LETTERS TO THE EDITOR

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Comments on ‘Safe magnetic resonance image scanning of the pacemaker patient: current technologies and future directions’

We read with great interest the article by Dr Jung et al.1 regarding current technologies and future directions of magnetic resonance imaging (MRI) in pacemaker patients. We agree with the authors that MRI in pacemaker patients is an area of increasing clinical relevance due to the quickly increasing numbers of both pacemaker/implantable cardioverter-defibrillator patients, and MR scans performed.

We would like to comment on three aspects addressed in the current article: First, the assembly of devices listed in the ‘safety protocol for performing MRI in patients implanted with conventional devices’ reproduced from Drs Nazarian and Halperin,2 is, in our opinion, questionable. Announcing ‘satisfactory previous MRI testing’ in these devices does not seem to conform with good scientific practice, as the rational for this designation has never been adequately justified by investigations published in the peer-reviewed literature. From own spot test investigations in several devices, our group found at least one of these devices to be very vulnerable to electric interactions with the MRI, ultimately leading to device malfunction (Kappa 701®). Due to the very complex subject matter of the safety of medical devices in the MR scanner, testing/operating terms and conditions should always be clearly specified, and vague or even exaggerating wording should be strictly avoided to rule out unnecessary patient risks.

Secondly, we would like to reinforce the position of the authors of the article, that the decision of whether or not an MRI should be performed on a patient with an implanted medical device, should always be made in a thorough individual consideration of the anticipated values and risks. This on the other hand makes a high specific expertise of the account-able physician a prerequisite, as not only virtually innumerable variables in the patients and implanted devices exist4-9 but there are also many variables in the MRI surrounding and imaging sequences, which affect patient risks in a positive or negative way.10-12 Vice versa, a substantial number of techniques are at hand for experienced investigators, which can be used to further define, limit, or even eliminate the latter.9,10 This again strengthens the viewpoint, that patients with implanted non-MR-conditional medical devices requiring an MRI should preferably be scanned in specialized, experienced centres.

Finally, in the interest of company independence, it should be pointed out, that the SureScan/Revo MRI pacemaker system (Medtronic) is not the only system on the market which has obtained official accreditation for use in the MRI in Europe, but similar devices from the competitors, namely Biotronik (ProMRI) and St Jude (Accent MRI), have also become freely available several months ago.

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References

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Safe MRI scanning of the pacemaker patient: current technologies and future directions. Reply to the Letter by Dr Nordbeck, Dr Bauer, and Dr Ritter

We thank Dr Nordbeck, Dr Bauer, and Dr Ritter for their interest in our manuscript ‘Safe MRI Scanning of the Pacemaker Patient: Current Technologies and Future Directions’. The protocol published by Nazarian and Halperin1 and summarized in our article is meant to illustrate one reasonable algorithm for minimizing the risks associated with scanning patients with conventional devices. It is important to emphasize that, as stated in the article, this protocol is used at a single institution and, while based on the authors’ careful analysis of the risks of magnetic resonance imaging (MRI) in patients with various implantable cardiac arrhythmia devices, has not been subjected to rigorous, double-blind analysis to assess its impact on the safety of scans, nor—as Dr Nordbeck and colleagues note in their letter—does Nazarian’s characterization of certain devices as having ‘satisfactory previous MRI testing’ ensure that scanning these devices
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is indeed safe for all patients under all conditions. In our publication, the algorithm also served as an illustration of the complexities associated with scanning patients with conventional implantable devices.

As noted in the article, the US guidelines for safe MRI scanning summarize what we view as reasonable parameters for scanning patients with conventional pacemakers/implantable cardiac devices, including documentation of informed consent, careful analysis of the risks and benefits of treatment, provision of specialized personnel and emergency medical equipment, monitoring during the procedure, and appropriate follow-up. Both the US and European guidelines currently limit the use of MRI in patients with pacemakers to those with life-threatening or severely quality-of-life limiting conditions. The second point made by the authors of the letter bears repeating. It is quite clear that the safety of MRI scanning in patients with implanted medical devices is driven by a number of factors, including the device itself (ferromagnetic content, internal circuitry and switch design, lead geometry, and programming, among other factors), scan parameters (including, but not limited to, field strength), and—of course—individual patient parameters. Each must be taken into consideration regardless of whether the implanted device is an older device that is highly prone to electromagnetic interference, a newer conventional device, or an MRI-conditional device. Even in the case of MRI-conditional devices, appropriate caution is warranted. Each of the currently available MRI-conditional devices has clearly delineated requirements under which the scan may be safely conducted. These guidelines must be followed for optimal risk reduction.

The authors of the letter are entirely correct in indicating that, since the time this article was accepted for publication, several additional devices with features that are intended to enhance safety in the MRI environment have become available in Europe. In October 2011 the Accent MRI/Tendril MRI pacing system from St. Jude Medical (MI, USA) became freely available in Europe. This system allows full-body MRI scans (1.5 Tesla) with no zone restriction and a specific absorption rate of up to 4 W/kg. The Accent MRI pacemaker and Tendril MRI lead study, conducted under an investigational device exemption (IDE) from the US Food and Drug Administration (FDA), is a randomized, clinical trial assessing the safety and efficacy of the Accent MRI system in patients with standard bradycardia who are indicated for a pacemaker. A subset of patients will be randomized to receive an MRI after enrollment in the study. BIOTRONIK (Berlin, Germany) offers a variety of MRI conditional single and dual chamber pacemakers and a choice of MRI conditional leads which have Conformité Européenne (CE) accreditation. These implants can be identified by the additional wording ‘ProMRI’. On April 2012, BIOTRONIK introduced CE approved MRI conditional implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices, the Lumax series 740 (by Biotronik) and the Evia HF-T (by Medtronic). Non-clinical testing has demonstrated that the BIOTRONIK MRI conditional pacing, ICD and CRT systems are safe for use in the MRI environment when used according to the instructions in the manual. However, no clinical trials have been undertaken with these systems in patients. So far, the Revo MRI SureScan pacemaker system (Medtronic, MI, USA) is the only system on the market which has been tested in patients and has been approved by the FDA on February 2011. In conclusion, we entirely agree with the Nordbeck and colleagues’ comments. The advisability of MRI in patients implanted with non-MR-conditional devices must be considered on a case-by-case basis and with careful evaluation of the potential benefits and risks of the procedure. Newer MR-conditional devices, when used in accordance with the manufacturers’ instructions, have the potential to reduce both the risks and the burdens associated with this procedure.

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References

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