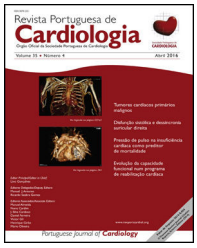
Revista Portuguesa de Cardiologia 40 (2021) 53–55

Revista Portuguesa de
Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org



COMMENTARY

Breaking down the barriers: Re-evaluating risk of MRI in patients with cardiac implantable electronic devices via collaborative practice

Quebrando as barreiras: reavaliar o risco da ressonância magnética cardiaca em doentes com *devices* eletrónicos implantados através de trabalho de equipa

João B. Augusto[a,b,c], **Charlotte Manisty**[b,c,*]

[a] *Cardiology Department, Hospital Prof Doutor Fernando Fonseca, Amadora, Portugal*
[b] *Institute of Cardiovascular Sciences, University College London, London, UK*
[c] *Barts Heart Centre, London, UK*

Introduction

> Coming together is a beginning. Keeping together is progress. Working together is success
>
> Henry Ford

Over the past 60 years, close interaction between engineers, scientists, clinicians and industry has led to rapid technological developments in both medical imaging and medical devices. The results benefit our patients on a daily basis and include state of the art magnetic resonance imaging (MRI) scanners and sequences, alongside complex cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable cardiac defibrillators (ICDs). However, despite intensive collaboration within groups to bring about these developments, a lack of cross-disciplinary communication across both the clinical environment and between industry partners has until recently prevented patients with CIEDs accessing MRI, even when clinically indicated. Historically, this has led to use of second line or invasive imaging techniques with delays to diagnosis and treatment, and likely negative impacts on clinical outcomes.[1,2]

Recently, however, there has been considerable progress with the development of MR-conditional CIEDs and increasing recognition that the risk of scanning patients with non-MR conditional CIEDs is lower than previously believed.[3–6] This is increasing in importance: globally both rates of CIED implantation and demand for MRI are increasing[2,7] as it becomes the first-line modality for diagnosis and planning of many treatments across multiple specialties, including neurology, orthopedics and cancer. The clinical utility of MRI in patients with CIEDs has been shown to be higher than for the general population, leading to diagnosis and management changes in over a third of patients,[6,8] increasing up to 75% of ICD patients undergoing cardiac resonance imaging.[9] Many CIED patients, however, still report challenges accessing MRI, and barriers still need to be broken down to enable equitable provision of scans to cardiac device patients.[10,11] At the heart of this lies the need for partnership between radiology and cardiology departments to facilitate improved provision of MR imaging to patients with CIEDs. One key step to delivery is access to guide-

* Corresponding author.
E-mail address: c.manisty@ucl.ac.uk (C. Manisty).

lines and recommendations that have been developed and agreed by both radiology and cardiology groups to ensure that there is appropriate representation and input from both disciplines. Almeida et al.[12] have produced such a Consensus Document, with endorsement from Portuguese Society of Cardiology and Portuguese Society of Radiology and Nuclear Medicine and should be congratulated on this contribution, which is likely to enable many centers to start or expand MRI services for CIED patients. Although guidelines have been written by several international cardiology and radiological societies,[13–17] available evidence changes rapidly and a detailed workflow including the logistics and timing of device re-programming and levels of supervision required is currently lacking. This Consensus Document provides recommendations including example checklists for departments to enable standardization of workflows. This should not only help clinicians and hospitals to initiate CIED-MRI services, but also ensure all safety steps are followed to minimize the potential for adverse clinical events.

The Consensus Document[12] also provides protocols for scanning non-MR conditional devices where clinically indicated and where patients consent to accept the risk of undergoing MRI. This risk is increasingly recognized to be very low; published data from three major US safety registries[4–6] (including patients undergoing thoracic MRI scans, those with abandoned leads and pacemaker-dependent patients with ICDs *in situ*) found no major complications where appropriate protocols were adhered to. Understanding risk in this context however remains complex. Currently, international MR-labeling of CIEDs is binary with devices categorized into MR-conditional (where the device is considered safe to undergo MRI scanning provided specific conditions are met) or MR-unsafe (where undergoing MRI would pose an unacceptable risk to the patient). Non-MR conditional is a term used for devices where formal testing and approvals are not currently in place, or where one or more of the conditions for an MR-conditional device cannot be met. Unfortunately, this labeling system fails to account for degrees of risk or indeed the risk of the patient not undergoing MR imaging at all. There have been no clinical adverse events reported in patients with non-MR conditional leads undergoing MRI, and yet patients are commonly refused scans with MR-conditional generators, but not leads. A patient with an MR-conditional pacemaker generator but leads from different manufacturers (therefore with a non-MR conditional CIED system) with suspected spinal cord compression clearly has a different risk/benefit profile to a pacemaker-dependent patient with a non-MR conditional ICD with redundant (abandoned) leads for whom a knee MRI is requested. Realistically, it is infeasible (and indeed not in device manufacturers' interests) for every potential lead and generator combination to undergo the rigorous safety testing necessary for systems to be labeled MR-conditional, meanwhile some patients are undergoing alternative invasive diagnostic testing where actuarial risks of MRI are extremely low. Encouraging centers to enable patients with non-MR conditional CIEDs to access MRI will build on the safety evidence currently available, and will hopefully promote the confidence to reduce barriers still further in the future. Consensus documents and published workflows will help momentum to gain, and it may not be long before only generator (and not lead) MR-conditionality is considered clinically relevant.

It is also important to recognize that barriers to MRI in CIED patients are present even prior to the scan being requested. As cardiologists, we are responsible for education of both our patients with CIEDs and referrers from other specialties that the presence of a CIED is no longer a contraindication to MRI. Resources are available (such as www.mrimypacemaker.com) which provide information for all potential stakeholders, however careful discussion with patients in clinics will help to promote understanding. At the time of device implant we should ensure that a fully MR-conditional system be used where available and, given the retrospective re-labeling of many leads as MR-conditional, the choice of generator manufacturer should be carefully considered during elective replacement. Cardiology departments should support radiology services in providing MR scans to their patients, and try to enable streamlined workflows with 'one-stop' combined services where possible.[18] Finally, partnerships are needed with device and scanner manufacturers to further ensure that device design incorporates adaptations to aid MRI workflows and that implant details can be readily shared between departments and hospitals where needed.

Central to all of these processes is communication and partnership. A broad network approach is needed nationally, but multidisciplinary teams at the regional and local levels must not be forgotten. These are essential to educate clinicians, referrers and even patients. Strategies such as the one from the current Consensus Document improve confidence, facilitate decision-making and highlight that working together is the key to success.

Funding

CM is directly and indirectly supported by the University College London Hospitals (UCLH) and Barts NIHR Biomedical Research Centres.

Conflicts of interest

The authors have no conflicts of interest to declare.

References

1. Nazarian S, Reynolds MR, Ryan MP, et al. Utilization and likelihood of radiologic diagnostic imaging in patients with implantable cardiac defibrillators. J Magn Reson Imaging. 2016;43:115–27.
2. National Institute of Cardiovascular Outcome Research. National Audit of Cardiac Rhythm Management Devices; 2016. http://www.bhrs.com/audit [Accessed 27 October 2020].
3. Vuorinen A-M, Pakarinen S, Jaakkola I, et al. Clinical experience of magnetic resonance imaging in patients with cardiac pacing devices: unrestricted patient population. Acta Radiol. 2019;60:1414–21.
4. Russo RJ, Costa HS, Silva PD, et al. Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. N Engl J Med. 2017;376:755–64.
5. Nazarian S, Hansford R, Rahsepar AA, et al. Safety of magnetic resonance imaging in patients with cardiac devices. N Engl J Med. 2017;377:2555–64.

6. Gupta SK, Ya'qoub L, Wimmer AP, et al. Safety and clinical impact of MRI in patients with non-MRI-conditional cardiac devices. Radiol: Cardiothorac Imaging. 2020;2:e200086.
7. NHS England Operational Information for Commissioning. Diagnostic imaging dataset. Available via: National Health Service. https://did.hscic.gov.uk [Accessed 27 October 2020].
8. Strom JB, Whelan JB, Shen C, et al. Safety and utility of magnetic resonance imaging in patients with cardiac implantable electronic devices. Heart Rhythm. 2017;14:1138–44.
9. Bhuva AN, Kellman P, Graham A, et al. Clinical impact of cardiovascular magnetic resonance with optimized myocardial scar detection in patients with cardiac implantable devices. Int J Cardiol. 2019;279:72–8.
10. Celentano E, Caccavo V, Santamaria M, et al. Access to magnetic resonance imaging of patients with magnetic resonance-conditional pacemaker and implantable cardioverter-defibrillator systems. Europace. 2018;20:1001–10.
11. Sabzevari K, Oldman J, Herrey AS, et al. Provision of magnetic resonance imaging for patients with 'MR-conditional' cardiac implantable electronic devices: an unmet clinical need. Europace. 2017;19:425–31.
12. Almeida AG, António N, Saraiva C, et al. Consensus document on magnetic resonance imaging in patients with cardiac implanted electronic devices. *Rev Portuguesa Cardiol*.
13. Brignole M, Auricchio A, Baron-Esquivias G, et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy: the task force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).
14. Indik JH, Gimbel JR, Abe H, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm. 2017;14:e97–153.
15. Sommer T, Luechinger R, Barkhausen J, et al. German Roentgen Society statement on MR imaging of patients with cardiac pacemakers. Rofo. 2015;187:777–87.
16. Verma A, Ha ACT, Dennie C, et al. Canadian Heart Rhythm Society and Canadian Association of Radiologists consensus statement on magnetic resonance imaging with cardiac implantable electronic devices. Can J Cardiol. 2014;30:1131–41.
17. Gandjbakhch E, Dacher J-N, Taieb J, et al. Joint Position Paper on magnetic resonance imaging in patients with cardiac electronic implantable devices. Arch Cardiovasc Dis. 2020;113:473–84.
18. Bhuva AN, Feuchter P, Hawkins A, et al. MRI for patients with cardiac implantable electronic devices: simplifying complexity with a ''one-stop'' service model. BMJ Qual Saf. 2019;28:853–8.