Overview observational, noncomparative studies

Table 1. Overview of results of evidence found in non-comparative observational studies.

Pacemakers

Author, year	Methods	N	MRI	Results
Xiong, 2018	Cohort, all patients with CIEDs undergoing MRI	86 patients Of which: 35 pacemaker-dependent	86 MRIs 1.5T Siemens Sonata	Discomfort symptoms: N=12 (14%) Such as: excessive anxiety, significantly higher blood pressure (10% higher than the base value), significantly faster heart rate (10% faster than the base value); there appeared pacemaker abnormalities in a total of 10 patients, such as increased impedance (20% greater than the base value), abnormalities in perception or pacemakers (appeared pace-making and self-rhythm), disorders in perception or pacemakers (severe heart rate overrun or arrest), hypotension or blackness, no syncope and disturbance of consciousness
Okamura, 2017	Prospective study, all pacemaker independent patients	442 patients, all non-conditional Of which 9 with nearly depleted battery (5 ICD, 4 pacemaker) and therefore included	568 MRIs Of which 13 in patient with nearly depleted battery 1.5T	Events: N=4 (all with pacemakers implanted before 2005) Of which: N=2 full reset and changed to VVI 60 N=1 entering ERI and changed to VVI 65 N=1 programming was not allowed
Williamson, 2017	Prospective follow up study (including 2629 patients)	526 patients with SureScan pacing system	872 MRIs Type of MRI not specified	No MRI-related complications MRI-related observations: n=6 Of which: N=2 arterial fibrillation N=2 chest pain and warmth (stop of MRI) N=1 failure to capture N=1 sudden rise of pacing threshold Artefacts: N=1 unable to interpret
Bireley, 2020	Retrospective review study, all patients with PM	21 patients (all children) (21 pacemakers)	44 MRIs	No adverse events

	scanned between 2010 and 2018	Age at first MRI: median 10.9 (range 0.7-40.7) Of which n=3 conditional	1.5T Philips Ingenia®, or Siemens MAGNETOM Symphony®	battery voltage was reduced: 2.78 V pre-MRI versus 2.77 V at follow up (p = 0.02)
Ikeya, 2016	Review of charts	162 patients conditional devices: n=162	262 MRIs 1.5T Achieva Nova; Philips, Amsterdam, the Netherlands/ MAGNETOM Symphony; Siemens, Munich, Germany Head: n=125 Spine: n=72 Abdomen: n=27 Heart: n=20 Pelvis: n=16 Other: n=2	N=3 accidently mode not changed to MRI-mode Case 1: DDD pacemaker, brain MRI No complications Case 2: DDD pacemaker, abdomen MRI symptoms of chest discomfort and palpitations

Pacemaker + ICD

Author, year	Methods	N	MRI	Results
Köning, 2022	Retrospective cohort, including all patients with a CIED undergoing MRI	127 patients conditional devices: n=89 pacemaker: 92.1% Transvenous ICD: 6.3% Subcutaneous ICD: 1.6% Months since implantation: generator 32.5 lead 45.3	188 MRIs 1.5T, a maximum gradient field strength of 45mT/m and a maximum gradient slew rate of 200T/m/s using solely receiving coils Head or extremities: 40.4% Extrathoracic torso: 55.3% Thorax: 4.3%	Any complication of a CIED after MRI: n=2 (1.6%) (both MRI conditional) Beginning device or lead failure, minimal clinical conditions: n=3 (all MRI conditional) Discomfort: 1.6% Increase of ventricular threshold: 0.8% Decrease of amplitude >50%: 4.6% Increase of pacing threshold >1V: 3.1% 1-year rehospitalization: 37.8%
Navarro, 2022	Prospective study	147 patients Of which: 132 pacemaker (83 non-conditional) 15 ICD (10 non-conditional)	147 MRIs 1.5T Philips Achieva	No adverse events No ventricular or atrial tachycardia episodes Artefacts: 11/17 (64.7%)

Pacemaker, ICD, CRT

Author, year	Methods	N	MRI	Results
Schukro, 2019	Observational study	338 patients Of which: 298 pacemakers 25 ICD 8 CRT-ICD 7 CRT 52% 1.5T MRI conditional	446 regions 0.2T Magnetom Concerto scanner (Siemens Medical, Erlangen, Germany), operating Larmor frequency 8.25 mHz; maximal gradient amplitude 20mT/m; maximal slew rate 40mT/m/ms; maximal	Severe nausea n=1 (MRI stopped) No other complications, adverse events, artefacts

		Time since implantation: 4.1 ± 3.2 years	radiofrequency power 1800 W	
Gillam, 2018	Epidemiological data review	56 patients Of which: N=16 non-compatible CIEDs N=40 compatible CIEDs	72 MRIs Not specified	Non-compatible: Death: n=0 hospital admission within 30 days: n=3 Compatible: Death: n=0 hospital admission within 30 days: n=2

Pacemaker, ICD, ILR

Author, year	Methods	N	MRI	Results
Bhuva, 2019	Prospective cohort	133 patients 22% implantable loop recorders (ILR) 40% permanent pacemakers (PM) 38% ICDs 42% non-MRI conditional	136 CMRs 1.5T (Siemens Aera) with a 30-channel phased array receiver coil at Normal Operating Mode (SAR limit b2W/kg)	Artefacts: proportion of completely or almost completely diagnostic scans (Grades 0–1) ILR: 87% PM: 84% ICD: 11% CRTDs: 13% Segments with artefact: non-MRI conditional ICDs: 75 (59–90)% MRI conditional ICDs: 73 (55–79)% No complications
Murray, 2019	Retrospective review of reports	225 patients, all with conditional CIEDs Of which: 86 pacemakers 15 ICDs 24 ILR	225 MRIs 1.5T (Magnetom Avanto—Tim SQ engine, Siemens)	Complications: N=1 diaphragmatic stimulation N=1 Assura ICD could not be reprogrammed to its original settings N=1 dizziness

ICD, CRT

Author, year	Methods	N	MRI	Results
Rinaldi, 2020	Observational study, patients from ENABLE MRI study (n=237)	159 patients undergoing MRI ICD or CRT-D pulse generator in left or right pectoral region	159 scans 1.5T, according to device instructions >6 weeks after implantation	asystole in the MRI scanner room: n=1 (not yet in the MRI bore, therefore excluded) death (non-MRI related): n=5 Conclusion: no adverse events in the MRI
Bauer, 2019	ProMRI PROVEN study,	194 patients, all MRI conditional ICD and CRT-D/-P systems (Biotronik SE & Co. KG, Berlin, Germany)	146 MRIs 1.5T Siemens, General Electric, and Philips MRI ≥9 weeks after implantation Exclusion zone of MRI: heart region	No adverse events during MRI or follow up (1 month) MRI-procedure related events: N=1 implant site warmth, pain in shoulder N=1 implant site warmth, one electrode was warmer

				N=1 a low-intensity vibration around the ICD pocket and implant site paresthesia The pacing impedance at pre-MRI vs. one month post-MRI was 528 ± 82 vs. 525 ± 86 Ω (RV), 719 ± 183 vs. 762 ± 170 Ω (LV), and 569 ± 72 vs. 578 ± 68 Ω (RA). Painless shock impedance was 70 ± 11 vs. 71 ± 12 Ω. P-wave amplitude in the ICD DX systems was 6.5 ± 5.7 vs. 6.3 ± 5.6 mV. Battery status in all 146 devices was 100% at one month post-MRI.

ICD

Author, year	Methods	N	MRI	Results
Zbinden, 2019	Prospective, non-randomized, multicenter ProMRI 3T ENHANCED Master Study	129 patients ICD	112 MRIs 3T Siemens, General Electric, and Philips MRI >5 weeks after implantation Exclusion zone of MRI: heart region	Panic attack prior to start of MRI: n=1 (therefore excluded) No adverse events The raw (non-transformed) difference in pacing thresholds between 1month and pre-MRI measurement was 0.1± 0.1 V in the right atrium (median 0.0, IQR 0.2 to 0.0, range -0.3 to 0.2), and 0.0± 0.1 V in the right ventricle (median 0.0, IQR 0.1 to 0.0, range 0.3 to 0.2). The raw difference in atrial and ventricular sensing amplitudes at 1month vs. pre-MRI was 0.0± 0.5mV (median 0.1, IQR 0.3 to 0.1, range 1.2 to 2.0) and 0.0± 1.1mV (median 0.0, IQR 0.5 to 0.4, range 4.3 to 5.8).
Nazarian, 2019	Prospective multicenter study, including patients from a pre-defined nondiagnostic MRI Ready IDE study	220 patients (198 for primary analysis) Durata and Optisure HV leads and the Ellipse VR ICD	198 MRIs 1.5T GE Healthcare (Little Chalfont, UK), Siemens (Erlangen, Germany), or Phillips (Eindhoven, the Netherlands)	Mean follow up: 2.3 ± 1.0 months No adverse events or complications the RV threshold change success was ventricular capture threshold increase of ≤0.5 V for 0.5 ms: n=0

Pacemaker, ICD, leads

Author, year	Methods	N	MRI	Results
Gakenheimer, 2020	Retrospective review of charts, of all patients with CIEDs (without generator) undergoing MRI	40 patients (n=20 under the age of 18) Pacemaker: 43 MRIs ICDs: 7 MRIs	54 MRIs (of which 10 conditional) Cardiac: n=29 (54%) 1.5T	Artefacts: 1) no effect to image: n=3 (5%) 2) mild image degradation but no change to the diagnostic utility: n=8 (15%)

		Abandoned leads without a CIED: 7 MRIs Abandoned leads were present in 18 (33%) and epicardial leads in 20 (37%) of the MRIs		3) artifact rendered the MRI scan diagnostically useless: n=9 (17%) No artifact present: n=34 (63%) Adverse events: n=4 Of which: Warmth in the left lateral chest during cardiac: n=2 Tingling sensation near the cut, uncapped end of an abandoned lead: n=1 Pause in heart rhythm: n=1

Pacemaker, ICD, leads, CRT

Author, year	Methods	N	MRI	Results
Gupta, 2020	Prospective registry,	532 patients, with non-conditional CIEDs Pacemakers 46% ICDs 30% cardiac resynchronization therapy (CRT) pacemakers 4% CRT defibrillators 17% abandoned leads 2%	608 MRIs 1.5T Optima MR450 W; GE Healthcare, Waukesha, Wis	Change in device function: Lead impedance change >10%: n=1 N=0 for lead sensing change, lead threshold change, battery voltage change N=0 for change in: patient rhythm, oxygen saturation, heart rate, blood pressure, symptoms of chest pain or burning, syncope, cardiac arrest, death

Leads

Author, year	Methods	N	MRI	Results
Nguyen, 2020	Retrospective reviewing of prospective data, two phases: brain and lumbar spine; thoracic spine imaging	81 patients (156 leads) Time since implantation: 74 (58–107) days	169 MRIs 1.5T General Electric, Siemens, or Philips scanners	No adverse events Atrial pacing capture threshold

Pacemaker, ILR, leads

Author, year	Methods	N	MRI	Results
Gopalakrishnan, 2021	Retrospective analysis, only on non-programmable devices	94 patients 23 vagal nerve stimulators (VNS), 22 implantable loop recorders, 16 spinal stimulators, 5 peripheral nerve stimulators, 3 bladder stimulators, 2 deep brain stimulators, 1 gastric stimulator, 1 bone stimulator, 1 WATCHMAN	127 MRIs 1.5T GE Healthcare, Waukesha, Wis	No adverse events No device malfunction/issues

		device, 22 abandoned PM/ICD leads 1 VNS lead.		
Schaller, 2021	Cohort study, all patients presented at the hospital were included	139 patients CIEDs and at least 1 abandoned lead	200 MRIs 1.5T (not further specified)	6 adverse events: RA 0.3 to 0.1 mV RA 6 to 2.1 mV RA 6 to 3 mV RA 2 to 1 mV LV 6 to 3.1 mV Sternal burning (unable to continue MRI) No adverse events in 83 patients (143 MRIs) in follow up (mean ± SD: 15.77 ±. 14.4 months)