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Magnetic Resonance Imaging for Patients with Implantable Cardiac Devices: A Review of Safety and Guidelines

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Abbreviations

CI	Confidence interval
CIED	Cardiac implantable electronic device
CRT	Cardiac resynchronization therapy
CT	Computed tomography
HR	Hazard ratio
ICD	Implantable cardioverter-defibrillator
MRI	Magnetic resonance imaging
T	Tesla

Context and Policy Issues

Patients who have a cardiac implantable electronic devices (CIEDs), including pacemakers, cardiac defibrillators, and loop recorders, have generally been regarded as contraindicated for magnetic resonance imaging (MRI).[1,2] The imaging process produces a magnetic wave field that can affect the electric components of a CIED in a negative manner but also affect the image produced by the MRI.[2] The magnetic field can generate currents that can displace components within the CIED, damage the CIED and ultimately the myocardium, and, although rare, it can even potentially generate life-threatening arrhythmias.[2]

For patients with a CIED, it is estimated that there is a 50% to 70% chance that this patient will require an MRI.[2] While there are other imaging techniques, MRI is still the preferred method in some scenarios.[2]

In recent years, CIED manufacturers have developed “MRI-conditional” CIEDs, which are considered to have minimal risks associated with MRI scans within specific magnetic resonance environment; however, despite this, clinicians are still hesitant to perform MRIs on patients with CIEDs because patients with CIEDs have historically been considered as a contraindication for MRI examinations.[1,2] In addition, there is little guidance on how to appropriately perform MRI scans on patients with CIEDs, making it difficult for clinicians in practice.[1]

The objective of this review is to evaluate the safety of MRI for any indication using 1.5 Tesla (T) or 3.0T in adult patients who have an implantable cardiac defibrillators, loop recorders or pacemakers and review the guidelines on how to minimize the risk in this patient population. The focus of this review is on non-conditional or conventional devices and conditional devices outside the specified parameters. Conditional devices are those that have demonstrated to have minimal safety hazards in a given specified magnetic resonance environment (Appendix 6).[3]

Research Questions

1. What is the evidence regarding the safety of performing magnetic resonance imaging on people with implantable cardiac defibrillators, loop recorders, or pacemakers?
2. What are the evidence-based guidelines regarding performing magnetic resonance imaging on people with implantable cardiac defibrillators, loop recorders, or pacemakers?

Key Findings

Two systematic reviews and 11 primary studies were identified when considering the safety of magnetic resonance imaging (MRI) examinations in patients with implanted cardiac electronic devices, including pacemaker, cardiac defibrillators, and loop recorders. The identified studies were for devices that were considered non-MRI-conditional or conventional. All identified publications were observational studies with small sample sizes. Few adverse events were reported, but some included palpitations and sensations near the device during the MRI scan.

It may be difficult to generalize to the Canadian population as all of the studies were conducted outside of Canada and there may be variations on devices that are available from country-to-country.

Evidence of limited quality from non-randomized observational studies suggested that patients with non-conditional or conventional implanted cardiac electronic devices generally have a low risk of adverse events. No evidence-informed guidelines were identified to mitigate risks in this patient population.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including Medline via OVID, the Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies containing safety data, and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and March 4, 2019.

Selection Criteria and Methods

Two reviewers completed the first level of screening while one reviewer completed the second level of screening of included studies with a second reviewer reviewing selected articles. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults who have implantable cardiac defibrillators, loop recorders, or pacemakers
Intervention	MRI for any indication (using 1.5T or 3.0T MRI) Subgroups: - Those with conditional devices used outside of specified conditions - Those with non-conditional or conventional devices
Comparator	Any active comparator No comparator

Outcomes	Q1: adverse events to the patient; adverse event to the device (e.g. device malfunction or failure during or after the scan; battery malfunction; impedance) Q2: guidelines regarding mitigating risks to those with implantable devices who need to undergo MRI; guidelines for imaging/not imaging those with the devices; contraindications; patient selection; protocols and procedures
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, guidelines

MRI = magnetic resonance imaging; T = Tesla

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, individual studies captured in a selected systematic review, irrelevant population, studies that did not have an appropriate intervention or comparator groups, studies that evaluated irrelevant/non-clinical outcomes, case studies, MR conditional devices that were tested within their conditions or were published prior to 2014. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included systematic reviews were critically appraised by one reviewer using AMSTAR,[4] randomized studies were critically appraised using Downs and Black,[5] and guidelines were assessed with the AGREE II instrument.[6] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 534 citations were identified in the literature search. Following screening of titles and abstracts, 486 citations were excluded and 48 potentially relevant reports from the electronic search were retrieved for full-text review. Two potentially relevant publications were retrieved from the grey literature search for full text review. Of these potentially relevant articles, 37 publications were excluded for various reasons, and 13 publications met the inclusion criteria and were included in this report. These comprised one systematic review, one meta-analysis, and 11 non-randomized studies. Appendix 1 presents the PRISMA[7] flowchart of the study selection.

Summary of Study Characteristics

Additional details regarding the characteristics of included publications are provided in Appendix 2.

Study Design

One systematic review[8] and one meta-analysis[9] were included that were published in 2018.[8,9] Shah et al.[8] searched the literature from January 1990 to October 2017 and consisted of 70 observational studies including case reports, case series, and prospective studies.[8] It then removed 39 studies due to insufficient data reported or data reported in aggregate, and combined 31 studies into a meta-analysis.[8]

identifies the studies that were included in the systematic review.[8] For the meta-analysis, Shurrab et al.[9] conducted a literature search from the inception of the databases up to August 28, 2017 and consisted of six studies including retrospective and prospective non-randomized studies. None of these studies were included in the systematic review by Shah et al.

Eleven non-randomized clinical trials were identified. [10-20] Three were published in 2019, four in 2018, three in 2017, and one in 2016. Four of these non-randomized studies were prospective case series.[10,14,16,20] Four were retrospective cohort studies.[12,15,17,18] Two were retrospective case series studies.[11,19] One was a prospective cohort study.[13]

Country of Origin

The authors of the systematic reviews were based in the United States[8] and Canada.[9] Eight of the non-randomized trials were conducted in the US.[10,11,14-18,20] There was one non-randomized trial each from Korea,[12] Italy,[13] and Finland.[19]

Patient Population

Shah et al.[8] included studies where patients received an MRI scan in the presence of a non-MRI-conditional cardiac implantable electronic device (CIED).[8] Shurrab et al.[9] included studies where adults with either an MRI-conditional or conventional pacemaker underwent an MRI scan.

One study evaluated 35 patients with a mean age of 70.1 years old who have pacemakers or implantable cardioverter-defibrillator (ICD) undergoing a variety of MRI procedures.[12] Another study included 25 patients who received a prostate MRI and have CIEDs, including pacemakers and ICDs.[18] The study by Vuorinen et al. including 1000 clinically indicated MRI scan in adult patients who have a cardiac pacing device with a mean age of 69.5 years old (range 18 years old to 97 years old).[19] One study included all patients who have a non-MRI-conditional CIED who underwent a cardiac MRI examination where the patients have a mean age of 59 years old.[11] Lupo et al. included 120 patients, median age 67, with a conventional pacemaker or convention ICD.[13] One of the non-randomized studies considered adult patients who were having MRI examinations with non-conditional CIEDs including pacemakers, ICDs and cardiac resynchronization therapy (CRT) where there were 38% female patients with a mean age of 65 years old.[15] Padmanabhan et al. investigated adult patients with CIEDs who had a 1.5T brain MRI but excluded those who had device implantation before 2005.[17] Nazarian et al. included patients (median age 69.3) who have a legacy or conventional pacemaker or ICD who were clinically indicated for a MRI.[14] One study included patients (mean age 66.4) who were clinically indicated for a MRI and have a non-MRI conditional CIED where the battery was nearly depleted.[16] One study included patients who were over the age of eight years of age with a permanent pacemaker or ICD, including both MR-conditional and non-conditional devices, and required an MRI.[20] Camacho et al. including patients who clinically needed an 1.5T MRI (mean age 66) and were unable to receive other imaging, laboratory, surgical or other.[10]

Interventions and Comparators

The systematic review included studies that assessed the use of MRIs in patients with non-MRI conditional CIEDs[8,9] and the authors of the meta-analysis included studies that examined an MRI-conditional (Medtronic Revo SureScan Pacing System) or conventional pacemakers.[9]

One primary study compared patients receiving MRIs with MRI-conditional devices with those who have conventional devices.[12] For the study that conducted 1.5T MRI examination of the prostate, it considered patients with and without CIEDs.[18] Four studies did not have a comparator group but specifically evaluated patients who underwent a 1.5T MRI examination.[14,16,19,20] One study assessed patients who received a 1.5T cardiac MRI examination,[11] while another study compared those that received a 1.5T thoracic MRI scan and those who received a non-thoracic MRI scan.[15] Lupo et al. compared patients who received MRI examinations with those who received a chest x-ray, thoracic computed tomography (CT), or routine follow-up.[13] In one primary study, patients with non-MRI-conditional CIEDs receiving MRIs were compared to three groups: 1) patients without CIEDs who underwent MRIs, 2) patients with CIEDs who underwent CTs, and 3) patients without CIEDs who underwent CTs.[17] In Camacho et al.'s study, MRI scans of 1.5T were performed in patients with conventional and MRI-conditional CIEDs.[10]

Outcomes

The outcomes that were considered by the systematic review and meta-analysis included the following: unintended programming changes,[8] lead failure,[8] lead dislodgement.[9] electrical resets,[8] inappropriate anti-tachycardia therapies,[8] and patient reported symptoms.[8,9]

One primary study considered device interrogation including battery voltage, pacing thresholds and patient reported symptoms.[12] Tanaka et al. assessed for serious (life-threatening) cardiac-device related adverse events, death from any cause and quality MRI image analysis.[18] One study investigated generator failure power-on reset, unexpected battery depletion and patient reported outcomes including discomfort, pain, warm sensation near the device and palpitations.[19] The study by Do et al. looked at clinical deterioration including death, device generator failure requiring replacement, lead failure requiring replacement, new onset of atrial or ventricular arrhythmias, loss of capture in pacemaker dependent patients or electrical reset.[11] Four endpoints were considered in the study by Lupo et al.: 1) onset of arrhythmias or other cardiac or non-cardiac events requiring life-support procedures, 2) onset of arrhythmias or other cardiac or non-cardiac events prompting interruption of the examination and not requiring life-support procedures, 3) modification of the functional status of the device after MRI, and 4) any other adverse event, including related or unrelated to the MRI examination.[13] One study monitored for patient reported symptoms or arrhythmias and power on reset,[15] while another one considered long-term mortality.[17] Nazarian et al. study reported on generator failure, power-on reset, changes in pacing threshold or sensing that required system revision or programming changes, battery depletion, cardiac arrhythmias, inhibition of pacing, inappropriate delivery or anti-tachycardia pacing or shock, and patient-reported events, including discomfort, warm sensations and palpitations.[14] One study assessed whether or not devices indicated elective replacement or if they were replaced due to battery depletion after the MRI examination.[16] In Yadava et al.'s study, the outcomes included arrhythmias requiring anti-tachycardia pacing and/or defibrillation and tachyarrhythmias needing defibrillation that were not effectively treated.[20] Camacho et. al reported on patient reported safety outcomes, whether or not the diagnostic question was answered and the image quality including if there were artefacts.[10]

Summary of Critical Appraisal

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Systematic Reviews and Meta-Analyses

The identified systematic review [8] was designed a priori using a comprehensive literature search but it is unclear if there was duplicate study selection and data extraction.[8] However, grey literature was not included in the search strategy.[8] The full list of included studies can be found in the supplementary materials of the study while the excluded studies were not available.[8] The characteristics of the studies were available.[8] Since the scientific quality of the studies were not documented, it is unclear if it was considered when the authors were formulating the conclusion.[8] The methods seemed appropriate to combine the studies, though different study designs were combined in the meta-analysis, and publication bias was assessed.[8] Information on conflict of interest was not provided.[8] The meta-analysis by Shurrab et al.[9] was designed a priori but the comprehensiveness of the literature search strategy was unclear. Study selection and data extraction were performed by three reviewers and a grey literature search was performed.[9] Characteristics of the included studies were available and the quality of the individual studies was considered when forming conclusions.[9] The methods used to meta-analyse the studies seemed appropriate; however the impact of publication bias was not assessed.[9]

Primary Studies

In the comparative study by Han et al., the objectives were clearly described but the methods and outcomes of interest were less evident.[12] It was a small, non-randomized study that can introduce bias and given the small sample size, it may not capture rare adverse events but the baseline characteristics of the two groups were similar.[12] The follow-up was short, an average of five months, making the longer-term effects unclear but the statistical analyses were clear and those who withdrew from the study were clearly identified.[12] The authors' conclusions seemed appropriate and they have declared no conflicts of interest; however, the study was conducted in South Korea may not be generalizable for the Canadian context.[12]

Tanaka et al. conducted a retrospective cohort analysis with matched controls to reduce risk of confounding bias where the objectives, methods and outcomes of interest were clearly described.[18] However, this was a small, non-randomized study conducted in one center in the US, which may make it difficult to generalize for the Canadian population.[18] No patients were lost to follow up and the statistical analyses were appropriate where the authors' conclusion were consistent with the results.[18] However, the authors did not provide funding information and their conflicts of interest.[18]

One of the cohort studies included a large number (n=1000) of MRI scans and the objectives, methods and outcomes of interest were clearly defined.[19] However, this was a descriptive, non-randomized study, without control groups, and there may be confounding bias that can be introduced and affect the safety outcomes.[19] The author's conclusions were appropriate for the study and they had declared no conflict of interest.[19] Given that this study was completed in Finland, it may not be reflective of the Canadian context.[19]

The study by Do et al. described the objectives clearly in the study but the methods and outcomes were not provided as clearly in this small, single center, non-randomized study.[11] Follow-up was short and ranged from one to six months with missing data that is not accounted for.[11] Authors conclusions seemed appropriate and conflicts of interest and funding were declared but one of the authors is documented as the inventor of this imaging technique which may influence the outcomes of this study.[11]

Lupo et al. clearly described the objectives, methods and outcomes for this study, using an appropriate statistical analyses and applying Bonferroni correction for multiple comparisons when conducting the statistics.[13] It was a single center study conducted in the United States with follow-up of only three hours post-MRI examination, making the long-term safety unclear.[13] Baseline characteristics between the two groups were balanced and the authors' conclusions were appropriate as per the results.[13] The authors also declared their conflicts of interests as well as the funding source for the study.[13]

In the study by Nyotowidjojo et al., the objectives were clearly described and the authors' conclusions were appropriate given the study results; however, the methods were not clear as it was described both as a prospective and retrospective analysis.[15] The outcomes were not clearly described and no comparative analysis was done.[15] About half of the data was missing and it is unaccounted for and no information on conflict of interest or funding was provided.[15]

Padmanabhan et. al clearly described the objectives, methods, and outcomes of this single center database review.[17] The baseline characteristics for comorbidities was unclear between the comparative groups but the statistical analyses was appropriate for this study.[17] The follow-up period was shorter than the initial definition due to the data that was available and needed to extrapolate outcomes.[17] The authors declared their conflicts of interest but this was conducted in the United States and it is unclear if it is applicable for the Canadian health system.[17]

For the primary study by Nazarian et al., objectives, methods and definitions of the outcomes were provided clearly for this study of a large population of 1509 patients.[14] However, the long term follow-up (median = 1 year) was only available for about 60% of the patients and those that were lost to follow-up were not explained.[14] The cardiac MRI that was used was considered non-diagnostic and may limit its usability in a clinical setting.[14] The statistical analyses were appropriate and the results were presented in the text and tables and the authors formulated conclusions consistent with the results.[14] The conflicts of interest and funding sources for the study were documented.[14]

Okamura et al. clearly described the objects, methods, and outcomes were clearly provided in the study; however, this was a small, non-randomized study consisting of nine patients.[16] Descriptive results are available and the descriptive and summary statistical analyses seemed appropriate with the results described clearly in the text and tables.[16] The authors' conclusions were consistent with the study results and they have declared their conflict of interest.[16]

A single center, non-randomized study was conducted by Yadava et al. and the inclusion criteria included patients aged eight and over but the baseline characteristics of the population was unclear; however, the objectives, methods, and outcomes were clearly described.[20] Descriptive analyses was appropriate for the methods used and the results were clearly described with appropriate conclusions provided.[20] About 40% of the data was missing and the follow-up was short (median = 35 days), making it difficult to understand the long-term effects.[20] The authors have declared they have received fees from various manufacturers of CIEDs.[20]

Camacho et al. provided objectives and methods clearly in the study but the definitions for the outcomes were not as clear.[10] Although it included both MRI-conditional and conventional CIEDs, comparisons were not made and only descriptive statistics was provided.[10] The results were clearly presented in the study and the authors' conclusions

were consistent with the findings, but it was conducted in a single center in the US, making the generalizability difficult for the Canadian perspective.[10] No information was provided for conflicts of interest.[10]

Summary of Findings

Appendix 4presents a table of the main study findings and authors' conclusions.

Safety of performing magnetic resonance imaging on people with implantable cardiac defibrillators, loop recorders, or pacemakers

Conditional Devices

No studies were identified for patients with conditional devices receiving MRI examinations beyond specified conditions; therefore, no summary can be provided. Conditional devices when used within a specified environment seem to have evidence to support their safety and have demonstrated to have minimized adverse events (see Appendix 6).

Non-Conditional Devices or Conventional Devices

In the one identified systematic review, electrical reset was identified in 94 out of 5908 MRI scans, a rate of 1.6%. It was observed in older pacemakers and defibrillator pulse generators that were made prior to 2006; of note, they found that this was more likely to occur with the Medtronic devices compared with other brands.[8] Patient reported symptoms were considered infrequent at a rate of 0.3% and the symptoms included palpitations.[8] In the meta-analysis, rates of pacemaker dislodgement and pericardial complications were statistically significantly higher in the MRI-conditional group as compared with the group with conventional pacemakers.[9] The overall complication rate was 6 percent in the MRI-conditional group and 3% in the conventional group, but this difference was not statistically significant.[9] Sensing parameters of atrial and ventricular leads were lower in the MRI-conditional group immediately after MRI and at follow up of six weeks to 12 months.[9]

In one of the primary studies, a total of 35 patients, for a total of 43 scans, were identified where 14 had a MR-conditional ICDs and 21 had a conventional ICDs. No generator or lead failure resulting in battery problems were reported and there were no statistical differences for lead impedance between the two groups.[12] A study specifically evaluating patients receiving prostate MRI examinations included six patients with MRI-conditional CIEDs and 19 patients with MRI-unsafe CIEDs found no patient reports of any symptomatic events and subjective analysis of MRI images were not statistically different between the different types of CIEDs ($p > 0.05$).[18] However, one death was reported at 42 months post MRI but it was due to progression of metastatic prostate cancer.[18] In 1000 MRI examinations of 793 adult patients, Vuorinen et al. reported 86.9% of the scans were done in patients with conventional cardiac pacemakers and found one device that went into elective replacement indicator mode, three patients reported symptoms that were believed to be unrelated to the MRI examination, and one power-on reset occurred.[19] In a comparative study, patients with conventional pacemakers or conventional implantable cardioverter defibrillator receiving MRIs were compared to a control group including those receiving chest x-rays, CT scans or follow-up visits, found there were no differences in adverse event reporting (95% confidence interval [CI] 0% to 2.6%) but noted 42% of the cardiac MRIs had artifacts.[13] None of the MRI scans were prolonged nor interrupted due to disturbances or sensations due to the cardiac device.[13] Nyotowidjojo et al. included 238 patients with MRI non-conditional CIEDs for a total of 99 thoracic scans and 240 non-thoracic scans and found no patient reported symptoms and no adverse clinical outcomes or arrhythmias.[15] In one

study, for the estimated five-year mortality rate, there was no difference between patients who had CIEDs and received MRI (33.9%) versus CT (37.3%) scans (hazards ratio [HR] 0.814, 95% CI 0.593 to 1.117, p = 0.20).[17] For those who received MRI examinations, the five-year mortality rate was higher in those who have a CIED at 33.9% compared to those without a CIED at 25.6% (HR 1.463, 95% CI 1.019 to 2.099, p = 0.04) but there was no statistical difference for those who have a CIED and received a MRI scan and those who have no CIED but received a CT scan where the five-year mortality rate was 33.9% and 32.3% respectively (HR 1.149, 95% CI 0.818 to 1.613, p = 0.42).[17] In a study with 1509 patients, 58% with pacemakers and 42% with ICDs, who underwent 2103 MRI examinations, there were nine examinations in eight patients that reported power on reset (0.4%, 95% CI 0.2% to 0.7%) and one patient experienced a pulling sensation in his chest during the examination.[14] In nine patients with nearly depleted batteries in their CIEDs, one patient had a pacemaker where the pacing mode could not be changed after the MRI and in the patients with ICDs, all six ICDs were considered to be of normal function after the MRI scan.[16] Yadava et al. reported on 227 patients, where 170 patients had a permanent pacemaker and 71 had an ICD with 14 of these devices being MR-conditional, and had 293 MRIs found 12 patients with arrhythmias that required anti-tachycardia pacing with a mean follow-up of 354 days.[20] One study reported on 104 patients where 74 (65.4%) MRI scans were done in patients with a pacemaker and 39 (34.5%) MRI scans were done in patients with an ICDs and for a total of 113 MRI examinations where in three MRI scans patients experienced clinical symptoms including heating, tingling and palpitations.[10] Artifacts were seen in four images but only if the CIED was also in the field of view but the diagnostic question was answered in all of the MRI examinations.[10] One study included 111 patients who underwent 114 cardiac MRI examinations and found there were 14 (13%) and 3 (3%) MRI examination studies with some artifact and severe artifact respectively.[11] No reports of death, new arrhythmias, immediate generator or lead failures, electrical resets, or pacing capture failures in this study.[11]

Evidence-based guidelines regarding performing magnetic resonance imaging on people with implantable cardiac defibrillators, loop recorders, or pacemakers

No evidence-based guidelines were identified for mitigating risks to those with implantable devices who clinically require MRI examinations; therefore, no summary can be provided.

Limitations

The included studies of the systematic review and all of the identified primary studies consisted of observational studies, indicating there is a paucity of high quality evidence evaluating the safety of MRI examinations in patients with CIEDs, particularly with devices that are considered to be non MRI-conditional or conventional.[8,10-20] Nine of the primary studies were single-arm with no comparator group; therefore, it is difficult to know the true safety concerns when patients with CIEDs undergo a MRI examination.[10-12,14-16,18-20] However, it is unsurprising that there is limited high quality evidence as it would be difficult to conduct a randomized trial to determine the safety surrounding MRI examinations in patients who already have an implanted cardiac device. All of the identified evidence utilized 1.5T MRI examinations, no evidence was found for 3T MRI scans; therefore, further research will be needed to determine whether or not it would be safe for patients with CIEDs to undergo a 3T MRI examination.

Many of the studies consisted of small sample sizes, which may make it difficult to detect rare adverse events associated with MRI examinations with patients with CIEDs. Although the identified systematic review included 70 studies, there were only 5099 patients

included, which would be may not be a large enough sample size to detect rare serious adverse outcomes.[8]

All of the identified primary studies and systematic review were conducted outside of Canada and may have slightly different implications on the Canadian health system as the availability of CIEDs may vary from country to country. The meta-analysis was conducted by a group of Canadian authors; however, it is unclear where the primary studies included in the analysis were conducted.

No evidence-based guidelines were identified, making it difficult to inform recommendations or procedures in clinical situations involving patients with CIEDs requiring MRI examinations.

Conclusions and Implications for Decision or Policy Making

A total of 13 relevant publications were identified, including one systematic review,[8,9] one meta-analysis,[9] and ten primary studies.[10-20]

The available evidence suggests that there are very few adverse events associated with MRI examinations in patients who have implanted cardiac electronic devices. Some studies report patients experiencing symptoms such as palpitations and warming sensations but it appears to be an infrequent occurrence, even with non-MRI-conditional devices. However, there is a paucity of high quality evidence that is available for this population. Further research addressing the use of non-MR-conditional cardiac devices with higher quality evidence may help reduce uncertainty.

There were two guidelines that were reviewed as a part of this report; however, one of them was not considered an evidence-based guideline while it was not possible to retrieve the full text of the other. Although it was not considered an evidence-based guideline, the recommendations suggested the risk of adverse events is relatively infrequent and seems to be consistent with the conclusions of the reported studies, including devices that are considered non-conditional.[2] Considering the limited availability of evidence-informed guidelines, clinicians will need to discuss the risks and benefits associated with MRI examination in this patient population with safety evidence that may be of lower quality, and policy makers will be reliant on the existing evidence to implement policy for this population.

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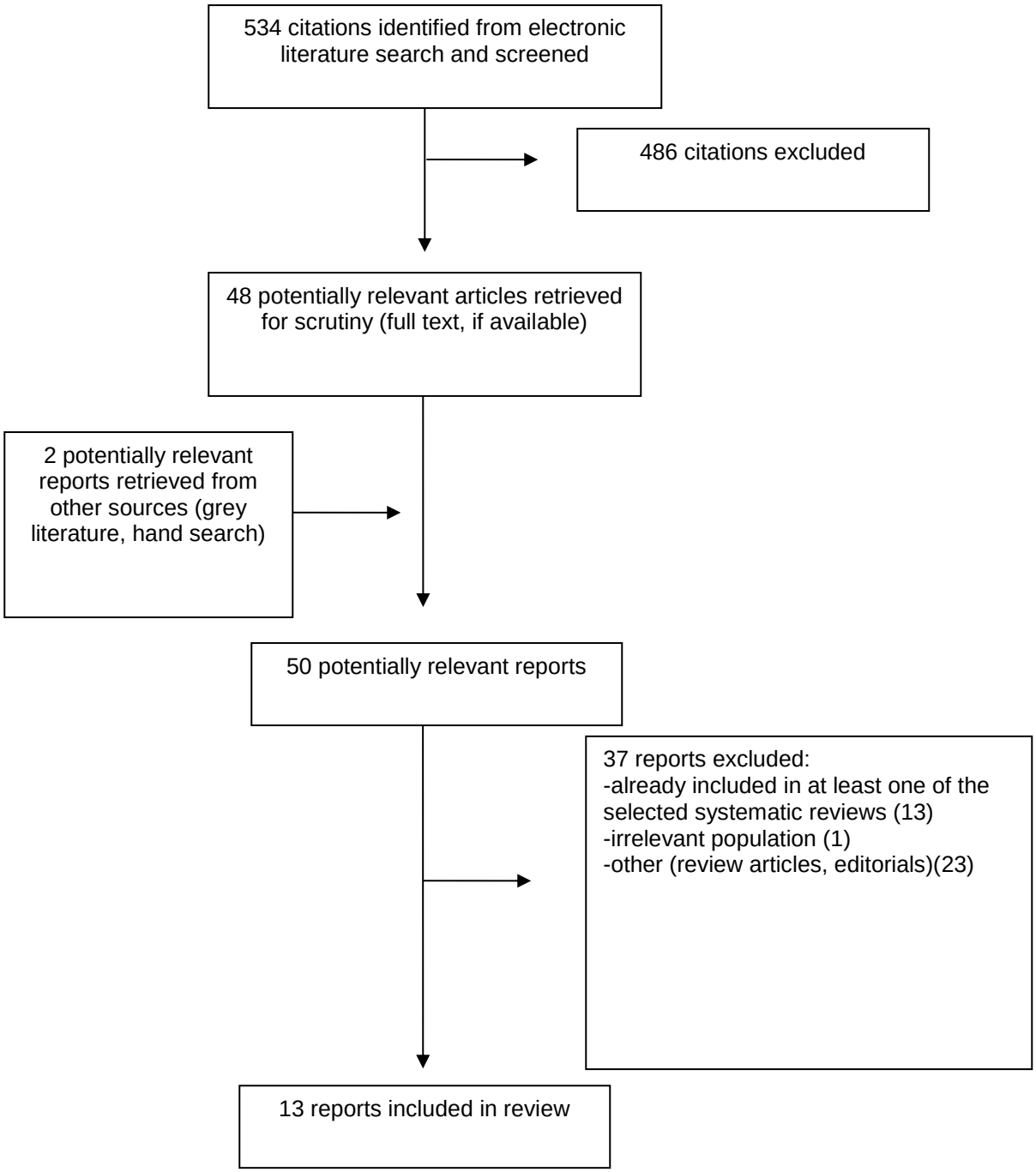
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Study Designs and Numbers of Primary Studies Included	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Shah, 2018[8] **United States**	Systematic review and meta-analysis of observation studies, including case reports, series, prospective studies from January 1990 to October 2017 Systematic review included 70 studies including 5099 patients undergoing a total of 5908 MRI scans Meta-analysis included 31 studies	Must include MRI scanning in the presence of a non-MRI conditional CIED	Non-MRI conditional CIED	Unintended programming changes: changes in CIED compared to the mode that it was programmed to prior MRI Lead failure: need for lead replacement or revision Electrical resets: reversion to manufacturer-specified parameters Inappropriate anti-tachycardia therapies: anti-tachycardia pacing or internal defibrillation shocks due to interference Symptoms: patient verbalizing complaint
Shurrab, 2018[9] **Canada**	Meta-analysis of comparative trials Search up to August 28, 2017 Six studies (5 retrospective and 1 prospective non-randomized study) for a total for 2118 patients.	Adult population Patients must have either MRI-conditional pacemaker or a conventional pacemaker	MRI-conditional pacemaker Conventional pacemakers	Rate of pacemaker lead dislodgement (atrial and ventricular) Pericardial complications (eg. pericarditis, pericardial effusion, cardiac tamponade) Overall complications Pacemaker parameters (sensing and packing thresholds and impedance)

CIED = cardiac implantable electronic device; MRI = magnetic resonance imaging;

Table 3: Characteristics of Included Primary Clinical Studies

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Han 2019[12] **South Korea**	Retrospective cohort study	35 patients with pacemakers or ICDs who underwent 1.5T MRI scans Mean age 70.1 years old MRI locations included brain, spine, abdomen/pelvis and extremities	MRI scans with MR-conditional group (must have MR-conditional leads and MR-conditional generators) compared with conventional group	Device interrogation including battery voltage, pacing thresholds, P-wave and R-wave amplitudes, pacing lead impedances, high-voltage impedance Patient reported symptoms Mean follow-up of 5 months
Tanaka 2019[18] **United States**	Retrospective cohort analysis	25 patients with CIED (pacemakers or ICD) from January 2012 to June 2016 who received a prostate MRI	Patients received 1.5T prostate MRI with CIED Patients received 1.5T prostate MRI without CIED	Serious cardiac device-related adverse events (life-threatening events due to MRI or pacing system) during or after MRI Death from any cause Qualitative MRI image analysis
Vuorinen 2019[19] **Finland**	Retrospective case series	The first 1000 clinically indicated MRI exams in patients with cardiac pacing devices from November 2011 to April 2017 Adult patients mean age 69.5, range (18 to 97 years old)	1.5 T MRI	Generator failure, power-on reset, unexpected battery depletion, patient-reported events (discomfort, pain, warm sensation near device, palpitations)
Do 2018[11] **United States**	Retrospective case series	All patients with non-MRI conditional cardiac IEDs who underwent a cardiac MRI between April 2013 to October 2016 Mean age 59 ± 14 years old	Cardiac MRI scan with 1.5 T	Clinical deterioration or death during the study; device generator failure requiring replacement, lead failure requiring replacement, new onset atrial or ventricular arrhythmia, loss of capture in pacemaker dependent patients or electrical reset Within 1 to 6 months

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Lupo 2018[13] **Italy**	Prospective cohort study	Patients with a conventional pacemaker or conventional ICD From December 2016 to November 2014 120 patients (90 males) with median age of 67 years old (interquartile 51 to 67) with 142 MRIs compared to 95 patients (72 males) with median age of 67 years (interquartile range 59 to 75) for 50 chest x-rays or CTs and 48 outpatient visits	Patients who needed an MRI as it was indispensable for diagnosis and/or treatment planning Patients who received a chest x-ray or thoracic CT or referred to routine follow-up	Primary safety endpoints included: 1) onset of arrhythmias or other cardiac or non-cardiac events requiring life-support procedures; 2) onset of arrhythmias or other cardiac or non-cardiac events prompting interruption of the examination even though not requiring life-support procedures; 3) modification of the functional status of the device after MRI (full or partial electrical reset); 4) any other adverse event related or unrelated to MRI During or within 3 hours of MRI examination
Nyotowidjojo 2018[15] **United States**	Retrospective cohort study	Adult patients with MRI non-conditional CIED (pacemaker, ICD, and CRT) from December 2013 to July 2016 Mean age 65 ± 15 years with 38% female	1.5T thoracic MRI scan 1.5T non-thoracic MRI scan	Patient reported symptoms or arrhythmias; power on reset Follow-up 3 to 6 months after MRI scan
Padmanabhan 2018[17] **United States**	Retrospective cohort study using databases	Adult patients with CIED who underwent an 1.5T brain MRI excluding those who had device implantation before 2005	Patients with non-MRI-conditional CIEDs with brain MRIs Patients without CIEDs who underwent brain MRI Patients with CIEDs who underwent brain CT Patients without a CIED who underwent a CT	Long-term mortality Five years
Nazarian 2017[14] **United States**	Prospective, non-randomized study (ie. Case series)	Patients with a pacemaker (58%) or ICD (42%) that was not	1.5 T MRI	Adverse events: generator failure, power-on reset,

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
		considered to be MRI-conditional (ie. Conventional or legacy) with a clinical indication for MRI Median age 69.3 with IQR 57.7 to 78.1		changes in pacing threshold or sensing that require system revision or programming changes, battery depletion, cardiac arrhythmia, inhibition of pacing, inappropriate delivery of anti-tachycardia pacing or shock, patient-reported events (discomfort, warm sensation, palpitations).
Okamura 2017[16] **United States**	Prospective, non-randomized, single center study (ie. Database review)	Adult patients with MRI scans from January 2008 to May 2015 with non-MRI conditional CIEDs who were clinically indicated for an MRI and had a nearly depleted CIED battery Mean age 66.4 years ± 10.8 years	1.5T MRI scan	Clinical events of patients with nearly depleted battery before MRI scan and devices indicated elective replacement or were replaced due to battery depletion within 3 months after MRI scan
Yadava 2017[20] **United States**	Prospective case series	Patients over the age of 8 with a permanent pacemaker or ICD who medically required an MRI including those with MR-conditional and non-conditional ICDs	1.5T MRI scans	Arrhythmias requiring anti-tachycardia pacing and/or defibrillation Tachyarrhythmias needing defibrillation that were not effectively treated 1 to 6 weeks post MRI and longer if possible
Camacho 2016[10] **United States**	Prospective case series	Patients with clinical need for MRI but are not able to receive alternative imaging, laboratory, surgical or other examination Received 1.5T MRI scan Mean age 66 years old, range (20 to 89)	1.5T MRI in patients with conventional and MRI-conditional CIEDs	Patient reported safety outcomes Diagnostic question Quality of the imagines including artefacts

CHD = coronary heart disease; CIED = cardiovascular implantable electronic device; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; IED = implanted electronic device; IQR = interquartile range; MRI = magnetic resonance imaging; T = Tesla

Appendix 3: Critical Appraisal of Included Publications

Table 4: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR[4]

AMSTAR Item		Shah et al. 2018[8]	Shurrab et. al. 2018[9]
Was an a priori design provided?		+	+
Was there duplicate study selection and data extraction?	Selection	?	+
	Extraction	?	+
Was a comprehensive literature search performed?		+	?
Was the status of publication (i.e. grey literature) used as an inclusion criteria?		X	X
Was a list of studies (included and excluded) provided?	Included	+	+
	Excluded	-	-
Were the characteristics of the included studies provided?		+	+
Was the scientific quality of the included studies assessed and documented?		X	+
Was the scientific quality of included studies used appropriately in formulating conclusion?		?	+
Were the methods used to combine the findings of studies appropriate?		+	+
Was the likelihood of publication bias assessed?		+	X
Was conflict of interest included?		X	+

Table 5: Strengths and Limitations of Clinical Studies using Downs and Black[5]

Strengths	Limitations
Han, 2019[12]	
• Objectives were clearly described in the study. • Comparative study to help identify the safety with MR-conditional ICDs compared with conventional ICDs. • Baseline characteristics seem balanced between the two groups. • Statistical analyses were appropriate for the study. • Clearly identified why someone had withdrew from the study. • Authors' conclusions were correct as per study results. • Authors declared no conflicts of interest.	• Methods and outcomes of interest were not provided in the study. • Small, non-randomized study which can introduce bias and affect the outcomes of the study. • Relatively short follow up, average of five months, making long-term safety outcomes unclear. • Conducted in South Korea, may not be applicable for the Canadian health system.
Tanaka, 2019[18]	
• Objectives were clearly described in the study. • Methods and outcomes of interest were provided in the study. • Retrospective cohort analysis with matched controls, will	• Small, non-randomized study which can introduce bias and affect the outcomes of the study. • Single center study, making results difficult to generalize.

Strengths	Limitations
reduce the risk of confounding bias. • Statistical analyses were appropriate for the study. • No patients were lost to follow-up. • Authors' conclusions were correct as per study results.	• Baseline characteristics seem balanced between the two groups. • Conducted in US, may not be applicable for the Canadian health system. • Conflict of interest and funding information was not provided.
Vuorinen, 2019[19]	
• Objectives were clearly described in the study. • Methods and outcomes of interest were not provided in the study. • Statistical analyses were appropriate for the study. • Large cohort for follow-up (1000 scans). • Authors' conclusions were correct as per study results. • Authors declared no conflicts of interests.	• Non-randomized study without a control group which can introduce bias and affect the outcomes of the study. • Descriptive analyses only, as it is non-comparative it is difficult to determine the true safety effects. • Conducted in Finland, may not be applicable for the Canadian health system.
Do, 2018[11]	
• Objectives were clearly described in the study. • Statistical analyses were appropriate for the study. • Authors' conclusions were correct as per study results. • Authors declared their conflicts of interest and their funding.	• Methods and outcomes of interest were not provided clearly in the study. • Small, single center, non-randomized study without a control group which can introduce bias and affect the outcomes of the study. • Relatively short follow up, one to six months, making long-term safety outcomes unclear. • There is missing data and it is unclear why it is missing. • Conducted in United States, may not be applicable for the Canadian health system. • One of the authors is the inventor of the imaging technique and can bias the outcomes.
Lupo, 2018[13]	
• Objectives were clearly described in the study. • Methods and outcomes of interest were provided clearly in the study. • Statistical analyses were appropriate for the study. • Applied Bonferroni correction for multiple comparisons when doing statistical analyses. • Baseline statistics between the two groups were balanced at the beginning with the exception there was more time between device implantation and study enrollment in the MRI group. • Authors' conclusions were correct as per study results. • Authors declared no conflicts of interest. • Funding of the study was declared.	• Small, single center, non-randomized study without a control group which can introduce bias and affect the outcomes of the study. • Relatively short follow up, 3 hours post examination, making long-term safety outcomes unclear. • Conducted in United States, may not be applicable for the Canadian health system.
Nyotowidjojo, 2018[15]	
• Objectives were clearly described in the study. • Authors' conclusions were correct as per study results.	• Methods were not clearly described, in one section of the article, it suggests this was a prospective cohort study while in another section, it suggests it was a retrospective analysis. • Outcomes were not clearly provided in the methods section. • Small, single center, non-randomized study without a control group which can introduce bias and affect the outcomes of the study.

Strengths	Limitations
	• No comparative analysis was done for clinical outcomes between the two groups. • Relatively short follow up, 3 to 6 months post examination, making long-term safety outcomes unclear. • There is missing data, approximately half, and it is unclear what has happened to the missing data. • Conducted in United States, may not be applicable for the Canadian health system. • No declaration of conflicts of interest or funding for this study.
Padmanabhan, 2018[17]	
• Objectives were clearly described in the study. • Methods and outcomes of interests were provided clearly in the study. • Statistical analyses were appropriate for the study. • Clinically relevant outcome of mortality is useful to aid clinical decisions. • Cohort study and compared treatment against control to try to determine the risks associated with treatment group. • Authors' conclusions were correct as per study results. • Authors declared no conflicts of interest.	• Single center, database review study may increase bias to the results. • Baseline characteristics for comorbidities, including atrial fibrillation, chronic kidney disease, COPD, diabetes, hypertension and ischemic heart disease were quite different between the groups and may also affect the outcomes. It was unclear if this was controlled for in the analyses. • The defined follow-up period was for five years but the median follow-up for each of the groups was under two years. This was then used to extrapolate to a 5-year mortality hazards ratio. • Conducted in United States, may not be applicable for the Canadian health system.
Nazarian, 2017[14]	
• Objectives and methods were clearly described in the study. • Definitions of outcomes of interests were provided. Appropriate objective measures were used. • Large study (1509 patients) • Statistical analyses seemed appropriate for this type of study. • Results were clearly described in the text and tables as necessary. • Authors' conclusions were correct as per study results. • Authors' conflict of interests were provided.	• Cardiac MRI used in this scenario was non-diagnostic and may limit the usability of these results. • Conducted in US, which may not be reflective of the Canadian health system. • Long-term follow up results for device interrogation was only available for 63% of the patients. It was unclear why there was missing information for almost 40% of the patients. • Authors have received funding from the manufacturers of various ICEDs.
Okamura, 2017[16]	
• Objectives, methods, and outcomes were clearly described in the study. • Statistical analyses seemed appropriate for this type of study. • Results were clearly described in the text and tables as necessary. • Authors' conclusions were correct as per study results. • Authors declared conflict of interest.	• Small, nine patients, non-randomized study without a control group which can introduce bias and affect the outcomes of the study. • Case series study, blinding is not possible as there was only one intervention. • Single center study in United States, may not reflect Canadian healthcare system. • As there is no comparisons, only descriptive results are available.
Yadava, 2017[20]	
• Objectives, methods and outcomes were clearly described in the study. • Descriptive statistical analyses seemed appropriate for this type of study. • Results were clearly described in the text and tables as	• Single center study, making it difficult to generalize results. • Non-randomized trial may introduce bias and overestimate the outcomes the results. • Inclusion criteria included anyone 8 years and older but the baseline characteristics on the entire population is unclear.

Strengths	Limitations
necessary. • Authors' conclusions were correct as per study results.	• Short-term follow up at one to six weeks, no long term safety outcomes. • About 40% of the follow-up data was missing and was not accounted for. • Conducted in the US, may not reflect Canadian healthcare system. • Authors have declared that they have received fees from various manufacturers of CIEDs.
Camacho, 2016[10]	
• Objectives and methods were clearly described in the study. • Descriptive statistical analyses seem appropriate for this type of study. • Results were clearly described in the text and tables as necessary. • Authors' conclusions were correct as per study results.	• Definitions of outcomes of interests were not provided. • Single center study, making it difficult to generalize results. • Although both MRI-conditional and conventional CIEDs were of interest, no comparisons were done. • Non-randomized trial may introduce bias and overestimate the outcomes the results. • Descriptive results. • Conducted in the US, may not reflect Canadian healthcare system. • No declaration of conflicts of interests.

ICD = implantable cardioverter-defibrillator; US = United States;

Appendix 4: Main Study Findings and Authors' Conclusions

Table 6: Summary of Findings Included Systematic Reviews and Meta-Analyses

Main Study Findings	Authors' Conclusion
Shah, 2018[8]	
• Lead failure: found in 3 leads from 3 brands; Medtronic model 5076 after 1 month of brain MRI; Boston Scientific Model 0148; Biotronik Selox ST 60 after 1.5T cranial MRI • Electrical reset: identified in 94 MRI scans, a rate of 1.6%; all observed with an older pacemaker and defibrillator pulse generator prior to 2006; more likely to occur with Medtronic devices compared to other brands • Patient symptoms: infrequent (0.3%) with reports of palpitations	"This systematic review and meta-analysis demonstrates that clinical events after MRI in patients with a non-MRI conditional CIED are infrequent, although lead and vital device function remains clinically unchanged for the very large majority of patients. Given low event rates after MRI in non-MRI conditional CIED recipients, there is a reasonable expectation of safety in patients with appropriately screened and programmed non-MRI conditional devices."[8] (*p*1007)
Shurrab, 2018[9]	
• Rate of pacemaker lead dislodgement was higher in the MRI group 3% vs. 1% (OR 2.47, 95% CI 1.26 to 4.83, p = 0.008) • Pericardial complications: higher in the MRI group 2% vs. 1% (OR 4.23, 95% CI 1.18 to 15.10, p = 0.03) • Overall complication rate: non-statistical increase in the MRI group 6% vs. 3% (OR 2.02, 95% CI 0.88 to 4.66, p = 0.10) • Sensing parameters of atrial and ventricular leads: lower in the MRI group immediately after MRI and at follow up (6 weeks to 12 months); for atrial leads p = 0.007 and for ventricular leads p = 0.012 • For ventricular packing, MRI group was higher p = 0.038	"This meta-analysis supports the safety of conventional PPMs in comparison with the Medtronic MRI-conditional Revo SureScan Pacing Systems with 5086 leads. The rate of pacemaker lead dislodgement was significantly higher in the MRI group. In addition, there were significantly more pericardial complications and a numerically higher overall complication rate in comparison with the conventional group."[9] (*p*238)

CI = confidence interval; MRI = magnetic resonance imaging; OR = odds ratio; T = Tesla

Table 7: Summary of Findings of Included Primary Clinical Studies

Main Study Findings	Authors' Conclusion
Han, 2019[12]	
• Total of 35 patients, 14 with MR-conditional ICDs while 21 with conventional ICDs • 43 scans were performed, 16 (37.2%) in those with MR-conditional ICDs and 27 (62.8%) with conventional ICDs. • Average 5.4 months follow-up with a range of 0.2 to 13.8 months • No generator/lead failure or battery problems were reported. • Lead impedance, sensing and capture threshold: no statistical differences between the pre- and post-MRI between the two groups except for atrial lead threshold where it was higher in the conventional group compared with the MR-conditional group (p = 0.02)	"In conclusion, MRI may be performed safely in patients with MR-conditional or conventional pacemakers or ICDs if a strict protocol based on device selection is used and careful monitoring is conducted. These results may help support the current guidelines and could provide evidence to guide further research."[12] (*p*106)
Tanaka, 2019[18]	
• 28 MRI studies in 25 patients where 12 patients had pacemakers and 13 had ICDs. • 6 patients have MRI conditional CIEDs, 19 patients with MRI-	"In conclusion, in this study, patients with a CIED could safely undergo prostate 1.5-T multiparametric MRI under controlled conditions with acceptable diagnostic image quality using a

Main Study Findings	Authors' Conclusion
unsafe CIED. • No reports of patients complaining about any symptomatic events. • Mean time for follow-up post MRI was 4.67 days ± 5.29 days (range 1-20 days) • 1 death occurred at 42 months post MRI due to progression of metastatic prostate cancer. • Subjective analysis of images were not statistically different between the groups (p > 0.05).	low-SAR protocol."[18] (*p*4)
Vuorinen, 2019[19]	
• 1000 MRIs in 793 adult patients with cardiac pacing device • 869 (86.9%) scans in patients with conventional cardiac pacemakers, 61 (6.1%) scans with ICDs, 39 (3.9%) scans in patients with CRT with defibrillator, 31 (3.1%) scans with CRT with pacemaker device. • 1 adverse effect on pacing device detected and it went into elective replacement indicator mode. • 3 patients reported symptoms (cold or chest pain at device) but unlikely due to MRI exam. • 1 power-on reset reported.	"In conclusion, if MRI examinations in patients with cardiac pacing devices are performed in a controlled and monitored environment, these can be conducted safely also in an unrestricted patient population, including pacing-dependent patients and patients with MR-unsafe cardiac pacing devices."[19] (*p*7)
Do, 2018[11]	
• 111 patients with 114 cardiac MRIs • Deaths, new arrhythmias, immediate generator or lead failures, electrical resets, or pacing capture failures in dependent patients did not occur in any patients • Artifact in MRI study: 14 (13%) studies with 3 (3%) with severe artifact	"CMR can be performed safely in non-MRI-conditional CIEDs using a standardized protocol. Right atrial, ventricular and left ventricular lead impedances decreased immediately following the scan and persisted through follow-up, but did not result in the need for lead replacement or revision. Use of a wideband technique for LGE sequences yielded artifact-free myocardial images in 87% of studies."[11] (*p*7)
Lupo, 2018[13]	
• 127 patients received 142 MRIs compared to 95 patients received a total of 98 chest x-rays, CTs or follow-up visits • Study group with MRIs examinations had 50% with conventional pacemakers and 50% with conventional ICDs • Control group with chest x-rays, CTs or follow-up visits had 40/98 (41%) measurements with conventional pacemakers and 58/98 (59%) had conventional ICDs. • Adverse events reported between the two groups were not different (95% CI 0% to 2.6%) • Examinations were not prolonged nor interrupted due to disturbances or sensations due to device • If needed, devices could be reprogrammed post MRI, ie. No malfunctions were reported • 42% of cardiac MRIs had artifacts	"In conclusion, this study adds evidence for a favourable risk-benefit ratio of 1.5-T MRI in cPM/cICD carriers."[13] (*p*2413)
Nyotowidjojo, 2018[15]	
• 238 patients with a MRI non-conditional CIEDs for a total of 339 scans with half the patients having pacemakers, 36 with CRT-defibrillator • 99 scans of the thoracic region vs. 240 non-thoracic region • No patient reported symptoms (no statistical analyses)	"MR scanning of patients with nonconditional CIEDs was performed successfully without clinically significant changes in CIED function or adverse outcomes, using a specified institutional protocol, regardless of region scanned (thoracic vs nonthoracic)."[15] (*p*594)

Main Study Findings	Authors' Conclusion
• No adverse clinical outcomes or arrhythmias (no statistical analyses)	
Padmanabhan, 2018[17]	
• CIED patients receiving MRI: n = 289 • CIED patients receiving CT: n = 282 • No CIED patients receiving CT: n = 289 • No CIED patients receiving MRI: n = 289 • Estimated 5 year mortality rate: • Comparing between the two CIED groups: no statistical difference 33.9% for those receiving MRI and 37.3% for those receiving CT (HR 0.814, 95% CI 0.593 to 1.117, p = 0.20) • Comparing between the two groups who received MRI scans: higher mortality rate in those with CIED compared to those with CIED 25.6% vs. 33.9% (HR 1.463, 95% CI 1.019 to 2.099, p = 0.04) • Comparing between the CIED group who received a MRI scan (33.9%) and the no CIED group who received a CT scan (32.3%), there were no statistical differences (HR 1.149, 95% CI 0.818 to 1.613, p = 0.42)	"Cranial MRI of patients with pacemakers, defibrillators, and resynchronization devices is safe when performed along with real-time monitoring and protocols implemented by multispecialty, integrated care teams. Under these conditions, no differences in mortality occurred among this population when compared with patients without cardiac devices who underwent CT. These findings support changing policy to facilitate access to MRI for patients with non–MRI-conditional CIEDs in need of such imaging."[17] (*p*7-8)
Nazarian, 2017[14]	
• 1509 patients with a total of 2103 MRIs performed • 880 (58%) have a pacemaker and 629 (42%) with ICD • Power-on reset: 9 MRI exams (0.4%, 95% CI 0.2% to 0.7%) and 8 patients experienced power-on reset during MRI exam (0.5%, 95% CI 0.2% to 0.9%) • Patient reported symptoms: 1 patient reported pulling sensation in his chest during MRI	"In conclusion, we studied the safety of MRI performed on 1.5-Tesla MRI scanners in 1509 patients who had legacy cardiac pacemakers or legacy ICD systems, using a prespecified safety protocol. In only one case — a patient who had a pacemaker battery that was near the end of its battery life — device programming failure occurred, which resulted in the need for replacement of the device. Changes in device parameters were infrequent, and none resulted in long-term clinically significant adverse events."[14] (*p*2563)
Okamura, 2017[16]	
• 569 MRI scans completed in 442 patients and 13 scans were identified in 9 patients with nearly depleted batteries • Patients with pacemakers (implanted before 2015): immediately after the scan 3 patients had potential for significant problems with 1 patient where pacing mode cannot be changed • Patients with ICDs: 6 patients and pacing was not affected and was considered normal function immediately after the scan	"Nonpacemaker-dependent patients with pacemakers and ICDs with a nearly depleted battery can safely undergo MRI under careful monitoring with ECG and pulse oximetry. However, close attention should be paid because scanning of old devices can result in PoR or ERI during the scan and the experience with these devices and MRI scanning is limited."[16] (*p*481)
Yadava, 2017[20]	
• 227 patients who had 293 MRI scans • 2.8% ICDs were MR-conditional • 39.9% thoracic scans • Median follow-up of 354 days (IQR 65 to 629 days): 12 patients had arrhythmias requiring anti-tachycardia pacing	"MRI can be performed safely in patients with CIEDs using a protocol for patient selection and device programming. Appropriate supervision with hemodynamic monitoring and device interrogation before and after MRI is essential. Although clinically significant changes in device parameters are occasionally seen after MRI, these alterations are usually transient and rarely require device revision or reprogramming."[20] (*p*101)

Main Study Findings	Authors' Conclusion
Camacho, 2016[10]	
• 113 MRIs in 104 patients where 74 (65.4%) of the MRIs were done in those with pacemakers and 39 (34.5%) were those with ICDs • For the pacemakers (n = 74), 60 (81.1%) had conventional devices vs. 15 (18.9%) had MRI-conditional devices • 3 MRI exams: patients experienced clinical symptoms, all transient including heating at the pocket site, tingling at the pocket site, palpitations • Diagnostic questions: answered in all MRI examinations • 4/113 images had artefacts but only if the CIED was in the field of view • No artefacts for MRIs of brain, spine, neck, pelvis or extremities	"Patients with CIEDs (conventional and MRI conditional) safely underwent MRI at 1.5 T. Sixty-three percent of devices required reprogramming before MRI acquisition. Device-related artifacts occurred when the device was included in the FOV. Device-related artifacts obscured adjacent tissues, in particular those immediately surrounding the pulse generator. Otherwise, studies were not limited by device-related artifacts."[10] (*p*604)

CIED = cardiovascular implantable electronic device; ICD = implantable cardio-defibrillator; MR = magnetic resonance; MRI = magnetic resonance imaging; PoR = Power on Reset; CT = computed tomography; SAR = specific absorption rate

Appendix 5: Studies Included in Shah et al.

Table 8: Studies Included in Shah et al.

Primary Study Citation	Systematic Review Citation
	Shah et al. (2018)[8]
Ali (2016)	✓
Anfinsen (2002)	✓
Atar (2016)	✓
Baser (2012)	✓
Bertelsen (2017)	✓
Boilson (2012)	✓
Bovenschulte (2012)	✓
Buendia (2010)	✓
Buendia (2011)	✓
Burke (2010)	✓
Cohen (2012)	✓
Dandamudi (2016)	✓
Del Ojo (2005)	✓
Dickfeld (2011)	✓
Fiek (2004)	✓
Fontaine (1998)	✓
Forleo (2010)	✓
Friedman (2013)	✓
Fritzsche (2006)	✓
Garcia-Bolao (1998)	✓
Gillam (2017)	✓
Gimbel (1996)	✓
Gimbel, Bailey, Tchou, Ruggieri, Wilkoff (2005)	✓
Gimbel, Kanal, Schwartz, Wilkoff (2005)	✓
Gimbel (2008)	✓
Gimbel (2009)	✓
Goldsher (2006)	✓
Goldsher (2009)	✓
Heatlie (2007)	✓
Higgins (2014)	✓
Higgins (2015)	✓

Primary Study Citation	Systematic Review Citation
	Shah et al. (2018)[8]
Higgins (2016)	✓
Horwood (2017)	✓
Hwang (2016)	✓
Inbar (1993)	✓
Junttila (2011)	✓
Kaasalainen (2014)	✓
Maffe (2012)	✓
Martin (2004)	✓
Mason (2017)	✓
Mesubi (2014)	✓
Millar (2010)	✓
Mikolich (2007)	✓
Mollerus (2008)	✓
Mollerus (2010)	✓
Muehling (2014)	✓
Naehle (2006)	✓
Naehle (2008)	✓
Naehle (2009)	✓
Naehle (2011)	✓
Nazarian (2006)	✓
Nazarian (2011)	✓
Nemec (2006)	✓
Njeim (2016)	✓
Pulver (2009)	✓
Roguin (2005)	✓
Rozner (2005)	✓
Russo (2017)	✓
Samar (2017)	✓
Sardanelli (2006)	✓
Shah (2017)	✓
Sheldon (2015)	✓
Sommer (2000)	✓
Sommer (2006)	✓
Strach (2010)	✓

Primary Study Citation	Systematic Review Citation
	Shah et al. (2018)[8]
Stevens (2014)	✓
Strom (2017)	✓
Vahlhauc (2001)	✓
Wolllmann (2005)	✓

Appendix 6: Conditional Devices Used Within Specified Environments

MRI conditional devices have been engineered to minimize the potential for undesired interactions with MRI machines that could result in the compromise of the device function or impact patient safety.[21] One aim of this review was to summarize the safety outcomes observed when conditional cardiac devices are used outside of the approved conditional conditions. No studies were identified that examined the use of conditional devices in conditions outside of those prescribed by the manufacturer; however, 16 clinical studies[22-36]) were identified that reported on the safety of MRI for participants with conditional implanted cardiac devices.

In the clinical studies, few MRI-related adverse events were reported. No MRI-related adverse events were observed in participants undergoing 1.5T MRI for cardiac, spine, or brain imaging.[22,23,30-35] Six studies examined 1.5T MRI for imaging in various parts of the body.[24,36 25-28] No adverse events were observed in four studies.[25-28] Murray et al.[24] reported three minor, acute MRI-related events. Gold et al. observed minor events in five patients, including warmth at the site of the device, low back pain, burning sensation and tachycardia. None of the participants sustained any prolonged harms.[36] No adverse events were observed in participants undergoing 3T MRI.[22,28] Williamson et al.[29] did not specify which type of MRI machine they were using but also reported no adverse events.

The results of these studies suggest that MRI-conditional devices are safe when used in accordance with the conditions outlined by the manufacturer. The safety of these devices when used outside of the prescribed MRI settings is unclear.

Appendix 7: Additional References of Potential Interest

Guidelines with Unclear Methodology

Verma A, Ha AC, 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(10):1131-1141.

Publications where full text was not able to be obtained

Gniadek-Olejniczak K, Makowski K, Olszewski A, Tomczykiewicz K, Krawczyk A, Mroz J. State-of-the-art approach towards magnetic resonance imaging of the nervous system structures in patients with cardiac implantable electronic devices. *Neurol Neurochir Pol.* 2018;52(6):652-656.