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

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

# Appendix A – Evaluation Table

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

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

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

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

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

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

Citation	Conceptual	Design/Method	Sample/Setting	Variable Studied	Measurement	Data Analysis	Findings	Appraisal:
	Framework			and Their				Worth to Practice
Willes C. D.I.	News	Description	N ACA manage	Definitions	C	Detients men	No MDI seleted	C to a state of the second sec
W likoff, B.L.,	None	Prospective	N = 464 were	Pacemaker	Sequences were	Patients were	No MRI related	Strengths:
Bello, D.,		Randomized	randomized to	performance,	performed at	monitored for	complications	This trial documented
Taborsky, M.,		Control Trial	undergo an MRI	pacing capture	1.51 and	arrhythmias,	occurred during	the ability of the
Vymazal, J.,			scan between 9-12	threshold,	included scans	symptoms, and	or after the MRI.	pacemaker to be
Kanal, E.,			weeks post	evaluation 9-12	with high	pacemaker system		exposed in a
Heuer, H.,			implant. MRI	weeks prior to	radiofrequency	function during 14		controlled fashion to
Sommer, T.			group $n = 258 \text{ or}$	MRI, during MRI,	power	non-clinically		MRI in a 1.5T scanner
(2011).			not undergo an	and immediately	deposition	indicated relevant		without adverse
Magnetic			MRI (control	after MRI.	and/or high	brain and lumbar		impact on patient
resonance			group n = 206)	Technical	gradient dB/dt	MRI sequences.		outcomes or
imaging in			after successful	observations and	exposure.			pacemaker function.
patients with a			implantation of	adverse events				Limitations:
pacemaker			specially	were evaluated.				Data only from 1.5T
system			designed dual					magnetic field. Use of
designed for			chamber					MRI scanners on
the magnetic			pacemaker and					pacemaker patients
resonance			leads.					was specifically
environment.								limited to well-defined
Heart Rhythm								conditions in the trial
Society , 8, 65-								and safe use outside
73.								of these conditions
								was not demonstrated.
								Critical Appraisal
								Tool & Rating:
								John Hopkins
								Research Evidence
								Appraisal Tool, IA.

Framework     and Their     Worf	orth to Practice
Definitions	
Bailey, W.M., None Prospective N = 245 with Pre-MRI, atrial and Device interrogation 216 patients One adverse Strem	engths:
Mazur, A., Single, Non- stable baseline ventricular sensing was performed at completed the MRI event possibly This s	s study
McCotter, C., randomized study pacing indices and thresholds. enrollment, pre and and 1-month post- related to the demo	nonstrated the
Woodard, P.K., implanted with a Using post MRI scan, and 1 MRI follow up. implanted safety	ety and function
Rosenthal, L., Biotronik Entovis investigational and 3 months post Statistical analysis system and the of the	he ProMRI
Johnson, W., & pacemaker and software. MRI. was based on the MRI procedure pacem	emaker.
Mela, T. (2016). Sertox leads. proportion of the occurred, Limit	nitations:
Clinical safety of leads or patients adverse device Samp	nple size was
the ProMRI satisfying end-point effect-free rate insuff	ufficient to
pacemaker criteria. Two-sided of 99.6%. The obser	erve rare
system in patients 95% CIs for the study advers	erse effects of
subjected to parameters were demonstrated MRI e	I on the patient
thoracic spine and given. the clinical popul	ulation. The
cardiac 1.5T safety and numb	nber of cardiac
magnetic efficacy of the MRI w	I was lower than
resonance ProMRI thorac	racic MRI and
imaging scanning pacemaker could	ld
conditions. system. under	erestimate the
Heart Rhythm risk o	c of cardiac
Society , 13, 464- MRI.	I.
471. Criti	tical Appraisal
Tool	ol & Rating:
John	n Hopkins
Resec	earch Evidence
Appro	oraisal Tool , II
A.	

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

Citation	Conceptual	Design/Method	Sample/Setting	Variable Studied	Measurement	Data Analysis	Findings	Appraisal:
	Framework			and Their				Worth to Practice
				Definitions				
Van der Graaf,	None	Abstract	This review paper	6 studies and 4	Reviewed clinical	An overview of	With	Strengths:
A.W.M., Bhagirath,			provides an	clinical trials were	trials and	all available MRI	appropriate	This abstract
P., & Gotte, M.J.W.			overview of the	reviewed.	numerous	conditional	monitoring	demonstrated the
(2014). MRI and			currently		literature to	devices and their	and	MRI safety of
cardiac implantable			available data		study the safety	individual	application	pacemakers and
electronic devices;			related to CIEDs		of MRIs and	restrictions was	of a safety	ICDs.
current status and			and MRI and		CIEDs.	given.	protocol, MRI	Limitations:
required safety			attempts to offer				can be safely	Data was limited to
conditions.			an up-to date and				performed in	the 6 studies and
Netherlands Heart			clinically useful				patients with	4clinical trials.
Journal , 22, 269-			summary for the				CIEDs.	Studies with use of
276. Retrieved from			practicing					higher magnetic
http://dx.doi.org/10.			cardiologist. Six					strength should have
1007/s12471-014-			studies and four					been included.
0544-x			clinical trials were					Critical Appraisal
			reviewed.					Tool & Rating:
								John Hopkins
								Research Evidence
								Appraisal Tool , III
								A/B.

### EXPANDING MAGNETIC RESONANCE IMAGING MANUSCRIPT

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
				Definitions				
Nordbeck, P.,	None	Clinical Review	This clinical	Reviewed clinical	14 pacemaker	14 pacemaker	Appropriate	Strengths:
Ertl, G., &		and Update	review provides a	trials over the last	studies and 13	studies and 13	monitoring and	This review
Ritter, O.			better	20 years.	ICD studies.	ICD studies	application	demonstrated the
(2015).			understanding of			assessed the	of a safety	MRI safety of
Magnetic			the mechanisms			outcome in 1.5T	protocol, MRIs	pacemakers and
resonance			responsible for			MR scanners.	can be safely	ICDs.
imaging safety			life-threatening			There were no	performed in	Limitations:
in pacemaker			complications as			adverse events	patients with	Data was limited to
and			well as technical			reported.	CIEDs.	14 pacemaker
implantable			advances					studies and 13 ICD
cardioverter			allowing an					studies. Studies
defibrillator			increasing					with use of higher
patients: How			number of					magnetic strength
far have we			pacemakers and					(>1.5T) should
come?			ICDs to safely					have been
European			undergo MRIs.					included.
Heart								<b>Critical Appraisal</b>
<i>Journa</i> 1, 36,								Tool & Rating:
1501-1511.								John Hopkins
								Research
								Evidence
								Appraisal Tool , III
								A/B.