CORRESPONDENCE

MRI in Patients With Pacemakers: Overview and Procedural Management

by Dr. med. Henning Bovenschulte, Dr. med. Klaus Schlüter-Brust, Prof. Dr. med. Thomas Liebig, Prof. Dr. med. Erland Erdmann, Prof. Dr. med. Peer Eysel, PD Dr. med. Carsten Zobel in volume 15/2012

Two Further Aspects

The warming of electrode tips depends materially on the magnetic field intensity of the MRI scanner. Critical lead length with particularly intense warming are about 50 cm for a magnetic field intensity of 1.5 tesla and about 25 cm for 3 tesla, but these depend on different parameters (1–3). In spite of higher specific absorption rate (SAR) values of identical sequences, a lesser degree of radio frequency (RF)-induced warming was measured in vitro for 3 tesla than for 1.5 tesla (3). Combined with an transmit-receive head coil, in which RF fields are restricted to the head, patients with pacemakers can benefit from the advantages offered by MRI scans of the cerebrum at 3 tesla (2). This has been our standard procedure since 2008 in cases with an appropriate clinical indication.

The authors report on about an MRI-compatible pacemaker system and similar systems. This statement in this form is dangerous and requires clarification. The standards E-DIN 6877-1 and ASTM F2503-8, which form the basis for the CE certification, contain only the terms “MR-safe”, “MR-conditional”, and “MR-unsafe”.

The MRI-compatible pacemaker systems mentioned by the authors are all MR-conditional, which means that they should be exposed to MRI scanning only within the context of precisely defined restrictions. In this aspect, MR-conditional pacemaker systems from different manufacturers vary widely (exclusion/inclusion of thorax region, maximum permitted SAR value of MRI sequences, type of patient monitoring, and others). All these limitations have to be known for MR-conditional pacemakers, in order for MRI scans to be performed only within the limitations imposed by the manufacturers.

Even though the rates of complications in published studies have been low, MRI scans in patients with “conventional” (MR-unsafe) pacemakers or implantable cardioverter/defibrillators (ICD) should continue to be provided only at centers with proven expertise and under stringent safety precautions.

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Conflict of interest statement

Dr Nähle has received travel and hotel expenses, honoraria for conducting commissioned clinical studies, and funding for a research project initiated by him, from Medtronic.

Dr Luchinger has received honoraria for acting as an adviser, conference participation fees, travel and hotel expenses, and honoraria for conducting scientific medical educational events, as well as funding for a research project initiated by him from Medtronic.

Special MRI-Compatible Leads

Two device manufacturers (Medtronic, St Jude Medical) developed special pacemaker systems to avoid thermal injuries due to induced electrical potentials under MRI. Their underlying active principles differ, however. For clinical practice this means that only leads and pacemaker aggregates from the same manufacturer should be implanted. The feasible combination of leads and devices from different manufacturers leads to a loss of MRI-compatibility in every case. Thus far, only specially designated pacemaker systems from Medtronic and St Jude Medical are licensed for unlimited MRI scans with a magnetic field intensity of up to 1.5 tesla. According to the manufacturer's own information, the Biotronik devices marked as “Pro MRI” should also be combined only with Biotronik Pro-MRI leads (without special conduction algorithms), but they are not suitable for MRI scanning of the thorax or abdomen.

In spite of individual MRI scans in patients with pacemakers that remained uneventful, doctors should be warned against uncritically adopting this practice. I was asked to assess the complete failure of a defibrillator with resynchronization function (CRT-D) as a result of an accidental MRI scan of the head. Another serious criticism relates to one manufacturer's practice of marketing ICD systems as MRT-compatible when the ICD leads were not actually specially developed for this purpose but were still marked “Pro-MRI.” Observations of individual MRI scans among ICD patients that are not backed up by relevant study results (a prerequisite for gaining licensing approval in the US) are not sufficient in order to classify these ICD systems as MRI-compatible as long as the trunk is excluded.

In general, all pacemaker or ICD patients should be informed individually about the MRI-compatibility of their system and potential limitations, and this might be documented in the pacemaker passport.

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The author has held contracts as an adviser to Medtronic, Biotronik, and St Jude Medical. He has received conference delegate fees, travel expenses, and hotel expenses, as well as honoraria for preparing medical educational events from Medtronic, St Jude Medical, and Biotronik, and is in receipt of external funding from Medtronic, St Jude Medical, and Biotronik.

In Reply:

We thank our correspondents for their valuable suggestions and additional points. They underline again the intention of our review article, which was to make it clear that MRI scans are no longer absolutely contraindicated in patients with pacemakers, but that for every individual case, a decision will have to be made about whether the potentially serious risks are balanced out by a corresponding benefit for the patient. The complexity of such a risk assessment arises materially from the multitude of available pacemaker systems and probes and their possible combinations. Dr Hansky rightly reminds us that when using technically possible combinations of MRI-compatible aggregates with non-MRI-compatible probes or MRI-compatible probes

from another manufacturer, the licensing approval for the complete system for conducting MRI scans is void. This also underlines the need for specialist cardiological consultations and monitoring even of patients with presumably MRI-compatible systems before they undergo an MRI scan.

We thank Dr Nähle and Dr Lühinger for their helpful addendum relating to the use of 3 tesla in combination with restricted RF fields to the head when investigating the cerebrum, as well as their detailed explanation of the relevant terminology used in the context of CE certification of pacemakers.

The contributions from Dr Hansky as well as from Dr Nähle and Dr Lühinger also underline the position we took in our article, that MRI scans in patients with pacemakers should be conducted only at experienced centers and under stringent safety precautions. This also applies for the new MRI-conditional pacemaker systems.

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Dr Zobel has received conference delegate fees and travel expenses from Medtronic, Pfizer, and Lilly. Furthermore he has received honoraria for preparing medical educational events from St Jude Medical, Medtronic, Bayer, and Boehringer Ingelheim.

Dr Bovenschulte declares that no conflict of interest exists.