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RESEARCH LETTER

In Vivo Study of Electromagnetic Interference With Cardiac Contractility Modulation Devices at Power Frequency

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Cardiac contractility modulation (CCM) has been Food and Drug Administration-approved since March 2019 as a non-excitatory stimulation therapy for symptomatic heart failure. CCM delivers high-energy pulse trains via 1 or 2 ventricular septal leads (right ventricle [RV]/right ventricular local sense lead [LS]) in the absolute refractory period of the heart cycle leading to, i.a., increased calcium flux into cardiomyocytes. Therefore, appropriate sensing of intrinsic heart signals via right atrium (RA)/RV/LS lead for proper timing is of crucial importance to ensure safe and effective functioning as high energy pulse delivery in the vulnerable phase can cause arrhythmia.

In vivo studies from our group have shown that pacemakers[1] and implantable cardioverter-defibrillators[2] are susceptible to electric and magnetic fields (EMF). Thus, electromagnetic interference (EMI) with cardiac electronic devices may pose risk to patients even under daily life EMF exposure at frequencies of 50Hz/60Hz, the worldwide power grid frequency.[3] Still, hitherto nothing is known about EMI with CCM devices.

We therefore initiated a clinical in vivo provocation study and systematically exposed patients with CCMs (Figure [A and B]) to 50Hz-EMF with strengths up to 30 kVm^{-1} and 2.55 mT considering worst-case conditions (eg, whole-body exposure, maximal inspiration). The data that support the findings of this study are available from the corresponding author upon reasonable request. We determined the interference thresholds, ie, the lowest field strength at which interference could be observed. Tests were performed with maximum and nominal sensitivity.

The study design was approved by the Ethics Committee at the Rhenish-Westphalian Technical University of Aachen Faculty of Medicine (ClinicalTrials.gov Identifier NCT01626261). Inclusion/exclusion criteria and the detailed study design were described elsewhere.[1,2]

Fifteen patients were included (10 Optimizer III and 5 Optimizer IV_s, Impulse Dynamics; 10 male/5 female; 9 ischemic cardiomyopathy/6 dilated cardiomyopathy; mean ejection fraction, 29.6±6.3%, all initial New York Heart Assocation Class III). All gave written informed consent.

No device defects or software resets were seen because of EMF exposure. All implanted electricals remained unchanged after the test. Eight CCMs showed interference in the tested field range at nominal sensitivity, while all 15 devices could be disturbed at maximum programmed sensitivity. All observed sensing failures were related to constructive or destructive superposition of intracardiac signals and EMFs (Figure [C and D]). In the 8 patients with EMI when programmed to nominal sensitivity 14 interferences were detected at different field strengths (RA: 5x noise, 1x short AV; RV: 3x PVC, 1x noise, 1x oversensing; LS: 3x inhibit). At maximum sensitivity all CCMs were disturbed with 56 registered artifacts (RA: 16x noise, 11x short-AV, 6x long-AV; RV: 10x PVC, 3x noise, 2x oversensing; LS: 4x inhibit, 4x alert) (Figure [E]). Lowest interference thresholds (nominal and maximum sensitivity depicted by "/") were determined

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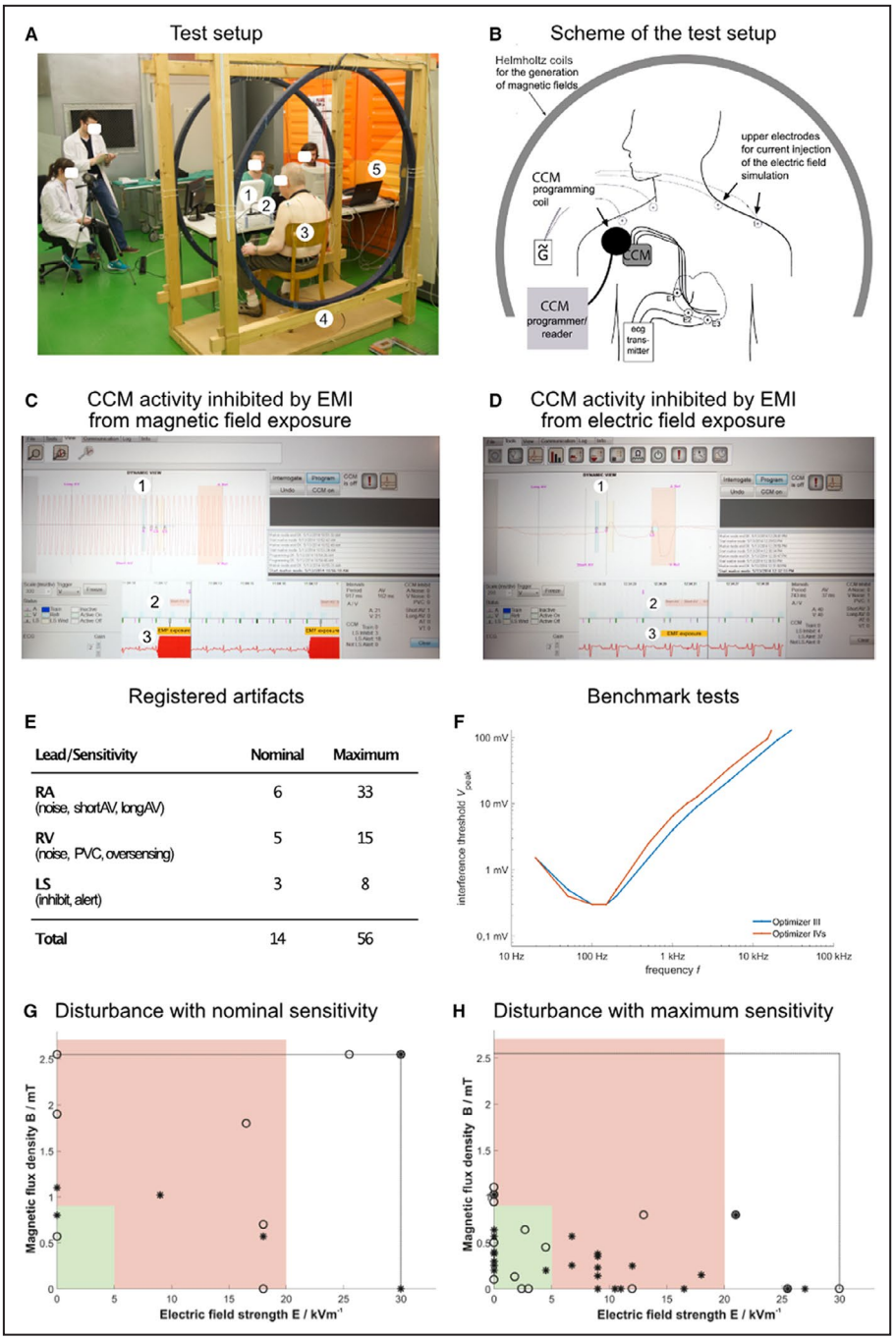

at 18/2.4 kVm^{-1} in single electric fields, 0.57 mT/0.1 mT in single magnetic fields, and 9 kVm^{-1}+1.02 mT/1.8 kVm^{-1}+0.13 mT in combined EMFs. Regarding the 2 device generations (Optimizer III and IV_s) no differences in EMF sensing could be observed. In vitro benchmark tests confirm this result as both devices have nearly the same interference threshold in the tested frequency range (Figure [F]). With respect to the Institute of Electrical and Electronics Engineers standard C95.1-2019 only 2 patients programmed to nominal sensitivity values showed interference within the exposure range for general public (Figure [G]). When CCMs were programmed to maximum sensitivity 13 patients exhibited EMI in the exposure range for general public (Figure [H]). Thus, our data indicate little interferences for CCMs programmed to nominal sensitivity with daily life EMFs. However, when CCMs were programmed to maximum sensitivity and/or exposed to strong EMF—as it may occur in an occupational environment—inappropriate sensing was frequently detected.

While under nominal sensitivity settings EMI only led to (inadequate) therapy withhold, under maximum sensitivity settings additionally oversensing in the LS alert window was seen 4x. LS-alert episodes may initiate

Figure. Electromagnetic interference testing in cardiac contractility modulation (CCM) devices: test setup, examples, and results.
A, Test setup. (1) Active cardiac device programmer, (2) CCM programmer, (3) Patient, (4) Helmholtz coil, (5) Computer to control and monitor electric and magnetic fields generation. **B**, Scheme of the test setup. **C** and **D**, Example of (**C**) magnetic and (**D**) electric field exposure: (1, 2) Short-AV is inappropriately detected, CCM activity is inhibited, (3) Electric and magnetic fields exposure indicated by orange rectangle on the surface ECG. **E**, Table with number of registered artifacts in case of electromagnetic interference with CCMs programmed to nominal and maximum sensitivity. Eight CCMs with nominal sensitivity settings were disturbed and all 15 with maximum sensitivity. **F**, Benchmark tests were conducted where a noise signal with different frequencies (20–20 kHz) was fed into the RA/RV/LS channel with gradually increasing amplitude (starting at 0.1 mV) until the device showed impaired sensing. Optimizer III and Optimizer IVs show the same reaction on electric and magnetic fields exposure. **G** and **H**, Interference thresholds of all tested patients with CCM (asterisk: Optimizer III, circle: Optimizer IVs) with nominal sensitivity (**G**) and maximum sensitivity (**H**). Field ranges for general public exposure (green) and occupational exposure (red) as mentioned in IEEE standard C95.1-2019 were shown. With nominal sensitivity 8 of 15 patients with CCM showed interference in the tested field range (dotted line). Within the exposure range for general public only 2 patients showed interference. Programmed to maximum sensitivity all 15 devices showed electromagnetic interference and in 13 patients electromagnetic interference was seen in the exposure range for general public. CCM indicates cardiac contractility modulation device; EMI, electromagnetic interference; LS indicates right ventricular local sense lead; PVC, premature ventricular capture; IEEE, Institute of Electrical and Electronics Engineers; RA, right atrium; and RV, right ventricle.

inappropriate therapy delivery; although high energy pulse train delivery in the vulnerable phase of the heart cycle is unlikely but cannot be excluded; thus, indicating that in most cases EMIs in CCM devices do not pose a significant patient risk but may lead to therapy withhold and subsequent impaired effectiveness of the intended heart failure therapy.

If devices have to be programmed to higher sensitivity (eg, because of low-amplitude intracardiac signals), EMI has to be considered. For power lines or certain electrical machines (eg, hair dryers), EMF emissions were reported with a maximum field strength of 7.5 kVm^{-1} at the ground[4] and 2 mT at the surface,[5] respectively. Those field strengths lie above the interference threshold of the tested CCM devices even with nominal sensitivity resulting in device malfunctioning. To reduce the risk of EMI with CCM, optimization to a maximal intraoperative electrical signal amplitude is crucial, thus, allowing programming to higher sensitivity values. In addition, a previous study with 160 pacemakers and patients with implantable cardioverter-defibrillators suggested that a more horizontal orientation of the lead tip and a lead tip position near the center of the body may reduce EMI.[6] Moreover, implementation of memories for noise episodes or dedicated error memories would help to estimate the influence of EMI on the functioning of CCMs and optimize therapy delivery.

ARTICLE INFORMATION

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REFERENCES

1. Stunder D, Seckler T, Joosten S, Zink MD, Driessen S, Kraus T, Marx N, Napp A. In vivo study of electromagnetic interference with pacemakers caused by everyday electric and magnetic fields. *Circulation*. 2017;135:907–909. DOI: 10.1161/CIRCULATIONAHA.116.024558.
2. Napp A, Joosten S, Stunder D, Knackstedt C, Zink M, Bellmann B, Marx N, Schauerte P, Silny J. Electromagnetic interference with implantable cardioverter-defibrillators at power frequency: an in vivo study. *Circulation*. 2014;129:441–450. DOI: 10.1161/CIRCULATIONAHA.113.003081.
3. Napp A, Stunder D, Maytin M, Kraus T, Marx N, Driessen S. Are patients with cardiac implants protected against electromagnetic interference in daily life and occupational environment? *Eur Heart J*. 2015;36:1798–1804. DOI: 10.1093/eurheartj/ehv135.
4. Korpinen L, Kuisti H, Elovaara J, Virtan V. Cardiac pacemakers in electric and magnetic fields of 400-kV power lines. *Pacing Clin Electrophysiol*. 2012;35:422–430. DOI: 10.1111/j.1540-8159.2011.03327.x.
5. Farag AS, Dawoud MM, Selim SZ, Cheng TC, Marcus AM, Penn D. Electromagnetic fields in the home. *Electr Power Syst Res*. 1998;45:73–89. DOI: 10.1016/S0378-7796(97)01224-8.
6. Seckler T, Stunder D, Schikowsky C, Joosten S, Zink MD, Kraus T, Marx N, Napp A. Effect of lead position and orientation on electromagnetic interference in patients with bipolar cardiovascular implantable electronic devices. *Europace*. 2017;19:319–328. DOI: https://doi.org/10.1093/europace/euv458.