

HOLTER ECG MONITORING AS METHOD FOR ASSESSING INTERACTION OF IMPLANTED PACEMAKER AND SOURCE OF ELECTROMAGNETIC INTERFERENCE

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Abstract

The aim of the study was to assess the interaction of the cardiostimulation system of the patient and the source of electromagnetic interference (EMI) during the patient's work by Holter monitoring of ECG. Finally, to analyze ECG recording and evaluate possible pacemaker (PCM) program responses to the presence of EMI. The observation was performed in the selected patient with the single-chamber conventional pacemaker during practicing of a profession in an industrial environment with a real risk of interaction with the defined source of interference. The heart rhythm was monitored with a standard Holter monitor and the measurement was repeated during three work shifts. The PCM was revised before each measurement and at the same time the programming was adjusted for monitoring purposes. The ECG record was back-analyzed and the device response to the presence of EMI was evaluated. No program response to the presence of an interfering electromagnetic field (EMF) was observed from the ECG recording analysis. This program response would manifest to abnormalities in the ECG curve (asynchronous pacing, pacing inhibition, competitive pacing). There were no events in the PCM memory indicating the effect of the EMI.

Keywords

ECG monitoring, Holter monitor, pacemaker, cardiostimulation, electromagnetic interference

Introduction

The pacing function of cardiac implantable electronic devices (CIEDs) is based on the same principle. The device senses and interprets electrical intracardiac signals from poles of each lead located in different heart chambers. Detection and misinterpretation of potentials that are not physiological heart activity may cause inadequate function of the pacemaker. The consequences can be clinical or technical and it may endanger the current health condition of the patient with the cardiac implant. The bradyarrhythmia treatment (pacing) may be inhibited and subsequent bradycardia or complete asystole may occur in patients without intrinsic rhythm. The presence of EMI can also initiate temporary program changes. Exposure to a strong magnetic field can activate the Magnet Response algorithm and cause an

asynchronous pacing. The device will usually return to its original function after removing the source of interference [1, 2].

Living with pacemaker

According to the manufacturer's recommendations, patients with an implant are not recommended to be exposed to such situations where there is a risk of EMI due to strong electric or magnetic fields. This has certain limitations. These recommendations are strict in professional life and patients are sometimes not allowed to practice their jobs. Especially in the case of PCMs, it is necessary to individually consider the real clinical risk for the patient, his individual needs, in connection with the impact of restrictions on his personal or professional life. Thus, manufacturers in their patient guidelines often refer patients to their doctor's consultations [3].

Research summary

We focus on patients with a conventional pacemaker in our research and this article is subpart of it. Pacemaker systems are worldwide the most often implanted CIEDs. Almost 10 thousand PCM were implanted in the Czech Republic according to official statistics from the Czech Society of Cardiology in 2020. This is about 70 % of all CIEDs implanted in our country [4]. We suppose that the behavior of the PCM in the presence of EMF can be analyzed from a surface ECG. Any interaction would be manifested by abnormalities in the cardiac electrogram. EMI may not be a clinically significant risk in patients with a sufficient heart rate. This can be achieved by optimizing of the device programming. Modern devices have a lot of software options that can be customized by clinicians and thus eliminate the risk for the patient. The function of implantable cardioverter-defibrillators (ICDs) is different and the behavior differs in the presence of EMI because of advanced antitachyarrhythmic therapy-related algorithms [5]. So, it is difficult to predict risks and therefore we don't consider ICDs in our research. CIEDs also have an important diagnostic function that we use for our purposes [6]. For our observation we have chosen the patient with the PCM while performing his work.

Methods

The measurement took place in the patient's work environment, with a risk of interaction with the industrial EMF. The electromagnetic environment was mapped prior to the observation. Possible damage to the PCM electronics was ruled out due to strong electromagnetic fields and the clinical risk to the patient with the cardioimplant. The operation of such industrial machines is not recommended and it is not possible as a profession according to the recommendations of CIED manufacturers. The patient was under direct supervision with ECG monitoring. The interaction analysis by this method was performed within a more comprehensive *in vitro* study. The patient had implanted a standard pacing system and was not dependent on cardiostimulation. Informed consent was signed by the patient before the start of the measurement. The research was approved by the ethics committee of Liberec Regional Hospital.

Patient with pacemaker

The patient was indicated for bradyarrhythmia treatment by a single-chamber (1D) PCM for a persistent atrial fibrillation with a slow ventricular response. The system is implanted from the left side, located subcutaneously above the pectoral muscle, with the bipolar intracardiac lead leading intravenously and actively

fixed to the area of the right ventricle (as shown in Fig. 1). The system is a conventional programmable PCM with the integrated memory to store intracardiac episodes. The programmability of the device allows you to set the different configuration of pacing and sensing. The PCM is programmed to inhibited single-chamber mode with the frequency adaptive pacing VVIR. Base rate frequency is 60/min. The PCM has a programmable ventricular sensitivity and also a response to the presence of a magnetic field ($> 1\text{mT}$), which can inhibit pacing or temporarily switch the device to an asynchronous mode (depends on programming). Other parameters are in factory default settings. The system is made of non-magnetic materials (compatible with magnetic resonance imaging). The electrical parameters of the pacemaker and the lead (impedance, threshold, sensing) are stable in time from last follow-up. The patient had 86 % of ventricular pacing according to last diagnostic data.

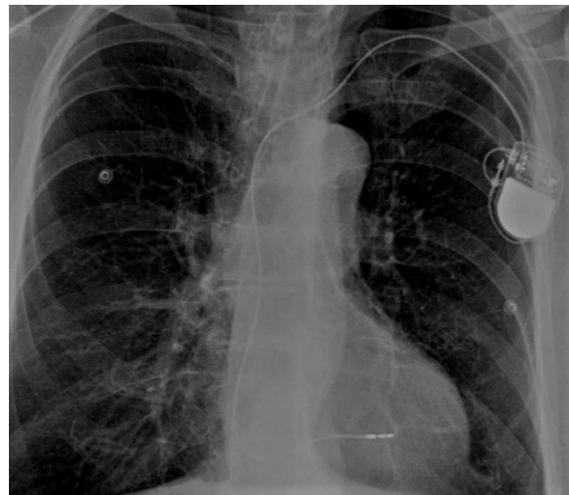


Fig. 1: The standard patient's placement of the single-chamber pacemaker system in the anteroposterior X-ray projection.

Source of EMI

The evaluation of the interaction was carried out in the working environment. The industrial machine with which the patient works was evaluated as the only potential source of disturbing EMFs. The risk part is an electromagnet (electromagnetic chuck) for clamping workpieces. Accordingly, we excluded possible damage to the PCM, because the magnetic field (MF) was in the range of tens of mT. The level was measured manually by the gaussmeter with the linear probe. The patient is close to the EMI source during normal work shift. Distances between the PCM system (the patient's chest) and the clamping electromagnet are about 0.5–1 meter. The normal operating position is obvious in Fig. 2.

The electromagnetic chuck is composed of a several coils in series powered by DC voltage source, so it produces a strong static MF. Magnetic flux density

varies across the surface of chucks, because of the internal location of coils. The maximum value was 30 mT near the edges of clamping surface. The closer to the center, the weaker magnetic field. We have also found that there was alternating 50 Hz component up to 4 mT in the EMF characteristic. Near the clamping surface, near the edges again, there was a real risk of interaction of the PCM with the interfering field. The time-variable component of the EMF can inhibit pacing and the static field can cause a magnet response. The risk decreases exponentially with increasing patient distance from the machine.



Fig. 2: The normal position and distance of the patient during operating the industrial machine.

Observation methodology

The measurement took place during three work shifts, where the patient operates an industrial machine, the EMI source. Each work shift lasted less than 8 hours. The patient was equipped with a 5-lead ECG Holter monitor. Prior to the measurement, the PCM programming was optimized to minimize the clinical consequences of EMI exposure and for ECG analysis of the Holter recording. The diagnostic function and storage of intracardiac events were also modified. We considered the operation of specific active algorithms in interpretation of paced events from ECG curves obtained from both recording methods [7]. The setting changes are shown in Tab.1. Retrospective analysis of the device's behavior was performed from this data.

Table 1: The setting changes in PCM programming.

Parameter	Change
Sensitivity	4 mV bipolar
Magnet Response	ASYN (freq. 90/min)
Diagnostics	High Rate Diagnostics 150/min (8 cycles)

ASYN – Asynchronous Pacing Mode VOO.

The possible interaction of the disturbing field with the PCM system would lead to abnormalities on the ECG curve in the Holter recording. Observed endpoints in the recording were:

- Pacemaker inhibition
- Asynchronous pacing of higher frequency
- Competitive pacing
- Higher pacing rate at Max Sensor Rate

The pacemaker inhibition can occur when an intermittent sensing of EMI signals as intrinsic rhythm is present. The asynchronous pacing of higher frequency (in the case of this PCM at frequency 90/min) can occur because of the device response to magnetic field (Magnet Response algorithm) or sustained detection of high frequency EMI (Noise Reversion function). Competitive pacing may be the result of an asynchronous pacing. Higher pacing rate at Max Sensor Rate frequency (in this case 130/min) may be the result of the sensor (accelerometer) being affected by an external field.

Electrical parameters of the device and the lead were checked by programmer after each measurement. The memory of intracardiac events in the PCM was also checked for the events meeting the detection criteria. Sensing episodes of non-physiological external signals that affected PCM function could be stored here.

The continuous recording from the ECG Holter monitor was analyzed retrospectively by professional using the appropriate analytical software. This program allows the interpretation of stimulation spikes as paced rhythm. The summary reports were created from each analysis.

Results

Repeated measurement has not shown that the level of interfering EMFs in the work environment during the normal practicing of the patient's profession affects the function of his implanted 1D PCM.

No target abnormalities were seen on the electrocardiogram from Holter monitor to indicate incorrect PCM behavior in the presence of an EMF. Only occasional movement artifacts were present. The recording was well interpreted. Two morphologies of the QRS complex, paced and endogenous, alternated throughout, as shown in Fig. 3. This is appropriate for the patient's diagnosis. Observed abnormalities on ECG recording were primary endpoints of this paper.

No events indicating the PCM's interaction with an interfering EMF were stored in the device memory. The electrical parameters of the system were stable during the research. The PCM programming remains in the optimized settings, as stated in the introduction to the article. Analysis of events in the PCM memory was secondary for this article.

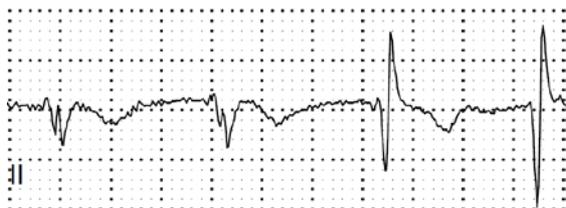


Fig. 3: Electrocardiogram of the patient from the Holter monitoring. Limb Lead II.

Discussion

Analysis of the PCM response to an interfering EMF by Holter ECG monitoring is one of a few options to assess the clinical significance of a given interaction. However, it requires a sufficient knowledge of the electromagnetic environment and the behavior of the pacemaker system in the presence of EMF. Unfortunately, this approach is more time consuming. The diagnostic function of the device is not sufficient for given purposes, because it stores only a part of events meeting detection criteria. It is offered to use unipolar pacing for better interpretation of the ECG recording due to apparent stimulation spikes.

The risk of the interaction of EMF and the pacemaker system is related to various factors. It depends on the properties of the EMF, the characteristics of its electrical and magnetic components, the mechanism of EMI transmission or the orientation against the source. The danger to the patient decreases in a proportion to increasing distance from the EMF source. Sensing of EMI signals is also affected by individual proportions of the patient. Current CIEDs have active elements that are programmable and may reduce the EMI sensitivity. We can minimize risks by optimizing the PCM programming and also reduce limitations for the patient set by device manufacturers. These recommendations sometimes do not reflect the individual patient's needs.

Conclusion

The danger to which the patient was exposed during the measurement is minimal due to the characteristics of the generated EMF, the examined pacemaker and the patient's diagnosis. But the interaction is real and therefore there are certain prevent limitations for the patient given by manufacturers of CIEDs and clinicians. Not every potentially dangerous source of EMF is necessarily a real threat to the patient. Our patient had optimized PCM programming to minimize the clinical consequences of EMI, which was done before the research starts. We excluded the possible influence of the electromagnetic working environment on the proper function of the pacemaker during normal work

shifts by repeated observations. The patient was instructed about a safe behavior and compliance to safety precautions (mainly safe distances). The outcome combines results from Holter monitor analysis and PCM diagnostics. This paper demonstrates a different approach to the issue and the described measurement follows (is an extension) the clinical study focusing on in vitro simulation.

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Conflict of interest

Authors declare no conflict of interest.

Ethical statement

Authors state that the research was conducted according to ethical standards.

Informed consent

Informed consent was obtained from the patient participating in this study.

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