gained diffusion also in papers investigating EMI in hospitals. Indeed, the use of commercial handsets makes it difficult to compare and reproduce results from previous studies: since most of the EMI phenomena occur in the near field regions, the antenna patterns of commercial devices play a rule [15].

Since systematic analysis of the clinical relevance of the observed effects have not been carried out in most of the study, it is difficult to obtain the probability of clinically significant EMI. According to Irnich and Tobish [3], there is no realistic danger for drop controlled, infusion and syringe pumps. The most serious effects reported so far included a reversal in the motor drive of an IVAC 960 exposed to a GSM phone [1], and an acute epinephrine poisoning probably due to resetting of the pump to the maximum delivery rate (999 mL per hour) [14]. All the other potentially dangerous effects consisted in shutdown of the pump, or in displaying various error modes and alarms, most of the time requiring an external intervention to be restarted.

The recommendations issued to mitigate the EMI risk include either the definition of a separation distance or the total banning of mobile phones from intensive care areas and surgical theatres, if not from the entire hospital. The various proposed recommendations are mostly based on the precaution principle to the risk minimization, rather than on the results of the published study. The "1-m rule" or the "arm's length rule", as well as the total ban from intensive care and surgical rooms are the most suggested recommendations. Education and sensibilitazion of medical and nurse staff has been also suggested.

If the GSM phone emitted power is reduced, the risk of EMI significantly decreases, as we demonstrated in a previous work [15]. If an adequate base station signal is present, GSM phones are designed to automatically reduce the emitted power to battery saving. Morissey [20] investigated the feasibility of an improved signal coverage as a mean for reducing the emitted power of GSM phones. He compared the power level fluctuations of a GSM phone while walking through a facility with poor and moderate-good coverage. In the presence of an adequate base station signal, the average power barely exceeded 0.01 W. This level corresponds to 0.08 W peak-power. Although we found that a limitation of the mobiles to peak power levels as low as 0.05 W for 900 MHz and 0.0025 W for 1800 MHz is required for the total immunity of the pumps tested, values lower than 0.08 W would significantly reduce the probability of EMI (< 20%). The limitation of the mobile power may be thus obtained increasing the field coverage by install-

ing in the hospital in-building repeaters amplifiers or dedicated mini base-stations.

The problem of infusion pump in the domestic environment has so far received poor attention. The fast developing of information technology and telecommunication infrastructures in the hospitals makes even harder to develop effective guidelines for EMI mitigation. The harmonized international standard on EMC of medical devices (IEC-EN 60601-1-2:2003) has been recently revised to cover the frequency band up to 2.5 GHz, and it has also increased the minimum immunity requirements for life supporting devices from 3 V/m to 10 V/m.

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