European Journal of Radiology 83 (2014) 1387–1395

Contents lists available at ScienceDirect

European Journal of Radiology

journal homepage: www.elsevier.com/locate/ejrad

MRI with cardiac pacing devices – Safety in clinical practice

Touko Kaasalainen[a,b,*], Sami Pakarinen[c,1], Sari Kivistö[a,2], Miia Holmström[a,3], Helena Hänninen[c,4], Juha Peltonen[a,d,5], Kirsi Lauerma[a,6], Outi Sipilä[a,7]

[a] HUS Medical Imaging Center, Helsinki University Central Hospital, POB 340 (Haartmaninkatu 4), 00290 Helsinki, Finland
[b] Department of Physics, University of Helsinki, Finland
[c] HUS Department of Cardiology, Helsinki University Central Hospital, POB 340 (Haartmaninkatu 4), 00290 Helsinki, Finland
[d] Department of Biomedical Engineering and Computational Science, School of Science, Aalto University, Helsinki, Finland

ARTICLE INFO

Article history:
Received 11 February 2014
Received in revised form 8 April 2014
Accepted 13 April 2014

Keywords:
Magnetic resonance imaging
Cardiac pacemaker
Safety protocol

ABSTRACT

Objectives: The aim of this study was to introduce a single centre "real life" experience of performing MRI examinations in clinical practice on patients with cardiac pacemaker systems. Additionally, we aimed to evaluate the safety of using a dedicated safety protocol for these patients.
Materials and methods: We used a 1.5 T MRI scanner to conduct 68 MRI scans of different body regions in patients with pacing systems. Of the cardiac devices, 32% were MR-conditional, whereas the remaining 68% were MR-unsafe. We recorded the functional parameters of the devices prior, immediately after, and approximately one month after the MRI scanning, and compared the device parameters to the baseline values.
Results: All MRI examinations were completed safely, and each device could be interrogated normally following the MRI. We observed no changes in the programmed parameters of the devices. For most of the participants, the distributions of the immediate and one-month changes in the device parameters were within 20% of the baseline values, although some changes approached clinically important thresholds. Furthermore, we observed no differences in the variable changes between MR-conditional and MR-unsafe pacing systems, or between scans of the thorax area and other scanned areas.
Conclusion: MRI in patients with MR-conditional pacing systems and selected MR-unsafe systems could be performed safely under strict conditions in this study.

1. Introduction

The number of implanted cardiac pacemakers (PM) continues to grow in Western countries as pacing indications broaden and life expectancy increases. Enormous advancements in new technologies and comprehensive research ensure improved and more versatile device-based therapies for growing patient populations. Currently, more than two million patients worldwide have implanted PM devices [1]. At the same time, the utilisation of magnetic resonance imaging (MRI) as a non-invasive diagnostic tool is growing, especially in the diagnostics of central nervous system, abdominal and musculoskeletal disorders, tumours, and some cardiovascular diseases [2,3]. Estimates indicate that each patient with a PM or implantable cardioverter and defibrillator (ICD) has a 50–75% likelihood of showing a clinical indication for MRI over the lifetime of their cardiac device [4].

The presence of a cardiac pacing device has previously been considered an absolute contraindication for MRI, and thus served as grounds for excluding patients from MRI examinations. Concerns have been related to possible pacemaker-MRI interactions, which may, in the worst cases, lead to life-threatening situations [4–6]. The potential hazards of performing MRI on PM patients include interactions of pacing devices and their components with a strong magnetic field as well as gradient and radiofrequency fields. These interactions may increase the pacing rate, inhibit pacing, cause asynchronous pacing or induce random pacing rates [5,7–11]. MRI may also reset PM devices when the generator voltage drops below

* Corresponding author at: Tel.: +358 50 4272300; fax: +358 9 47171339.
E-mail addresses: touko.kaasalainen@hus.fi (T. Kaasalainen), sami.pakarinen@hus.fi (S. Pakarinen), sari.kivisto@hus.fi (S. Kivistö), miia.holmstrom@hus.fi (M. Holmström), helena.hanninen@hus.fi (H. Hänninen), juha.peltonen@hus.fi (J. Peltonen), kirsi.lauerma@hus.fi (K. Lauerma), outi.sipila@hus.fi (O. Sipilä).
[1] Tel.: +358 50 4271092.
[2] Tel.: +358 50 4270877.
[3] Tel.: +358 50 4270553.
[4] Tel.: +358 50 4279865.
[5] Tel.: +358 50 4272921.
[6] Tel.: +358 50 4270621.
[7] Tel.: +358 50 4270807.

http://dx.doi.org/10.1016/j.ejrad.2014.04.022
0720-048X/

a critical preset level determined by the manufacturer [10–12]. In addition to changes in pacing rates and power-on-resets, current may be induced to the pacing leads and discharge heat into the myocardium. This heat may then produce scar tissue in the myocardium around the lead tips, altering the capture thresholds and thus impairing the function of the pacing device [7,8]. However, because of the increasing prevalence of cardiac pacing systems and the high frequency of clinical indications and needs for MRI, cardiac pacing device manufacturers have recently introduced MR-conditional (devices are always classified according to the MR task group of the American Society for Testing and Materials (ASTM) International to either to be as MR-safe, MR-conditional, or MR-unsafe) PM and ICD systems which permit safe MRI scans under certain imaging conditions [13–16]. In addition, valuable clinical information from MRI examinations is needed for treating patients with MR-unsafe pacing devices. Thus, despite the potential for some adverse outcomes, patients with MR-unsafe PMs and ICDs have been scanned in some hospitals using particular precautions [7–12,17–26]. According to these studies and the recently published guidelines of the European Society of Cardiology (ESC) [27], patients with a selected modern cardiac device can be scanned in MRI with an acceptable risk/benefit ratio even though the cardiac device bears no MR-conditional labels. Nevertheless, some of these studies have also reported changes, though mainly clinically irrelevant, in pacing capture threshold, lead impedance and battery voltage after MRI [7–9,11,17–22,28]. Additionally, some studies have also reported the transient and reversible "power-on" resetting of the devices, magnet-mode pacing and frequent premature ventricular contractions with no adverse consequences for the patient or for device function [8,10–12,17].

The literature offers several different proposed MRI safety protocols for MRI examinations of patients with cardiac pacing devices [8,9,18,23,24,27]. These protocols show considerable differences, as some centres have excluded pacemaker-dependent patients and patients with ICDs, whereas others have imposed limitations on scanning body regions or have restricted specific absorption rate (SAR) values. The aim of this study was to introduce and evaluate our broader safety protocol for performing MRI examinations of patients with different cardiac pacing devices, including bradycardia PMs, ICDs and CRTs (cardiac resynchronisation therapy device), and to summarise our "real life" experiences of scanning these patients.

2. Materials and methods

2.1. Developing a safety protocol

The safety protocol was developed in close co-operation between the Departments of Cardiology and Radiology in the autumn of 2011 after an increase in the demand for MRI in patients with different pacing devices. The multiprofessional safety group comprised cardiologists, radiologists, physicists and radiographers. The protocol incorporated common elements from the protocols in the published literature [8,9,18,23,24,27] and was accepted by the Departments of Radiology and Cardiology. The accepted protocol involved procedures for both MR-conditional and MR-unsafe cardiac pacing devices and imposed no limitations on patients' dependency on pacemakers or the body regions to scan. The safety protocol was introduced to personnel (including radiologists of all sub specialists) in several meetings in order to implement it into the clinical practice.

The safety protocol and step-by-step procedures appear in Figs. 1 and 2 and are described below. Each patient was evaluated separately and processed according to the protocol. We performed no emergency MRI examinations.

2.2. Patient selection

We performed 68 consecutive MRI examinations for 64 patients with pacing devices at the Helsinki University Central Hospital, Finland, between November 2011 and May 2013. The local institutional review board approved the study, and the patients provided their written informed consent prior to MRI.

After receiving a referral from a requesting physician, a radiologist evaluated the need for an MRI study. If alternative imaging techniques (e.g. ultrasound or CT) could provide similar information at less risk to the patient, MRI was avoided. However, when MRI was considered necessary and the preferred imaging modality for the patient, the referral was sent to the Department of Cardiology, where a cardiologist evaluated the feasibility of performing MRI for the patient. If the patient was known to have abandoned or non-fixated leads, MRI was never performed. Additionally, when the pacing device was manufactured before 2000, MRI was only seldom performed. A cardiologist added to the patient's electric medical records (EMR) the imaging decision, the type of pacing device and leads, as well as the patient's dependency on the pacemaker. After the cardiologist's evaluation, the referral was sent back to the Department of Radiology, where a department secretary assigned an examination time for the patient for at least six weeks after the PM installation and informed the referral unit, the pacemaker policlinic, and the radiologists and physicists of it.

2.3. Device interrogation and programming prior to MRI

On the day of the MRI examination, the patient entered into the pacemaker policlinic, where a cardiologist recorded device parameters, especially lead impedances and capture thresholds, sensing signal amplitudes, and battery voltage. No MRI would have been performed if the patient showed any evidence of inadequate pacemaker function. When needed, we assessed the patient's dependency on the PM with transient inhibition of pacing. The pacing mode was programmed to monitor-only (OAO/OVO/ODO) for non-PM-dependent patients in order to avoid MRI-induced competitive pacing and possible proarrhythmias. Furthermore, the pacing mode was programmed to asynchronous (AOO/VOO/DOO) for patients with no stable intrinsic rhythm. Additionally, since asynchronous pacing mode yields a constant pacing rate, patients participating in cardiac MRI (CMR) were normally programmed to that mode. Whenever possible, we disabled all other pacing functions, including the magnet rate, premature ventricular complex, noise, ventricular sense, and conducted atrial fibrillation responses. The ICDs were programmed to therapy-off mode to avoid delivering therapy as a result interpreting noise as tachyarrhytmia. Furthermore, we programmed the MR-conditional systems according to the instructions of the pacing device manufacturers. We added the device settings and parameters to the patient EMR.

2.4. MRI scanning and patient monitoring during MRI

Before scanning, radiographers checked the EMR system to ensure that the patient had visited the pacemaker policlinic and that the pacemaker was programmed for the MRI. Whenever the patient had an MR-unsafe PM or ICD system, a cardiologist participated in the MRI examination. Otherwise, the patient arrived alone to the radiology department and returned after the examination to the pacemaker policlinic for reprogramming. We updated the safety protocol after 61 patients, at which point the cardiologist typically stopped following the MRI scanning in the radiology department, but remained available by phone in case of an emergency, whereas the radiologist continued monitoring the patient's heart rhythm.