Mobile Intensive Care Unit: Technical and clinical aspects of interhospital critical care transport

van Lieshout, E.J.

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Chapter 2

Interference by new generations mobile phones on critical care medical equipment

Erik Jan van Lieshout
Sabine N. van der Veer
Reinout Hensbroek
Johanna C. Korevaar
Margreeth B. Vroom
Marcus J. Schultz

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ABSTRACT

Introduction The aim of the study was to assess and classify incidents of electromagnetic interference (EMI) by second and third generation mobile phones on critical care medical equipment.

Methods EMI was assessed with two General Packet Radio Service (GPRS) signals (900 MHz, 2 W, two different time-slots occupations) and one Universal Mobile Telecommunications System (UMTS) signal (1947,2 MHz, 0.2 W), corresponding with maximal transmit performance of mobile phones in daily practice, generated under controlled conditions in the proximity of 61 medical devices. Incidents of EMI were classified according to an adjusted critical care event scale.

Results A total of 61 medical devices in 17 categories (27 different manufactures) were tested and demonstrated 48 incidents in 26 devices (43%); 16 (33%) were classified hazardous, 20 (42%) significant and 12 (25%) light. The GPRS-1 signal induced most EMI-incidents: 41%, GRPS-2: 25% and UMTS: 13% ($p < 0.001$). The median distance between antenna and medical device of EMI-incidents was 3 cm [range 0.1–500 cm]. One hazardous incident occurred beyond 100 cm (in a ventilator with GRPS-1 signal at 300 cm).

Conclusions Critical care equipment is vulnerable to EMI by new generations wireless telecommunication technologies with median distances around 3 cm. The policy to keep mobile phones '1-meter' from the critical care bedside in combination with easily accessed areas of unrestricted use still seems warranted.

INTRODUCTION

Electromagnetic interference (EMI) by second generation mobile phones on medical equipment has been reported extensively and seems clinically relevant in about 10 % of medical devices [1-7]. The growth in use and decrease in size of mobile phones intensifies the discussion on present hospital restrictions of mobile phone use in patient areas, violated by healthcare workers themselves to improve patient care by better communication [8]. Critical incidents caused by mobile phones are probably rare but potentially lethal and most likely not recognized as such [9;10].

The first generation mobile phones are mainly used for voice whereas new generations telecommunication systems enables us to have wireless internet access to send and receive data even at the patient's bedside [11]. Data transmission may be more concerning in the context of EMI. However, these new systems entered the market however, with limited proof of their safety in the critical care environment [12]. Unfortunately, studies on EMI-induced incidents are characterized by technical description of incidents only, whereas classification of their clinical relevance is needed to update evidence based policies on modern mobile phones use [3;13].

The aim of the present study is to assess and classify incidents of EMI by second and third generation telecommunication signals on 61 critical care devices.

METHODS

Medical equipment

A total of 61 different medical devices (27 different manufactures) in 17 categories was allocated for EMI tests (table 1). The details of the devices are summarized in the Additional file 1. All devices were tested according to an international test protocol during full operation and in different modes; a simulator (i.e., EKG-simulator, artificial lung, syringe filled with saline) was connected if relevant [14]. The tests were performed on devices in use for patient care by two different hospitals (Academic Medical Center, Amsterdam and Kennemer Gasthuis, Haarlem, the Netherlands) to maximize the number of devices and were tested under similar test conditions.

Table 1. Categories of medical devices, interference distances and type of incidents per signal

Type of device or incident	Number of devices		Distance[a] (cm)	Type of incident per signal[b]		
	Tested	Influenced		GPRS-1	GPRS-2	UMTS
Intensive care unit ventilator	9	7	1.5 [0.1–300]	6H, 1L	2H, 1S, 1L	1H, 2S, 1L
Critical care monitor	13	7	3 [0.1–500]	4S, 3L	2S, 4L	
Syringe pump	7	3	5 [0.1–50]	2H, 1S	S	S
Volumetric infusion pump	4	1	30	S	S	S
Intra-aortic balloon pump	2	1	0.1	L		
Haemofiltration/dialysis	5	1	15	H		
External pacemaker	4	1	3	H		
Defibrillator	3	1	0.1			L
12-lead EKG	1	1	150	S	S	S
Fluid warmer	2	1	6	S	S	
Enteral feeding pump	2	1	30	H	H	
Air humidifier	1	1	5	H		
EKG telemetry	1	0				
Forced-air warming unit	3	0				
Mobile suction unit	1	0				
Critical care bed	2	0				
Continuous-airflow mattress	1	0				
Type of incident[b]						
Hazardous			3.5 [0.1–300]			
Significant			25 [0.1–500]			
Light			0.1 [0.1–3]			
Total	61	26 (43%)	3 [0.1–500]	25 (41%)	15 (25%)	8 (13%)

GPRS, General Packet Radio Service; UMTS, Universal Mobile Telecommunications System; EKG, electrocardiogram.
[a]Results are shown as median [range]. [b]Hazardous (H) is defined as a direct physical influence on patient by unintended change in equipment function; significant (S) is defined as an influence on monitoring with a significant level of attention needed, causing substantial distraction from patient care; light (L) is defined as an influence on monitoring without a significant level of attention needed.

Signals

The General Packet Radio Service (GPRS) signals had time slot durations of 1113 ms and a repetition frequency of 217 Hz (GRPS-1) or 556.5 ms / 27,1 Hz (GPRS-2), both with 0.2 MHz channel bandwidth and a carrier frequency of 900 MHz. This GPRS-technology, based on Time Division Multiple Access technology and available for data transfer in Europe, United States, Australia and parts of Asia, was chosen for its upcoming use for data transmission [11] . GPRS is considered a 2.5 generation wireless telephony system.

The Universal Mobile Telecommunications System (UMTS) signal had a bandwidth of 5 MHz and a carrier frequency of 1947.2 MHz. This Wideband Code Division Multiple Access-Frequency Division Duplex technology is considered a third generation wireless telephony system. A signal generator (HP/Agilent E4433B/ESG-D Digital RF 250 kHz-4GHz), provided with a GSM/W-CDMA module, was used in combination with external control equipment (laptop and additional pulse generator) for timing purposes. The signals were amplified and their power level controlled at 2W for GRPS in active time slots and 0.2 W for UMTS. These levels of power correspond with maximal transmit performance of mobile phones in daily practise and were chosen to mimic a worst case but at the same time realistic scenario to maximize the chance of detecting EMI-related incidents.

The signals were radiated towards the medical apparatus through an electrically balanced handheld antenna without reflecting obstacles nearby. Special attention was paid to poorly shielded locations in device housings (e.g., connectors, sensors, seams in housing). The initial distance between antenna and device was 500 cm and decreased until 0 cm of the device housing or until any incident occurred [14]. In case of any interference the test was repeated three times to assess reproducibility.

Classification of incidents

The observed incidents during normal operation of each device were documented in detail. Two board certified and experienced intensivists classified in consensus of opinions the severity of the observed incidents according to an adjusted critical care adverse event scale [15]. The scale ranges from light (influence on monitoring without significant level of attention needed, e.g., disturbed display), significant (influence on monitoring with significant level of attention needed causing substantial distraction from patient care, e.g., incorrect alarm or inaccurate monitoring of blood pressure) to hazardous (direct physical influence on patient by unintended change in equipment function, e.g., total stop of ventilator or syringe pump).

Statistical analysis

Median, maximum and minimum were given if no normal distribution was established. Distances were expressed in centimetres (cm). The distance between the antenna and device was set at 0.1 cm if an incident occurred when the antenna is held against the housing of the device. Percentages of critical care devices disturbed by second and third generation telecommunication signals (GPRS-1, GPRS-2 and UMTS) were compared using the Cochran's Q test. Difference between median distances between antenna and device at which incidents occurred were analysed using the Friedman test. A linear-by-linear chi-square test was performed to test for a trend in the frequency of incidents in relation to the year of purchase of the device.

RESULTS

Electromagnetic interference (EMI) by GPRS or UMTS signals on critical care medical equipment was demonstrated in 26 of the 61 device tests (43%)(table 1). A total of 48 incidents were identified and classified as 16 (33%) hazardous, 20 (42%) significant and 12 (25%) light.

The GPRS-1 signal induced the highest number of incidents of EMI: 41% (25/61), followed by GRPS-2 = 25% (15/61) and UMTS = 13% (8/61) ($p < 0.001$). The same holds true for the hazardous incidents; GPRS-1 = 20% (12/61), GPRS-2 = 5% (3/61), and UMTS = 2% (1/61) ($p < 0.001$). The medical devices and descriptions of all incidents are listed in the Additional file 1.

Hazardous incidents occurred in devices for therapy due to definition. In mechanical ventilators 9 hazardous incidents (in 7 ventilators out of 9 tested, median distance 3 cm, range [0.1-300] varied from 'total switch off and restart' to changes in set ventilation rate. In syringe pumps 2 hazardous incidents (in 2 pumps out of 7 tested, distances 0.1 and 2 cm) demonstrated a complete stop without or an incorrect acoustic alarm. One hazardous incident in a renal replacement device (out of 5 machines tested, distance 15 cm) showed a stop after an incorrect air detector alarm. One external pacemaker (out of 3 tested, distance 3 cm) demonstrated a hazardous incident with incorrect inhibition of the pacemaker.

The median distance between antenna and device at which all type of incidents occurred was 3 cm, range [0.1–500 cm]. Incidents occurred at greater distance with the GPRS-1 signal (median = 5 cm) compared to GPRS-2 (median = 3 cm) and UMTS (median = 1 cm), although the differences were statistically not significant ($p = 0.12$).

Hazardous incidents occurred at a median distance of 3.5 cm (range 0.1 – 300 cm). Beyond 100 cm one hazardous incident at 300 cm in a ventilator with the GRPS-1 signal and two significant incidents at 150 cm in a 12 leads EKG device with GPRS 1, GPRS-2 and UMTS signals (see Additional file 1).

No relation could be demonstrated between the year of purchase of medical devices and the number of incidents (p = 0.67).

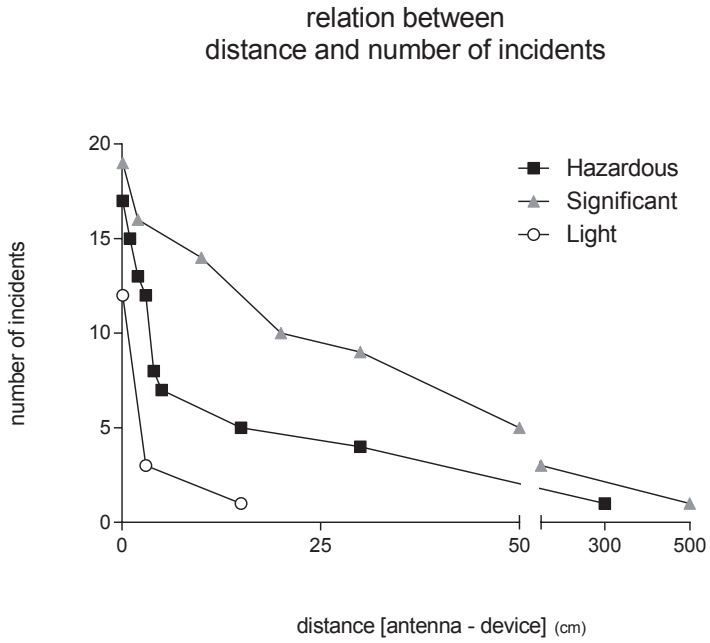

Figure 1

DISCUSSION

The present study demonstrates two new findings in the field of interference by mobile phones on medical equipment.

Firstly, the 2.5 generation mobile communication network GPRS is able to induce a higher rate of EMI-incidents compared to what is known of the first generation network Global System for Mobile Communications (GSM) at comparable distances [1;3;7]. Secondly, the median distance at which EMI-incidents by new generations cellular phones take place (3 cm) falls within the '1 meter rule' as proposed to be a safe distance in patient areas although the range demonstrated in this study is considerable [0.1-500 cm] [1;5;11;16].

Studies on EMI by first generation mobile phones are based on the GSM network used in Europe, the United States, Australia and part of Asia or based on Code Division Multiple Access (CDMA), mostly used in the USA [2;3]. Meanwhile GPRS and UMTS networks are used for their advanced properties to transmit video and data wirelessly at a higher speed besides regular voice telephony [12].

Our finding of EMI induced by UMTS with hazardous incidents is in contrast to what was demonstrated in the only study to date on UMTS by Wallin et al. recently [12]. No critical UMTS-incidents in 76 medical devices were reported besides interference noise on loudspeakers of two ultrasonic Doppler devices. Their only critical incident with GPRS was a total stop of one infusion pump (out of twelve tested) at a distance of 50 cm. Both GPRS and UMTS did not demonstrate any interference on four IC-ventilators tested. Three of those ventilators were also tested in our study and opposite to Wallin et al., showed significant and hazardous GRPS-incidents and one light UMTS-incident. There may be two possible explanations for these differences. Firstly, Wallin e.a used a different GPRS signal with a frequency of 1800 MHz and an output power of 1 W instead of 900 MHz with 2 W used in the present study. The lower carrier wave frequency of the GPRS signal with its corresponding

2 W in our study was chosen for its availability in many continents. GPRS is used worldwide with different frequency bands (900 & 1800 MHz) in different continents and therefore many "tri or quad bands" mobile phones are sold for their worldwide operation [3;13]. Secondly, both studies differ in their selection from worldwide available medical equipment. Our results apply on the tested devices only as specified including the year of purchase and, consequently are a limitation of the present study.

Another limitation of this study are the test conditions. The only method to obtain reproducible results in testing EMI by mobile phones is a standard signal generator to control output power as used in Wallin's and our study [3;12]. The use of commercially available mobile phones in its ringing mode will generate irreproducible results on a different location for all mobile phones (GSM, GPRS, and UMTS) regulate their output power depending on the nearby cell base station of the telecom provider [4;17]. If such a station is nearby a mobile phone constantly minimize its required output power, in GPRS as low as 5-10% (50-100 mW) to increase its battery lifespan. In our study the output power was controlled and set at maximal level to mimic a worst case but at the same time realistic scenario. In healthcare facilities the coverage of telecommunication networks could be poor due to its structures and consequently induces mobile phones to transmit at maximal power which increases risk of EMI [1;12]. Therefore, due to our worst case scenario it is not to be expected that in daily practise critical EMI incidents with GPRS or UMTS would be more frequent than reported in our study.

Health care applications of new wireless telecommunication technologies are reaching the bedside (i.e., intelligent pager system with smart phones, personal digital

assistants with internet access or telemonitoring interhospital IC-transport) with potential clinical benefits [2;8]. On the other hand critical care equipment, with closed loop systems to eliminate human resources and errors, demands permanent technology assessment to assure its performance including electromagnetic compatibility with other devices [2].

The international standard on electromagnetic compatibility by the International Electrotechnical Commission in its present form is insufficient to safeguard medical equipment completely from EMI by GSM mobile phones and our results show the same holds for GPRS and UMTS [11;18]. The present industrial standard lacks stipulations to eliminate EMC in medical equipment. Manufactures are allowed to comply with the standard by reporting at which distance EMI occurs only. Reasons why even new medical devices still demonstrate EMI by mobile phones would be speculative such as complex medical industrial design, rapidly changing telecommunications signals or costs. This leads one to suspect that the undesirable situation of EMI in the critical care environment will not be eradicated in the near future.

This study piles up to the objective evidence that restrictive use in the critical care environment is sensible without overstressing negligible risks [11;19].

CONCLUSIONS

The "1 meter rule", as the minimal distance to keep a mobile phone away from medical equipment or the bedside as proposed in the past, seems safe although the rule does not exclude EMI by new generations mobile phones entirely. Restrictive policies should be facilitated by offering numerous areas that are easily accessed throughout the healthcare facility where the use of mobile phones is clearly permitted.

KEY MESSAGES

- The present study demonstrated incidents of electromagnetic interference by second and third generation mobile phones in 43% of 61 critical care medical devices of which 33% were classified as hazardous.
- The hazardous incidents varied from a total switch off and restart of a mechanical ventilator, complete stops without alarms in syringe pumps to incorrect pulsing by an external pacemaker.
- The ***median*** distance of all incidents was 3 cm with a considerable range up till 500 cm.
- The policy to keep mobile phones '1-meter' from the critical care bedside in combination with easily accessed areas of unrestricted use still seems warranted.

LIST OF ABBREVIATIONS

EMI = electromagnetic interference; GPRS = General Packet Radio Service;
UMTS= Universal Mobile Telecommunications System;
GSM = Global System for Mobile Communications

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS CONTRIBUTIONS

EJvL designed the study, performed the measurements, assisted in the statistical analyses and drafted the manuscript. SvdV designed the study, helped in performing the measurements and interpreting the results and participated in drafting the manuscript. RH designed the study, performed the measurements and participated in drafting the manuscript. JK performed the statistical analysis and participated in drafting the manuscript. MBV and MJS participated in the study design, in interpreting the results and in drafting the manuscript. All authors read and approved the final manuscript.

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additional file 1: list of medical devices and descriptions of all incidents

type of device (year of purchase)	interference (distance in cm)	signals	classification H or S or L H = Hazardous, S = significant, L = light	details of interference
mechanical ventilator				
Dräger Evita 4 (1996)	3	GPRS-1 & 2	*H*	total reset with restart and return to normal functioning with corrects settings within 30 sec
Dräger Babylog 8000 (1991)	0,1	GPRS-1	*H*	inspiration time changed from 0,80 s to 0,77 and interference on pistons (clicking rattle sound)
	2 / 0,1	GPRS-2 / UMTS	*H*	single, irregular timed tidal volume produced
Dräger Evita 1 (1992)	5	GPRS-1	*H*	in volume controlled testmode tidal volume was changed >10%, no interference in pressure control testmode
Siemens Servo 300 (1999)	4	GPRS-1	*H*	respiratory rate increased > 25%
	0,1	GPRS-2 / UMTS	*S*	indication leds switched to service mode, ventilation functions not influenced
Siemens Servo 900C (1984)	3	GPRS-1	*H*	inspiration time changed inconsistently
	0,1	UMTS	*L*	interference on display, ventilation functions not influenced
Siemens Servo i (2002)	0,1	GPRS-1 & 2	*L*	display changed to other menu, ventilation functions not influenced
Hamilton Galileo Gold (2001)	300	GPRS-1	*H*	expiration timing incorrectly with changed ventilation rate in volume controlled ventilation test mode
	10	UMTS	*S*	in display volume and flow curves disturbed, normal pressure curve and ventilation functions not influenced
Dräger Evita 2 (1995) & Hamilton Raphaël color (2004): no electromagnetic interference by GPRS or UMTS				
critical care monitor				
HP M1275A / 76A (1995)	50 / 30	GPRS-1 / 2	*S*	spikes on EKG curve
Philips MP90 (2003)	10	GPRS-1	*S*	value and curve of systolic pressure raised +10 mmHg
	0,1	GPRS-2	*L*	loudspeaker produces 217 Hz noise
Philips IntelliVue MP50 (2004)	0,1	GPRS-1 & 2	*L*	incorrect alarm: "Multi Parameters Module decoupled"
Philips IntelliVue MP30 (2004)	0,1	GPRS-1	*S*	at 0,1 cm from invasive pressure module arterial pressure curve and value influenced
	0,1	GPRS-2	*L*	at 0 cm from invasive pressure module no additional interference
Siemens SC6000P (2004)	0,1	GPRS-1	*L*	horizontal lines on display without impeding readability

additional file 1: list of medical devices and descriptions of all incidents (continued)

type of device (year of purchase)	interference (distance in cm)	signals	classification H or S or L H = Hazardous, S = significant, L = light	details of interference
Novametrix C02 SMO+ 8100 (2001)	500 / 30	GPRS-1 / 2	*S*	block shaped interference on curve with false value
Novametrix NiC02 7300 (2003)	3	GPRS-1 & 2	*L*	display changed to other menu, cardiac output monitoring not influenced
Siemens SC9000 (1996), Siemens SC7000 (1999), Spacelabs Scout (1998), Philips M4 transport (M3046A-3000A) (2002), Datex Pulse Oximeter Oscar II (1991), Dräger Capno sensor Evita 2 (1995): no electromagnetic interference by GPRS or UMTS				
syringe pump				
Alaris IVAC 591 (1993)	50 / 10	GPRS-1 / 2	*S*	at 50 cm from pump or separate drip sensor: incorrect alarm (type P2), pump function not influenced
	2	UMTS	*S*	at 2 cm from separate drip sensor: incorrect alarm (type P2), pump function not influenced
Fresenius Vial Module DPS (2004)	5	GPRS-1	*H*	pump stopped without acoustic alarm
Graseby 3500 (1998)	0,1	GPRS-1	*H*	pump stopped with incorrect acoustic alarm ("Clampo open")
BBraun Perfusor secura FT (1992), BBraun Perfusor fm (1996), BBraun Perfusor Compact (1999), BBraun Secura FT+ (1994): no electromagnetic interference by GPRS or UMTS				
volumetric infusion pump				
Alaris IVAC 598 (2002)	30 / 20	GPRS-1&2/UMT	*S*	at 30 cm for separate drip sensor: incorrect alarm (type P2), pump function not influenced
BBraun Infusomat P (2003), Fresenius Vial module MVP PT (1996), Fresenius Vial base unit A (1996): no electromagnetic interference by GPRS or UMTS				
intra-aortic balloon pump				
Arrow ACAT 1Plus (2000)	0,1	GPRS-1	*L*	spikes on arterial pressure curve
Datascope 97 (1994): no electromagnetic interference by GPRS or UMTS				
hemofiltration/dialysis machine				
Kimal Hygieia Plus (1999)	15	GPRS-1	*H*	at 15 cm from air detector incorrect alarm 'air in line' with subsequent stop of treatment
BBraun Diapact CRRT (1997), Fresenius 4008H (2002), Gambro AK200 Ultra S (2002), Hospal Integra Physio (2002): no electromagnetic interference by GPRS or UMTS				
external pacemaker				
Biotronik EPD 20/A	3	GPRS-1	*H*	in VVI-mode inhibition of pacemaker
Medtronic 5388 (2004), Medtronic 5348 (2004), Medtronic 5375 (1991): no electromagnetic interference by GPRS or UMTS				
defibrillator				
Philips AED HeartStart M3860A (2004)	0,1	UMTS	*L*	noise from loudspeaker
Medtronic Lifepack 12 (2001), Medtronic Lifepack 20 (2002): no electromagnetic interference by GPRS or UMTS				
EKG 12 leads				
GE MAC 5000 (2002)	150	GPRS-1 & 2	*S*	spikes in all 12 leads

additional file 1: list of medical devices and descriptions of all incidents (continued)

type of device (year of purchase)	interference (distance in cm)	signals	classification H or S or L H = Hazardous, S = significant, L = light	details of interference
	150	UMTS	*S*	shift in baseline in leads I-III
EKG telemetry				
HP M1400A transmitter, ceiling antenna & monitor (1999): no electromagnetic interference by GPRS or UMTS				
forced air-warmer				
The Surgical Company Warm Air Hypoth. syst. (2004), Nellcor WarmTouch (2004), Augustine Medical Bair Hugger500E (1994): no electromagnetic interference by GPRS or UMTS				
fluid warmer				
Level1 System250 FluidWarmer (1995)	10 / 2	GPRS-1 / 2	*S*	temperature on display changed without apparent influence in function
Mallinckrodt Infusate Warmer FW-588 (2003): no electromagnetic interference by GPRS or UMTS				
enteral feeding pump				
Sherwood Med. Kangaroo 324 (1993)	30	GPRS-1 & 2	*H*	when bottle was empty alarm 'empty bottle' was not given
Tyco Healthcare Kangaroo 624 (2002): no electromagnetic interference by GPRS or UMTS				
air humidifier				
Fisher & Paykel MR850AFU (2002)	5	GPRS-1	*H*	startup routine was performed with return to normal function
mobile suction unit				
Laerdal Suction Unit (2004): no electromagnetic interference by GPRS or UMTS				
continuous airflow mattress				
Hill-Rom anti-decub. Primo (2003): no electromagnetic interference by GPRS or UMTS				
critical care bed				
Hill-Rom Total Care (2003), Hill-Rom Avant Guard 1400 (2002): no electromagnetic interference by GPRS or UMTS				

H = Hazardous: direct fysical influence on patient by unintended change in equipment function
S = Significant: influence on monitoring with significant level of attention needed causing substantial distraction from patient care
L = Light: ….without significant level