Safety of Implantable Pacemakers and Cardioverter Defibrillators in the Magnetic Field of a Novel Remote Magnetic Navigation System

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Safety of Pacemakers and ICDs. ***Introduction:*** **Electromagnetic interference with pacemaker and implantable cardioverter defibrillator (ICD) systems may cause temporary or permanent system malfunction of implanted devices. The aim of this study was to evaluate potential interference of a novel magnetic navigation system with implantable rhythm devices.**

Methods: **A total of 121 devices (77 pacemakers, 44 ICDs) were exposed to an activated NIOBE II® Magnetic Navigation System (Stereotaxis, St. Louis, MO, USA) at the maximal magnetic field strength of 0.1 Tesla and evaluated *in vitro* with respect to changes in parameter settings of the device, changes of the battery status/detection of elective replacement indication, or alterations of data stored in the device.**

Results: **A total of 115 out of 121 (95%) devices were free of changes in parameter settings, battery status, and internally stored data after repeated exposition to the electromagnetic field of the remote magnetic navigation system. Interference with the magnetic navigation field was observed in 6 pacemakers, resulting in reprogramming to a power-on-reset mode with or without detection of the elective replacement indication in 5 devices and abnormal variance of battery status in one device. All pacemakers could be reprogrammed to the initial modes and the battery status proved to be normal some minutes after the pacemakers had been removed from the magnetic field.**

Conclusion: **Interference of a remote magnetic navigation system (at maximal field strength) with pacemakers and ICDs not connected to leads with antitachycardic detection and therapies turned off is rare. Occurring functional abnormalities could be reprogrammed in our sample. An *in vitro* study will give information about interference of devices connected to leads.** *(J Cardiovasc Electrophysiol, Vol. 21, pp. 1136-1141, October 2010)*

electromagnetic interference, pacemaker, defibrillator, remote magnetic navigation system

Introduction

Magnetic navigation systems are a promising technical innovation that allow remote direction of catheters and guide wires in the cardiovascular system. Application of remote magnetic navigation has been proven to be feasible in the ablation of ventricular and supraventricular tachyarrhythmias,[1-14] in guiding wires for complex coronary angioplasty procedures[15-17] or septal ablations in hypertrophic cardiomyopathy,[18] and in facilitating complex lead placement for cardiac resynchronization therapy.[19] It has also been reported that remote magnetic navigation application in some circumstances allowed interventional access to the treatment of diseases that otherwise probably would have not been amenable to an interventional therapeutic procedure.[16,17] Additionally, recent studies have shown that the remote catheter navigation approach in comparison to a standard manual approach may reduce fluoroscopy exposure to both the interventionalist and the patient while ensuring similar acute success rates in both groups for the ablation of supraventricular tachyarrhythmias.[20-22]

With increasing experience and further research it is anticipated that the application of the remote magnetic navigation system will move ahead in clinical cardiology. This increase in potential applications will present the physician with recipients of implantable pacemakers (PMs) or cardioverter defibrillators (ICDs) in whom a remote magnetic navigation procedure may be indicated or at least deemed desirable, in particular with respect to an increasing number of carriers of ICDs due to extended indications for primary and secondary prophylaxis of sudden cardiac death.[23] However, the presence of an implanted rhythm device is currently considered to be a contraindication for the use of magnetic navigation systems. Data about potential interference are limited to a case report indicating temporary system malfunction with loss of capture and occurrence of power-on-reset,[24] and to a small series of ICD recipients who underwent ablation of ventricular tachycardias without documented interference between

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the remote magnetic navigation system and their ICDs.[3] Interferences of implanted rhythm devices with other magnetic fields emitted by mobile phones,[25-30] metal detector gates,[31] or magnetic resonance imaging[32-40] are well characterized but cannot be conferred to the remote magnetic navigation systems as its static magnetic field differs in field strength and frequency.

Until now, there is no systematic prospective study investigating potential interactions between the remote magnetic navigation field and different PM and ICD devices. Therefore, the following study was designed to perform an analysis whether or not PM or ICD devices are adversely affected by the magnetic field of remote navigation system.

Methods

PM and ICD devices explanted for various reasons (e.g., elective replacement time due to battery depletion nearly reached, system upgrading, infection) were used for *in vitro* testing of potential electromagnetic interference in a remote magnetic navigation system. Devices were excluded from the study if the elective replacement indication had already been reached or if suspected device malfunction had been the reason for explantation.

PMs and ICDs were interrogated in a room separated from the magnetic navigation system and were set to the following parameters. In PMs the pacing mode was randomly assigned to VVI or V00. These 2 modes were selected as they represent pacing modes that would be applied during remote magnetic navigation in patients with or without intrinsic rhythm, respectively. The base rate was set between 40 and 70 bpm according to the base rate at explantation. ICDs were programmed to the VVI mode (V00 mode not programmable in ICDs) at a base rate of 30–70 bpm (according to the base rate at explantation) with tachyarrhythmia detection and antitachycardia therapies switched off. After documentation of the device settings, PMs and ICDs were exposed to the magnetic field of a NIOBE II® Magnetic Navigation System (Stereotaxis, St. Louis, MO, USA).

For interference testing the magnetic navigation system was active in navigation position at its maximum strength of 0.1 Tesla and at its minimal magnet-to-magnet distance. Each device was put into the activated magnetic field on the examination table and was moved in the area between the 2 magnets for about 10 seconds. As a next step the device was put on the examination table and the magnetic vector was turned through 360° in all 3 axes in space. Finally, the device was put directly on one of the active magnets and moved on its surface in different directions for about 10 seconds. The device was then interrogated and evaluated for changes in the parameter and battery settings.

Potential changes in the device settings were evaluated with respect to (1) reprogramming consistent or nonconsistent with the power-on-reset mode, (2) significant changes in the battery status (either display of "elective replacement time" despite unchanged battery voltage and/or battery impedance or changes in battery voltage $\geq$0.05 V or in impedance $\geq$1 kΩ), (3) changes in stored data of the device, and (4) reprogrammability of the device.

The protocol of interference testing was performed 3 times for each device. If none of the above mentioned alterations were detected the testing was stopped for the respective device. In the case of abnormal findings the devices were reprogrammed to their initial modes and a more detailed protocol was applied to identify the trigger for device alteration. This more detailed protocol included the interrogation of the device after each of the following steps that was performed three times each and included:

- *Switching the magnetic field on and off:* The device was positioned on the examination table while the magnets were inactive. The magnetic field was activated 3 times with a fixed left lateral vector for 10 seconds with 5 seconds breaks in between. Magnets were inactivated and the device was removed from the magnetic field.
- *Moving the device in a stable magnetic field:* Active magnetic field with left lateral vector. The device was rotated for 10 seconds in the center of the magnetic field.
- *Movement of the magnets from stowed position to navigation position and back:* The device was put on the patient's examination table and the magnets were moved from stowed position to navigation position and back to stowed position, simulating the beginning of the magnetic navigation procedure.
- *Movement in front of one inactivated magnet:* The device was rubbed against the sheathing of one magnet in stowed position simulating a patient passing one of the magnets.

Interrogations and evaluation after each of these steps aimed at the detection of reprogramming, battery changes and alteration in stored data as described above.

Results

A total of 121 devices (56 different pacemaker types and 30 different ICD types) of 8 manufacturers underwent testing for potential electromagnetic interference in the magnetic field of a NIOBE II® Magnetic Navigation System.

A total of 115 of 121 devices (95%) showed no interference with the magnetic navigation system in the screening protocol. The PMs are listed in Table 1 and the ICDs in Table 2.

The 6 devices with interference consisted of 4 out of 4 tested pacemakers from the Medtronic Kappa 400 series (battery status: 2.71 V, 2.66 V, 2.62 V, 2.53 V), one out of 2 tested pacemakers from the Medtronic Kappa 700 series (battery status: 2.62 V) and one out of one tested Biotronik Stratos pacemaker (battery status: 3.45 kΩ).

One Medtronic Kappa 401/403 (Medtronic, Minneapolis, MN, USA) showed in all of the 3 screening tests inappropriate detection of elective replacement indication. After a few minutes outside the magnetic field the system returned to normal values. Additionally, in one of the 3 tests power-on-reset with the date tested was detected with a switch to VVI 65 bpm in conjunction with detection of ERI in the future (10 February 2014).

The 3 other Kappa 401/403 models did not detect power-on-reset or elective replacement indication; however, the programmed parameters were changed according to a power-on-reset mode with a base rate of 65 bpm and stored implantation dates were lost. In all of the Kappa 400 models a reprogramming to the initial settings was possible.

The Kappa KDR 731 pacemaker detected a power-on-reset in all 3 screening tests, but did not change the pacing rate to the expected rate of 65 bpm. In this case the implantation date was reprogrammed to the date and time of power-on-reset. After successful reprogramming of the

TABLE 1

Pacemakers Tested in the Electromagnetic Field of the Remote Magnetic Navigation System

Manufacturer	Model	Number of Tested Devices	Battery Status at Time of Testing
Devices without interference with the magnetic field			
Biotronik	Axios	1	2.75 V
	Axios DR	1	2.78 V
	Axios S	1	2.76 V
	Cyclos DR	2	2.79, 2.78 V
	Philos D	1	2.79 V
	Philos DR-U	1	2.72 V
	Philos II SR	1	2.79 V
	Philos S	1	2.79 V
	Philos SLR	1	2.76 V
	Philos SR	1	2.79 V
	Protos	1	2.79 V
	Protos VR/CLS	1	3.45 V
ELA	Rhapsody DR 2510	1	2.39 kΩ
	Symphony DR 2550	1	1.31 kΩ
Guidant/Boston	Altrua 40	1	Good
	Insignia I Entra	2	Good, good
	Insignia I Plus	3	Good, good, good
	Insignia I Ultra	2	Good, good
	Meridian DDD 976	1	Ok
Intermedics	Marathon DR 294–09	1	2.50, 2.56 V
Medtronic	Adapta ADDR06	1	2.78 V
	AT 501	1	2.76 V
	EnPulse E2SR01	1	2.70 V
	EnRhythm MRI	1	2.90 V
	Insync III 8042	3	2.90, 2.63, 2.94 V
	Insync III Marquis 7279	1	3.04 V
	Kappa KD 901	1	2.75 V
	Kappa KDR 703	1	2.75 V
	Kappa KDR 801	1	2.74 V
	Kappa SR 901	1	2.74 V
	Sensia L SEDRL 1	3	2.75, 2.73, 2.76 V
	Sensia SES01	1	2.77 V
	Sigma SDR 303	1	2.76 V
	Versa VEDR01	1	2.75 V
Sorin	Neway VDR	1	<1 kΩ
St. Jude	Affinity DR 5330	2	2.76, 2.76 V
	Frontier 5508	1	2.77 V
	Frontier 5510	1	2.76 V
	Identity ADx XL DR 5386	2	2.80, 2.76 V
	Identity DR 5370	3	2.61, 2.64, 2.74 V
	Identity SR 5172	1	2.69 V
	Integrity Adx SR 1560	1	2.79 V
	Integrity AFx DR 5346	3	2.73, 2.76, 2.86 V
	Microny II SR +	1	2.78 V
	Regency SCX 2408L	1	99.7 bpm
	Verity Adx XL SR 5156	1	2.79 V
	Victory XL DR 5386	1	2.81 V
	Victory XL DR 5816	3	2.79, 2.79, 2.82 V
	Zephyr XL DR 5826	1	2.77 V
Vitatron	C60 DR	1	2.75 V
	Saphir 3	1	2 kΩ
	T60 DR	1	2.75 V
	T70 DR	1	0.9 kΩ
	Vita 2 SSI	1	3.7 kΩ
Devices with interference with the magnetic field			
Medtronic	Kappa KDR 731	1	2.62 V
	Kappa KDR 401/403	4	2.71, 2.66, 2.62, 2.53 V

TABLE 2

ICDs Tested in the Electromagnetic Field of the Remote Magnetic Navigation System (No ICD Showed an Interference)

Manufacturer	Model	Number of Tested Devices	Battery Status at Time of Testing
Biotronik	Belos VR	1	5.74 V
	Belos VR-T	1	MOL2
	Lexos VR	1	6.1 V
	Lumax 300 VR-T	1	3.17 V
	Lumax 540 HF-T	1	3.05 V
ELA	Ovatio VR 6250	1	6.36 V
Guidant/Boston	Cognis 100-D	1	2.05 Ah
	Contak Renewal 4 HE	1	2.59 V
	Contak Renewal 4 RF HE	1	3.02 V
	Teligen 100	1	Ok
	Ventak Prizm 2 DR	4	2.82, 2.67, 2.59, 2.81 V
	Ventak Prizm 2 VR	3	2.64, 2.70, 2.63 V
	Vitality 2 DR	1	3.21 V
Medtronic	Maximo VR 7232	1	3.03 V
	EnTrust D154ATG	1	2.96 V
	Gem 7227	2	2.58, 2.58 V
	Gem III AT 7276	1	2.57 V
	Gem III VR 7231	1	2.57 V
	InSync III 8042	2	2.625, 2.8 V
	InSync III Marquis 7279	1	3.04 V
	InSync Marquis 7277	1	2.81 V
	Intrinsic 7288	2	3.06, 3.09 V
	Jewel 7250	1	4.96 V
	Marquis DR 7274	2	2.74, 2.82 V
	Marquis VR 7230	1	3.16 V
	Maximo DR 7278	1	3.07 V
	Maximo VR 7232	5	2.88, 2.96, 3.03, 3.00, 2.86 V
St. Jude	Atlas II VR V-168	1	3.15 V
	Atlas VR	1	2.55 V
	Current DR RF 2207–36	1	>3.20 V
	Epic + DR V-236	1	2.55 V

device the power-on-reset warning given by the pacemaker disappeared.

The tested Biotronik Stratos LV pacemaker (Biotronik, Berlin, Germany) showed divergences in the battery voltage >0.05 V in one of the 3 tests. After a few minutes outside of the magnetic field interrogated battery voltage resumed to the initial value. Pacing parameters were unchanged in this device in all of the testings. A detailed test protocol was not performed for this device.

In the detailed test protocol for the Kappa devices the detection of elective replacement indication or changes in the pacing settings were reproducible (Table 3). Any of the different steps could cause inappropriate detection of elective replacement indication or changes in the pacemaker setting. Again, all the devices were reprogrammable to the initial parameter settings. We did not observe an influence of different pacing modes on the interference with the magnetic navigation system.

Discussion

In light of increasing application of remote magnet navigation to support complex cardiac interventions,[1-19,21,22] compatibility of the remote magnetic navigation system with PMs and ICDs has become of clinical interest. To the best of our

TABLE 3
Detailed Test Protocol for Pacemakers Showing Interference in the Screening Test Protocol

Step of Detailed Test Protocol	Parameter	Kappa KDR 401/403	Kappa KDR 401/403	Kappa KDR 401/403	Kappa Kappa KDR 401/403	Kappa KDR 731
Step 1: Switching the magnetic field on and off	Change in parameters consistent with power on reset	3	1	0	2	0
	Change in parameters not consistent with power on reset	0	1	0	2	0
	Significant change in battery status	0	0	0	0	0
	Detection of ERI	2	0	0	0	0
Step 2: Moving the device in a stable magnetic field	Change in parameters consistent with power on reset	0	3	3	1	3
	Change in parameters not consistent with power on reset	0	3	3	1	0
	Significant change in battery status	0	0	0	0	0
	Detection of ERI	0	0	0	0	0
Step 3: Movement of the magnets from stowed position to navigation position and back	Change in parameters consistent with power on reset	0	3	0	0	0
	Change in parameters not consistent with power on reset	0	3	0	0	0
	Significant change in battery status	0	0	0	0	0
	Detection of ERI	0	0	0	0	0
Step 4: Movement in front of one inactivated magnet	Change in parameters consistent with power on reset	0	0	3	3	3
	Change in parameters not consistent with power on reset	0	3	0	3	0
	Significant change in battery status	1	0	0	0	0
	Detection of ERI	1	0	0	0	0

0 indicates no interference, 1–3 indicates the number of each test step (3 tests per step for every device) that showed alterations.

knowledge, this is the first *in vitro* study to investigate potential interference in a large number of PM and ICD devices.

The main finding of our study is that the tested PM and ICD devices do not suffer permanent damage due to the magnetic field of the NIOBE II® Magnetic Navigation System. However, on exposure to the electromagnetic field of the magnetic navigation system, a small number of devices showed changes in the pacing settings according to a power-on-reset, alteration of the pacemaker's base rate, inappropriate detection of elective replacement indication, disturbance of stored data in the device such as implantation dates, and temporary changes in battery voltage. All the devices could be reprogrammed to the initial settings.

The only pacemakers that showed interference with the magnetic field of the remote navigation system were the Medtronic Kappa 400 and 700 series. Whether this can explain a previously reported loss of capture during a magnetic navigation assisted electrophysiological examination that also occurred in a Medtronic Kappa 400 device[24] remains unclear. Although the study investigated a large number of different PM and ICD models without interference, it certainly cannot be concluded that magnetic navigation assisted procedures are safe in these types of implanted rhythm devices. In many of these models only a single device was tested and the absence of interference may just have been by chance. However, as in none of the 121 devices was a permanent damage observed, and as observed changes in the pacing settings could be easily reprogrammed to the initial values, magnetic navigation system application should neither be considered strictly contraindicated in PM and ICD recipients.

In our study the interference of the magnetic field with devices was investigated without leads connected for 3 reasons: (1) To our knowledge there is no method for functional assessment of leads, for example, using a heart simulator, which would not itself be influenced by the magnetic field. (2) A prerequisite for *in vivo* testing of devices and leads is to first exclude permanent damage to the device by the magnetic field. (3) Myocardial damage by heating of the leads seems to be unlikely due to the low strength of the magnetic field.

In the detailed 4-step protocol every contact with the magnetic field could unpredictably induce changes in devices' function, whereby no explicit trigger could be identified.

Conclusion

Interference of a magnetic navigation system with pacemaker or defibrillator devices not connected to leads with antitachycardic detection and therapies turned off is rare and does not result in permanent damage of the devices themselves. A subset of devices is suspected to be prone to reprogramming similar to the power-on-reset mode when exposed to the magnetic field. All devices could easily be reprogrammed to the initial settings. An *in vitro* study will give information about interference of devices connected to leads.

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