The Kora Pacemaker is Safe and Effective for Magnetic Resonance Imaging

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ABSTRACT

BACKGROUND: The impact of magnetic resonance imaging (MRI) on pacemakers is potentially hazardous. We present clinical results from a novel MRI conditional pacing system with the capability to switch automatically to asynchronous mode in the presence of a strong magnetic field.

AIMS: The IKONE (*Assessment of the MRI solution: **KO**RA* 100™ *and Beflex™ pacing leads system)* study is an open-label, prospective, multicenter study aimed at confirming the safety and effectiveness of the system, when used in patients undergoing MRI of anatomical regions excluding the chest.

METHODS: Primary eligibility criteria included patients implanted with the system, with or without a clinically indicated MRI. The primary endpoint was to confirm no significant change in pacing capture thresholds at 1 month after an MRI, with an absolute difference of ≤0.75 V between the pre- and 1-month post-MRI for both atrial and ventricular capture thresholds.

RESULTS: Out of 33 patients enrolled (mean age: 72.8 ± 11.4 years, 70% male, implant indication or device), 29 patients implanted with the MRI conditional system underwent an MRI 6–8 week postimplant. The study reached its primary endpoint: the mean absolute difference in pacing capture threshold at 1-month post-MRI versus pre-MRI was less than 0.75 V in the atrium (Δ = 0.18 ± 0.16 V, *P*-value <0.001) and in the ventricle (Δ = 0.18 ± 0.22 V, *P*-value <0.001). There were no adverse events related to the MRI procedure nor were there reports of patient symptoms or discomfort associated. MR image quality was of diagnostic quality in all patients.

CONCLUSION: Lead electrical performance as measured by difference in capture thresholds were not impacted by MRI. This first clinical evaluation of a novel MRI conditional system demonstrates it is safe and effective for use in out-of-chest, 1.5-T MR imaging.

KEYWORDS: 1.5-T MRI, pacemaker, bradycardia lead

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Introduction

Magnetic resonance imaging (MRI) has been contraindicated in standard permanent cardiac pacemakers due to the strong gradient and radiofrequency (RF) fields that may interact with the pacemaker and lead system. New MRI conditional pacemakers allow patients to safely undergo MRI examinations.[1] Specific guidelines concerning device programming and patient monitoring have been developed to allow such procedures. This has successfully limited the occurrence of adverse events; nevertheless, each MRI procedure in pacemaker patients requires the support of both a pacemaker specialist (cardiologist or specialist in electrophysiology, to program and monitor the implanted device) and an MRI radiologist.

MRI conditional pacing systems are safe for use in MRI only under certain conditions. Patients implanted with such pacemaker systems may benefit from the access to MRI examination. The effect of MRI on pacing thresholds was shown to be limited – a change of less than 1 V in studies involving 800 patients.[2–8]

The objective of the *Assessment of the MRI solution: **KO**RA* 100™ *and Beflex™ pacing leads system* (IKONE) study is to evaluate a new MRI conditional pacing system (KORA 100™ pacemaker) in pacemaker patients.

Methods

IKONE study design. The IKONE study (ClinicalTrials.gov Identifier: NCT02175797) is a pivotal, prospective, open-label, nonrandomized, multicenter study. Patients implanted with devices under investigation were invited by the investigators to enroll in the study. They performed a pre-MRI visit between 6 and 8 weeks after pacemaker implantation. The MRI examination was performed within 24 hours after the pre-MRI visit; devices were interrogated just after the MRI examination (post-MRI assessment). A follow-up visit was planned 1 month after (1-month post-MRI)

visit. Devices were interrogated for lead measurements and recordings (pacing capture threshold [PCT], sensing amplitude, and impedance in each cardiac cavities, if applicable) pre-MRI, post-MRI, and at 1-month post-MRI. The study was terminated after completion of the 1-month follow-up visit.

Devices under investigation. Devices implanted in the study were KORA 100™ pacemakers (single- [SR] or dual-chamber [DR], Sorin CRM SAS) and Beflex™ pacing leads (RF45D and/or RF46D, Sorin CRM SAS).

Implanted pacemakers provide a range of anti-bradycardia therapies, including dual-sensor rate response pacing and various programmable parameters. The asynchronous MRI pacing mode (OOO, VOO, and DOO) is activated manually or after detection of a strong magnetic field (automatic mode [AutoMRI mode]); when the magnetic field is no longer detected, the pacemaker reverts automatically to the original programming mode. In the asynchronous MRI pacing mode, the KORA 100™ delivers bipolar pacing (5 V at 1 ms) at a basic rate of 50 min^{-1} to 120 min^{-1} in the cardiac chambers defined by the programming mode. In addition, the activity sensors, sleep apnea monitoring, atrial fibrillation (AF) prevention algorithms, rate response pacing, and fallback mode-switch are disabled in the MRI mode.

The Beflex RF45D or RF46D pacing leads (lengths of 52 cm and 58 cm, respectively) are bipolar, endocardial, steroid-eluting, silicon-insulated leads with an extendable/retractable active-fixation helix for permanent pacing and sensing of either the atrium or the ventricle, with a 6-French (F) lead body and implanted using a 7-F introducer. Eight to 10 turns are needed for complete helix extension.

All devices and algorithms investigated in this study are CE-marked and approved in the participating country as MRI conditional devices.

Study population. Patients previously implanted with the devices under investigation were enrolled in each study center. Patients with persistent AF were implanted with a SR device. Pacemakers were implanted in the left or right pectoral region with one or two leads. Patients were required to be willing and able to undergo MRI examination even if one was not medically required. MRIs excluded the chest region, according to the device labeling. Main exclusion criteria were permanent AF for DR devices only, diaphragmatic/phrenic stimulation, and incessant ventricular tachyarrhythmia. The protocol was approved by the French Ethics Committee of Rouen. The study complies with the Declaration of Helsinki and was conducted according to Good Clinical Practices. All patients signed an informed consent.

Magnetic resonance examination. For MRI examinations not medically required, the patient with his/her physician decided on the anatomical region to scan.

The pre-MRI visit consisted of a standard pacemaker follow-up, with clinical evaluation of the patient and measurement of device electrical performance. The investigators ensured that patients could be safely scanned by checking they fulfilled all the following conditions: height >1.47 m, pacemaker implanted in the left or right pectoral region, residual battery longevity of at least 10%, PCT <2.0 V at 0.35 ms. Devices were turned onto AutoMRI for the purpose of the study.

MRI examination was conducted by the radiologist of the center, with commercially available MRI scanners, under the following conditions: whole-body–averaged specific absorption rate (SAR) as reported by the MRI equipment 2.0 W kg^{-1} or less (3.2 W kg^{-1} or less for head scanning), the total duration of RF exposure (or total MRI scanning time, excluding pauses between sequences) less than 40 minutes, MRI of hydrogen proton nuclei using a static magnetic field of 1.5 Tesla (T), horizontal cylindrical bore magnet, maximum gradient slew rate of 200 T m^{-1} s^{-1} per axis and maximum amplitude of 50 mT m^{-1} per axis. Patients had to lie in the supine or prone position, scanning was limited to out-of-chest anatomical regions (MRI landmark at the eye level or above and at the hip level or below); under these conditions, head, neck, hip, pelvis, or lower extremities were in the authorized scanning area. At a minimum, the patients' cardiac stability needed to be monitored using at least one of the following methods: electrocardiography, pulse oxymetry, or noninvasive blood pressure measurements. The AutoMRI mode was automatically deactivated when the patient was removed from the MRI system. Verbal communication with the patient was maintained during scanning. Images were reviewed by the center radiologist for clinically relevant findings (presence of significant distortion or artifact due to the pacing system); patients were informed of findings, as appropriate.

Study endpoints. The primary objective was to demonstrate a less than 0.75-V change in atrial and ventricular PCTs from the pre-MRI visit to the 1-month post-MRI visit.

The secondary objectives were (i) to demonstrate the stability of atrial and ventricular PCTs at 0.35 ms from pre-MRI visit to post-MRI visit and the stability of atrial and ventricular sensing thresholds at 0.35 ms from pre-MRI visit to post-MRI visit and from pre-MRI visit to 1-month follow-up visit and (ii) to report serious adverse events (SAEs), including relation to the MRI examination. The causality of adverse events toward the protocol, devices, or the MRI procedure was determined by the investigators.

Statistical analyses. Sample size was calculated based on the co-primary criteria of the absolute value of the differences between atrial and ventricular thresholds compared to 0.75 V. A systematic literature review on pacemaker patients undergoing MRI examination has shown that no variation of PCT greater than 1 V had been reported, when comparing pre-MRI and 1-month MRI examination.[2–8] Based on these conclusions, the PCT difference (between 1 month after MRI and pre-MRI) was set at 0.75 V and mean differences were compared to this value. For atrial PCT, assuming a mean difference pre-MRI to 1-month follow-up visit of 0.28 ± 0.49 V, a sample size of 17 patients would achieve 90% power to detect

a mean difference of 0.47 V between the null hypothesis and an alternative hypothesis of 0.75 V, by using a one-sided, one-sample *t*-test, with a significance level (alpha) of 0.0125. For ventricular PCT, assuming a mean difference pre-MRI to 1-month follow-up visit of 0.32 ± 0.58 V, a sample size of 26 patients would achieve 90% power to detect a mean difference of 0.43 V between the null hypothesis and 0.75 V, using a one-sided one-sample *t*-test, with a significance level (alpha) of 0.0125. The overall sample size was increased to 33 patients in order to account for up to 20% attrition rate and ensure that 26 patients will have primary end point data.

Quantitative data are expressed as mean ± standard deviation or as the median with interquartile range, depending on the distribution of the data. Counts and percentages denote categorical variables. The primary endpoint was analyzed on the full analysis set (FAS) population, ie, enrolled patients who performed their MRI examination and with available data for the primary endpoints (atrial or ventricular pacing thresholds at 0.35 ms). All other analyses were performed on the enrolled population. The primary endpoints were tested using a one-sided *t*-test with an alpha risk of 0.025; a Bonferroni adjustment was applied to correct multiplicity and the alpha risk set to 0.0125. All other analyses are descriptive statistics. Missing data for primary and secondary criteria regarding electrical stability were not replaced. All analyses were conducted using the SAS® software release 9.2 (SAS Institute, Cary, NC, USA).

Results

Implantation, enrollment, and follow-up until the MRI examination. A total of 33 patients (29 DR and 4 SR) were enrolled in four centers in France between February and May 2014. Mean age at enrollment was 72.8 ± 11.4 years. Seventy percent of patients were male with a mean body mass index of 27.5 ± 3.9 kgm^{-2}. Baseline patient characteristics are provided in Table 1. Mean follow-up duration was 48.6 ± 24.9 days, with 29 (87.9%) patients completing the study.

Right atrial leads were positioned in the appendage (26 patients, 89.7%), in the atrial wall (2 patients, 6.9%), and in the septum (1 patient, 3.4%). Right ventricular leads were positioned in the septum (21 patients, 63.6%) and in the apex (12 patients, 36.4%).

Three patients withdrew consent after enrollment. One patient was excluded due to a high pacing threshold recorded during the pre-MRI visit. Consequently, 29 patients underwent MRI.

MRI examination. Scanned anatomical regions avoided the thoracic or abdominal regions: head (14, 42.4%), knee (5, 15.2%), hips (5, 15.2%), lumbar spine (2, 6.1%), ankle (1, 3.0%), prostate (1, 3.0%), and pelvis (1, 3.0%). Mean duration of MRI examinations was 16 min (max: 32 min) with three to six MRI sequences per examination, with mean SAR of 0.71 W kg^{-1}. During MRI examinations, no rhythm disorder (including AF, ventricular tachycardia, premature ventricular contraction, etc.) was observed. MRI images were free of artifacts and abnormalities. The AutoMRI mode operated as designed.

Table 1. Demographic characteristics.

VARIABLES	ALL PATIENTS (*n* = 33)
Demographics	
Age, mean ± SD	72.8 ± 11.4
Male gender, *n* (%)	23 (69.7%)
Implant indication, *n* (%)	
Atrio-ventricular block	14 (42.4%)
Bundle branch block	2 (6.1%)
Sinus node disease	10 (30.3%)
Syncope	7 (21.2%)
Arrhythmias history, *n* (%)	
Atrial arrhythmias*	13 (39.4%)
Ventricular extrasystole	1 (3.0%)
Heart disease, *n* (%)	
Coronary artery disease	10 (30.3%)
Cardiomyopathy	8 (24.2%)
Valvular heart disease	12 (36.4%)
Associated conditions	
Arterial hypertension	22 (66.7%)
Bypass	7 (21.2%)
Valve replacement	8 (24.2%)
Angioplasty	6 (18.2%)
Diabetes mellitus	10 (30.3%)

Notes: *Includes fibrillation/flutter/tachycardia.
Abbreviation: SD, standard deviation.

Primary endpoints. One patient was excluded from the final analysis set (FAS) of 28 patients as PCTs were not measured per protocol (pacing width 0.35 ms). The mean atrial and ventricular pacing thresholds (measured at 0.35 ms) measured pre-MRI and 1-month post-MRI are displayed in Table 2. The mean absolute difference for both chambers was statistically significantly lower than 0.75 V (*P*-value <0.001), confirming the stability of the PCT 1-month post-MRI for both cardiac chambers and demonstrating successful co-primary endpoint comparisons.

Secondary endpoints. The mean atrial and ventricular PCTs (measured at 0.35 ms), sensing amplitude, and impedance measured during visits and mean absolute variation between visits for each parameter are displayed in Table 2. With minimal mean absolute variation in atrial and ventricular PCTs from pre-MRI visit to post-MRI visit and in atrial and ventricular sensing amplitudes from pre-MRI visit to post-MRI visit and from pre-MRI to 1-month follow-up visit, these secondary objectives were reached.

Table 2. Stability of mean PCT, sensing amplitude, and impedance after the MRI examination.

MEAN ± SD (MIN–MAX)	PRE-MRI	POST-MRI	1 MONTH POST-MRI	MEAN ABSOLUTE VARIATION AT 1-MONTH POST-MRI	MEAN ABSOLUTE VARIATION POST-MRI
PCT					
RA	0.76 ± 0.33 V (0.25–1.75)	0.79 ± 0.31 V (0.25–1.50)	0.81 ± 0.35 V (0.50–2.00)	0.18 ± 0.16* V (0.00–0.50)	0.11 ± 0.19 V (0.00–0.50)
RV	0.76 ± 0.32 V (0.25–1.50)	0.88 ± 0.27 V (0.50–1.50)	0.85 ± 0.22 V (0.50–1.50)	0.18 ± 0.22* V (0.00–1.00)	0.10 ± 0.20 V (0.00–0.85)
Sensing amplitude					
RA	4.48 ± 1.82 mV (0.84–6.14)	4.53 ± 1.64 mV (1.52–6.14)	4.55 ± 1.61 mV (1.52–6.14)	0.77 ± 1.02 mV (0.00–3.66)	0.62 ± 1.00 mV (0.00–2.94)
RV	11.75 ± 3.62 mV (4.35–15.00)	11.89 ± 3.60 mV (4.47–15.00)	11.78 ± 3.90 mV (3.88–15.00)	0.57 ± 0.72 mV (0.00–2.30)	0.30 ± 0.57 mV (0.00–2.47)
Impedance					
RA	477 ± 72 Ω (382–626)	536 ± 87 Ω (401–692)	482 ± 81 Ω (375–656)	29 ± 32 Ω (0–152)	64 ± 83 Ω (0–235)
RV	578 ± 151 Ω (403–1164)	627 ± 173 Ω (390–1336)	602 ± 183 Ω (390–1382)	39 ± 44 Ω (1–218)	55 ± 71 Ω (0–243)

Note: *$P < 0.001$, comparison with the prespecified value 0.75 V.
Abbreviations: RA, right atrium; RV, right ventricle; SD, standard deviation; V, volt.

No SAEs experienced during the study were considered by the investigators to be MRI related. One patient with documented paroxysmal AF at enrollment experienced heart failure decompensation due to AF and underwent IV treatment. A second patient reported dizziness and lightheadedness 52 days before MRI and soon after enrollment. A loss of capture from the apex was detected, probably due to fibrosis at the lead tip. Consequently, the ventricular lead was repositioned from the apex to the septum, 38 days before the MRI evaluation. In a third patient excluded from the FAS due to a protocol deviation (patient had a high pre-MRI PCT, 2.5 V at 1 ms, disqualifying patient for MRI), the post-MRI PCT remained elevated (1.75 V, at 1 ms). Subsequent fluoroscopic imaging confirmed lead dislodgement.

No adverse event related to the pacemaker or protocol was observed during the study. Additionally, no rhythm disorders or adverse reactions were observed during or up to 1 month after MRI examination.

Discussion

The IKONE prospective, nonrandomized, single-arm, multicenter study aimed to demonstrate the safety and effectiveness of KORA 100™ and Beflex™ lead MRI conditional pacing system under 1.5-T MRI scanning. The IKONE study was conducted in 33 patients implanted with the system, 29 of whom underwent MRI. The study successfully demonstrated both co-primary endpoint objectives, namely, the mean difference between pre- and 1-month post-MRI of less than 0.75 V for both atrial and ventricular pacing thresholds. Moreover, no patient experienced an MRI-related adverse event, supporting the conclusion that the KORA™ and Beflex™ lead pacing system is safe and effective in a 1.5-T MRI environment. Additionally, all MRI images were of diagnostic quality, without artifacts or abnormalities and Beflex lead electrical performance remained stable.

Implications in clinical practice. The main novelty in the pacing system assessed lies in the MRI mode switching automaticity. This automatic feature potentially reduces the time during which the patient is in asynchronous pacing mode compared to other devices for which two visits are needed just before and shortly after the MRI procedure. Beyond a potential reduction in the workflow burden of MRI examination, the limited duration during which the pacemaker is in the asynchronous mode may be desirable for pacemaker-dependent patients, in whom the asynchronous mode may negatively impact on AV synchrony.

The main limitation of the system is certainly the restriction of the anatomical region able to be scanned in patients implanted with the system (out-of-chest anatomical region).

Guidelines and recommendations for MRI scan in pacemaker patients. While some published literature suggests that MRI could be considered with "conventional" (ie, non-MRI conditional) pacemakers, the risk–benefit ratio must be weighed carefully.[4,9] Several risks limit the use of MRI procedures in pacemaker patients and justify the need for MRI conditional pacing systems; the most important one is the so-called "antenna effect", which can trigger heating at the tip of the lead, accompanied with subsequent tissue damage, an increase in PCT, capture loss, or arrhythmia induction.[10]

Available recommendations to guarantee the patients' safety in the MRI environment include evaluating device before and after the scan; continuous monitoring as well as verbal communication with the patient; and finally an electrophysiology technician and a physician being present during

Table 3. Characteristics of commercially available 1.5-T MRI conditional pacemakers.

PACEMAKER MODELS	ADVISA MRI, ENSURA-MRI	ACCENT RF MRI ACCENT MRI		ELUNA, EPYRA, ETRINSA EVIA, ESTELLA, ENTOVIS, ECURO			INGENIO, FORMIO VITALIO		KORA 100™	KORA 250
Manufacturer	Medtronic	St Jude		Biotronik			Boston Scientific		Sorin	
Maximum SAR depending on leads	≤2 W kg^{-1}	≤2 W kg^{-1}	≤4 W kg^{-1}	≤2 W kg^{-1}		≤4 W kg^{-1}	≤2 W kg^{-1}	≤4 W kg^{-1}	≤2 W kg^{-1}	
MRI conditional leads	CapSureFix CapSure Sense	Trendril STS Isoflex	Tendril MRI	NC	Safio Setrox	Solia Sello	Fineline II Sterox	Ingevity	Beflex	
Scanning zone	Full body	Out-of-chest	Full body	Out-of-chest	Full body		Full body		Out-of-chest	Full body
MRI mode	Manual	Activator™ hand-held device		Manual			Manual (timer)		AutoMRI	
Size/weight	12.7 cc/22 g	13.1 cc/24 g		Evia: 12 cc/25 g			Ingenio: 14 cc/32 g Formio: 12 cc/24.5 g		8 cc/20 g	

the scan, with appropriate equipment for resuscitation or any medical emergency, should the need arise.[9] Monitoring requirements also include electrocardiogram, pulse oxymetry, and in some cases noninvasive blood pressure measurement and breathing sensors.[11]

Commercially available MRI conditional pacing systems. In a recent review on MRI conditional devices, Nordbeck et al describe the first MR conditional pacemaker system, the devices development, and the related clinical studies over the last 10 years.[10] Fourteen studies assessed 1.5-T MRI scanners in 806 patients. To date, several 1.5-T MRI conditional systems are available (Table 3). There are similarities among the various systems. Unlike some other implantable devices, pacing systems are never MRI safe but many are MRI conditional. Currently approved pacing systems are conditionally safe when used at 1.5-T and with a maximum slew rate of 200 T m^{-1} s^{-1}. The KORA™ and Biotronik systems have a maximum permitted scan time of 40 minutes RF exposure and 30 minutes examination time, respectively, while other systems do not. All systems recommend avoiding a lateral position in which the pacing system could be closer to the side of the MRI magnet. Lastly, it is possible to scan without restrictions of the anatomical region with the St. Jude Medical, Biotronik, Medtronic, and Boston Scientific pacing systems. Sorin has developed a full-body MRI conditional system which is CE-marked since May 2015.

Conclusion

A novel MRI conditional pacemaker system composed of the KORA 100™ pacemaker and the Beflex™ lead has the ability to switch automatically to asynchronous mode (AutoMRI mode) in the presence of a strong magnetic field. This system, designed to undergo out-of-chest 1.5-T scanning, was found safe and effective in a prospective, pivotal, open-label, multicenter trial.

The enclosed study is an open-label, prospective, multicenter study aimed at confirming the safety and effectiveness of the system when used in patients undergoing magnetic resonance imaging (MRI) with chest exclusion zone. Thirty-three patients were included in the study. We demonstrated that the implanted system was safe and effective for out-of-chest, 1.5-T MRI. In contrast to other MRI conditional devices, the Kora™ pacemaker is the only one to automatically switch from programmed to asynchronous mode when detecting a strong magnetic field. This is of great interest when dealing with such devices in routine practice.

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Author Contributions

Conceived and designed the experiments: AS, AM, MB, AO, AL. Analyzed the data: AS, AO. Contributed to the writing of the manuscript: AS, AL, AO. Agree with manuscript results and conclusions: AS, AM, MB, AO, AL. Jointly developed the structure and arguments for the paper: AS, AL, AO. Made critical revisions and approved final version: AS, AM, AL, AO. All authors reviewed and approved of the final manuscript. The authors thank Frederique Maneval, MSc, scientific writer who contributed to writing and technical editing of the manuscript.

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