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REVIEW

Safe magnetic resonance image scanning of the pacemaker patient: current technologies and future directions

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Magnetic resonance imaging (MRI) is the imaging modality of choice in many clinical situations, and its use is likely to grow due to expanding indications and an ageing population. Many patients with implantable devices are denied MRI except in cases of urgent need, and when scans must be performed they are complicated by the need for burdensome and costly personnel and monitoring requirements that have the net effect of restricting access to scans. Several small studies, enrolling a total of 344 patients, suggest that some patients with conventional systems may undergo MR examinations without clinically overt adverse events. However, a number of potential interactions exist between implantable cardiac devices and the static and gradient magnetic fields and modulated radio frequency (RF) fields generated during MR scans; nearly all studies have reported pacing capture threshold changes, troponin elevations, ectopy, unpredictable reed switch behaviour, and other 'subclinical' issues with pacemakers and implantable cardioverter-defibrillators (ICDs) in patients who have undergone MRI. Attention has turned to devices that are specifically designed to be safe in the MRI environment. A clinical study of one such device documented its ability to be exposed to MRI in a 1.5 T scanner without adverse impact on patient outcomes or pacemaker system function. Such new technologies may enable scanning of pacemaker and ICD patients with reduced concerns regarding the short- and long-term effects of MRI. As importantly, these devices may increase the number of centres that are able to safely perform MRI and, thus, expand access to scans for patients with these devices.

Keywords Pacemakers • MRI • Safety • Implantable defibrillators

Introduction

Magnetic resonance imaging (MRI) has rapidly become the imaging modality of choice in many therapeutic areas as a result of its ability to provide superior soft tissue contrast without exposing patients to the risks associated with invasive procedures, ionizing radiation, or contrast agents. For these reasons, the use of MRI is likely to grow due to the confluence of expanding indications for its use and an ageing population with a corresponding increase in disease states that could benefit from MRI.[1–3]

Worldwide, ~5 million patients are implanted with a pacemaker or implantable cardioverter-defibrillator (ICD). As these patients are generally older and sicker than the general population, estimates suggest that these patients have between a 50 and 75% likelihood of having a clinical indication for MRI over the lifetime of the device.[1] In total, it has been estimated that ~200 000 patients with devices had an indication for an MRI scan in 2004.

As the majority of current implantable cardiac devices is not approved for use in the MR environment, many patients with implantable devices are excluded from MRI except in cases of urgent need. Current US guidelines for safe MRI scanning strongly discourage MR examination of pacemaker and ICD patients, except in cases of urgent need.[4] Similarly, current European guidelines for safe MRI indicate that patients should have life-threatening or 'severely quality-of-life- limiting' conditions.[5] In both guidelines, exceptional scans can be performed under stringent safety conditions with documentation of informed consent and careful analysis of the risks and benefits of treatment, provision of specialized personnel and emergency medical equipment, monitoring during the procedure, and extensive follow-up.

The conditions imposed by current guidelines are burdensome and costly, and have the net effect of dramatically restricting access to a potentially beneficial diagnostic modality in a clinically important patient population. Several questions must be asked: first, what do

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Table 1 Indications for MRI in patients with pacemakers/implantable cardiac defibrillators[a]

Patient group	European recommendation	US recommendation
Pacemaker-dependent patients (very high risk)	If underlying rhythm is too slow, reconsider indication. The threshold for imaging and safety requirements are higher, but no absolute contraindication	MRI should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks
ICD patients (non-dependent) (high risk)	The patient must have a documented, extremely serious, life-threatening, or severely quality-of-life- limiting condition	MRI should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks
Pacemaker patient (non-dependent) (low risk)	The patient must have a documented, very serious, life-threatening, or severely quality-of-life-limiting condition	MRI is discouraged and should only be considered in cases in which there is a strong clinical indication and in which the benefits clearly outweigh the risks

ICD, Implantable cardiac defibrillators; MRI, magnetic resonance imaging.
[a]Data from Levine *et al.*[4] and Rougin *et al.*[5]

current guidelines say about safe MRI in the pacemaker patient? Second, do these guidelines represent an overreaction based on current data? Third, what can we do to ensure safe scans in patients implanted with current devices? Fourth—and finally—what is the role of new MRI-conditional technologies in the context of the current clinical environment? This review will explore each of these issues.

What do current guidelines say about safemagnetic resonance imaging?

Recommendations exist to guide MRI scanning in patients with pacemakers and ICDs. In general, both US and European guidelines do not impose absolute contraindications against MRI. The European guidelines strongly recommend against MRI in pacemaker patients, except in situations where the patients have a documented extremely serious, life-threatening, or 'severely quality-of-life-limiting' condition (*Table 1*).[5] Similarly, the American Heart Association (AHA) guidelines indicate that MRI examination of non-pacemaker-dependent patients is discouraged, except in cases with a strong clinical indication and in which the benefits clearly outweigh the risks.[4] Among pacemaker-dependent patients and those with ICDs, MRI examination is generally not recommended except under highly compelling circumstances.

Both sets of guidelines impose stringent monitoring requirements. In the European guidelines an advanced cardiac life support-certified health-care provider must be present during the entire exam to monitor the patient and perform cardiac life support if needed.[5] A cardiologist and a pacemaker/ICD programmer should be present during the scan. Monitoring requirements include electrocardiogram (ECG), pulse oximetry, and in some cases non-invasive blood pressure measurement and breathing sensors. A crash cart with an external defibrillator-pacemaker must be present during the scan. Following examination of pacemaker patients, a physician with electrophysiology experience should interrogate the pacemaker and reprogram as needed.[4] In patients with ICDs, the physician should perform post-scan device reprogramming and defibrillation threshold testing.

Are we overreacting to potential hazards?

Questions remain regarding whether safe scans can be conducted in patients implanted with current devices. Several small studies have been published concerning newer conventional pacemaker systems; these reports suggest that some patients may undergo MR examinations without clinically overt adverse events and, potentially, without burdensome monitoring requirements.

In a report by Martin *et al.*,[6] 54 non-pacemaker-dependent patients underwent a total of 62 MRI examinations at 1.5 T. Restrictions were not imposed on the type of pacemaker present in the patient, nor were limitations placed on the type of MRI examination. Scans included cardiac, vascular, and general MRI studies using a range of whole-body averaged specific absorption rates (SARs). Overall, a total of 107 leads and 61 pulse generators were evaluated. No overt adverse events occurred in this study. In a second study conducted by Sommer *et al.*,[7] 82 pacemaker patients underwent a total of 115 MRI examinations at 1.5 T; radiofrequency (RF)-induced lead heating was minimized by limiting the specific absorption rate to 1.5 W/kg. As in the Martin study, all MR examinations were completed safely. Similarly, in a third study conducted by Nazarian *et al.*[8] in 55 patients (of whom 31 had permanent pacemakers and 24 had ICDs), again, there were no overt clinically relevant adverse events. In a recent study conducted by Mollerus *et al.*,[9] scans were successfully completed in 52 non-pacemaker-dependent patients with no immediate adverse effects.

Several additional small studies have evaluated safety at low field strength (0.5 T) with no serious clinical repercussions.[7,10,11]

Potential adverse events associated with magnetic resonance imaging

It is worthwhile to note that only about 1500 scans of patients with pacemakers or ICDs have been reported in the literature in any form,[12] far too few to completely allay concerns about MR scans in patients implanted with conventional devices. Many of these

reports consist of very small series and case reports. At the time of this writing, well-designed clinical studies reported in reputable venues have included a grand total of 344 patients, of whom 81 were studied at a field strength of 0.5 T,[7,10,11] 13 at a field strength of 2.0 T,[13] and 250 at a field strength of 1.5 T.[6,8,9,14,15]

A number of potential interactions exist between implantable cardiac devices and the static and gradient magnetic fields and modulated RF fields generated during MR scans, including mechanical forces on ferromagnetic components, RF-induced heating of leads, unintended cardiac stimulation, interference with pacemaker function, and electrical reset.

Force and torque on the implanted device is a concern that has been reduced due to the lower ferromagnetic content of current pacemakers. Studies conducted at 1.5 T found that the force in pacemakers and ICDs at this field strength ranges from 0.05 to 3.6 N and 1.0 to 5.9 N.[16] Notably, the amount of force generated at 1.5 N was dependent upon not only on the amount of ferromagnetic material employed in the design of the device, but also the year the device was manufactured. These data illustrate the considerable advances that have been made in conventional pacemaker design over the last decade.

Increases in pacing capture thresholds—attributable to heating of pacemaker leads during MRI—are common enough to be potentially clinically significant. *In vitro* temperature increases of up to 63.1°C have been observed at a field strength of 1.5 T; animal studies have demonstrated increases of up to 20.8°C at 1.5 T.[17,18] In the study conducted by Martin *et al.*,[6] 40 (37%) leads had pacing threshold changes, and 10 (9.4%) leads underwent significant change (defined as a change >1 voltage or pulse−width increment or decrement). Two leads required a change in programmed output.

In the Sommer study, scans were conducted with significant precautions against RF-induced heating, including limiting the specific absorption rate to <1.5 W/kg, and excluding anatomic regions with full coverage of the pacemaker lead loop, including the thoracic spine, heart, and breasts.[15] The total active scan time was also limited to 30 min. Despite these precautions, cardiac troponins were increased in 4 of 114 examinations; in one case these increases were associated with a significant increase in pacing-capture threshold.[15] Pacing-capture threshold changes ≥1.0 V were identified in six cases, and statistical analysis showed that there was a significant increase in pacing-capture threshold from pre- to post-MRI ($P = 0.017$). Possible long-term effects of scanning were observed in two cases, in which increased pacing-capture threshold was not detected until the 3 month follow-up. These changes were considered likely to be related to scar tissue development around the lead tips as a result of RF-related thermal injury.

The behaviour of reed switches (open or closed) and the pacemaker (synchronous or asynchronous) in conventional devices are often not predictable in the strong static magnetic field of the MR device. This has potentially important implications, particularly in the pacemaker-dependent patient. The state of the reed switch in various orientations and positions in the magnetic fields of 0.5, 1.5, and 3.0 T was evaluated by Luechinger *et al.*[19] When oriented parallel to magnetic fields, reed switches closed at 1.0 ± 0.2 mT and opened at 0.7 ± 0.2 mT. In low magnetic fields (<50 mT), reed switches were closed and in high magnetic fields (>200 mT), reed switches opened in 50% of orientations. These data are supported by the results of the Sommer study, in which the reed switch remained inactivated in 44.7% of patients.[15]

Electrical reset, an emergency safety feature that guarantees minimal pacemaker function in the case of battery voltage dips, has been demonstrated to occur in patients with implanted devices subjected to MRI. Electrical reset presents an important safety hazard for two reasons. First, if reset occurs concomitant with an open reed switch, bradycardia/asystole may occur in patients with low intrinsic heart rates as a result of inhibition of pacemaker output by time-varying gradient fields. Second, the default pacing mode may not provide adequate functionality for some patients.[5] In the study conducted by Sommer *et al.*,[15] post-MRI interrogation showed that electrical pacemaker reset occurred in 7 (6.1%) examinations. In all cases, however, the pacemaker could be reprogrammed to the parameters used prior to the MRI scan.

Ectopy has been reported in patients with pacemakers and ICDs. In a study conducted by Mollerus *et al.*,[9] 52 non-pacemaker-dependent patients with a total of 119 leads underwent 59 MRI scans of any landmark. Scans were conducted using usual protocols with standard peak-specific absorption rates for the scan. Both telemetry and pulse oximetry plethysmographic waveform were observed throughout the scans for ectopy. Seven patients had ectopy observed either on telemetry or on observation of the oxygen saturation plethysmographic waveform. According to the investigators, ectopy was likely due to normal device noise-rejection behaviour.

Solution: a protocol for performing safe magnetic resonance imaging in patients with conventional devices

Nazarian and colleagues recently published the safety protocol used in their institution to improve safety in patients with pacemakers and ICDs (*Figure 1*). The authors recommend that device generators prone to electromagnetic interference (generally older devices), as well as patients with leads that are prone to movement (e.g. patients with <6 weeks time since device implant and those with no fixation), be excluded. Scanning should also be avoided in patients with device leads that are prone to healing (e.g. non-transvenous epicardial and capped leads), and pacemaker-dependent patients with ICDs.

The authors suggest programming to an asynchronous, dedicated pacing mode in pacemaker-dependent patients to reduce the risk of inappropriate inhibition of pacing due to detection of radiofrequency pulses. To avoid inappropriate activation of pacing in non-pacemaker-dependent patients, the authors suggest programming to a non-tracking ventricular or dual-chamber inhibited pacing mode and deactivation of rate response, premature ventricular contraction response, ventricular sense response, and conducted atrial fibrillation response to ensure that sensing of vibrations or radiofrequency pulses does not lead to unwarranted

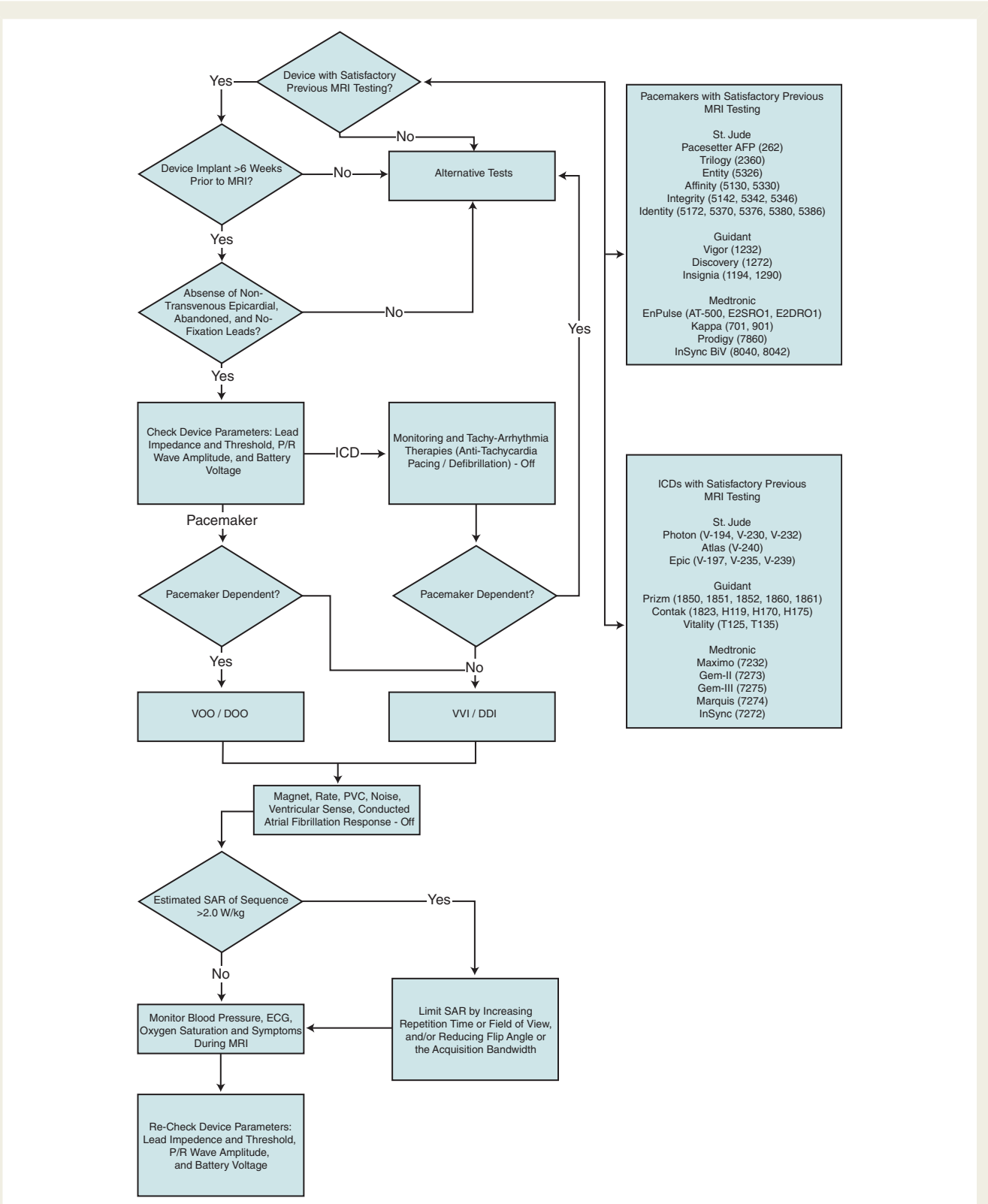

Figure 1 A safety protocol for performing MRI in patients implanted with conventional devices. Reproduced from Nazarian and Halperin.[20] ECG, electrocardiography; MRI, magnetic resonance imaging; PVC, premature ventricular complex; SAR, specific absorption rate.

pacing. When possible, asynchronous pacing is minimized in non-pacemaker-dependent patients through deactivation of the magnet mode. The authors also usually deactivate tachyarrhythmia monitoring to avoid battery drainage due to recording of multiple RF pulse sequences as arrhythmic episodes. Because reed-switch function can be unpredictable during MRI, therapies should be

disabled to avoid unwarranted antitachycardia pacing or shocks. Finally, to reduce the risk of thermal injury and changes in lead threshold and impedance, the authors recommend limiting the estimated whole-body, averaged specific absorption rate of MRI sequences to <2.0 W/kg.

The protocol also has provisions for extensive monitoring during MRI. Blood pressure, ECG, pulse oximetry, and symptoms should be monitored for the duration of the examination. A radiologist and cardiac electrophysiologist (or an individual trained in advanced cardiac life support familiar with device programming and troubleshooting) are present at all scans. At the end of the examination, all device parameters should be checked and programming should be restored to pre-MRI settings.

Another solution: can we be magnetic resonance imaging safe by design?

While it appears that MRI scans can be performed in some device patients without immediate clinical consequences, a sufficient number of patients have not yet been evaluated using these protocols, nor has there been sufficient long-term follow-up to determine if there are long-term effects on outcomes. Moreover, these protocols limit scans to centres with substantial experience in this patient population, effectively limiting access to MRI for a substantial percentage of the population.

Recently, attention has turned to devices that are 'safe by design'. These devices have extensive design modifications to improve MRI compatibility. One such system includes a heavily modified pulse generator (EnRhythm MRI SureScan) and leads (CapSureFix MRI leads) that together are designed specifically to mitigate the potential hazards associated with MR scans. Design modifications to the device and leads include (i) modification of the leads to reduce the potential for radiofrequency lead-tip heating; (ii) revision of the internal circuitry to reduce the potential for cardiac stimulation; (iii) reductions in the amount of ferromagnetic materials in the device; (iv) changes to internal circuit protection to prevent disruption of the internal power supply; and (v) replacement of the reed switch with a Hall sensor to improve predictability in static magnetic fields.[21] In addition, a dedicated programming care pathway was developed to facilitate the choice between asynchronous vs. non-stimulation modes, increase the pacing output to 5.0 V/1.0 ms during MRI scanning, prevent programming to the MRI mode in the absence of positive system-integrity checks, and simplify restoration of pre-scan program states and values.

Initial clinical experience with the 'SureScan' system compared with conventional dual-chamber devices was reported in 2010 in a small, single-centre feasibility study.[22] In this study, 107 consecutive patients were implanted with either the MRI-compatible device or a conventional dual-chamber, active-fixation lead, non-MRI system. Implantation success was 100% for both groups; lead cephalic and subclavian access were 63.0 and 37.0%, respectively, for MRI patients and 70.2 and 29.8%, respectively, for those with the non-MRI system; subclavian vein puncture was required to place at least one lead in 40% of MRI patients and 31.6% of conventional-system patents. There was a non-significant trend towards shorter procedural times with the conventional system. No complications were observed at a median follow-up of 6.8 months.

The EnRhythm device was recently evaluated in a large-scale, prospective, multicentre, randomized study published in 2010.[21] In this study, patients were enrolled who met Class I or II dual-chamber, pacemaker-implant indications according to current American College of Cardiology (ACC)/AHA/Heart Rhythm Society (HRS) guidelines; patients could be pacemaker-dependent or non-pacemaker-dependent. Following successful implant, patients ($N = 464$) were randomized to undergo an MRI scan between 9 and 12 weeks post-implant or not to undergo MRI. Clinical evaluation of pacemaker-system function was conducted immediately before and after the scan and at 1 week and 1 month post-MRI. The primary study end points were the MRI procedure complication-free rate and capture and sensing performance between the MRI and control groups.

A total of 464 patients were randomized after successful implantation; of these, 211 patients underwent MRI and completed the 1 month post-MRI visit. The complication-free rate was 100% (e.g. no patient experienced MRI-related complications). No inhibition of pacemaker output, asystole, sustained ventricular arrhythmias, unexpected changes of heart rate, or electrical resets occurred during MRI. At 1 month following MRI scanning, the expected rate of pacemaker system-related complications was expected to be 80% and was measured to be 91.7% ($P < 0.001$ vs. the expected rate). System-related complications at 1 month included lead dislodgement ($n = 17$), elevated capture thresholds ($n = 9$), pericardial effusion ($n = 3$), and failure to capture ($n = 3$). None of these complications were judged related to the scan. Notably, there were no differences between the MRI and control groups in the proportions of patients who experienced an increase in pacing capture threshold, the proportion of patients who maintained the sensed electrogram amplitudes above 1.5 mV (atrial) or 5 mV (ventricle), and there were no differences between the two groups in impedance results.

It is important to note that this study examined an 'MRI-conditional' scenario in that the static magnetic field strength was limited to 1.5 T, with a maximum specific absorption rate value of 2 W/kg for each sequence and a maximum gradient slew rate of 200 T/m/s. The position of the isocentre of the RF transmitter coil was required to be above the superior surface of the C1 vertebra or below the inferior surface of the body of T12. No conclusions can be drawn from this study about the safety of scans conducted between these landmarks; however, these restrictions still permit scanning of the complete cervical region and most of the thoracic region by widening the field of view.

As noted previously, conventional pacemakers are associated with cardiac myocardial injury even when used under carefully controlled conditions as indicated by increases in troponin I levels and increases in pacing capture thresholds. This study is notable in that only one increase in pacing capture threshold was observed (0.2%), compared with 3.1% in the study by Sommer *et al.*[15] and 9.4% in the report published by Martin *et al.*[6] Although neither of these trials demonstrated immediate clinical implications associated

with this damage, it is reasonable to assume that such damage may influence intermediate- and long-term outcomes. These data suggest that the design of the MRI-conditional system has the potential to dramatically reduce the incidence of subclinical myocardial injury, although the longer-term implications of this effect remain to be described.

Conclusions

The current literature suggests that MRI scans can be conducted safely in patients with conventional ICDs. However, it is important to note that only about 1500 scans have been reported in the medical literature;[12] of these, prospective clinical studies designed specifically to assess the safety of MRI in this patient population have included a total of 344 patients, of whom a significant percentage were evaluated at 0.5 T. To consider a drug, device, or procedure 'safe' after successful scans in 344 patients conducted in centres with considerable expertise is a considerably lower standard than is usual in medicine and is unlikely to reflect the rates of complications in real-world clinical practice.

Moreover, while all scans were completed without overt clinical adverse events occurring during the scan or during follow-up periods of up to 6 months, potentially clinically relevant changes in pacemaker/ICD and lead function—including changes in pacing capture threshold, increases in cardiac troponin levels, electrical reset, changes in battery voltage, and unpredictable reed switch behaviour—were observed in all studies.

As a result of these concerns, labelling of conventional devices is conservative and cautions physicians against the use of MRI. An editorial, written on behalf of the US Food and Drug Administration (FDA), indicates that 'while the FDA recognizes that there are pacemaker and ICD patients for whom, on a case-by-case basis, the diagnostic benefit from MRI outweighs the presumed risks . . . those risks have not yet been characterized and mitigated sufficiently to justify the routine use of MRI examination in those populations'.[23]

New technologies may enable scanning of pacemaker and ICD patients with reduced concerns regarding the short- and long-term effects of MRI. These devices may increase the number of centres that are able to safely perform MRI and thus expand access to scans for patients with these devices. Furthermore, burdensome monitoring requirements may be reduced after sufficient real-world clinical expertise has been gained with MRI-conditional devices, expanding access and reducing the costs of scanning these patients. It must, however, be emphasized that these devices have been adequately evaluated only at field strengths of up to 1.5 T and—as 3.0 T MR scanners come into broader use—there is an urgent need to evaluate the safety of scanning these devices at higher field strengths. Given the acknowledged value of MRI in a broad range of therapeutic areas—as well as the increasing number of pacemaker/ICD patients who could benefit from MRI—it is clear that new technologies that can improve the safety of scans are to be welcomed.

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