ESC European Society of Cardiology

Europace (2020) **22**, 288–298
doi:10.1093/europace/euz343

CLINICAL RESEARCH
Pacing and cardiac resynchronization therapy

Magnetic resonance imaging in non-conditional pacemakers and implantable cardioverter-defibrillators: a systematic review and meta-analysis

Dian A. Munawar[1,2], Joel E.Z. Chan[1], Mehrdad Emami[1], Kadhim Kadhim[1], Kashif Khokhar[1], Catherine O'Shea[1], Shinsuke Iwai[1], Bradley Pitman[1], Dominik Linz[1], Muhammad Munawar[2], Kurt Roberts-Thomson[1], Glenn D. Young[1], Rajiv Mahajan[1,3], Prashanthan Sanders[1], and Dennis H. Lau [1]*

[1]Department of Cardiology, Royal Adelaide Hospital and Centre for Heart Rhythm Disorders, University of Adelaide, 1 Port Road, Adelaide SA 5000, Australia; [2]Department of Cardiology and Vascular Medicine, Faculty of Medicine, University of Indonesia, Jakarta, Indonesia; and [3]Department of Cardiology, Lyell McEwin Hospital, Adelaide, Australia

Received 9 September 2019; editorial decision 27 November 2019; accepted 30 November 2019

Aims There is growing evidence that magnetic resonance imaging (MRI) scanning in patients with non-conditional cardiac implantable electronic devices (CIEDs) can be performed safely. Here, we aim to assess the safety of MRI in patients with non-conditional CIEDs.

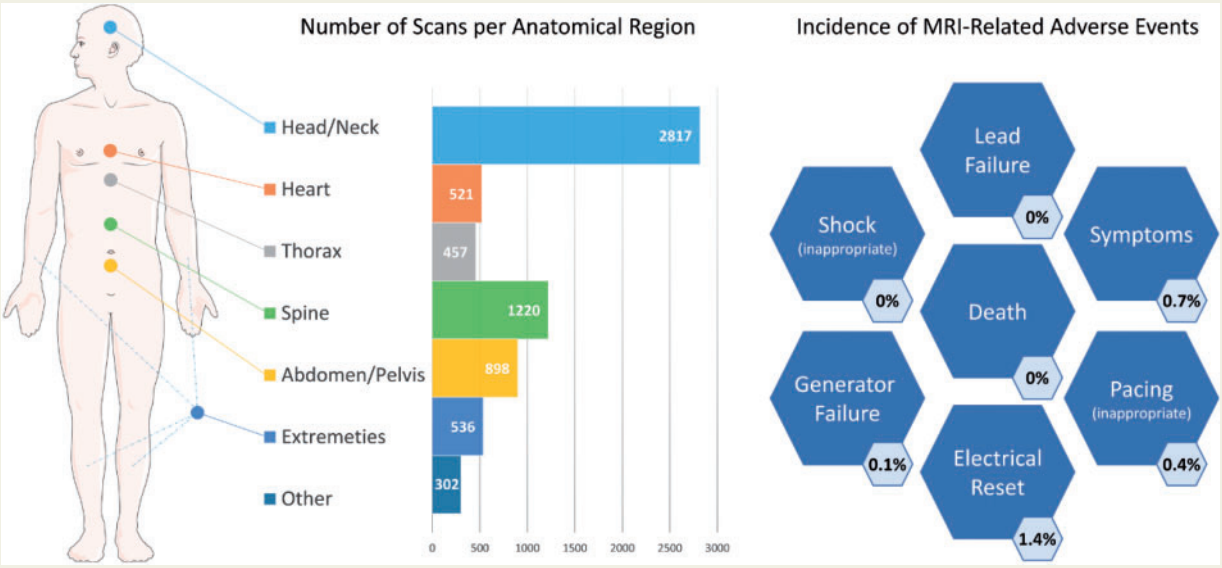
Methods and results English scientific literature was searched using PubMed/Embase/CINAHL with keywords of 'magnetic resonance imaging', 'pacemaker', 'implantable defibrillator', and 'cardiac resynchronization therapy'. Studies assessing outcomes of adverse events or significant changes in CIED parameters after MRI scanning in patients with non-conditional CIEDs were included. References were excluded if the MRI conditionality of the CIEDs was undisclosed; number of patients enrolled was <10; or studies were case reports/series. 35 cohort studies with a total of 5625 patients and 7196 MRI scans (0.5–3 T) in non-conditional CIEDs were included. The overall incidence of lead failure, electrical reset, arrhythmia, inappropriate pacing and symptoms related to pocket heating, or torque ranged between 0% and 1.43%. Increase in pacing lead threshold >0.5 V and impedance >50Ω was seen in 1.1% [95% confidence interval (CI) 0.7–1.8%] and 4.8% (95% CI 3.3–6.4%) respectively. The incidence of reduction in P- and R-wave sensing by >50% was 1.5% (95% CI 0.6–2.9%) and 0.4% (95% CI 0.06–1.1%), respectively. Battery voltage reduction of >0.04 V was reported in 2.2% (95% CI 0.2–6.1%).

Conclusion This meta-analysis affirms the safety of MR imaging in non-conditional CIEDs with no death or implantable cardioverter-defibrillator shocks and extremely low incidence of lead or device-related complications.

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

* Corresponding author. Tel: +61 8 8313 9000; fax: +61 8 8362 2273. *E-mail address*: dennis.h.lau@adelaide.edu.au
Published on behalf of the European Society of Cardiology. All rights reserved. © The Author(s) 2020. For permissions, please email: journals.permissions@oup.com.

Graphical Abstract



Keywords Magnetic resonance imaging • Cardiac implantable electronic devices • Pacemakers • Implantable cardioverter-defibrillators • Cardiac resynchronization therapy • Meta-analysis

What's new?

- Magnetic resonance imaging (MRI) in patients with non-conditional cardiac implantable electronic devices (CIEDs) is safe when strict programming protocol and patient monitoring are adhered to.
- This meta-analysis showed that in 5625 patients with non-conditional CIEDs, MRI-related adverse events were low and changes in CIED parameters were non-clinically significant.

Introduction

The use of cardiac implantable electronic devices (CIEDs) is on the rise due to prolonged life expectancy and the expanding indications for CIEDs implantation. It has been estimated that the need for a magnetic resonance imaging (MRI) scan within one year of device implantation and over the lifetime of the patient with CIED is around 10% and 75%, respectively.[1] With the recent development of MRI-conditional CIEDs, MRI scanning in patients with MRI-conditional CIEDs is increasingly being performed. However, a recent population-based cohort study showed that around 90% of all CIEDs in current use are non-conditional in the MRI environment.[2] Traditionally, MRI has been considered contraindicated in the CIED population, due to safety concerns relating to the exposure to static and gradient magnetic fields as well as radiofrequency energy. As a result, patients with older generation non-conditional CIEDs are likely to be denied access to MRI scans in many centres.

There is growing evidence that MRI scanning in patients with non-conditional CIEDs can be performed safely without patient harm or clinically significant changes in CIEDs parameters with appropriate device programming, patient screening and monitoring.[3] To this end, the 2017 Heart Rhythm Society expert consensus statement provided a Class IIa recommendation (level of evidence B) for MRI scanning of non-conditional CIEDs.[4] More recently, the evidence base for the safety of MRI scanning in non-conditional CIEDs has grown significantly with additional data from almost 2000 patients.[5–7] Here, we performed an updated systematic review and meta-analysis to evaluate the safety of MRI scanning in patients with non-conditional CIEDs.

Methods

Literature search and data sources

This meta-analysis was registered on PROSPERO (CRD42019118485) and conducted in accordance with the MOOSE guidelines (Supplementary material online, *Table S1*). Searches were conducted using the medical scientific electronic databases: PubMed, EMBASE, and CINAHL from inception to 5 December 2018 to identify all relevant studies. The search used keywords of 'magnetic resonance imaging' AND 'pacemaker' OR 'implantable cardioverter defibrillator' OR 'cardiac resynchronization therapy'. The search was limited to the articles in the English language and human studies. All references obtained through the

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

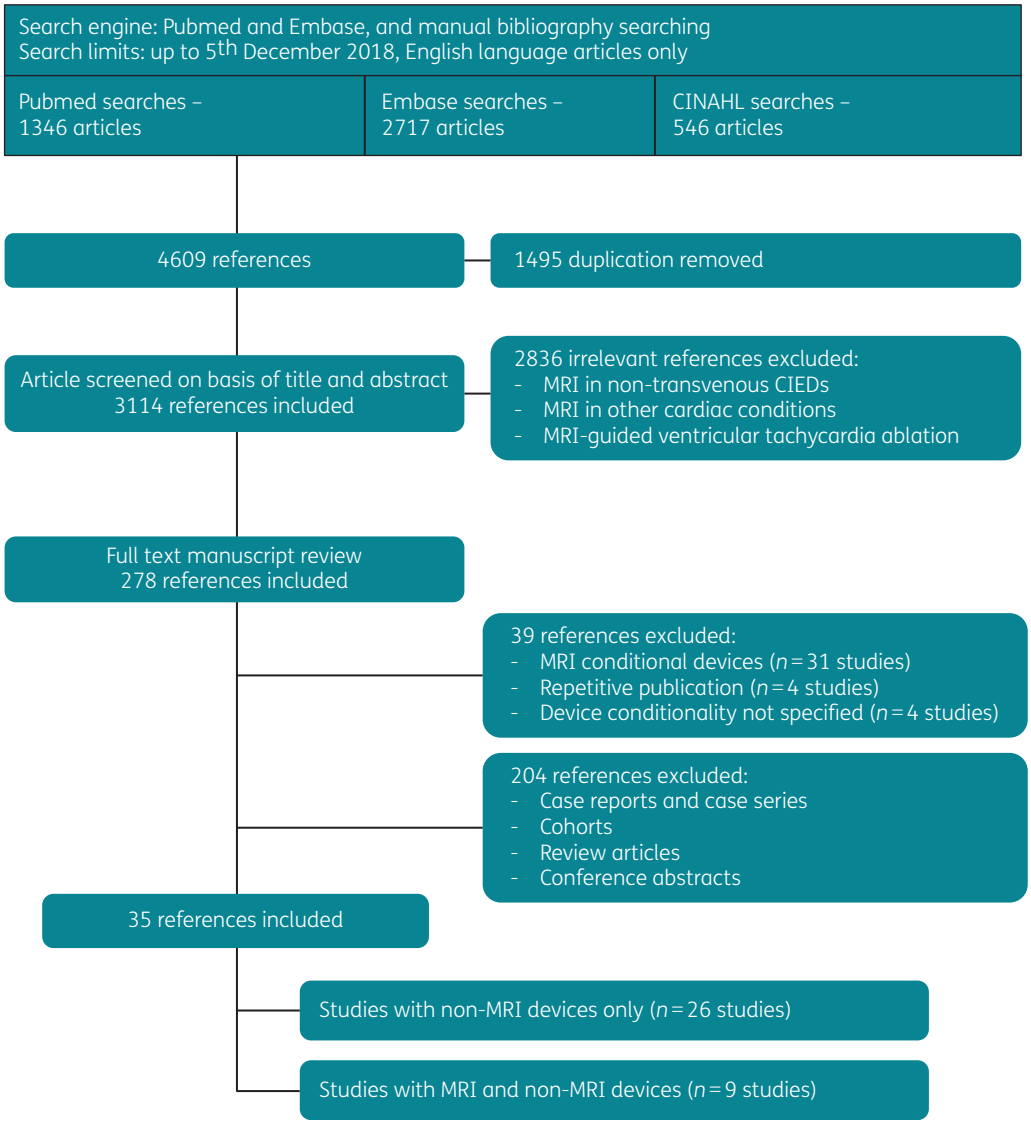


Figure 1 A CONSORT diagram showing search methodology. CIED, cardiac implantable electronic device; MRI, magnetic resonance imaging.

databases were reviewed manually. Bibliographies of retrieved articles and reviews were searched manually for additional publications.

Study selection and quality assessment

Citations were included if the following criteria were met: (i) enrolment of patients with non-conditional CIEDs undergoing MRI scanning; and (ii) adverse events during or immediately after MRI scanning were assessed. Studies were excluded if the MRI conditionality of the CIEDs was undisclosed or if they included <10 patients or if they were review/case reports/series. Eligibility assessment was performed independently by two investigators (D.A.M. and J.E.Z.C.). Disagreements were resolved by consensus. Selected publications were analysed for the following outcomes: (A) adverse events relating to MRI scans, comprising of (i) death; (ii) peri-procedural symptoms—including heating or torque at generator site, chest pain, or palpitation; (iii) electrical reset—defined as reversion to manufacturer's specified parameters (indicated as Safety Mode, Reset Parameters, or Back-Up mode); (iv) lead failure—defined as failure of lead function requiring replacement or revision; (v) generator failure—defined as inability to communicate with CIEDs via device programmer or sudden drop in battery voltage requiring replacement; and (vi) inappropriate pacing; (B) changes in CIEDs parameters, comprising of: (i) pacing lead threshold increase (≥0.5 V, ≥1.0 V, or ≥50%); (ii) amplitude decrease (≥50% for P wave and ≥25% and ≥50% for R wave); (iii) pacing lead impedance increase (≥50% or ≥50Ω); and (iv) battery voltage decrease (>0.04 V).

Data extraction sheet was developed based on Cochrane Consumers and Communication Review Group's data extraction template and refined accordingly. Assessment of the methodological quality of clinical trials included was performed according to the Cochrane Collaboration's tool for assessing risk of bias. The relevant checklists are included in the Supplementary material online.

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

Table 1 Composite study characteristics by MRI type

	≤1.5 T	>1.5 T
Number of studies	32	4
Number of patients	5541	84
Number of pacemaker-dependent patients	559	2
Number of devices		
Permanent pacemaker	3506	75
Implantable cardioverter-defibrillator	1845	6
Implantable loop recorder	9	1
Leads		
Atrial leads	2554	68
Right ventricular leads	3046	78
Left ventricular leads	281	1
Defibrillator leads	1845	6
Abandoned leads	26	0
Epicardial leads	8	0

MRI, magnetic resonance imaging.

Statistical analysis

This meta-analysis was carried out utilizing the StatsDirect Statistical software (Version 3.1.21, StatsDirect Ltd, Cambridge, UK). For nominal values, the pooled weighted proportion was used with its 95% confidence interval (CI). The Mantel–Haenszel fixed effect and the Der Simonian–Laird random effect models were followed when heterogeneity was found among studies by means of I^2 and the statistical Cochran's Q tests. I^2 values of <25%, 25–50, and >50% normally correspond to small, medium, and large heterogeneity, respectively. Statistical significance was defined as $P < 0.05$.

Results

A total of 4609 English citations were identified using the search strategy. After removing duplication, 3114 studies were screened based on the title and abstract. A total of 2836 studies were excluded on account of relevance (*Figure 1*). After secondary review of the full-text articles in the remaining 278 selected studies, 204 studies were excluded because they were review articles, case reports or case series, cohort studies, or conference abstracts. A total of 39 studies were excluded due to repetitive publication ($n = 4$), not including non-conditional devices ($n = 31$), and undisclosed conditionality of the CIEDs ($n = 4$). As a result, 35 cohort studies (Supplementary material online *Table S2*) with a total of 5625 patients and 7196 MRI scans (0.5–3 T) in non-conditional CIEDs were included in the analysis (*Table 1*).

Of the 35 included studies, 31 studies ($n = 5518$) utilized 1.5 T MRI, three studies ($n = 78$) utilized >1.5 T MRI, and one study utilized both 1.5 and 3 T MRI ($n = 29$).[8] Ten studies recruited pacemaker-dependent patients ($n = 561$), in which two of these patients had 3 T MRI. There was a total of 2622 atrial pacing leads, 3124 right ventricular pacing leads, 289 left ventricular pacing leads, and 1851 defibrillator leads. None of the patients with abandoned ($n = 26$) or epicardial leads ($n = 8$) had 3 T MRI. Majority of the MRI scans were for head and neck (39%), spinal (17%), and abdomen/pelvis regions (12%). The details of the study design are provided in *Table 2*.

Adverse events relating to magnetic resonance imaging scans

Figure 2 demonstrates the pooled proportion of peri-procedural events.

Death

Magnetic resonance imaging scan-related mortality was reported in nine studies ($n = 2122$ patients). These studies showed no death occurred during or immediately after the procedure.

Symptom of heating or torque

Symptom associated with either torque or heating of the generator or lead, chest pain, or palpitation, induced by MRI was described in 25 studies ($n = 4531$ patients) with an overall incidence of 0.71% (95% CI 0.35–1.18%).

Electrical reset

Of 25 studies ($n = 4896$ patients), electrical resets occurred in 76 patients with 83 MRI scans, yielding the absolute incidence of 1.43% (95% CI 0.64–2.54). Notably, in the studies disclosing the details of these devices, all resets occurred in older generation CIEDs that were first released in the market before 2005 (Supplementary material online, *Table S4*).

Lead and generator failure

Fifteen studies (3995 patients) examined the outcome of lead or generator failure. Of these, there were no cases of non-conditional lead failure reported. Additionally, two cases of generator failure were reported in two studies, with pooled absolute incidence of 0.14% (95% CI 0.05–0.28%). In one study, the implantable cardioverter-defibrillator (ICD) generator could not be interrogated during post-MRI evaluation. However, it was reported that anti-tachycardia therapy was left in the active mode during MRI, therefore, multiple anti-tachycardia pacing therapy attempts due to false ventricular fibrillation detection were notable in this particular case.[9] The other study showed battery longevity <1 month following an electrical reset, which resulted in the inability to change mode due to battery status.[5] Both devices were immediately replaced.

Inappropriate pacing

A total of 2772 patients were included in 16 studies reporting the outcome of inappropriate pacing. This analysis showed an incidence of 0.37% (95% CI 0.09–0.53). Most cases demonstrated a decrease in heart rate temporarily during MRI procedure due to pacing inhibition, except in one case, the pacing rate was increased to magnet rate (Guidant Insignia).

Implantable cardioverter-defibrillator shocks

No ICD shocks occurred during MRI scans of non-conditional ICDs (10 studies, $n = 911$ patients). In these studies, tachyarrhythmia therapies including anti-tachycardia pacing and shocks, were deactivated before the MRI scans.

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

Table 2 Detailed study characteristics

Study	Year	*N*	Study design		Procedure details			Age		Gender	
					EP cardiologist	Resuscitation equipment	Others	Mean/median	SD/IQR (range)	Male	Female
All CIED (PPM and ICD)											
≤1.5 T											
Lupo *et al.*	2018	120	Prospective	Single centre	Y	NM	NM	67	51–76	90	30
Strom *et al.*	2017	123	Prospective	Single centre	NM	NM	NM	70	19	NM	NM
Higgins *et al.*	2015	198	Prospective	Single centre	N	NM	ACLS-certified cardiac device nurse; staff radiologist; MRI physicist	66	57–77	216	182
Naehle *et al.*	2011	32	Prospective	Single centre	NM	NM	NM	60	23–76	NM	NM
Cohen *et al.*	2012	109	Retrospective	Single centre	N	NM	Cardiologist with experience in CIEDs	74	11	76	33
Russo *et al.*	2017	1246	Prospective	Multicentre	N	Y	Physician, nurse practitioner, or physician assistant with cardiac device expertise and training in ACLS	73	14	579	420
Do *et al.*	2018	111	Retrospective	Single centre	NM	NM	ACLS-trained physician/NP/PA	59	14	NM	NM
Samar *et al.*	2017	136	Prospective	Single centre	Y	Y	EP nurse	NM	NM	NM	NM
Nazarian *et al.*	2017	1509	Prospective	Multicentre	RN or EP	NM	RN who had experience in cardiac device programming and training in cardiac life support	69	58–78	961	548
Halshtok *et al.*	2010	18	Prospective	Single centre	Y	Y	Device technicians	59	11–94	15	3
Sheldon *et al.*	2015	40	Prospective	Multicentre	N	Y	Pacing nurse, technician, radiologist, and physicist	66	9–24	16	40
Mollerus *et al.*	2008	103	Prospective	Single centre	Y	Y	NM	NM	NM	NM	NM
Yadava *et al.*	2017	213	Prospective	Single centre	N	Y	EP nurse or physician assistant with experience in CIEDs functioning and ACLS	63 (PPM), 56 (ICD)	NM	NM	NM

Continued

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

Table 2 *Continued*

Study	Year	*N*	Study design		Procedure details			Age		Gender	
					EP cardiologist	Resuscitation equipment	Others	Mean/median	SD/IQR (range)	Male	Female
Horwood *et al.*	2016	136	Prospective	Single centre	NM	NM	Device nurse who was trained in ACLS	63	12	117	25
Dandamudi *et al.*	2016	51	Retrospective	Single centre	Y	Y	NM	59	14	40	18
Camacho *et al.*	2016	14	Retrospective	Single centre	Y	NM	NM	66	20–89	68	36
Hwang *et al.*	2016	29	Retrospective	Single centre	N	NM	Cardiologist	64	17–83	20	20
Mason *et al.*	2017	163	Prospective	Single centre	N	Y	Cardiologist and ACLS-trained personnel (imaging nurse)	66	24–93	102	76
Kaasalainen *et al.*	2014	42	Prospective	Single centre	N	Y	Cardiologist present when MR-unsafe PPM or ICD (later available by phone); radiologist	67	14	37	27
Shah *et al. et al.*	2017	89	Prospective	Single centre	Y for PPM dependent	NM	Physician with expertise in device management (typically an EP fellow)	65	NA	68	37
>1.5 T											
Gimbel *et al.*	2008	14	Prospective	Single centre	Y	NM	NM	NM	NM	NM	NM
Hwang *et al.*	2016	29	Retrospective	Single centre	N	NM	Cardiologist	64	17–83	20	20
PPM only											
≤1.5 T											
Sommer *et al.*	2006	82	Prospective	Single centre	Y	Y	–	67	4–89	53	29
Strach *et al.*	2010	114	Prospective	Single centre	Y	Y	–	59	9	72	42
Vahlhaus *et al.*	2001	32	Prospective	Single centre	N	Y	Cardiologist—for cardiac rhythm analysis and resuscitation	NM	NA	NM	NM
Sommer *et al.*	2000	44	Prospective	Single centre	NM	NM	One staff member, adjacent to the patient, provided continuous surveillance during the MR imaging examination	NM	NA	NM	NM

Continued

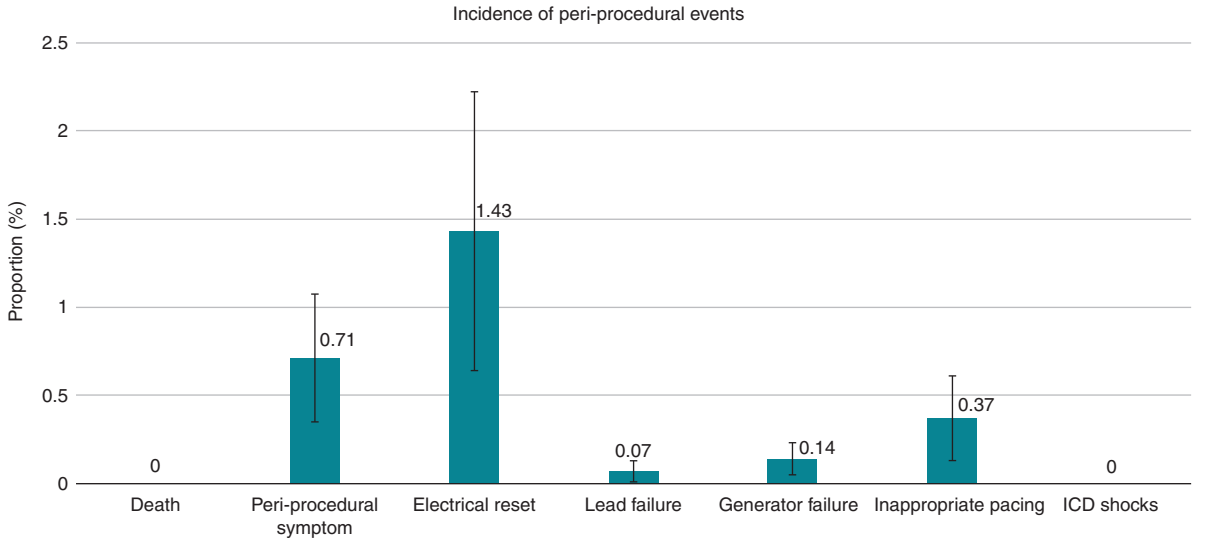
Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

Table 2 *Continued*

Study	Year	*N*	Study design		Procedure details			Age		Gender	
					EP cardiologist	Resuscitation equipment	Others	Mean/median	SD/IQR (range)	Male	Female
Martin *et al.*	2004	54	Prospective	Single centre	Y	Y	—	NM	NM	NM	NM
Naehle *et al.*	2009	47	Retrospective	Single centre	N	Y	ACLS-trained personnel	NM	NA	NM	NM
Muehling *et al.*	2014	356	Prospective	Single centre	N	Y	Cardiologist	61	9	229	127
Bertelsen *et al.*	2017	179	Retrospective	Single centre	N	NM	Cardiac team within 10 min	NM	NA	NM	NM
>1.5 T											
Del Ojo *et al.*	2005	13	Prospective	Single centre	N	Y	Member of research team	70	5.41	10	3
Naehle *et al.*	2008	51	Prospective	Single centre	Y	Y	NM	66	10–84	31	13
ICD only											
≤1.5 T											
Naehle *et al.*	2009	18	Prospective	Single centre	Y	Y	NM	62	NA	NM	NM
Dickfeld *et al.*	2011	22	Prospective	Single centre	NM	NM	NM	58	15	21	1
Junttila *et al.*	2011	10	Prospective	Single centre	NM	NM	NM	59	7	9	1
Mesubi *et al.*	2014	31	Prospective	Single centre	NM	NM	NM	62	13	30	1

ACLS, Advance Cardiac Life Support; CIED, cardiac implantable electronic device; EP, electrophysiology; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; MRI, magnetic resonance imaging; N, no; NA, not available; NP; nurse practitioner; PA, physician assistant; PPM, permanent pacemaker; RN, registered nurse; SD, standard deviation; Y, yes.

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020



	Death	Peri-procedural symptom	Electrical reset	Lead failure	Generator failure	Inappropriate pacing	ICD shocks
No. of events	0	19	76	1	2	6	0
No. of subjects	2122	4531	4896	3995	3995	2772	911
No. of studies	9	25	25	15	15	16	10

Figure 2 Incidence of MRI-related adverse events. ICD, implantable cardioverter-defibrillator; MRI, magnetic resonance imaging.

Changes in cardiac implantable electronic device parameters

The pooled proportion of patients who had changes in the CIED parameters before and after MRI scans were analysed (*Figure 3*).

Lead threshold

Twelve studies with a total of 7987 leads in 3604 patients reported the incidence of increased pacing threshold. Pooled analysis was performed in the group of studies stratified by an absolute increase of ≥0.5 V (six studies), ≥1.0 V (four studies), or ≥ 50% (two studies). A significant increase in pacing threshold was observed in 1.1% (95% CI 0.7–1.8%; I^2 34.5%), 1.0% (95% CI 0.1–2.9%; I^2 69.3%), and 1.1% (95% CI 0.2–2.8%; I^2 81.6%), respectively.

Lead impedance

Eight studies (n = 3284 patients, 7713 leads) analysed the change in lead impedance. The incidence of impedance changes >50Ω (five studies) and >50% (three studies) in low voltage devices was 4.8% (95% CI 3.3–6.4%; I^2 62.9%) and 0%, respectively. There were 132 of 727 scans (n = 658 patients) with high voltage lead impedance change of >3Ω (22.4%, 95% CI 13.7–32.5%; I^2 70.5%).

P- and R-wave sensing

The incidence of decreased P- and R-wave amplitudes of ≥50% were reported in six (n = 3274 patients, 2883 leads) and five studies (n = 3165 patients, 3515 leads), respectively. The pooled incidence of the decrease in P- and R-wave sensing were 1.5% (95% CI 0.6–2.9%; I^2 77.5%) and 0.4% (95% CI 0.06–1.1%; I^2 74.4%), respectively.

Battery voltage

Five studies (n = 1453 patients) evaluated the incidence of battery voltage drop of >0.04 V, with an incidence of 2.2% (95% CI 0.2–6.1%; I^2 90.3%).

Risk of bias within studies

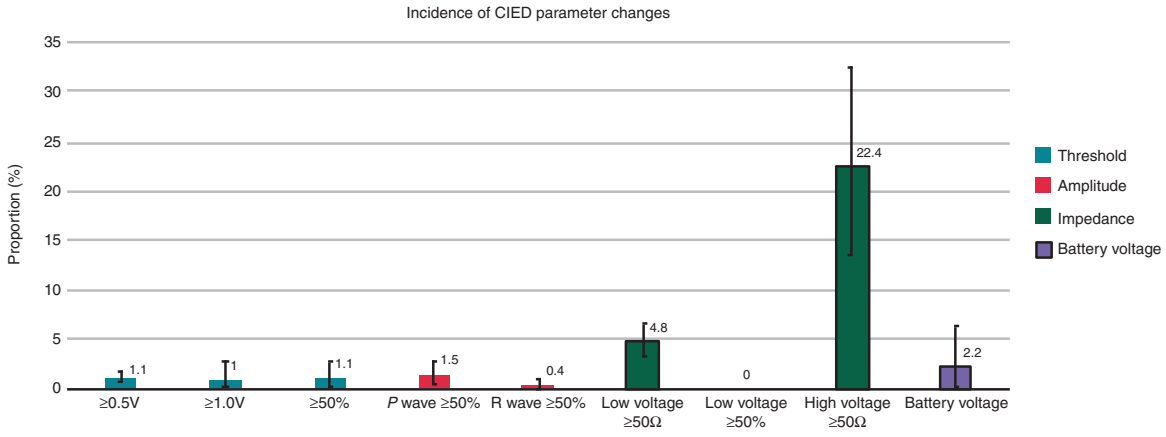
The risk of bias assessment in the included studies is shown in Supplementary material online, *Table S5*. All the studies included cohorts with appropriate study methodology and minimum risk of bias. No study was excluded based on study quality.

Discussion

This systematic review and meta-analysis of 5625 patients with non-conditional CIEDs who underwent 7196 MRI scans demonstrate no cases of death, ICD shocks or lead failure. The rate of adverse events was as follows: electrical reset (1.43%), symptom of heating or torque (0.71%), inappropriate pacing (0.37%), and generator failure (0.14%). Significant increase in lead pacing threshold was seen in up to 1.1%, while P- and R-wave sensing reduction of >50% was seen in 1.5% and 0.4%, respectively. Changes in pacing lead impedance of >50Ω and high voltage lead impedance of >3Ω were 4.8% and 22.4%, respectively, while decrease in battery voltage of >0.02 V was seen in 2.2%.

Taken together, this meta-analysis affirms the safety of MR imaging in non-conditional CIEDs with very low incidence of adverse events and non-significant changes in lead parameters. Of note, the evidence for MRI safety in patients with non-conditional CIEDs was derived primarily from scanners of ≤1.5 T. Of all 35 studies, only four studies performed MRI with 2T and 3 T machines. It remains unknown whether higher Tesla MRI scans will translate into higher theoretical

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020



	Threshold (atrial and ventricular leads)			Amplitude		Impedance			Battery voltage
				P wave	R wave	Low voltage	Low voltage	High voltage	
Cut-off value	≥0.5V	≥1.0V	≥50%	≥50%	≥50%	≥50 Ω	≥50%	≥3 Ω	≥0.04V
No. of events	32	8	32	35	12	134	0	132	32
No. of leads	3388	684	3915	2883	3515	3354	4359	727 scans	-
No. of subjects	1577	382	1645	3274	3165	1476	1808	658	1453
No. of studies	6	4	2	6	5	5	3	5	5

Figure 3 Incidence of CIED parameter changes. CIED, cardiac implantable electronic device.

risks of adverse events. Interestingly, evidence from *ex vivo* experiments showed less temperature increase with 3 T as compared to 1.5 T MRI scans.[10]

Potential hazards of magnetic resonance imaging environment to cardiac implantable electronic devices

Magnetic resonance imaging scans are traditionally contraindicated in patients with CIEDs due to initial reports of deaths when appropriate screening, reprogramming, and monitoring were not in place.[11] Potential interactions of CIEDs with the magnetic resonance environment can be due to one of the three electromagnetic fields present, namely the static magnetic field, gradient magnetic field, and radiofrequency field.[12] First, the radiofrequency and gradient magnetic fields in the MRI environment can produce high currents to result in the heating of the CIEDs' lead tip and injury of the surrounding myocardial tissue, leading to increases in pacing threshold and impedance.[13] In this meta-analysis, we found low incidence of changes in pacing lead parameters of sensing amplitude, pacing threshold, and impedance. Although the incidence of high voltage lead impedance changes of >3Ω appears high, this is likely of no clinical significance given that lead fractures were highly suspected only with abrupt impedance increase of >75% or >100Ω.[14]. Second, there is a potential of myocardial stimulation due to the radiofrequency and magnetic fields, leading to triggering of dangerous arrhythmias, inappropriate tachycardia or inappropriate pacing inhibition. While tachyarrhythmia therapy delivery during MRI is not likely to occur because of saturation in the magnetic field, permanent device failure might still happen after a given number of unsuccessful attempts to charge capacitor.[15] Our analysis did not find any significant issues with arrhythmias induction, inappropriate pacing or tachyarrhythmia therapy when appropriate CIEDs programming was undertaken for the MRI scans. Third, CIEDs can be susceptible to magnetic force and torque exerted by the static magnetic field of the MRI scanner, resulting in pulling or torque sensation without clinical consequences.[16] Reassuringly, <1% of the patients in our meta-analysis reported this symptom. Fourth, older generation CIEDs have magnet-activated reed switch that is aimed at preventing any interference during electrocautery surgery. However, when reed switch is activated by the static magnetic field, asynchronous pacing occurs at magnet rate and tachycardia therapy is disabled with potential risk for untreated tachyarrhythmias as well as accelerated battery depletion. Last, there is a risk of electrical reset of CIEDs in the MRI environment by any of the three electromagnetic fields that reverts all programming to factory default settings. In this meta-analysis, electrical reset appears to be occurring only in older generation devices that were first marketed before 2005.

Notably, all the included studies disclosed strict programming and monitoring protocol during the MRI scanning procedure. In general, CIEDs were programmed into asynchronous pacing, particularly in studies enrolling pacemaker dependent patients, or monitor only for non-pacemaker dependent patients. Tachyarrhythmia therapies, including anti-tachycardia pacing and shocks, were turned off during MRI scans. MRI procedures were supervised by either cardiologists or cardiac nurses who were trained in advanced cardiac life support and cardiac technicians with experience in device programming. Patient monitoring included a minimum of electrocardiogram and pulse oximetry.

Current practice of magnetic resonance imaging scans in patients with cardiac implantable electronic devices

Despite the availability of MRI-conditional devices and increasing evidence in the safety of MRI in non-conditional CIEDs, access for MRI scan in patients with CIEDs remains difficult. A population-based

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

study reported that in almost 17 000 patients with CIEDs, only 0.3% of patients had MRI.[2] In addition, it is also shown that MRI utilization is lower in ICD patients compared to non-ICD patients despite similar comorbidities.[17] In contrast, in well-prepared MRI centres, emergency MRI scans could also be performed safely in CIEDs patients.[18] Indeed, there are multiple barriers contributing to low rates of MRI uptake in the CIED population. The lack of MRI centres that provide services to CIEDs population might be one of the major reasons.[19] In more equipped MRI centres, real-world practice based on the current radiological guidelines is often limited to offering MRI scans to patients with CIEDs that are labelled as MRI-conditional.[20]

However, the 2017 HRS expert consensus Class IIa recommendation and the reaffirmed overall safety of MRI scans in patients with non-conditional CIEDs in this updated meta-analysis may encourage more MRI centres to offer scans to patients with non-conditional CIEDs with appropriate programming and monitoring protocol in place. Undoubtedly, the additional measures required to ensure MRI safety such as the expertise to determine clinical risk-benefit and suitability of CIEDs for MRI, to perform pre- and post-scan device programming, to manage any device-related adverse events and to arrange future follow-up; may continue to pose significant issues as these are resource-intensive and require close coordination between radiology and cardiology services.[19]

Study limitations

Our study was limited by observational cohort design in all included studies and their inherent potential biases. Several of the studies did not disclose the number of MRI scans based on device conditionality, so that data analysis based on the number of MRI scans could not be performed. In addition, more than half of the studies have small number of participants, which may underestimate the actual incidence of adverse events. Furthermore, significant study heterogeneity was evident in some of the analysis, partly because of the high number of possible combinations between device generator and lead models, MRI scanners with various field strengths, or different body areas scanned. The nature of the available data precluded differentiation between partial and full electrical reset of CIEDs. Information on the age of the CIEDs leads and the time between leads implants to MRI scanning were unavailable.

Conclusion

This systematic review and meta-analysis affirm the safety of MRI scanning in patients with non-conditional CIEDs when a strict selection and monitoring protocol is utilised.

Supplementary material

Supplementary material is available at *Europace* online.

Funding

D.A.M. was supported by the Indonesia Endowment Fund for Education, Ministry of Finance, and The Republic of Indonesia. M.E. was supported by Jitendra Vohra Scholarship from the University of Adelaide (UoA). K.Ka. was supported by Leo J Mahar Scholarship from the UoA. R.M. was supported by an Early Career Fellowship from the National Health and Medical Research Council and National Heart Foundation of Australia (HFA) and by the Leo J. Mahar Lectureship by the UoA. K.K. and B.P. are supported by The Hospital Research Fund (THRF) Biomed City Scholarship. K.K. was supported by Asia Pacific Heart Rhythm Society (APHRS) and the New Zealand Heart Foundation overseas fellowship scholarship. C.O.S. was supported by a Divisional Scholarship from the UoA. D.L. was supported by a Beacon Research Fellowship from the UoA. P.S. was supported by Practitioner Fellowships from the NHMRC and HFA. D.H.L. was supported by the Robert J. Craig Lectureship from the UoA and a mid-career fellowship from THRF.

Conflict of interest: The University of Adelaide reports receiving on behalf of Dr Mahajan lecture and/or consulting fees from Abbott and Medtronic. The University of Adelaide reports receiving on behalf of Dr Mahajan research funding from Abbott and Medtronic. P.S. reports having served on the advisory board of Biosense-Webster, Medtronic, Abbott, Boston Scientific, and CathRx. The University of Adelaide reports receiving on behalf of Dr Sanders lecture and/or consulting fees from Biosense-Webster, Medtronic, Abbott, and Boston Scientific. The University of Adelaide reports receiving on behalf of Dr Sanders research funding from Medtronic, Abbott, Boston Scientific, Biotronik, and Liva Nova. The University of Adelaide reports receiving on behalf of Dr Lau lecture and/or consulting fees from Abbott Medical, Bayer, Biotronik, BMS Pfizer, Boehringer Ingelheim, and Medtronic.

References

1. Williamson BD, Gohn DC, Ramza BM, Singh B, Zhong Y, Li S *et al.* Real-world evaluation of magnetic resonance imaging in patients with a magnetic resonance imaging conditional pacemaker system: results of 4-year prospective follow-up in 2,629 patients. *JACC Clin Electrophysiol* 2017;**3**:1231–9.
2. Gillam MH, Inacio MCS, Pratt NL, Shakib S, Roughead EE. Magnetic resonance imaging in people with cardiac implantable electronic devices: a population based cohort study. *Heart Lung Circ* 2018;**27**:748–51.
3. Russo RJ, Costa HS, Silva PD, Anderson JL, Arshad A, Biederman RW *et al.* Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. *N Engl J Med* 2017;**376**:755–64.
4. Indik JH, Gimbel JR, Abe H, Alkmim-Teixeira R, Birgersdotter-Green U, Clarke GD *et al.* 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. *Heart Rhythm* 2017;**14**:e97–153.
5. Nazarian S, Hansford R, Rahsepar AA, Weltin V, McVeigh D, Gucuk Ipek E *et al.* Safety of magnetic resonance imaging in patients with cardiac devices. *N Engl J Med* 2017;**377**:2555–64.
6. Yadava M, Nugent M, Krebsbach A, Minnier J, Jessel P, Henrikson CA. Magnetic resonance imaging in patients with cardiac implantable electronic devices: a single-center prospective study. *J Interv Card Electrophysiol* 2017;**50**:95–104.
7. Lupo P, Cappato R, Di Leo G, Secchi F, Papini GDE, Foresti S *et al.* An eight-year prospective controlled study about the safety and diagnostic value of cardiac and non-cardiac 1.5-T MRI in patients with a conventional pacemaker or a conventional implantable cardioverter defibrillator. *Eur Radiol* 2018;**28**:2406–16.
8. Hwang YM, Kim J, Lee JH, Kim M, Nam GB, Choi KJ *et al.* Cardiac implantable electronic device safety during magnetic resonance imaging. *Korean Circ J* 2016;**46**:804–10.
9. Russo RJ, Costa HS, Silva PD, Anderson JL, Arshad A, Biederman RWW *et al.* Risks of MRI in patients with a pacemaker or defibrillator. *N Engl J Med* 2017;**376**:2495.
10. Pisa S. Interaction between 3-T MRI systems and patients with an implanted pacemaker. *Appl Comput Electromagn Soc J* 2015;**30**:706–16.
11. Achenbach S, Moshage W, Diem B, Bieberle T, Schibgilla V, Bachmann K. Effects of magnetic resonance imaging on cardiac pacemakers and electrodes. *Am Heart J* 1997;**134**:467–73.
12. Cronin EM, Mahon N, Wilkoff BL. MRI in patients with cardiac implantable electronic devices. *Expert Rev Med Devices* 2012;**9**:139–46.
13. Luechinger R, Zeijlemaker VA, Pedersen EM, Mortensen P, Falk E, Duru F *et al.* *In vivo* heating of pacemaker leads during magnetic resonance imaging. *Eur Heart J* 2005;**26**:376–83. discussion 325-377.
14. Koneru JN, Gunderson BD, Sachanandani H, Wohl BN, Kendall KT, Swerdlow CD *et al.* Diagnosis of high-voltage conductor fractures in Sprint Fidelis leads. *Heart Rhythm* 2013;**10**:813–8.

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020

15. Roguin A, Schwitter J, Vahlhaus C, Lombardi M, Brugada J, Vardas P et al. Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices. *Europace* 2008;**10**:336–46.
16. Luechinger R, Duru F, Scheidegger MB, Boesiger P, Candinas R. Force and torque effects of a 1.5-Tesla MRI scanner on cardiac pacemakers and ICDs. *Pacing Clin Electrophysiol* 2001;**24**:199–205.
17. Nazarian S, Reynolds MR, Ryan MP, Wolff SD, Mollenkopf SA, Turakhia MP. Utilization and likelihood of radiologic diagnostic imaging in patients with implantable cardiac defibrillators. *J Magn Reson Imaging* 2016;**43**:115–27.
18. Ono M, Suzuki M, Isobe M. Feasibility, safety, and potential demand of emergent brain magnetic resonance imaging of patients with cardiac implantable electronic devices. *J Arrhythm* 2017;**33**:455–8.
19. Sabzevari K, Oldman J, Herrey AS, Moon JC, Kydd AC, Manisty C. Provision of magnetic resonance imaging for patients with 'MR-conditional' cardiac implantable electronic devices: an unmet clinical need. *Europace* 2017;**19**:425–31.
20. Expert Panel on MR Safety, Kanal E, Barkovich AJ, Bell C, Borgstede JP, Bradley WG Jr et al. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging* 2013;**37**:501–30.

EP CASE EXPRESS

doi:10.1093/europace/euz227
Online publish-ahead-of-print 27 August 2019

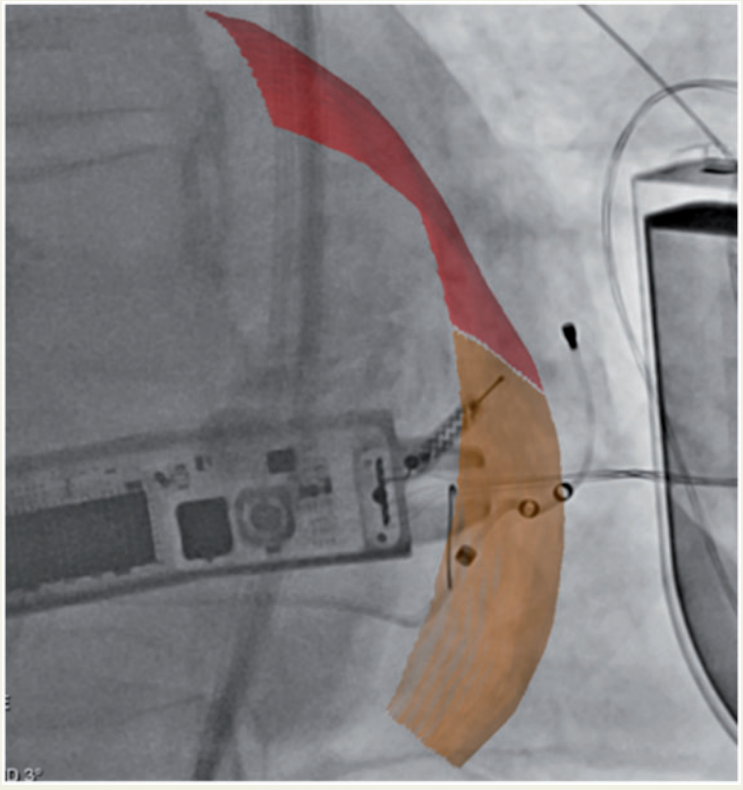
Combined computed tomographic perfusion and mechanics with predicted activation pattern can successfully guide implantation of a wireless endocardial pacing system

Baldeep Singh Sidhu [1,2]*, Angela W.C. Lee[1], Ulrike Haberland[1], Ronak Rajani[1,2], Steven Niederer[1], and Christopher Aldo Rinaldi[1,2]

[1]School of Biomedical Engineering and Imaging Sciences, King's College London, 4th Floor, North Wing, St Thomas' Hospital, London, SE1 7EH, UK; and [2]Cardiology Department, Guy's and St Thomas' NHS Foundation Trust, London, SE1 7EH, UK

* Corresponding author. Tel: 02071889257; fax: 02071881011. *E-mail address*: Baldeep.sidhu@kcl.ac.uk

The WiSE-CRT system (EBR Systems, CA, USA) delivers wireless endocardial left ventricular (LV) pacing and has a number of advantages, including early access to fast endocardial conduction and a pacing location unconstrained by coronary anatomy. Currently, the optimal location for the electrode is unknown. Pacing in an area of latest mechanical activation and avoiding myocardial scar is advisable. We hypothesized that cardiac computed tomography with dynamic perfusion would have the ability to identify areas of heterogenous perfusion and when combined with areas of latest mechanical and electrical activation, would be able to identify the optimal location for the endocardial electrode. A 70-year-old patient with ischaemic cardiomyopathy was listed for a WiSE-CRT system after their epicardial left ventricular lead resulted in phrenic nerve stimulation in all configurations. Cardiac computed tomography with dynamic perfusion identified areas of perfusion heterogeneity, latest mechanical and electrical activation, which were combined to predict the optimal pacing location between the basal inferior (coloured orange in *Figure 1*) and inferolateral (coloured red in *Figure 1*) segments. During the procedure, these segments were overlaid onto live fluoroscopy as shown in *Figure 1* and the greatest improvement in haemodynamic measurements corresponded to this target segment which was where the electrode was deployed.



The full-length version of this report can be viewed at: https://www.escardio.org/Education/E-Learning/Clinical-cases/Electrophysiology.

© The Author(s) 2019. Published by Oxford University Press on behalf of the European Society of Cardiology.
This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/by-nc/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

Downloaded from https://academic.oup.com/europace/article-abstract/22/2/288/5717383 by guest on 07 April 2020