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Expanding Magnetic Resonance Imaging Access for Patients with Cardiovascular Implantable Electronic Devices

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The author declares no conflict of interest

Executive Summary

There are over two million patients in the United States that have cardiovascular implantable electronic devices (CIEDs). In 2017, the Heart Rhythm Society (HRS) provided a consensus statement with guidelines and recommendations for device management of patients with magnetic resonance (MR) conditional as well as MR non-conditional CIEDs (Indik et al. 2017). In January 2018, the Centers for Medicare and Medicaid Services (CMS) proposed that a qualified physician, nurse practitioner (NP), or physician assistant (PA) with expertise in implanted permanent pacemakers (PM), implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemakers (CRT-P), or cardiac resynchronization therapy defibrillators (CRT-D) must directly supervise patients with CIEDs during magnetic resonance imaging (MRI).

Manuscript

A comprehensive review of literature was conducted using search terms. Search terms utilized were *magnetic resonance imaging, cardiac implantable electronic devices, MRI, MRI safety, MRI adverse effects, CIED, CIED interference, pacemaker, and implantable cardioverter defibrillator*. The following databases were accessed to search for relevant literature: Cochrane, CINAHL, PubMed, Evidence-Based Journals, Scopus, Medscape, Heart Rhythm Society, and American Heart Association. The search yielded 30 articles. The final yield was 12 articles. Articles were selected for inclusion if they addressed CIEDs, MRIs, safety, safety concerns, and written in the English language. Articles were excluded if they were more than ten years old and focused only on specific manufacturers.

Articles were critically appraised with the Johns Hopkins Nursing Evidence-Based Practice *Non-Research and Research Evidence Appraisal Tools* (Dang & Dearholt, 2018). These

tools provide a concise appraisal of the level and quality of the evidence. Articles initially considered were utilized to guide the literature review and selected studies. Articles were chosen based on the type of study as well as the number and type of CIEDs reviewed. The twelve articles selected for inclusion were prospective, single non-randomized studies, multi-center cohort studies, a retrospective study, prospective study, randomized control trials, a meta-analysis and systemic review, technical report, abstract, and clinical review.

Prospective, Single Non-Randomized Studies

Two of the nine studies included prospective, single non-randomized studies by Nazarian et al. (2017) and Bailey et al. (2016). Both studies reviewed CIED interrogation results before and after the MRI with utilization of a standardized device management protocol. Device interrogation with lead comparison was performed at enrollment, pre- and post-MRI scan, one-month post-MRI, and three-month post-MRI. Both studies compared the effects of thoracic and non-thoracic MRI on CIEDs. The results of these studies were consistent with other previously published reports that demonstrated no long-term clinically significant adverse events. Bailey et al. (2016) had a sample size of two-hundred forty-five patients and Nazarian et al. (2017) had one thousand five hundred nine patients. Limitations included small sample sizes and low number of cardiac MRIs but demonstrated MRI safety of PMs and ICDs.

Prospective, Multicenter Cohort Studies

Two prospective, multicenter cohort studies analyzed CIED interrogation results before and after the MRI with the utilization of a standardized protocol. All studies were performed in a 1.5 tesla (T) MRI scanner. The prospective, multicenter study by Jung, Sebastian, and Zvereva (2015) identified the prospective adverse event rate and parameter changes in non-MRI CIEDs using a device registry. Russo et al. (2017) analyzed PM and ICD data and confirmed the safety

of non-MRI conditional CIEDs that underwent clinically indicated non-thoracic MRI at 1.5T. Device or lead failure did not occur in both studies but was not predictive of findings with testing at higher magnetic strength greater than 1.5T.

Retrospective and Prospective Cohort Study

The only retrospective cohort study by Dandamudi et al. (2016) reviewed the device assessment reports in the electronic medical records of patients with CIEDs before and after the MRI with a CIED safety protocol. When a comprehensive CIED MRI protocol is followed, the risk of performing 1.5T MRI with the device in the isocenter including pacemaker dependent patients is low.

One prospective cohort study by Yadava et al. (2017) reviewed 277 patients who underwent 293 scans. The CIEDs included 170 PMs and 71 ICDs. Devices were interrogated before and after the MRI with the use of a standardized protocol. The study demonstrated no changes in device settings during an MRI. Long-term follow-up device assessment confirmed no adverse effects from 1.5T MRI.

Randomized Control Trials

Two randomized control trials (RCT) analyzed CIEDs before, during, and after the MRI with the use of an MRI scan protocol. The study by Shenthar et al. (2015), evaluated MRI safety without positioning restrictions in patients with MR conditional PM with non-MR conditional leads. Two hundred sixty-six patients were sampled with a two to one ratio to the MRI group or control group. There were no related complications immediately and at one-month post-MRI. The second RCT by Wilkoff et al. (2011) evaluated PM performance and pacing capture threshold nine to twelve weeks prior to the MRI, during the MRI, and immediately after the MRI. Four hundred sixty-four patients were randomized to undergo an MRI scan between nine

to twelve weeks post-CIED implantation. Patients were monitored for arrhythmias, symptoms, and PM system function during fourteen non-clinically indicated brain and lumbar MRI sequences. It was found that no MRI related complications occurred during or after the MRI.

Meta-analysis and Systemic Review

One meta-analysis and systematic review performed by Shah et al. (2018) utilized a random effects model for meta-analysis of continuous variables including device lead parameters such as capture threshold, sensing, and impedance; high-voltage ICD lead impedance, and battery voltage change. Safety outcomes were evaluated with descriptive analysis. Indexed articles from PubMed were queried between the years 1990-2017. The search yielded one thousand three hundred twenty-four records to review. Seventy studies were included for the systematic review, and five thousand ninety-nine patients were identified. The brain or cervical spine was imaged the most and thoracic imaging was completed in seven hundred seventy-three patients. The meta-analysis cohort included thirty-one studies. This analysis summarized the safety profile of five thousand nine-hundred eight MRI studies in five thousand ninety-nine patients with non-MRI conditional CIEDs in a span of twenty-five years. There were no reported deaths and three total lead failures. There were no relevant changes in lead, battery, or pulse generator performance. The observed changes were small, and inter-study variance was low. The findings suggest the need for ongoing monitoring.

Technical report/Clinical review/Abstract

The technical report by Viera, Lazoura, Nicol, Rubens, and Padley (2013) analyzed data from a multicenter device registry. Devices were interrogated before and after an MRI with the use of a standardized protocol. The report confirmed the need for utilization of a comprehensive safety protocol and substantiated the development of new generation MRI conditional CIEDs.

The only clinical review by Nordbeck, Ertl, and Ritter (2015) provided a better understanding of the structures responsible for life-threatening complications as well as technical advances supporting the safety of MRIs for CIEDs. Clinical trials were reviewed over the last twenty years, including fourteen PM and thirteen ICD studies. The studies assessed the outcome in 1.5T scanners and reported there were no adverse events.

The single abstract found in the literature review demonstrated CIED safety during an MRI with appropriate monitoring and application of a safety protocol. It provided an overview of available data related to CIEDs and MRIs and attempted to offer up-to-date and a clinically useful summary for practicing cardiologists.

Conclusion

In conclusion, literature reviewed between 2011 and 2018 showed non-conditional CIEDs undergoing 1.5T MRI were evaluated pre, intra, and post-MRIs. A CIED safety protocol was utilized in most studies. Many of the studies reported CIED reprogramming before and after the MRI. There were minimal to no MRI related complications or adverse effects.

Findings from all the studies support the safety of the MRI for patients with conditional as well as non-conditional CIEDs at the magnetic strength of 1.5T and validate the 2017 HRS consensus statement demonstrated in the evidence table (Appendix A). MRIs can be performed with appropriate monitoring and the utilization of a safety protocol. More research is needed to evaluate the safety of MRIs at higher magnetic strength, greater than 1.5T. Observational studies with larger sample sizes and involvement of multi-centers should also be considered. With the evidence supporting the safety of MRIs for all CIEDs and incorporating the recent CMS guidelines, healthcare organizations must take the opportunity to evaluate their CIED management capabilities to comply with current staffing recommendations.

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Shah, A. D., Morris, M. A., Hirsh, D. S., Warnock, M., Huang, Y., Mollerus, M., ... Lloyd, M. S. (2018). Magnetic resonance imaging safety in nonconditional pacemaker and defibrillator recipients: A meta-analysis and systematic review. *Heart Rhythm Society*, 1-8.

Shenthar, J., Milasinovic, G., Al Fagih, A., Gotte, M., Engel, G., Wolff, S., ... Nahle, C. (2015). MRI scanning in patients with new and existing CapSureFix Novus 5076 pacemaker leads: Randomized trial results. *Heart Rhythm Society*, *12*, 759-765.

Van der Graaf, A., Bhagirath, P., & Gotte, M. (2014). MRI and cardiac implantable electronic devices; current status and required safety conditions. *Netherlands Heart Journal*, *22*, 269-276. Retrieved from http://dx.doi.org/10.1007/s12471-014-0544-x

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Wilkoff, B., Bello, D., Taborsky, M., Vymazal, J., Kanal, E., Heuer, H., ... Sommer, T. (2011). Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. *Heart Rhythm Society*, *8*, 65-73.

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Appendix A – Evaluation Table

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Russo, R.R., Costa, H.S., Silva, P.D., Anderson, J.L., Arshad, A., Biederman, R.W.W., … Wolff, S.D. (2017). Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. New England Journal of Medicine, 376(8), 755-764.	None	Prospective, multicenter study	N= 1500 1000 cases in which patients had a pacemaker and in 500 cases in which patients had an ICD	Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning.	All studies were performed in a 1.5-tesla MRI	Data were analyzed separately for the pacemaker and ICD cohorts with the use of R statistical software, version 3.2.3.16. The Wilson score method without continuity correction was used to calculate 95% confidence intervals for single proportions for primary end-point events.	Device or lead failure did not occur in any patient with a non–MRI conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla	**Strengths:** Data from both pacemakers and ICDs. Multicenter study. **Limitations:** The results are not predictive of findings with all device lead combinations or higher MRI field strengths. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Yadava, M., Nugent, M., Krebsbach, A., Minnier, J., Jessel, P., & Henrikson, C.A. (2017). Magnetic resonance imaging in patients with cardiac implantable electronic devices. *Journal of Interventional Cardiac Electrophysiology* ,50, 95-104.	None	Prospective Cohort Study	N = 277 patients underwent 293 scans. The devices included 170 pacemakers and 71 ICDs	Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning.	All studies were performed in a 1.5-tesla MRI scanner. Statistical analysis was performed with the R programming language. The comparison of normally distributed variables between device groups was performed with two sample t tests and non-normally distributed variables were compared with two-sample Wilcoxon tests	Patients with permanent pacemakers (PPM) or implantable cardioverter-defibrillator (ICD) and a clinical indication for an MRI were considered. Exclusion criteria included newly implanted devices (<4 weeks), PPMs manufactured before 1996 and ICDs before 2000, epicardial and abandoned leads, and pacemaker dependent ICD patients. Pacemaker dependent patients were programmed to asynchronous pacing. Tachycardia detection and therapies were disabled for ICDs. Devices were interrogated pre and post-scan and at follow up 1-6 weeks later. Defibrillation threshold testing (DFT) was not completed post-scan. Patients were followed to monitor device therapies.	The devices included 170 pacemakers and 71 ICDs. Thirteen scans were aborted due to subjective complaints or artifact on imaging. Post-scan and follow-up interrogations showed no changes in device settings requiring reprogramming or revision. Long-term follow-up demonstrated that nine ICD patients had appropriate device shocks and one had four inappropriate shocks for atrial fibrillation.	**Strengths:** Data from both pacemakers and ICDs. **Limitations:** Follow-up data was not available for some of their patients due to the large number of them being referred from outside physicians. It was difficult to accurately obtain information about device parameters. Device malfunction could not be ruled out in those patients who were lost to follow-up. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Dandamudi, S., Collins, J.D., Carr, J.C., Mongkolwat, P., Rahsepar, A.A., Tomson, T.T., … Knight, B.P. (2016). The safety of cardiac and thoracic magnetic resonance imaging in patients with cardiac implantable electronic devices. *Academic Radiology*, *23* (12), 1485-1505.	None	Retrospective cohort study	N = 58 patients underwent 51 cardiac and 11 thoracic spine MRI exams.	The cardiac device information was acquired from interrogation reports in the electronic medical record, which included a mandatory device assessment pre- and post-MRI scanning, per the prespecified CIED safety protocol.	Devices were interrogated before and after imaging with reprogramming to asynchronous pacing in pacemaker dependent patients. The clinical interpretability of the MRI and peak and average specific absorption rates (SARs, W/kg) achieved were determined.	Twenty-nine patients had a pacemakers and 29 patients had ICDs. Ten patients were pacemaker dependent. Fifty-one patients had non-MRI conditional devices. There were no significant changes in atrial and ventricular sensing impedance, and threshold measurements. There were no episodes of device mode changes, arrhythmias, therapies delivered, electrical reset, or battery depletion. One study was discontinued because the patient experienced chest pain (not related to the exam).	When a comprehen-sive CIED MRI safety protocol is followed, the risk of performing 1.5T magnetic resonance studies with the device in the magnet isocenter, including pacemaker dependent patients is low.	**Strengths:** Data from both pacemakers and ICDs. Utilization of thoracic scans. **Limitations:** The study had a small sample size in addition to the small number of patients with repeat MRI exams.The retrospective nature of the study did not allow for control of all confounding variables, did not allow for control of all confounding variables. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Jung,W., Sebastian, J., Zvereva, V. (2015). MRI and implantable cardiac electronic devices. *Current Opinion in Cardiology* , 30(1), 65-73.	None	Prospective Study, Multicenter	N= 34 prospective studies from1998-2014.	The MagnaSafe registry determined prospectively the adverse event rate and device parameter changes in patients with non-MRI-conditional cardiac devices (pacemakers or ICDs) implanted after 2001, undergoing clinically indicated nonthoracic MRI at 1.5 T.	Data from MagnaSafe registry.	Data was extracted from 1.5T MRI scans.	Development of MRI conditional devices has improved the risk benefit. Risks have been low; however, minor risks have significant effects.	**Strengths:** Data from both pacemakers and ICDs. Studies from 1998-2014. Data extracted from all studies. **Limitations:** Data from all studies only used 1.5T magnetic field. Should test at higher magnetic strength. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Viera, M.S., Lazoura, O., Nicol, E., Rubens, M. & Padley, S. (2013). MRI in patients with cardiovascular implantable electronic devices. *Clinical Radiology*, 68(2013), 928-934.	None	Technical Report	Interim analysis of the multicentre MagnaSafe Registry	Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning.	Analysis of the multicentre MagnaSafe Registry	Risks were identified, need for comprehensive safety protocol.	New generation of MRI conditional pacemakers developed. Higher risk with ICD and CRT devices.	**Strengths:** Identification of risks, need for safety protocols. **Limitations:** Data from all studies only used 1.5T magnetic field. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Shenthar, J., Milasinovic, G., Al Fagih, A., Gotte, M., Engel, G., Wolff, S., …..Nahle, C. (2015). MRI scanning in patients with new and existing CapSureFix Novus 5076 pacemaker leads: Randomized trial results. *Heart Rhythm Society*, 12(4), 759-765.	None	Randomized Control Trial	N = 266; 2:1 ratio to the MRI group (177 patients) or to the control group (89 patients)	Devices were interrogated before and after MRI. The MRI scan protocol was modeled after the Advisa MRI safety and effectiveness trial using 1.5-T cylindrical MRI systems7.	Evaluate the safety of MRI without positioning restrictions in patients with an MR conditional pacemaker and currently a non–MR-conditional Medtronic CapSureFix Novus 5076 lead(s).	At 9-12 weeks post implant, the MRI group underwent MRI at 1.5T. Primary end-points were MRI-related complication-free rate and non-inferiority of the MRI group compared to the control group with the regard to the proportion of patients with increase of <0.5V in the right atrial and right ventricular pacing capture thresholds from immediately before MRI to 1 month post MRI.	No MRI-related complications occurred in 156 MRI scanned patients who were followed through 1 month post MRI. MRI scans can be performed safely.	**Strengths:** RCT. **Limitations:** Data from all studies only used 1.5T magnetic field. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, I A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Shah, A.D., Morris, M.A., Hirsh, D.S., Warnock, M., Huang, Y., Mollerus, M., …..Lloyd,, M.S. (2018). Magnetic resonance imaging safety in nonconditional pacemaker and defibrillator recipients: A meta-analysis and systematic review. *Heart Rhythm Society* , 1-8.	None	Meta-analysis and systematic review.	Queried indexed articles from PubMed and CINAHL from 1990-2017. The search yielded 1324 records to review. 70 studies were included for the systematic review. 5099 patients.	A random effects model was used for meta-analysis of continuous variables. Safety outcomes were evaluated with descriptive analysis.	For the primary safety objective, a 1-sided, 1-proportion binomial exact test was used, and the corresponding 1-sided 97.5% lower confidence bound was calculated.	70 studies on non-MRI conditional devices undergoing MRI were identified, allowing analysis of 5099 patients who underwent 5908 MRI studies. All lead characteristics and battery voltage showed minimal changes. Electrical resets were only found in older devices. Defibrillator function was unchanged and inappropriate were avoided.	This review demonstrated low lead failure and clinical event rates in non-MRI conditional pacemaker and ICD undergoing MRI. Observed changes were small and interstudy variance was low suggesting that the composite event rates offer a reasonable estimate of true effect. The observed adverse events reinforce the need for ongoing monitoring and caution.	**Strengths:** Large number of studies and significant number of patients. **Limitations:** Previously published, largely observational data. Unknown number of patients were implanted with Medtronic model 4076 and 5076 leads which may have lowered the clinical risk observed because these leads are MRI compatible. The data did not allow for review of all possible device, lead, and MR combinations to determine safety. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Wilkoff, B.L., Bello, D., Taborsky, M., Vymazal, J., Kanal, E., Heuer, H., …..Sommer, T. (2011). Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. *Heart Rhythm Society* , 8, 65-73.	None	Prospective Randomized Control Trial	N= 464 were randomized to undergo an MRI scan between 9-12 weeks post implant. MRI group n = 258 or not undergo an MRI (control group n = 206) after successful implantation of specially designed dual chamber pacemaker and leads.	Pacemaker performance, pacing capture threshold, evaluation 9-12 weeks prior to MRI, during MRI, and immediately after MRI. Technical observations and adverse events were evaluated.	Sequences were performed at 1.5T and included scans with high radiofrequency power deposition and/or high gradient dB/dt exposure.	Patients were monitored for arrhythmias, symptoms, and pacemaker system function during 14 non-clinically indicated relevant brain and lumbar MRI sequences.	No MRI related complications occurred during or after the MRI.	**Strengths:** This trial documented the ability of the pacemaker to be exposed in a controlled fashion to MRI in a 1.5T scanner without adverse impact on patient outcomes or pacemaker function. **Limitations:** Data only from 1.5T magnetic field. Use of MRI scanners on pacemaker patients was specifically limited to well-defined conditions in the trial and safe use outside of these conditions was not demonstrated. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , I A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Bailey, W.M., Mazur, A., McCotter, C., Woodard, P.K., Rosenthal, L., Johnson, W., & Mela, T. (2016). Clinical safety of the ProMRI pacemaker system in patients subjected to thoracic spine and cardiac 1.5T magnetic resonance imaging scanning conditions. *Heart Rhythm Society* , 13, 464-471.	None	Prospective Single, Non-randomized study	N = 245 with stable baseline pacing indices implanted with a Biotronik Entovis pacemaker and Sertox leads.	Pre-MRI, atrial and ventricular sensing and thresholds. Using investigational software.	Device interrogation was performed at enrollment, pre and post MRI scan, and 1 and 3 months post MRI.	216 patients completed the MRI and 1-month post-MRI follow up. Statistical analysis was based on the proportion of the leads or patients satisfying end-point criteria. Two-sided 95% CIs for the parameters were given.	One adverse event possibly related to the implanted system and the MRI procedure occurred, adverse device effect-free rate of 99.6%. The study demonstrated the clinical safety and efficacy of the ProMRI pacemaker system.	**Strengths:** This study demonstrated the safety and function of the ProMRI pacemaker. **Limitations:** Sample size was insufficient to observe rare adverse effects of MRI on the patient population. The number of cardiac MRI was lower than thoracic MRI and could underestimate the risk of cardiac MRI. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , II A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Nazarian, S., Hansford, R., Rahsepar, A.A., Weltin,V., McVeigh, D., Ipek, E.G.,….. Halperin, H.R. (2017). Safety of magnetic resonance imaging in patients with cardiac devices. *The New England Journal of Medicin* e, 377(26), 2555-2564.	None	Prospective, Single, Non-randomized study	N = 1509 who underwent 2103 thoracic and non-thoracic MRIs	Evaluated the safety of MRI, performed with the use of a prespecified safety protocol. Lead parameters were compared with the use of the Wilcoxon signed-rank test, with MRI examination as the unit of analysis.	The pacing mode was changed to asynchronous mode for pacing dependent patients and to demand mode for other patients.	In 9 MRI exams, 95% CI was reported. The most common notable change in device parameters immediately after MRI was a decrease in the P wave amplitude, which occurred in 1% of the patients. Lead parameters were compared with the use of the Wilcoxon signed rank test with MRI examination as the unit of analysis.	Lead parameters were compared with the use of the Wilcoxon signed rank test with MRI examination as the unit of analysis.	**Strengths:** This study demonstrated the MRI safety of pacemakers and ICDs. **Limitations:** Data was acquired at a single center and may not be generalizable to other clinical settings and MRI facilities. Unable to obtain long-term follow up information from 302 patients. The study did not perform defibrillation testing in patients who had an ICD. The numbers of each individual devices were small. Interactions of future systems cannot be ruled out. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, II A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Van der Graaf, A.W.M., Bhagirath, P., & Gotte, M.J.W. (2014). MRI and cardiac implantable electronic devices; current status and required safety conditions. *Netherlands Heart Journal* , 22, 269-276. Retrieved from http://dx.doi.org/10.1007/s12471-014-0544-x	None	Abstract	This review paper provides an overview of the currently available data related to CIEDs and MRI and attempts to offer an up-to date and clinically useful summary for the practicing cardiologist. Six studies and four clinical trials were reviewed.	6 studies and 4 clinical trials were reviewed.	Reviewed clinical trials and numerous literature to study the safety of MRIs and CIEDs.	An overview of all available MRI conditional devices and their individual restrictions was given.	With appropriate monitoring and application of a safety protocol, MRI can be safely performed in patients with CIEDs.	**Strengths:** This abstract demonstrated the MRI safety of pacemakers and ICDs. **Limitations:** Data was limited to the 6 studies and 4clinical trials. Studies with use of higher magnetic strength should have been included. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Nordbeck, P., Ertl, G., & Ritter, O. (2015). Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: How far have we come? *European Heart Journa* l, 36, 1501-1511.	None	Clinical Review and Update	This clinical review provides a better understanding of the mechanisms responsible for life-threatening complications as well as technical advances allowing an increasing number of pacemakers and ICDs to safely undergo MRIs.	Reviewed clinical trials over the last 20 years.	14 pacemaker studies and 13 ICD studies.	14 pacemaker studies and 13 ICD studies assessed the outcome in 1.5T MR scanners. There were no adverse events reported.	Appropriate monitoring and application of a safety protocol, MRIs can be safely performed in patients with CIEDs.	**Strengths:** This review demonstrated the MRI safety of pacemakers and ICDs. **Limitations:** Data was limited to 14 pacemaker studies and 13 ICD studies. Studies with use of higher magnetic strength (>1.5T) should have been included. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.