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Medical procedures and electromagnetic interference safety in patients with implanted pacemakers

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The number of patients with implanted pacemakers is steadily rising throughout the world. At the same time, a great variety of modern medical procedures that are routinely used in clinical practice can potentially cause changes in pacemaker settings and even lead to the total dysfunction of the device, which can also be referred to as electromagnetic interference (EMI). Therefore, specific therapeutic and diagnostic methods should be used rationally in patients with pacemakers and potential EMI must be considered. In the current review we discuss EMI causes, types of pacemaker malfunction and possible precautions, and the need of pacemaker settings control and correction after the procedures. Magnetic Resonance Imaging (MRI), therapeutic radiation, catheter radiofrequency ablation and some types of physiotherapy are thoroughly analyzed. We also discuss the importance of avoiding the irrational use of procedures that can be potentially dangerous for patients with implanted pacemakers.

Keywords: *pacemaker, electrical stimulation of the heart, electromagnetic interference, physiotherapy*

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Introduction

The number of patients with implanted devices for treatment of cardiac arrhythmias is steadily rising throughout the world due to the widespread use of pacemakers, implantable cardioverter-defibrillators (ICD) and cardiac re-synchronization therapy (CRT), and the increasing global life expectancy [1-3]. Over forty thousand pacemakers and two thousand ICDs are implanted in Russia annually. Moreover, more than one thousand CRT are performed each year [4]. Despite the fact that the number of pacemaker implantations in Russia is rising by 8-10%there are still 350-400 per 1 million people requiring pacemakers [3, 4].

Modern pacemakers are 'demand' pacemakers as they are able to sense intrinsic cardiac and extrinsic electrical activity and deliver electrical stimulus only when needed. Demand pacemakers can work in inhibitory and/or synchronized electrostimulation (ES) modes [5-7]. Moreover, most recent pacemakers can be characterized as complex programmable devices that have a variety of therapeutic and diagnostic functions and, therefore, require regular preventive maintenance and programming if necessary[1, 6-8].

Physiologic pacing with multifocal and frequency-adaptive pacemakers are used in more than 50% of cases in the western countries [5, 7, 9] and in 33,7% cases in the Russian Federation [4]. Multisensory systems development provided a reliable frequency adaptation of contemporary pacemakers and widened the range of their therapeutic options [2, 6, 9].

Technical characteristics of pacemakers and the risks of EMI

Apart from external electromagnetic waves sources, pacemaker electrical characteristics are also among the potential causes of EMI development [9, 10]. The typical range of the pacing impulse in modern pacemakers is 2,0-5,0 V and the amplitude of the recorded cardiac signals is 1,5-3,5 V [10, 11]. Demand pacemakers are known to be more susceptible to electromagnetic fields compared with asynchronous pacemakers [3, 7, 13]. In patients with frequency-adaptive pacemakers the external electrical signals can provoke pacemaker-mediated tachycardia [1, 13, 14]. In isolated atrial and atrial-ventricular pacing problems with sensing and/or atrial channel impulse capture may occur [5, 12].

Unipolar pacing with the anode-electrode is known to be more susceptible to EMI compared with bipolar pacing [15-16]. Floating atrial bipolar electrodes used in the VAT and VDD modes have been developed to minimize the risk of EMI and hypersensing [1, 5, 7]. When the devices with one atrial electrode (single-chamber pacemakers) are utilized, the lowest pacemaker sensitivity can be used and, therefore, the pacemaker becomes less susceptible to external electromagnetic signals [17]. In the bipolar pacing ST segment elevation and T wave amplitude are 40% less compared with the unipolar pacing that reduces the risk of EMI and pacemaker suppression [16].

In DDD mode atrial channel hypersensing caused by EMI can lead to automatic switch to VVI-stimulation or DDI pacing modes which are asynchronous [13, 16, 18]. The development of a high frequency ventricular electrostimulation due to atrial channel hypersensing to high frequency extracardial signals can be another negative effect of EMI in DDD mode. Interference of electromagnetic field and pacemaker ventricular channel can lead to total pacemaker inhibition and pronounced bradycardia and even asystole especially in "pacemaker-dependent" patients [19].

Magnetic Resonance Imaging (MRI) is a nuclear magnetic resonance-based imaging technique used to produce images of the organs and tissues and is also a source of a strong electromagnetic radiation [20, 21]. Studies have shown that 50-75% patients with implanted pacemakers may need to undergo MRI during the long-lasting period of constant pacing [22]. Clinical guidelines state that MRI is a relative contraindication in patients with pacemakers. MRI can be performed only after all risks and benefits have been evaluated [6].

A systemic review by Zikria et al. [2011] based on the metanalysis of 30 publications that studied the safety of a 1.5 Tesla (T) MRI in 1419 patients with implanted pacemakers showed no significant changes in the devices [21]. MRI was used to evaluate different parts of the body including the chest and the heart. The application of a magnetic field resulted in automatic switch of a pacemaker to an asynchronous mode and increased frequency of impulse production.

Prospective clinical studies showed that in 80-90% case patients with pacemakers undergoing MRI didn't have any serious adverse effects [24]. At the same time, some clinical reports identified various pacemaker dysfunctions that spontaneously resolved after MRI or were managed with programming [11, 23, 25]. These dysfunctions were caused by automatic asynchronous mode activation in the biologically controlled pacemakers, increased pacing threshold, system reset that brought the device to its factory settings and reduction in battery charge. The *in vitro* analysis of 1,5T MRI effects on implanted pacemaker revealed a significant overheating of an electrode [10].

Specific safety measures should be taken in patients who don't have MRI-conditional pacemakers and still require to undergo MRI examination [6, 26] Before the imaging the pacemaker-dependency should be evaluated and pacemaker settings should be carefully checked before and after the imaging. Non-pacemaker-dependent patients should be programmed to the 000 mode (turned off) and the biologically controlled modes should be switched to asynchronous mode. Low power MRI (0,5T) should be preferably used. During the MRI examination the patient should be under the care of a specialist.

The following pacemaker requirements have been developed in order to conduct imaging safely [22]: additional control when switching to the magnetic imaging mode; improved protection from electromagnetic interference that can cause power reset; utilization of electrodes that do not get overheated; elimination or minimization of ferromagnetic components. Since 2011 MRI-conditional implanted devices have been available. They have the SureScan™ function that can be activated before the imaging and makes the examination totally safe for the device [21].

Electrical defibrillation/cardioversion

For a long time, electricalcardioversion in patients with implanted pacemakershas been considered unsafe due to its possible negative effects on the generator and/or the electrode [26]. However, recently developed devices that have bipolar leads are better protected from the external electromagnetic waves [6, 7, 22]. Besides, the development of cardioverters/defibrillators with biphasic impulses increased effectiveness of this method, reduced energy consumption and decreased the risk of pacemaker damage [10].

Among the problems caused by electrical cardioversion/defibrillation in patients with implanted pacemakers were protection mode activation, short-term threshold increase, capture failure, pacemaker generator and electrical circuit dysfunction [10, 16]. Patients with unipolar pacemakers implanted in the right infraclavicular region developed capture failure in 50% of cases due to the increased threshold caused by the relatively high cumulative energy of electroconvulsive therapy [9]. Undersensing and total dysfunction of the pulse generator that required pacemaker reimplantation were also noted. However, no cases of total electrode dysfunction were reported.

The analysis of the "runaway pacemaker" syndrome causes revealed that in most cases it was associated with previous electrical defibrillation [27]. It is a phenomenon in which pacemaker causes sudden high-frequency ventricular electrical stimulation ("pacemaker tachycardia") with constantly increasing impulse frequency over 150 impulses per minute that may lead to ventricular fibrillation. Supposedly, it is caused by the pacemaker electrical circuit dysfunction due effects of cardioversion/defibrillation, when the pacemaker generates electrical impulses of various frequencies and amplitudes. An emergent pacemaker reimplantation is necessary in this case.

Most pacemaker manufacturers recommend using V00/A00 modes when performing electrical cardioversion to disable incoming signal amplifier in order to avoid pacemaker inhibition [17, 25]. Moreover, the time between two successive discharges should not exceed 5 minutes to allow the electrodes to cool down. After cardioversion/defibrillation the pacemaker has to be tested. In case of electrostimulation threshold increase the stimulating impulse voltage has to be also increased. In case of any changes in sensitivity threshold pacemaker has to be reprogrammed.

In patients with implanted pacemakers the lowest possible effective energy of cardioversion has to be used. Prior to the procedure the pacemaker should be programmed to the maximal impulse voltage [10]. Pacemaker dysfunction can be avoided if defibrillator electrodes are placed at least 15 cm from the pacemaker or anterior-posterior position can be used. In that case the electrical field is perpendicular, and not parallel, to the intra-cardial electrode.

Catheter radiofrequency ablation (RFA)

RFA ablation employs electric current in the radiofrequency range (450–500 kHz) [27]. Most implanted pacemakers in patients who underwent catheter RFA proved to be well protected from interference produced by the radiofrequency waves [10]. No cases of pacemaker inhibition or insufficient or excessive sen-

sitivity to cardiac signals (hypo- and hypersensing) were reported [28]. At the same time, patients with mostly monopolar electrodes included in another clinical study, were reported to have sensitivity (detection) and electrostimulation dysfunction [29].

For safe electrostimulation in patients requiring catheter RFA it is necessary to determine if the patient is pacemaker-dependent. In pacemaker-dependent patients temporary pacing should be provided [3, 27] Besides, prior to RFA, the frequency adaptation function of a pacemaker should be disabled. Radiofrequency exposition should be as short as possible, and the area of exposition has to be as far away from the pacemaker as possible. In non-pacemaker-dependent patients 000 mode can be used, which means turning the pacemaker off, or VVI mode with a frequency of stimulation lower than the heart rate [10]. In pacemaker-dependent patients asynchronous V00 mode has to be used. In patients with leadless pacing fewer pacemaker dysfunctions and/or electrode dysfunction during RFA of atrioventricular junction were observed compared with transvenous electrode implantation [29]. Therefore, it is important to test the pacemaker function after the RFA procedure.

Therapeutic radiation. High-energy radiation can have some various negative effects on the pacemaker such as direct circuit damage or intermittent EMI. New implanted pacemakers employ complementary metal oxide semiconductors (CMOS) that are very safe, energy efficient, and don't need much space [1, 7, 11]. Radiation was shown to cause some damage to the thin oxide layers and transistors due to the positive charge accumulation inside the pacemaker circuit that can cause battery dysfunction [10, 30]. The extent of damage depends on the radiation type, cumulative dose and pacemaker location. Various dysfunctions of the signal detection, telemetry, frequency adaptation and total inhibition can also occur [30, 31].

Salerno F. et al. [2016] tested the pacemaker activity during radiation therapy. The revealed problems were as follows [30]: temporary mode switch that continued during the radiation period; pacemaker damage and loss of impulse generation that lasted for the continuous period of time. Therefore, patients undergoing radiation therapy should always be closely monitored during the whole period of radiation treatment and for several weeks after it ends.

In case of absolute indications for radiation therapy some precautions have to be taken in patients with pacemakers [10, 31]. Before the radiation session begins it is important to determine if the patient is pacemaker dependent. Beam angle should be selected to minimize the radiation exposure of the pacemaker. A total limit of radiation cumulative dose shouldn't extend 2 Rad and should be controlled by the dosimeters. Besides, additional pacemaker shielding (1 cm) should be used. Direct radiation should be avoided and, if possible, the pacemaker should be moved to another suitable side. Patients have to be closely monitored all the time and temporary pacing should be available.

Electrocoagulation is one of the most widespread and cost-effective techniques used to cut or coagulate tissues [32]. The high-frequency alternating current can cause pacemaker inhibition or high-frequency ventricular stimulation initiation, which is especially common in patients with dual chamber atrial-ventricular pacing and frequency-adaptive pacing because of the coagulation signals detection that imitate atrial potentials [16]. Moreover, current, which is generated by the electrocoagulator, can cause thermal myocardial damage due to the high current concentration in the "electrode-tissue" contact zone and that can result in the pacemaker threshold increase [10]. Electrocoagulation near the pacemaker can lead to the pacemaker switching to the asynchronous mode or its inhibition because of the hypersensing [13]. As such, electrocoagulation has to be bipolar and shouldn't be performed close to the pulse generator (<15 cm). Current should be perpendicular to the electrode and each coagulation episode shouldn't last longer than several seconds. Pacemaker should be programmed to the asynchronous V00 mode and/or additional endocardial electrode for temporary electrostimulation should be implanted [26]. It was shown that the use of ultrasound scalpel in the electrocoagulation zone decreases the risk of EMI [10]. Also, the minimal energy power should be used for coagulation.

Smart devices used for heart rate monitoring

Interactive telecommunication technologies are lately becoming more widely used for various medical needs such as at home monitoring of patients with implanted antiarrhythmic devices with Home Monitoring function [33-35]. According to the clinical guidelines, it is important to provide telemonitoring of all patients with ICDs, cardiosynchronizing therapy and in pacemaker-dependent patients who make up to 20% of all patients with pacemakers [6].

New telemedical technology make it possible to perform remote monitoring of the implanted devic-

es for treatment of cardiac arrhythmias functioning and allow to register adverse cardiovascular events in time to alleviate their negative effects [34]. As such, safety and compatibility of telemonitoring systems in patients with pacemakers is of great interest. Wireless electrical devices should also be studied more closely in patients with pacemakers due to the high magnetic field strength. However, the unlimited use of this technology in patients with implanted pacemakers can't be recommended yet [6].

Abudan A.A. et al. [2019] studied the safety of a smart device "AliveCor Kardia" (USA) in 251 patients with pacemakers [36]. During the ECG recording no adverse effects or changes in the work of the pacemakers were registered. ECG was correctly interpreted in 90% of patients with pacing and in 94,7% patients with spontaneous heart rhythm. It was shown that "AliveCor Kardia" has a perfect safety profile, doesn't interfere with pacemakers and can be used for remote heart rate monitoring.

Physiotherapy safety

For many years the established clinical practice and the lack of clinical studies on the physiotherapy safety in patients with pacemakers led to the development of quite a pessimistic attitude in cardiologists, physiotherapists and surgeons towards the use of physiotherapeutic methods in patients with pacing [37]. This, in turn, is associated with a potential risk of pacemaker dysfunction and unpredictable patient reaction during physiotherapy that induces electromagnetic fields. Modern physiotherapy guidelines that discuss indications and contraindications to different types of physiotherapy in patients with pacemakers are based not on the clinical studies but on the expert consensus opinion [6, 11, 38].

Indications and contraindications to physiotherapy in patients with pacemakers are known to depend on the specific physiotherapeutic method [10, 18, 37, 38]. Most guidelines state that among the physiotherapeutic methods that can safely be used in patients with pacemakers are [38]: manual therapy/stretching, acupuncture (except for electroacupuncture), magnetic therapy, pulse radiotherapy; laser therapy, ultrasound therapy, hyperbaric oxygen therapy, phototherapy. Interference electrotherapy, microcurrent therapy, transcutaneous electrical nerve/muscle stimulation, electroanalgesia and diathermia are contraindicated in patients with implanted pacemakers.

As most guidelines on physiotherapy in patients with pacemakers are based on separate clinical observations and small sample studies, most pacemaker manufacturers don't recommend the use of diathermy, transcutaneous electrical nerve/muscle stimulation and interference electrotherapy in this category of patients [12, 13, 38]. Some papers report on adverse effects of these types of physiotherapy on pacemaker function such as: pacemaker inhibition, decrease and increase in pacemaker sensitivity; automatic pacemaker switch to asynchronous mode; increase in impulse frequency (external magnet effect); decrease in impulse amplitude and etc. [10, 16, 33, 37]. EMI can sometimes cause generator and electrical circuit dysfunction that require a total device reimplantation [38].

The analysis of EMI causes showed that the risk of pacemaker system changes depends on electric current strength, the distance between the pacemaker and the body part that undergoes physiotherapy; the pacemaker and the stimulating electrodes location and the pacemaker functional parameters [38]. These changes are often temporary and disappear after the procedure is over, but still the pacemaker parameters have to be checked after each session and if necessary, the pacemaker has to be reprogrammed.

Techniques and preventive measures that improve the pacemaker interference resistance

Current pacemakers employ various techniques that improve their interference resistance [2, 5, 11]. An important technology is shielding of the pacemaker electric circuit, i.e. placing it inside a hermetically sealed titanium or stainless-steel case that makes the pacemaker relatively immune to the EMI [39]. Apart from that, special band pass filters are commonly used that protect the pacemakers from the high-frequency fields and, therefore, prevent the external signals detection and EMI development [11]. Devices that automatically switch biologically controlled pacemakers to the synchronous mode in the presence of strong interference are also used [5, 6]. Among the most recent technologies is the development of implanted leadless pacemakers that are less susceptible to EMI due to the absence of leads, small size and intra-cardial location of the device itself [29, 40]. EMI development can also be avoided if all precautions associated with the specific diagnostic or therapeutic procedure are taken.

The pacemaker that are manufactured in the Russian Federation should meet the set of specific technical standards known as GOST and, specifi-

cally, GOST 31212-2003 "Implantable pacemakers. General technical requirements and testing methods" (01.01.2015). The implanted pacemakers have a combined isolation system that is provided by the sealed case made of metal and is covered with special isolation material [11]. According to the GOST, there should be no pacemaker dysfunction after defibrillation and they also should be resistant to EMI. However, the electromagnetic requirements are still in the middle of development.

Temporary pacemaker reprogramming is recommended prior to the diagnostic or therapeutic procedure to minimize the EMI risk [12, 13, 16, 17, 38]: 1) Program the pacemaker to bipolar mode; 2) Evaluate the need of asynchronous pacing using the external magnet; 3) Program the pacemaker to the minimal sensitivity if it doesn't cause competitiveness between the spontaneous and artificial pacemakers; 4) program the impulse current to the maximum strength; 5) In patients with frequency-adaptive pacemakers turn off the frequency adaptation function; 6) Test the pacemaker before and after the procedure and preprogram it if necessary; 7) Use portable heart simulators to evaluate the risk of EMI in each specific case.

Conclusion

In the everyday life patients with implanted pacemakers are vulnerable to unfavorable effects of many sources of electromagnetic fields. The clinicians who are treating the patients with implanted pacemakers should be aware of these potential problems and take care of the safety measures in order to prevent the EMI. To fully understand the indications and contraindications of various medical procedures and to perform them safely in is crucial to understand the principles of their functioning and the pacemaker modes. Naturally, the patients with implanted pacemakers have to be fully evaluated prior to any diagnostic or therapeutic procedures in order to avoid any complications. In case of any uncertainties about the safety of a medical procedure the patient is strongly advised consult the specialist.

Taking into the account the absence and/or the inconsistency of the guidelines on the use of various diagnostic or therapeutic procedures that may interfere with pacemakers, further clinical studies have to be conducted in order to create the evidence-based guidelines.

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