Safety of active electronic implants operated nearby TETRA–transmitters

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Abstract

The purpose of this work is to investigate potential dangers for people carrying active electronic implants such as cardiac pacemakers resulting from the emissions of TETRA transmitters. The emitted electromagnetic fields of transmitters have the potential to influence the proper function of active electronic implants. Such investigations are very important, because a large part of the employees of the emergency services and authorities already use TETRA transmitters. Based on frequency of use in Austria and transmitted power we selected 5 transmitters used by emergency medical and ambulance services, police forces and fire brigades. The most common 12 cardiac pacemakers and 6 implantable defibrillators used in Austria were selected to investigate their vulnerability against emissions from TETRA transmitters. At 4 of 12 pacemakers and 2 of 6 pacemakers interference with the TETRA-transmitters occurred. The highest distance of interference between implant and transmitter was 40cm. The investigations are still not finished and will be continued with further types of implants. So the preliminary results of our in vitro studies showed that a safety distance of 40cm from the implant to the TETRA-device is reasonable.

1. Introduction

Most existing exposure limits for electromagnetic fields provided on a national and international level such as those given in the Directive 2004/40/EC [1] or the Council Recommendation 1999/519/EC [2] do not ensure protection of active electronic implants against malfunction. In other words, compliance with these limits does not guarantee safety of patients with active electronic implants. Taking the increasing number of patients with active electronic implants into account, the importance of this work is considerable: Looking only at cardiac pacemakers, about 50.000 citizens might be concerned in Austria. About 5.000 to 10.000 patients have implantable cardiac defibrillators in Austria. On the other hand, about 80.000 users of TETRA handheld transmitters are expected in the stage of the final development

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of the TETRA net. The fact that personnel of emergency services is very often in close contact with patients makes detrimental effects likely.

The available scientific evidence on the susceptibility of cardiac pacemakers or other electronic implants being exposed to the fields of TETRA transmitters is very limited. Schmid et al 2000 [3] found in in vitro studies that a hand held TETRA transmitter disturbed cardiac pacemakers up to distances of 70 cm, analogue transmitters caused disturbances up to 30 cm. However, Tahvanainen et al 2005 [4] observed no effects in a in vivo study. These two studies investigating only effects of two older TETRA transmitters do not allow any sound conclusions.

In a review on mobile phones and electronic implants performed by Cecil et al 2008 [5] the results from 35 studies were taken together. Out from about 4.500 cardiac pacemakers, almost 20 % of the implants were influenced by mobile phones. Usually a safety distance of 40 cm is sufficient to prevent from any event. The results of these studies give some indication on the possibility of influencing cardiac pacemakers or other implants due to TETRA transmitters, but due to several differences such as operational frequency, transmitted power or differences in locating the transmitter nearby the human body, studies on mobile phones do not allow sound conclusions regarding TETRA transmitters. We therefore decided to perform this project to protect citizens with active electronic implants. The results will help to complete the scientific evidence in this field.

2. Methods

The influence of 6 TETRA-transmitters on 12 pacemakers and 6 implantable defibrillators (ICD) was evaluated. The 6 TETRA-transmitters tested are from 4 manufacturers, 4 handheld transmitters and 2 TETRA-transmitters with external antennas for fixed applications (e.g. emergency dispatch center, cars). All handheld devices have a maximum transmitted power of 1W, all devices with external antenna 3W. The TETRA-devices are operating in the frequency range from 380 to 420 MHz.

For modelling the placement of the active electronic implants in the human body the implants are placed in saline water with 0,9g NaCl / liter. The saline water is filled in a block shaped bassin, this setup was already applied in several investigations in the scientific literature (e.g. Irnich 1996, [6]). The implant is placed on a non conductive plastic grid 16mm under the water surface. The antenna of the transmitter is positioned 10mm over the water surface directly over the connection of the electrodes at the implant. Numerical simulations and measurements showed that the positioning of the transmitter directly over the connection of the electrode gives the highest induced power at the input of the implant.

After exposing the active implant with the maximum power level of the TETRA-transmitter the recorded data of the implant were readed out and checked for any interference event.

3. Results

In Table 1 the results of the measurements are shown. The implants which showed no interference with any TETRA-device are summarized in one line, the sensitivity is denoted as range of all summarized implants.

Table 1: Results of the investigations of the influence of TETRA-devices on pacemakers and implanted defibrillators

				Handheld Transmitter (1W transmitted power)				Transmitter with external antenna (3 W)	
Pace-maker Number	Polarity	Sensitivity Atrium	Sensitivity Ventricle	A	B	C	D	E	F
1	bi/uni	0,1mV	0,5mV	5cm/ 28% 10cm/30% 20cm/56% 30cm/n.I.	20cm/38% 30cm/1%	10cm/35% 20cm/n.I.	0cm/30% 5cm/19% 10cm/1% 20cm/n.I.	20cm/57% 30cm/7% 40cm/1%	30cm/10% 40cm/1%
2	bipolar	0,4mV		0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/33% 5cm/n.I
	unipolar	0,4mV		0cm/31% 5cm/27% 10cm/20% 20cm/n.I	10cm/27% 20cm/n.I	5cm/22% 10cm/n.I	0cm/18% 5cm/25% 10cm/n.I	10cm/27% 20cm/n.I.	10cm/26% 20cm/29% 30cm/n.I.
3	bipolar	0,15mV		0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.
	unipolar	0,15mV		0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/57% 5cm/n.I.	0cm/95% 5cm/n.I.
4	bipolar	0,1mV	1mV	0cm/n.I.	0cm/1%	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/1%
	unipolar	0,4mV	1mV	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.
5-12	bi/uni	0,1-0,5mV	0,45-1mV	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.
Defibrillator									
1	bipolar	n.available	n.available	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/ 1 shock	0cm/n.I.	0cm/ 3 shocks
2	bipolar	0,15mV	0,15mV	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/ 1 shock 5cm/n.I.
3-6	bipolar	0,15mV	0,15mV	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.	0cm/n.I.

x cm/y %	% inhibition of pacemaker in a distance of x cm (50 % means that 50 % of the designated pacemaker pulses were not given by the implant)
x cm/ y shocks	Defibrillator triggered y number of shocks in a distance of x cm
n.I.	No interference
n. available	Sensitivity could not be set and readed out

From the 12 investigated pacemakers 4 showed interference due to the TETRA-transmitters. Two of the pacemakers were only influenced by the transmitters with 3 W maximum power, two were also disturbed by handheld transmitters (1 W maximum power) and the transmitters with the external antenna (3 W). Pacemaker Nr. 1 showed interference up to a distance of 40cm.

From the 6 investigated defibrillators 2 triggered an electric shock while being exposed by the TETRA-devices. At the defibrillator Nr. 1 a setting of the sensitivity was not possible, even the actual value of the sensitivity was not available. This defibrillator is setting the sensitivity automatically and it is

obviously reduced in the case of interference. This algorithm of changing the sensitivity has to be evaluated in detail before performing further investigations with this type of defibrillator.

4. Conclusions

The results of the measurements showed that in the worst case (highest sensitivity of implant, highest power level of transmitter) an interference of the active electronic implant due to the TETRA-devices can appear up to a distance of 40cm. Therefore a safety distance of 40 cm should be usually sufficient to prevent from any interference-event. The TETRA handheld radio should therefore be positioned by the personnel of emergency services so that a distance of 40cm to the implant is guaranteed. These results are similar to the investigation of the impact of mobile phones on active electronic implants found in the literature.

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