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ORIGINAL RESEARCH

First in-human results of the MAGiC robotic magnetic navigation radiofrequency ablation catheter

Gediminas Rackauskas[1,2] · Ricardas Kundelis[2,3] · Audrius Aidietis[1,2] · Jurate Barysiene[1,2] · Diana Sudaviciene[1,2] · Justinas Bacevicius[1,2] · Monika Kezeviciute[2] · Germanas Marinskis[1,2] · Niels Christian Foldager Sandgaard[3] · Christian Jøns[3] · Xu Chen[3] · Peter Karl Jacobsen[3]

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Abstract

Background Robotic magnetic navigation (RMN) has demonstrated clinical utility in treating arrhythmia patients by providing direct distal-tip control of an ablation catheter, enhancing catheter precision, safety, and stability with an atraumatic catheter design. We aimed to assess the first in-human efficacy and safety of the new RMN-guided MAGiCTM radiofrequency ablation catheter.

Methods This prospective, multicenter single-arm, unblinded study enrolled 67 patients with arrhythmias that met EHRA guidelines for catheter ablation. All patients were treated for their index arrhythmia with the MAGiC RMN catheter. All other devices used in the procedures were approved for treatment including a RMN System (Genesis/Niobe®) used to navigate the MAGiC catheter. Acute procedural success and adverse events were assessed for all patients through discharge from the hospital in the days following the procedure.

Results Sixty-seven patients were treated as follows: 25 cases of atrioventricular nodal reentrant tachycardia, 19 of premature ventricular contractions, 8 of Wolf-Parkinson-White (WPW) syndrome, 8 of atrial fibrillation, 3 of atrial flutter, and 4 of ventricular tachycardia. Acute procedural success was 94%. There was one cardiac tamponade due to perforation of the right ventricular outflow tract during ablation. Otherwise, no adverse events were observed.

Conclusion The results of this study demonstrate good acute efficacy and safety of the MAGiC RMN ablation catheter independent of underlying arrhythmias. Contact force and stability with MAGiC seem improved compared to previous catheters available with RMN, and therefore radiofrequency energy delivery needs careful attention, especially in thin areas of the myocardium. Additional long-term data are needed.

Keywords Robotic magnetic navigation · Radiofrequency ablation · MAGiC catheter · Supraventricular arrhythmias · Ventricular arrhythmias

1 Introduction

Radiofrequency catheter ablation has become a gold standard for treating cardiac arrhythmias, as reflected by the European Society of Cardiology (ESC) and European Heart Rhythm Association (EHRA) guidelines [1–4]. Over 600 arrhythmia patients per million are treated annually using catheter-based cardiac ablation procedures [5]. Catheter ablation procedures are performed for various arrhythmias using different energy sources and different ablation techniques in all four heart chambers. A substantial body of clinical data from randomized studies, large registries, and published literature demonstrates the safety and efficacy of radiofrequency catheter ablation.

✉ Gediminas Rackauskas
Gediminas.Rackauskas@santa.lt

1 Department of Cardiac Arrhythmias, Vilnius University Hospital Santaros Klinikos, Santariškių G. 2, Vilnius 08661, Lithuania

2 Clinic of Cardiac and Vascular Diseases, Institute of Clinical Medicine, Faculty of Medicine, Vilnius University, Vilnius, Lithuania

3 Department of Cardiology, Copenhagen University Hospital – Rigshospitalet, Inge Lehmanns Vej 7, Copenhagen 2100, Denmark

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The larger datasets documenting the clinical results of catheter ablation in daily clinical practice can be found in the German Ablation Registry study, which included over 12,500 patients from 52 centers, demonstrating that catheter ablation results in high procedural success, long-term symptom improvement, and patient satisfaction [5–8].

Robotic magnetic navigation (RMN) has demonstrated clinical utility in treating arrhythmia patients with an atraumatic catheter design [9]. A novel 8-F irrigated radiofrequency ablation catheter, MAGiC, facilitates the electrophysiological mapping of the heart and the transmission of radiofrequency (RF) current to the catheter tip. It includes a round, gold tip incorporating 25 irrigation ports and a "string-of-pearls" distribution of magnetic material along the catheter's flexible shaft, designed for more stability, precision, and maneuverability. The catheter is steered using RMN technology. The MAGiC catheter is designed as a variant of the Cerablate® Cool catheter with traditional pull-wire technology, that has been commercially available for several years and used in thousands of procedures. It is an evolution to the existing magnetic navigation catheters, building upon their designs.

Accordingly, this study represents the first-in-human clinical trial of the MAGiC catheter, sponsored by Stereotaxis, Inc. (St. Louis, USA) and Osypka AG (Rheinfelden, Germany). We evaluated the catheter's feasibility, acute performance, and safety in treating patients with different arrhythmias.

2 Methods

The study was approved by the local institutional ethics committee, and all patients provided written informed consent. The study was conducted following the principles of the Declaration of Helsinki. Prospective data collection included reporting of all clinical outcomes and adverse events.

2.1 Study population

Patients were included from Vilnius University Hospital Santaros Klinikos, Lithuania ($n = 34$) and from Rigshospitalet, Copenhagen, Denmark ($n = 33$). Eligible patients were 18 years or older with symptomatic atrial or ventricular arrhythmias with at least one documented episode to be treated within the previous 6 months. Key exclusion criteria included the presence of an intracardiac thrombus, patients in which the MAGiC catheter would need to cross a prosthetic valve, and patients with a previous cardiac ablation procedure within 30 days or a stroke within 6 months.

2.2 Pre-procedural management

Pre-procedural computed tomography or magnetic resonance imaging was not required. For left atrial/ventricular procedures, a cardiac computed tomography or transesophageal echocardiogram was done before the procedure to rule out left atrial thrombus. According to guidelines and local practice, unfractionated heparin was administered during the procedure. The procedures were performed under local anesthesia, conscious sedation, or general anesthesia.

2.3 Mapping protocol

A diagnostic catheter was placed in the coronary sinus and/or in the right ventricular apex based on the operators' preferences. Access to the left atrium and ventricle was obtained with transseptal puncture performed using fluoroscopy and pressure guidance (Rigshospitalet) or with intracardiac echocardiography catheter (8-F AcuNav, Siemens Health-care, Mountain View, California) in Vilnius. The MAGiC catheter was advanced through either a fixed-curve long sheath (SL1, SL0, SR0) or Agilis steerable sheath (Agilis NxT, Abbott, St. Paul, Minnesota). Fast anatomical mapping was performed for all participants with voltage and local activation time mapping using a multipolar mapping catheter from Abbott (HD Grid) and the MAGiC catheter. Some PVC and SVT cases were performed under zero fluoroscopy. All procedures were done by experienced RMN operators.

2.4 Ablation procedure

Sixty-seven patients received radiofrequency ablation with the irrigated MAGiC catheter (Fig. 1). The irrigation solution was normal saline, and the nominal irrigation rates during mapping and energy delivery were 2 and 10 ml/min, respectively. Ablation data recorded during RF ablation included real-time current output, surface temperature, impedance, and electrogram attenuation. The power settings during ablation were left to the operator's discretion, up to a maximum of 50 W. Navigation of the MAGiC catheter was performed using a Genesis or Niobe® Robotic Magnetic Navigation System, which has demonstrated clinical utility in our treatment of arrhythmia patients, as it provides for control of the tip of an ablation catheter, enhancing catheter precision and stability with an atraumatic catheter design. All other devices used

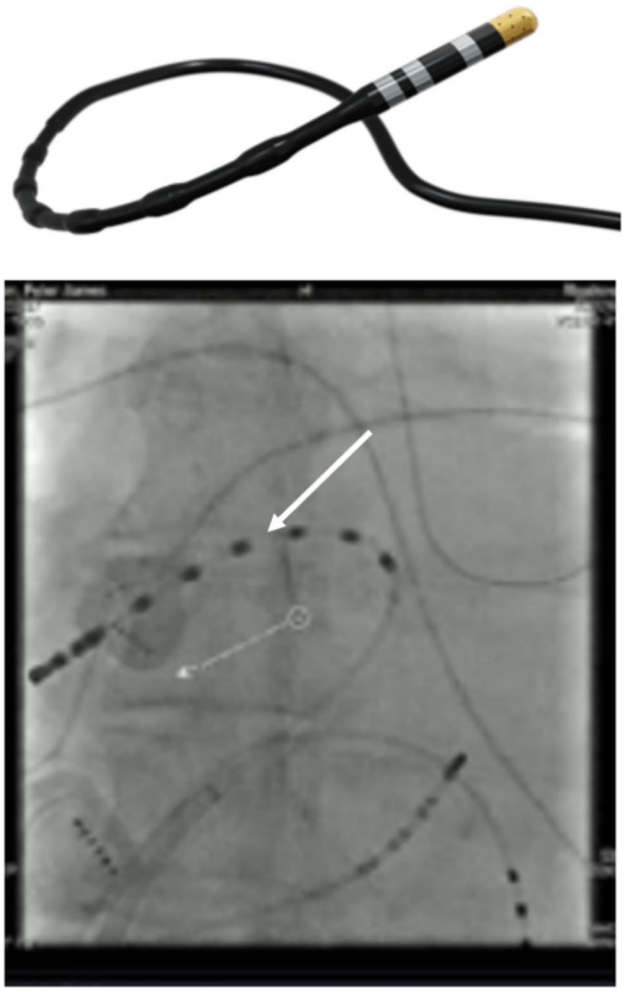

Fig. 1 The new 8-F irrigated radiofrequency ablation MAGiC catheter has a round gold tip incorporating 25 irrigation ports and a "string-of-pearls" shaft magnet design at the distal end of the catheter. Lower part of the figure shows the MAGiC catheter (white arrow) in the right side of the left atrium

during the procedures were approved devices used during the routine treatment of patients, including the EnSite™X electro-anatomical mapping system, EP WorkMate™ or EP-TRACER recording systems, and Ampere™ generator and CoolPoint™ pump. All investigations were within the scope of the device's intended use.

2.5 Data collection and study outcomes

This study aimed to gather safety and performance data on the MAGiC catheter. Acute procedural success and adverse events were assessed for all patients through discharge from the hospital in the days following the procedure. The primary endpoint is to estimate the acute procedural success across a range of treated arrhythmias, defined as the non-inducibility or lack of conduction of the treated index arrhythmia at the end of the procedure. The primary safety endpoint measured in the study is the freedom from serious adverse events (SAE) related to MAGiC. SAEs must be considered serious, occur before discharge, and be directly associated with MAGiC catheter for this endpoint. Additional endpoints included procedure details such as procedure time, total fluoroscopy time, total ablation time, and total volume of irrigation fluid used.

3 Results

3.1 Baseline characteristics

Sixty-seven patients enrolled in the study ranged in age from 18 to 81 years, with an average age of 55. Females represented 36 (54%) of the subjects. Target arrhythmias treated in these patients included AVNRT (25/67), PVC (19/67), WPW (8/67), atrial fibrillation (8/67), and atypical atrial flutter (3/67), VT (4/67). These arrhythmias were found in the four cardiac chambers and ventricular outflow tracts.

3.2 Procedural characteristics

The main patient baseline and procedural characteristics are presented in Table 1.

The procedure success rate, measured by the absence of the treated index arrhythmia at the end of the procedure, was 94% (63/67) across all patients. Acute success was 100% in AVNRT (25/25), WPW (8/8), atrial fibrillation (8/8), and atypical atrial flutter (3/3); 84% in PVC (16/19); and 75% in VT (3/4). Acute success was not achieved in 3 RVOT PVC and 1 VT (originated from the left ventricular mid-inferior and mid-inferoseptal regions).

One procedure-related SAE occurred, a cardiac tamponade. This was most likely caused by perforation of the anterior/free wall of the RVOT and was preceded by popping and was observed after 26 s of the last ablation at 50 W. At the start of the case, ablation was initiated at 30 W; however, as the effect on suppression of the PVCs was reversible, it was incrementally increased by 5–10 W every 20 s, with continuous monitoring for any unsuspected impedance changes and steam pops. During the last application, after an initial impedance drop, catheter impedance and temperature were stable without any increase or sudden changes before the perforation/tamponade. The blood was immediately drained from the pericardium during CPR (600 ml over 10 min) and after which the bleeding stopped with no further effusion observed. Initial rhythm during CPR was VF. The patient was cardioverted several times and treated according to standard algorithms with adrenaline 1 mg × 2, amiodarone 150 mg once and blood transfusions. After the pericardium was drained, the patient developed acute bilateral heart

Table 1 Patient baseline and procedural characteristics using MAGiC RMN ablation catheter

	Patients ($n = 67$)			
Sex				
Female	36 (54%)			
Male	31 (46%)			
Age (years)	55 [18–81]			
Patients with previous ablation	15			
Inpatient days after the procedure	1			
Index arrhythmia (type)	PVC	VT	SVT	AF
	19	4	36 [25 AVNRT/8 WPW/3 AFL]	8
Steerable sheath used	2	0	1	2
Procedure chamber	10 RV/5 LV/4 RV-LV	3 LV/1 RV-LV	24 RA/4 LA/3 RA-LA/1 RV/4 RA-RV-LV)	7 LA/1 RA-LA
Watts used	40 [20–50]	50 [30–50]	38 [17–50]	46 [35–50]
Joules	124 [1793–50843]	20,767 [9421–30074]	6395 [425–48112]	24,689 [10032–51138]
Total irrigation used (ml)	190 [83–344]	249 [139–354]	123 [53–275]	194 [62–350]
Ablation time (s)	298 [65–1328]	512 [194–887]	180 [17–983]	583 [212–1079]
Lesions no	9 [1–31]	14 [4–18]	9 [1–41]	37 [15–101]
Fluoro time (min: sec)	4:33 [0:00–15:12]	14:33 [4:12–24:48]	2:39 [0:00–6:42]	3:07 [1:12–14:54]
Fluoro dose (μGym^2)	175 [0–547]	893 [83–174]	102 [0–581]	139 [23–245]
Procedure time (skin-skin, min)	100 [41–183]	137 [110–195]	57 [31–120]	115 [72–189]
Acute success	84% (16/19)	75% (3/4)	100%	100%
Adverse events*	1	0	0	0

*Cardiac tamponade during ablation of PVC in RVOT — see text for details

failure/pulseless electrical activity (PEA) with an echocardiogram showing all heart chambers well perfused, no pericardial effusion, but LVEF/RVEF of < 10%. The patient was an 82-year-old male with PVCs from the RVOT as well as extensive comorbidities and poor quality of life, including heart failure (LVEF 30%), diabetes, prior stroke and severe pulmonary hypertension and reduced lung function. Before the ablation, the patient specifically rejected future treatment of cardiac arrest and/or cardiac surgery/intensive care in the case of complications during the procedure. According to the patient's wish, cardiopulmonary resuscitation was stopped after 45 min due to PEA without reversible causes, including no further pericardial effusion. Cardiac surgery could potentially have restored circulation and saved the patient. There were no signs of device-specific malfunction of the catheter.

Various procedure details were recorded for the study. The average time across the 67 procedures was 83 min (31–195 min). Atrial procedures (except for atrial fibrillation) were quicker with an average procedure time of 57 min. Ventricular and atrial fibrillation treatment procedures were slightly longer with an average procedure time of 137 and 115 min, respectively. Total fluoroscopy time across all

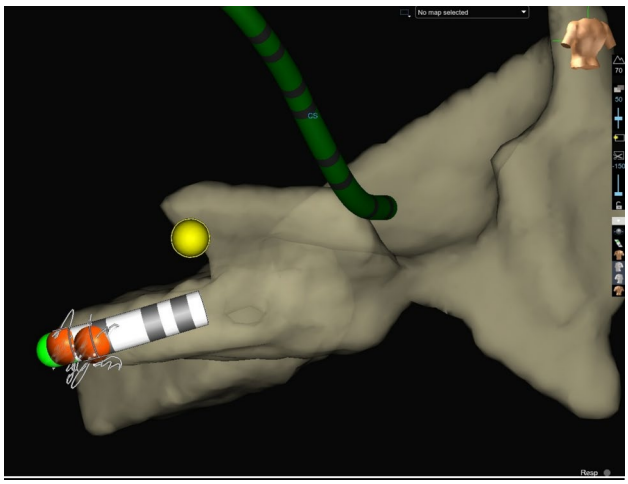

Fig. 2 Stability of the MAGiC ablation catheter tip during the radiofrequency energy application for the treatment of AVNRT (slow pathway ablation). Small movements of the catheter tip are appreciated with the Ensite X system AutoTracks feature (the size of the orange ablation dot, representing the mean position, is 3 mm). Noteworthy is the small upward movement due to typical onset of junctional rhythm. To increase safety, the magnetic vector is set septally downward as it helps to decrease the chance of inadvertent AV block. The yellow dot represents His bundle

Fig. 3 Key elements during a robotic magnetic navigation (RMN) procedure. **A** Navigant screen view during ablation of a left-sided atypical flutter. The top left shows the Ensite X 3D mapping window in local activation time (LAT) mode; the bottom left displays the RMN Navigant window; the right side presents EP system recordings, including local signals from the MAGIC catheter (yellow), coronary sinus (CS) recordings (blue), and right ventricular signals (red). **B** Operator workstation view during the RMN procedure. **C** Overview of the robotic magnetic navigation system setup

procedures averaged less than 5 min (0:00–24:48). Total ablation time averaged 298 s (17–1328 s). The total volume of irrigation fluid used across all procedures averaged 162 ml (53–467 ml). Outcomes were similar at the two participating centers. The stability of the catheter tip during the ablation was verified in real-time and analyzed after the procedure (Figs. 2 and 3).

4 Discussion

This is a first-in-human clinical study assessing the feasibility, acute effectiveness, and safety of a novel mapping and ablation RMN catheter. MAGiC catheter guided the rapid deployment of effective ablation lesion sets in various cardiac arrhythmias in all four cardiac chambers. The study revealed one cardiac tamponade/perforation that occurred during the ablation of PVCs in the RVOT using ablation with 50 W for 26 s. As no device-specific malfunction was identified, the event is thought to reflect known risks of RF ablation in a high-risk patient. Lower power limits in vulnerable regions and close monitoring for predictors (such as significant impedance drops in the first 10 s of ablation or base impedance drop over 18 Ω in the whole ablation) of steam pops during ablation could help avoid such adverse events [10–12].

Over previous years, over 5000 patients were treated with the primary magnetic ablation catheters available, Celsius RMT and Thermocool RMT at Rigshospitalet in Copenhagen and over 1500 at Vilnius University Hospital Santaros Klinikos. Increased catheter stability and precision, catheter safety, and reduced physical stress for the operator are acknowledged features offered by RMN. In our experience with MAGiC, these properties have been further enhanced. Catheter stability was noticeable even in cardiac anatomy where sliding is common with other catheters. Interestingly, in most procedures, the sheath tip was typically placed in a low IVC position where the sheath did not contribute to the direction or support of the ablation catheter. Despite this, MAGiC catheter remained more stable than we typically experience with other magnetic catheters even when a sheath supported those catheters. This could be due to the additional shaft magnets in the MAGIC catheter. The catheter's temperature stability during ablation seems to have improved compared to other RMN catheters as low irrigation rates are likely

to benefit patients undergoing longer procedures or with poor cardiac and renal function. The main new features of the MAGiC catheter compared to older versions of RMN catheters are additional magnets in the shaft of the catheter, increased active tip magnet volume of 41 mm^3 (compared to 16 mm^3 in earlier versions, e. g., Thermocool RMT), a gold dome-shaped tip and thermocouple placed at the distal tip instead of embedded in the electrode [13]. The catheter tip has more irrigation ports and is designed for a lower flow of irrigation (10 ml/min).

Since the MAGiC catheter has more magnetic parts and higher magnetic volume than previous RMN catheters, the contact force is likely higher and the contact more stable. This may translate into more effective lesion formation compared to other RMN catheters. This may allow for shorter duration ablation using the MAGiC catheter and/or lower power settings, comparable to settings for manual catheters, while ablating with the MAGiC catheter, especially in thin areas of the myocardium.

Although contact force is affected by various factors (magnetic field strength, amount of catheter shaft outside the sheath and direction of the magnetic field), in vivo models suggest that the MAGiC catheter seems to have better stability and higher contact force of over 20 g (during testing with field magnitude of 0.10 T, mean maximum force was 22.7 g, SD 0.9) compared to 10–15 g in older generation catheters. This is in concordance with our initial clinical experience, acute efficacy rates using the MAGiC catheter compared favorably to the data obtained from large independent registries assessing catheter ablation. The acute efficacy of MAGiC in this study can be compared favorably to the acute efficacy found in the German Ablation Registry [6–8]: AVNRT (100% for MAGiC compared to 98.9% in German Ablation Registry), AVRT (100% MAGiC vs 94.4% Registry), atrial fibrillation (100 MAGiC vs 95,9% Registry), and Focal Atrial Tachycardia such as WPW (100% MAGiC vs 84.3% Registry). The results in PVC (84% MAGiC vs 82% Registry) and VT (75% MAGiC vs 78% Registry) cases were comparable. Furthermore, a factor negatively influencing the efficacy results in the few PVC and VT patients was study protocol limitations only permitting use of MAGiC in the intracardiac chambers, where use of the catheter in coronary vasculature and the epicardium may have supported efficacy in these procedures.

This initial study in a cohort of 67 patients provides real-world clinical evidence that the MAGiC catheter is effective for delivering ablation therapy across all cardiac chambers. Since contact force and stability seem to have improved, attention should be placed on RF energy delivery and less energy may be sufficient in thin areas of the myocardium, such as the anterior/free wall of the RVOT.

5 Limitations

The short follow-up period of this first-in-human study and its observational design preclude robust comparisons with other RMN catheters and ablation technologies, limiting our ability to draw definitive conclusions about relative safety and efficacy. Additionally, the absence of a control group using the previous catheter versions without magnets in the shaft represents a further limitation, as it restricts our ability to isolate the impact of the magnetic integration on catheter performance and clinical outcomes.

A larger, multi-center study with standardized procedural protocols, long-term follow-up, and direct comparisons would be valuable to more comprehensively assess the catheter's performance, ablation efficacy, and safety in both endocardial and epicardial ablation. The safety profile of this novel technology should also be investigated across broader patient populations and clinical settings.

6 Conclusions

The results of this prospective study demonstrate the acute efficacy and safety of the MAGiC catheter for patients treated in the four cardiac chambers independent of their underlying arrhythmias. Acute efficacy was 94% across the 67 treated patients. Contact force and stability seem improved enabling more efficient ablation lesion delivery and necessitating attention to power settings in thin areas of the myocardium such as the RVOT. Additional long-term safety and efficacy data are needed.

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Data Availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest PKJ has received speakers fee from Stereotaxis.

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