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Single, remote-magnetic catheter approach for pulmonary vein isolation in patients with paroxysmal and non-paroxysmal atrial fibrillation ☆

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ABSTRACT

Background: The aim of the study was to investigate the safety and efficacy of a single, remote-magnetic catheter navigation system (MNS) for pulmonary vein isolation (PVI).
Methods: A total of 107 PVI procedures in 71 patients with paroxysmal (32%), persistent (38%) and longstanding-persistent (30%) atrial fibrillation (AF) were analyzed. A wide area circumferential radiofrequency ablation PVI was performed with either an 8 mm MNS (first 35 procedures) or an irrigated MNS (last 36 procedures) catheter. Electrical isolation was confirmed with circular pacing/sensing using the MNS catheter and a coronary sinus catheter. Our follow-up strategy in the first year and upon symptoms thereafter was: clinical check plus 12-lead ECG (100%) and 24 h-ECG recordings (76%) at 3 month intervals, trans-telephonic ECG (79%) twice daily and upon symptoms (4 weeks every 3 months), or ECG monitoring via implanted devices (9%).
Results: The mean procedure time at 1st PVI was 247 ± 61 min, and mean fluoroscopy time was 44 ± 18 min. The overall complication rate was 2%. Success rates did not differ at the 1st PVI regarding catheter type ($p = 0.931$) but were dependent on history of AF: patients with paroxysmal AF had the highest success rates of 58% and 29% after 1 and 3 years of follow-up, respectively ($p = 0.0084$).
Conclusion: PVI with a single MNS catheter is safe and is associated with short fluoroscopy exposition. Despite a rigorous follow-up strategy success rates favorably compare with recently published data on hand-held PVI. Thus, multipolar catheters or a 2nd trans-septal puncture may not be mandatory.

1. Introduction

Radiofrequency catheter ablation (RFA) of atrial fibrillation (AF) has become an important and increasingly used therapy in patients with symptomatic, drug refractory paroxysmal or persistent atrial fibrillation. However, pulmonary vein isolation (PVI) remains technically challenging even for experienced electrophysiologists. PVI involves complex catheter manipulation resulting in prolonged fluoroscopy and procedure times. A magnetic navigation system (MNS) using a magnetic field for single-catheter movement has gained widespread interest (Stereotaxis, Inc., Saint Louis, MO, USA). Early studies have reported initial safety data in performing catheter ablation via this "joystick ablation" in different clinical contexts: mapping [1,2], atrio-ventricular nodal reentrant tachycardia [3,4], accessory pathways [5–7], and left [8,9] or right ventricular tachycardia [10]. PVI with MNS has been studied in canines first [11]. Data regarding PVI using MNS in humans has been promising in terms of feasibility [12–14]. Studies comparing MNS and hand-navigated PVI were limited in terms of sample size (<50 MNS patients) [15–18] and/or duration of follow-up time (≤12 months) [15–22]. Common protocols include additional multipolar (circular) mapping catheters for MNS PVI [13–20,23–25] and often allow intra-procedural cross-over to hand-navigated PVI. The aim of the study was to evaluate a single catheter MNS approach in terms of safety and efficacy over long-term.

2. Methods

2.1. Study design and study population

This is a retrospective study performed at the Medical University of Vienna, Department of Cardiology, in unselected patients scheduled to undergo PVI with MNS. The diagnosis of paroxysmal, persistent or longstanding persistent AF was established using current guidelines [26,27]. All patients gave their written permission before PVI after informed consent was obtained. This study was approved by the local ethics committee. Inclusion criteria: symptomatic or clinically relevant atrial fibrillation (AF) refractory or intolerant to at least one Class I or III antiarrhythmic drug. Exclusion criteria: contraindications to anticoagulation, presence of a left atrial (LA) thrombus, life expectancy <1 year, and overt thyroid dysfunction. Patients with implanted devices such as pacemakers or defibrillators, and patients with depressed left ventricular function or more than mild valvular regurgitation/stenosis were not excluded from PVI.

☆ Statement: All authors have seen and approved the paper. The authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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2.2. Preprocedural imaging, anticoagulation and ablation procedure

All patients underwent cardiac computer tomography imaging prior to the procedure (Brilliance 64™, Philips MS, Best, The Netherlands). Patients already on oral anticoagulants had this exchanged for low-molecular-weight heparin 3 days before the procedure. For the remaining patients, anticoagulation was started after the procedure. Immediately before PVI transesophageal echocardiography was performed to exclude LA thrombus. At the beginning of the procedure, the patient's body was fixated with linen applied transversely at the level of the shoulders to prevent significant body movement during the ablation procedure. Patients were given per orally 20 ml of an iodinated oral contrast agent (Prontobarium [barium sulfate]; Bracco, Milan, Italy) for the demarcation of the esophagus from the adjacent heart. Deep sedation was initiated with intravenous propofol. After obtaining vascular access from the left femoral vein, one decapolar steerable diagnostic catheter was positioned in the coronary sinus (6Fr, Dynamic Deca, C.R. Bard, Inc., Lowell, MA, USA). Fluoroscopic imaging was performed in all patients using a digital imaging system (Artis, Siemens, Inc., Malvern, PA, USA). Fluoroscopically guided transseptal puncture was performed to position one sheath within the left atrium (SRO, 8.5Fr and BRK™ Transseptal Needle, St. Jude Medical, Inc., St. Paul, MN, USA). After placing the MNS catheter into the LA the sheath was immediately withdrawn into the right atrium and placed proximal to the transseptal puncture site. Intravenous heparin was administered to maintain an activated clotting time (ACT) between 300 and 350 s. Left atrial mapping was performed (NAVISTAR® RMT DS, 8 mm tip for the first 35 procedures and 3.5-mm-tip open-irrigated for the following 36 procedures, Biosense Webster, Inc., Diamond Bar, CA, USA) with the use of the MNS. Maps were compared with preprocedure CT images (Cartomerge™, Biosense Webster, Inc., Diamond Bar, CA, USA).

In brief, the MNS consists of two focused-field permanent magnets that are computer-controlled and located on either side of the body. The magnetic field creates a 360° omnidirectional rotation of the device by uniform magnetic field (0.08–0.1 T). The MNS is integrated with a modified C-arm single-plane digital imaging system. The combination of rotation, translation, and tilt movements of the magnets adjusts the magnetic field to any desired orientation in the spherical 20-cm diameter navigation volume. The maximum X-ray imaging angles are limited to approximately 30° left anterior oblique (LAO) and right anterior oblique (RAO). The operator is positioned in a separate control room. The catheter is advanced and retracted by a mechanical device ("CAS", Cardiodrive Catheter Advancement System, Stereotaxis, Inc., Saint Louis, MO, USA). All magnetic field vectors can be stored and, if necessary, reapplied while the magnetic catheter is navigated automatically. The video workstation-based user interface (Niobe II, Navigant™, Software User Interface, Stereotaxis, Inc., Saint Louis, MO, USA) used together with the permanent magnets and the CAS unit permits accurate orientation changes of the catheter by 1° increments and advancement or retraction by 1-mm steps. Additionally, X-ray image data can be transferred from the X-ray system to the user interface of the MNS to provide an anatomical reference [11].

Wide area circumferential ablation was performed and lesions placed in a point-by-point fashion (8 mm: 40 W, temperature limit 45 °C, 15 s; 3.5 mm irrigated: 30 W, temperature limit 45 °C, 25–30 s, step size 3 mm). After wide area circumferential ablation, the "bulls eye" feature was used. This feature allows circular, segmental catheter movements in 10° increments. The "bulls eye" feature was used to guide additional ablation at the tubular portion of each PV to achieve complete PVI. PV entrance block was confirmed by abolition of PV potentials (bipolar electrogram amplitude) confirmed with 32-fold threshold amplification on the EP Recording System (coronary sinus pacing for the left sided PVs). Finally, pacing at multipolar points in a circular fashion within the PV was performed to check for exit block. Switching over to manual navigation or vice-versa for any reason was not allowed.

2.3. Measurements

Echocardiography data was obtained from ACUSON Sequia C256® (Acuson, Mountain View, CA, USA). Mapping time, mapping points, LA mapping volume and ablation points in

Table 1
Patients' clinical, echocardiographic and procedure data stratified according type of catheter.

	N total	Total $n = 71$	8 mm $n = 35$	Irrigated $n = 36$	*P* for trend
Baseline characteristics					
Age (years)	71	55.9 ± 12	57.6 ± 12	54.2 ± 12	0.2448
Male (*n*)	71	54 (76%)	26 (74%)	28 (78%)	0.9469
Body mass index	71	27.6 ± 4.6	28.3 ± 4.6	26.9 ± 4.5	0.1899
History of atrial fibrillation					0.0625
Paroxysmal	71	23 (32%)	8 (23%)	15 (42%)	
Persistent	71	27 (38%)	18 (51%)	9 (25%)	
Longstanding persistent	71	21 (30%)	9 (26%)	12 (33%)	
Comorbidities					
Hypertension	71	59 (83%)	29 (83%)	30 (83%)	0.7924
Coronary artery disease	71	7 (10%)	3 (9%)	4 (11%)	1 *
Hyperlipidemia	71	19 (27%)	7 (20%)	12 (33%)	0.317
History of ischemic attack	71	5 (7%)	3 (9%)	2 (6%)	0.6737
COPD	71	3 (4%)	2 (6%)	1 (3%)	0.6142 *
Diabetes	71	5 (7%)	3 (9%)	2 (6%)	0.6737
Echocardiographic parameters					
Ejection fraction	71				0.7531 *
Normal LVEF		57 (80%)	29 (83%)	28 (78%)	
Mild LVEF reduction		11 (16%)	4 (11%)	7 (19%)	
Moderate LVEF reduction		2 (3%)	1 (3%)	1 (3%)	
Severe LVEF reduction		1 (1%)	1 (3%)	0	
Valves	71				
Regurg./stenosis (non-mitral)		6 (9%)	5 (15%)	1 (3%)	0.106 *
Normal mitral valve		33 (47%)	16 (44%)	17 (49%)	0.7429 *
Mild mitral regurgitation		18 (25%)	10 (29%)	8 (23%)	
Moderate mitral regurgitation		19 (27%)	8 (24%)	11 (31%)	
Severe mitral regurgitation		1 (1%)	1 (3%)	0	
Left atrium/septum					
A.p. parasternal long axis		47 ± 6	48 ± 7	46 ± 5	0.2685
Interventricular wall (mm)		12.8 ± 1.8	13.1 ± 1.6	12.5 ± 2.0	0.1079
PVI related complications	71				0.7924 *
No major complication		105 (98%)	50 (98%)	55 (98%)	
Pericardial effusion		1 (1%)	1 (2%)	0 (0%)	
Transient ischemic attack		1 (1%)	0 (0%)	1 (2%)	
Hemodynamic problems		0 (0%)	0 (0%)	0 (0%)	
Esophageal injury		0 (0%)	0 (0%)	0 (0%)	
Monitoring according procedures	107	$n = 107$	$n = 61$	$n = 46$	
12-lead ECG + clinical check		107 (100%)	61 (100%)	46 (100%)	1
24-h ECG monitoring		81 (76%)	50 (82%)	31 (67%)	0.1304
Event recorder monitoring		85 (79%)	51 (84%)	34 (74%)	0.3238
Monitoring device implanted		10 (9%)	4 (7%)	6 (13%)	0.4204

P-values are from one-way analysis or chi-square test or Fisher's exact test (*) for categorical data.