A Standardized Method for Evaluation of Pacemaker Safety on the Work Place – A Case Evaluation

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Summary

Electromagnetic alternating fields can interrupt the function of cardiac pacemakers. To secure patient safety, it is advisable to avoid potential sources of risk. As a consequence, pacemaker-dependent employees might have to give up their previous professional activity in some cases. A standardized method has been developed to perform individual evaluations. It allows in-vivo measurements of interfering influences on pacemakers. The examinations are based on a four-step concept: evaluating the working conditions, determining field exposure, testing the pacemaker function and programming and exposing the patient to a field in a simulator and testing the pacemaker function during this field exposure. The case of a 56-year-old, pacemaker-dependent arc welder, who was able to continue working as a result of our examination, is described.

Key Words

Pacemaker safety, electromagnetic interference, work place safety

Introduction

Modern pacemakers are the result of an ongoing technological and medical development that has occurred over the last 40 years. By this time, pacemaker therapy has become the standard therapy for bradycardia rhythm disturbances. In Germany alone, there are currently about 250,000 pacemaker patients. To a considerable extent, the general acceptance of pacemaker therapy can be traced back to the progress achieved in pacemaker miniaturization. While securing patient survival was the focus of early pacemaker therapy, today's sophisticated rate-adaptive, dual-chamber systems offer an overall improvement of the patient's quality-of-life. Contemporary pacemakers are considered to be extremely reliable and interference-resistant. As a rule, if their general health allows it, pacemaker patients can usually continue their normal, daily activities without limitations.

Due to its functioning principle, any pacemaker can be disturbed by electromagnetic alternating fields of sufficient energy. According to the information provided by various manufacturers, a pacemaker may or may not be disturbed by interference sources such as electrical tools. Due to the efforts of manufacturers, the danger of such electromagnetic interference has been reduced to a minimum [1,2]. However, recurring reports in the media continue to cast doubts on the safety of cardiac pacemakers and their ability to withstand electromagnetic interference. In the past, this has led to uncertainty among patients and attending physicians. Such trepidation is amplified by in vitro examinations of explanted pacemakers, which proved a possibility of the impairment of pacemaker function by electromagnetic interference [1-3]. So far, only a small number of measurements have been made on pacemaker patients. These studies examined the risk potential of individual device groups, such as induction cooking ranges and anti-theft systems [4,5]. These studies are individual analyses and do not allow general conclusions to be made.

Especially for pacemaker-dependent employees, it is often necessary to eliminate any potential danger that electrical devices might pose at their work place (e.g., electric welding machines). In the context of our studies, a new method has been developed, which allows a quantitative determination of disturbing influences due to electromagnetic interference in the patient. An electromagnetic alternating field is generated with the help of a Helmholtz coil. Thus, it becomes possible to study the influence of this field on the implanted pacemaker. This method makes it possible to simulate the electromagnetic fields that occur at the work place and measure possible interference directly at the patient.

Materials and Methods

Measuring equipment

The method presented is a non-destructive test method. The field strengths used are not sufficient to destroy the pacemaker leads or the pacemaker. Without providing any greater technical detail, the general apparatus will be described briefly. This apparatus enables patient exposure to a defined electromagnetic field by means of Helmholtz coils under laboratory conditions and, thus, provides the greatest safety precautions possible.

The Helmholtz coils consist of two coils with a diameter of 1.2 m; they are hung parallel to each other at a distance of 0.6 m. Each coil consists of 100 windings made of 2 mm^2 enameled copper wire. If the pair of coils is subjected to an alternating voltage, a spatially homogeneous electromagnetic alternating field forms between the coils. A signal generator generates the alternating field frequency of 50 Hz. An output amplifier connected on the load side provides the supply voltage for the Helmholtz coils. The strength of the alternating field is proportional to the current strength that is fed in. The system provides up to 1100 µT at 50 Hz. In accessible environments, homogeneous field strengths of such magnitude cannot occur. Induction under a transmission line is about 1 % of the stated strength. Inductions of tools and appliances are often stated in this range; however, they decrease with distance to a degree that the induced voltages are lower than those caused by the Helmholtz coils.

The magnetic alternating field causes a current field in the body, which is oriented vertically to the magnetic field along the body's contours. It is weakest on the inside and strongest on the outside. The amount of induced voltage can be estimated from the product of the angular frequency, the induction, and the area orthogonal to the magnetic field and enclosed by the conductor loop.

Therefore, for the acute measurements the patient is asked to sit between the coils in such a way that the upper body is oriented parallel to the coils. This orientation guarantees that the pacemaker leads, the pacemaker, and the patient form the largest possible effective conductor loop. This guarantees an optimal coupling of the electromagnetic field.

Monitoring the pacemaker function

During the measurements, the cardiac action is monitored by means of a four-channel ECG, and the blood pressure is measured continuously on a beat-to-beat basis (Finapress system). The pacemaker response is monitored using the pacemaker's telemetry functions. Modern pacemakers transmit marker signals on demand. These can be displayed and printed with the help of the pacemaker programmer. Based on these marker signals, disturbances in the pacemaker action can be clearly identified. Furthermore, some models offer the option of transmitting the intracardiac electrograms to an external device.

Patients safety

All examinations were performed under the supervision of a physician. An experienced physician continuously monitored the pacemaker response. The measuring sequence was ended as soon as a pacemaker disturbance was observed.

Results

We have developed the following four-step concept for the examinations:

- Evaluation of the exact working conditions;
- Calculation of the maximal field exposure under the existing working conditions;
- Testing of pacemaker function and programming and
- Acute field exposure in the simulator and testing of pacemaker function during field exposure.

So far, one patient has been examined using the method described above. He was a 56-year-old man who works as an arc welder. The patient was implanted with a DDD pacemaker (Actros DR, Biotronik, Germany) and bipolar leads two months before the examination. The pacemaker follow-up showed that

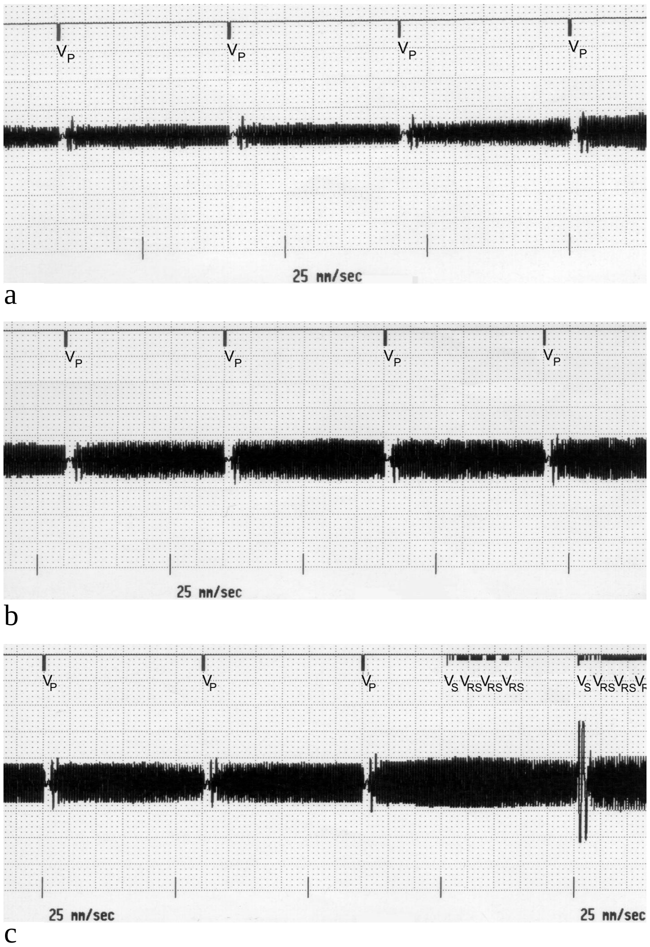

Figure 1. Programmer printouts of the intracardiac electrograms and marker channels with the ventricular sensitivity set to 2.5 mV in the unipolar sensing configuration. First refractory senses appeared at 425 µT.
a) Field strength 170 µT.
b) Field strength 350 µT.
c) Field strength 425 µT.
VP: ventricular pace; VS: ventricular sense; VRS: ventricular refractory sense. Note the increasing noise in the electrogram channel due to the increasing field strength, and the high number of VRS markers in c.

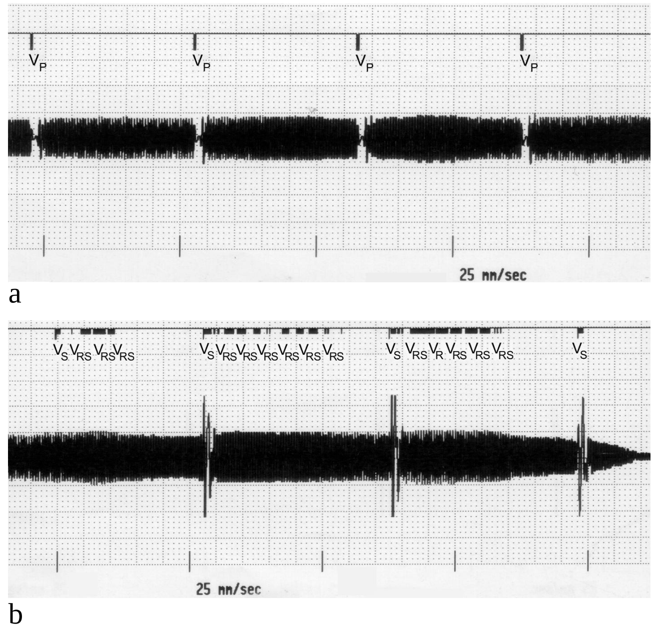

Figure 2. Programmer printouts of the intracardiac electrograms and marker channels with the ventricular sensitivity set to 5.5 mV in the unipolar sensing configuration. First refractory senses appeared at 930 µT.
a) Field strength 850 µT.
b) Field strength 935 µT.
VP: ventricular pace; VS: ventricular sense; VRS: ventricular refractory sense. Note the increasing noise in the electrogram channel due to the increasing field strength, and the high number of VRS in b.

the patient's DDD pacemaker had been programmed to the VVI mode due to atrial fibrillation. The programmed ventricular sensitivity was set to 5.5 mV in the unipolar sensing configuration.

Following our concept, the exact manner of working and the maximum field exposure that could be expected were determined. The professionally used welding device provides a maximum current strength of 260 A through a cable divided into two. Due to the geometry of the work place, the shortest distance between patient and cable is 0.5 m. Based on this information, the magnetic field strength caused by the cable can be calculated. At a distance of 0.5 m between patient and cable, the expected field strength in the area of the pacemaker is 100 µT. Assuming the distance between cable and pacemaker was 10 cm, i.e., the cable would directly touch the body, the effective field strength would be maximally 500 µT.

For the acute examinations, the patient was asked to sit between the two coils of the Helmholtz coil and to orient his upper body parallel to the coil plane. The pacemaker function was monitored via pacemaker telemetry. Both the intracardiac electrogram and the marker channel were transmitted. Two examinations were conducted in the unipolar sensing configuration and different ventricular sensitivity settings. With a programmed ventricular sensitivity setting of 2.5 mV, the first disturbances (Figure 1) were observed to appear at a field strength of 425 µT. These disturbances were so-called refractory events, which were displayed in the marker channel. With the ventricular sensitivity setting of 5.5 mV chosen by the referring cardiologist, first disturbances were observed at a field strength of 935 µT (Figure 2). These observed disturbances were also refractory events that could be seen in the marker channel.

Discussion

Electromagnetic alternating fields are ubiquitous in daily life and span the range from high-voltage transmission lines over radio stations to household appliances and electric machines at the work place. Electromagnetic alternating fields are invisible and can only be determined with special measuring methods. The effect of the alternating fields depends on their frequency and energy.

Electromagnetic alternating fields of sufficient strength can influence the function of cardiac pacemakers. Therefore, pacemaker-dependent patients are generally advised to avoid potential sources of interference. This leads, on the one hand, to insecurity for patients and involved physicians; on the other hand, this advice can have the result that pacemaker patients who are able to continue working may lose their previously held jobs.

The pacemaker can interpret a single disturbance pulse that it detects as a regular intrinsic cardiac action, an extrasystole, or a so-called refractory sense. The resulting pacemaker response depends on the type and the programming of the pacemaker. For instance, a misinterpretation can lead to the inhibition of necessary ventricular pacing. In case of a disturbance in the atrial channel of a DDD pacemaker, the disturbing pulse can trigger premature pacing of the ventricle. Without protective algorithms, lasting high-frequency interference can result in continuous, inadequate triggering of ventricular pacing or inadequate inhibiting. For that reason, modern pacemakers switch to the asynchronous VOO mode after reaching a certain rate limit (the exact rate limit is manufacturer-specific) in order to prevent asystole or tachycardia. Previously published results concerning the disturbing influences of electromagnetic alternating fields on pacemakers either referred to explanted pacemakers studied in vitro [1,2] or to individual studies on pacemaker patients with selected interference sources, such as anti-theft systems and cooking ranges [4,5].

The standardized method for simulating field exposure at the work place that has been presented in this study makes it possible to perform standardized case evaluations. This is necessary to enable decisions in individual cases on whether a pacemaker patient is at risk at his or her work place. In the case described above, the patient was able to resume his customary job as arc welder, as long as neither the ventricular sensitivity nor the pacemaker mode was changed. This case also highlights the importance of modern telemetry functions for evaluating the pacemaker function. Marker transmission allows direct monitoring of pacemaker function and clear identification of occurring disturbances.

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