Editorial

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Magnetic Resonance Imaging for Patients with Cardiac Implantable Electronic Devices: Reduced Concerns Regarding Safety, but Scrutiny Remains Critical

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Magnetic resonance imaging (MRI) enables high resolution investigations of soft tissues without the use of ionizing radiation. For this reason, MRI is currently the imaging modality of choice for diagnosing neurologic, musculoskeletal, and cardiovascular disease. However, MRI has long been considered a contraindication in patients with cardiovascular implanted electronic devices (CIEDs) such as cardiac pacemakers and cardioverter defibrillators, because the magnetic resonance (MR) field may interact with the device with catastrophic consequences, leading to severe complications and even death.[1] With the growth of aging population and new indication for device implantation in patients with heart failure or arrhythmia, the number of patients with CIEDs has also increased,[2] and the estimated probability of such a patient being indicated for MRI over their lifetime is 50-75%.[3] Therefore, it is important to understand the potential risks associated with MRI in patients with CIEDs and develop strategies to minimize such risks in the current context of technological advancement.

MR-conditional CIEDs, which represent devices demonstrated to pose no known hazards in a specified MRI environment and conditions of use, have been developed in an effort to help the increasing number of patients with CIEDs benefit from the advantages of MRI diagnostic investigations. Since their first introduction to the European Union in 2008, MR-conditional CIEDs have become the standard care for patients indicated for cardiac device implantation. The current recommendation is that MRI can be performed in patients with MR-conditional CIEDs if the magnetic field is under 1.5 T. This represents a moderate (class IIa) recommendation (evidence/opinion in favor of usefulness/efficacy rather than risk) based on level C evidence (consensus of expert opinion and/or small prospective, retrospective, or registry studies) according to the European Society of Cardiology (ESC) guidelines published in 2013,[4] and a strong recommendation based on moderate-quality evidence according to the Canadian Heart Rhythm Society and Canadian Association of Radiology consensus statement published in 2014.[5]

While the development of MR-conditional CIEDs has largely relieved the safety issues surrounding MRI use in patients with implanted cardiac devices, several problems remain to be addressed. First, a significant number of patients still carry non-MR-conditional CIEDs. Second, certain types of investigations require a magnetic field stronger than 1.5 T. Additional issues are of note, such as the inability to scan the thoracic area (MRI exclusion zone), artifacts caused by CIEDs that interfere with interpretation of the MRI scan, or concerns regarding the safety of repeated MRI.

A significant number of patients were implanted with non-MR-conditional CIEDs prior to the introduction of MR-conditional CIEDs. Because of the extremely unfortunate initial experience,[6] MRI has long been regarded as contraindicated in patients with non-MR-conditional CIEDs. However, accumulating evidence and increasing experience with MRI technology currently allow to perform MRI safely under a fairly broad range of conditions even in patients with CIEDs. The ESC recommended that when the benefit

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of undergoing MRI outweighs the potential risks, 1.5 T MRI can be performed in these patients with a low risk of complications, provided that appropriate precautions are taken.[4] The approach of the Canadian group is more conservative, considering that MRI is not routinely performed in patients with non-MR-conditional CIEDs. Therefore, the approach of the Canadian group does not constitute standard practice. However, in a clinical scenario where MRI might provide crucial information in the management of the patient's care, such a non-standard investigation may be allowed, with the understanding that it carries a risk of serious and potentially life-threatening complications.[5] Such allowance necessarily involves cooperation among the referring physician, cardiologist with expertise in CIED management, and MR radiologist.

According to the current guidelines, MRI can be performed in patients with CIEDs only using 1.5 T MR machine, because a higher field strength (>1.5 T) causes higher electromagnetic interference and local specific absorption rate (SAR). Electromagnetic interference may cause inhibition of pacing, asynchronous pacing, power-on-reset events, inappropriate tracking, inappropriate implantable cardioverter defibrillator therapies, and runaway pacing, resulting in potentially life-threatening ventricular arrhythmias.[1][7] Increased SAR is associated with higher risk of thermal injury.[8] Because SAR increases with the squared increase in magnetic field strength, using a magnetic field strength of 3.0 T instead of 1.5 T causes a four-fold increase in SAR, assuming other parameters are kept equal. By limiting the field strength to 1.5 T, it is ensured that patients with CIEDs experience SAR ≤2.0 W/kg during MRI. However, 3-T MRI is becoming increasingly used because it provides better image quality, shorter scan time, and better diagnostic strength, especially for the neurological, musculoskeletal, and abdominal imaging. While CIED manufacturer have recently released devices that are MR conditional in 3-T fields,[1] little information exists regarding the behavior of either MR-conditional of non-MR-conditional CIEDs during MRI performed at 3-T. Currently, 3-T MRI is not recommended.[5] However, because the use of 3-T MRI is increasing, it is expected that the experience of performing 3-T MRI in patients with non-MR-conditional or MR-conditional CIEDs will grow as well.[9][10]

MRI of the thoracic area of patients with CIEDs (scan exclusion zone) should be avoided, as it carries the risk of overheating the implanted device and surrounding tissue because of high SAR. However, even though both theoretical considerations and experimental findings suggest that patients with CIEDs carry additional risks,[11] there is yet no clear evidence from clinical trials suggesting that chest scanning, rather than scanning with a thoracic exclusion zone, is indeed associated with a higher incidence of adverse events.[1][12]

Along with the above consideration, there is an absolute contraindication for MRI in patients with pacing leads implanted <6 weeks before the MRI investigation, and in patients with abandoned or epicardial leads.[4][5] Non-MR-conditional CIEDs have ferromagnetic components, which cause movement and vibration of the cardiac device in the strong static and gradient magnetic fields of the MR system. A period of at least 6 weeks after implantation is required to ensure that the CIED is securely embedded into the tissue.[8] Some CIED manufacturers recommend that MRI should not be performed sooner than 6 weeks after implantation even for MR-conditional devices.[5] Nevertheless, the risk for lead and generator movement is extremely low,[13] and imaging may be performed earlier on a case-by-case basis if there is a clinical necessity. In the case of abandoned or epicardial leads, the contraindication is based on the so-called antenna effect, whereby an uncoiled wire resonates with the electric field of the radiofrequency coil, generating large electric fields in the vicinity of the lead tip, which may induce excessive heating of the CIED and surrounding tissue.[8] In vitro studies have revealed that overheating of the lead tips may occur during MRI,[1] and that abandoned or pericardial leads that are not cooled by blood flow may carry an increased risk of severe heating.[14]

Following a single-center retrospective study covering over 20 years of clinical experience with CIEDs and MRI under various conditions, Hwang et al.[15] reported little effect of MRI on the implanted devices even in patients with traditional contraindications for MRI, such as non-functional or epicardial leads, scanning in proximity to the device, device implanted <6 weeks prior to the MRI investigation, and MRI field strength of 3.0 T. In the context of the current evidence, it may be indeed concluded that MRI can be performed at a field strength of 3.0 T, in proximity to the device, and sooner than <6 weeks after device implantation when the benefits of the imaging evaluation outweigh the risks, no substitute imaging modality can provide the required information, and the MRI evaluation follows a well-established safety protocol and is performed with appropriate monitoring. However, abandoned or epicardial leads should still be considered an absolute contraindication, because of the risk of overheating. While uncommon, external burn during MRI can be severe, life threatening, and difficult to predict.[8][16] Therefore, caution should be applied when assessing the risk of overheating associated with abandoned or epicardial leads. Because of the difficulty associated with the assessment of inner heating around the lead, this adverse effect may easily have been overlooked in the study by Hwang et al.[15]; indeed, the authors mentioned this aspect as a limitation of their study. Therefore, their conclusion that MRI has little effect on CIEDs in patients with non-functional or epicardial leads should be carefully scrutinized.

While it is known that older CIEDs (typically those implanted before 2002) are more susceptible to electromagnetic interference,[13] it is not possible to verify this fact based on the study by Hwang et al.,[15] because the type of CIED was not included in their data. Additionally, no data was included regarding the SAR associated with the specific imaging protocols employed for MRI evaluation of their patients, making it difficult to ascertain the safety of 3-T MRI in patients with CIEDs, where SAR is the major concern.

Sabzevari et al.[17] recently evaluated the provision of MRI for patients with CIEDs and reported that, in England, only 46% of departments currently offer MRI scans to patients with CIEDs, even though 98% of departments are aware of the availability of MR-conditional devices. According to Sabzevari et al.,[17] there appears to be both under-referral and under-provision of MRI services for patients with CIEDs, in the context of an increasing population of such patients and greater clinical need for MRI scans. While cross-discipline education and collaboration may hold the key to facilitating the provision of MRI services to patients with CIEDs, the importance of adhering to clear safety protocols should not be overlooked.[17]

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