Magnetic versus manual catheter navigation for mapping and ablation of right ventricular outflow tract ventricular arrhythmias: A randomized controlled study

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BACKGROUND No randomized controlled study has prospectively compared the performance and clinical outcomes of remote magnetic control (RMC) vs manual catheter control (MCC) during ablation of right ventricular outflow tract (RVOT) ventricular premature complexes (VPC) or ventricular tachycardia (VT).

OBJECTIVE The purpose of this study was to prospectively evaluate the efficacy and safety of using either RMC vs MCC for mapping and ablation of RVOT VPC/VT.

METHODS Thirty consecutive patients with idiopathic RVOT VPC/VT were referred for catheter ablation and randomized into either the RMC or MCC group. A noncontact mapping system was deployed in the RVOT to identify origins of VPC/VT. Conventional activation and pace-mapping was performed to guide ablation. If ablation performed using 1 mode of catheter control was acutely unsuccessful, the patient crossed over to the other group. The primary endpoints were patients' and physicians' fluoroscopic exposure and times.

RESULTS Mean procedural times were similar between RMC and MCC groups. The fluoroscopic exposure and times for both patients and physicians were much lower in the RMC group than in the MCC group. Ablation was acutely successful in 14 of 15 patients in the MCC group and 10 of 15 in the RMC group. Following crossover, acute success was achieved in all patients. No major complications occurred in either group. During 22 months of follow-up, RVOT VPC recurred in 2 RMC patients.

CONCLUSION RMC navigation significantly reduces patients' and physicians' fluoroscopic times by 50.5% and 68.6%, respectively, when used in conjunction with a noncontact mapping system to guide ablation of RVOT VPC/VT.

KEYWORDS Magnetic navigation system; Magnetic catheter; Idiopathic ventricular arrhythmia; Right ventricular outflow tract; Noncontact mapping

ABBREVIATIONS BO = breakout; **EA** = earliest activation; **LBBB** = left bundle branch block; **MCC** = manual catheter control; **MEA** = multielectrode array; **MNS** = magnetic navigation system; **NCM** = noncontact mapping system; **RBBB** = right bundle branch block; **RMC** = remote magnetic control; **RVOT** = right ventricular outflow tract; **VA** = ventricular arrhythmia; **VPC** = ventricular premature complex; **VT** = ventricular tachycardia

(Heart Rhythm 2013;10:1178–1183)

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Introduction

Radiofrequency catheter ablation is recommended for the therapy of medically refractory ventricular arrhythmias (VA) including ventricular tachycardia (VT) or ventricular premature complexes (VPC) originating from the right ventricular outflow tract (RVOT), which often arises in patients without structural heart diseases. Success rates usually in excess of 80% have been reported.[1–5] However, catheter navigation within the RVOT can be technically challenging with increased fluoroscopic exposure to the patient and operator during mapping and may be complicated by the potential risks of perforation.

In recent years, remote magnetic navigation systems (MNS) have been successfully used for ablation of various arrhythmias.[6–8] In the RVOT, MNS could facilitate navigation and reduce fluoroscopic exposure while reducing risks of perforation due to the soft-tipped nature of the catheter. In this single-center randomized controlled study, we prospectively compared the performance and clinical outcomes of remote magnetic control (RMC) vs manual catheter control (MCC) during RVOT VA ablation.

The first two authors contributed equally to this study. This work was supported by grants from the National Natural Science Foundation of China (Grant 81170160), by the Program for Development of Innovative Research Team in the First Affiliated Hospital of Nanjing Medical University (Grant IRT-004), by the Six Peak Talents Foundation of Jiangsu Province (Grant 2011-WS-071), and by National "Twelfth Five-Year" Plan for Science & Technology Support (Grant 2011BAI11B13). Clinical Trial Registration: ChiCTR-TRC-11001550.

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1547-5271/$-see front matter © 2013 Heart Rhythm Society. All rights reserved. http://dx.doi.org/10.1016/j.hrthm.2013.05.012

Methods

Study population

Patients recruited had symptomatic idiopathic VT or VPC with a left bundle branch block (LBBB) morphology, inferior axis, precordial lead transition zone ≥V4, RVOT VPC burden ≥20% of total daily heart beats, and normal left ventricular ejection fraction on echocardiography. All patients had either failed treatment with or could not tolerate beta-blockers and/or Class III or IC antiarrhythmic medications. No patient had previously undergone ablation. Patients with underlying structural heart disease, polymorphic VA, any concomitant systemic illnesses, age < 18 years old, or who were pregnant were excluded from this study.

Consent and randomization

Consecutive patients who fulfilled the inclusion criteria and consented to the study were randomized to undergo ablation guided by either RMC or MCC. Randomization was performed using a random number generator, with sealed envelopes opened on the day of procedure. All patients gave written informed consent. The study was approved by the ethical committee review board of Nanjing Medical University, China, and prospectively registered with the Chinese Clinical Trial Registry (ChiCTR-TRC-11001550).

Patient preparation and noncontact mapping system setup

All antiarrhythmic drug therapies were discontinued at least 5 half-lives before ablation. Electrophysiologic studies were performed with patients in the fasting state. In all patients, a quadripolar diagnostic catheter was positioned in the right ventricular apex. A noncontact mapping system (NCM; EnSite, St. Jude Medical, St. Paul, MN) was used to map the origin of RVOT VA. This is our standard clinical practice as the use of NCM has been previously shown to facilitate mapping, reduce fluoroscopic exposure, and improve success rates.[9–11] Thus, a multielectrode array (MEA) was inserted via the left femoral vein and deployed in the RVOT. Spontaneous VT or VPC at baseline and during intravenous isoprenaline (1–4 μg/min) infusion were recorded. In patients without spontaneous VT or VPC, programmed ventricular stimulation was performed from the right ventricular apex and RVOT at 2 drive cycle lengths with up to 3 extrastimuli. In addition, incremental burst pacing at a cycle length up to 300 ms was performed. The filter settings for intracardiac electrocardiograms were 30 to 300 Hz. Twelve-lead ECGs and bipolar intracardiac ECGs were displayed and recorded at a paper speed of 100 mm/s (Bard Lab System, CR Bard Inc, Lowell, MA). Recordings were stored on optical disk for offline analysis. During the procedure, intravenous heparin was given to maintain an activated clotting time between 250 and 300 seconds.

Remote magnetic navigation

The MNS (Stereotaxis Inc, St. Louis, MO) was used in patients randomized to the RMC group. The MNS used 2 large magnets positioned on either side of the procedure table to generate a composite magnetic field for directional catheter orientation, as described previously.[6,12] The magnets were computer controlled via a workstation (Navigant, Stereotaxis Inc, St. Louis, MO) to effect a change in the orientation of a stable magnetic field within the patient's chest. Combined field strength of 0.08 T was produced in navigation mode. As navigation was best performed with a fixed table position, the table position was optimized and isocentered before starting magnetic navigation. While the magnets were positioned next to the patient, only limited angulation of the C-arm was possible (approximately 28° in the right and left anterior oblique angulations; Figure 1).

Remote catheter advancement and retraction from the control room were performed using a catheter advancer system (Cardiodrive, Stereotaxis) positioned on the high anterior thigh. Remote control of the fluoroscopy system was also possible from the control room. The 4-mm-tip ablation catheter (8Fr Helios II, Stereotaxis) contains 3 magnets within the distal tip segment, which aligns with the field produced by the external magnets to allow for effective catheter orientation. Once the external magnets were in

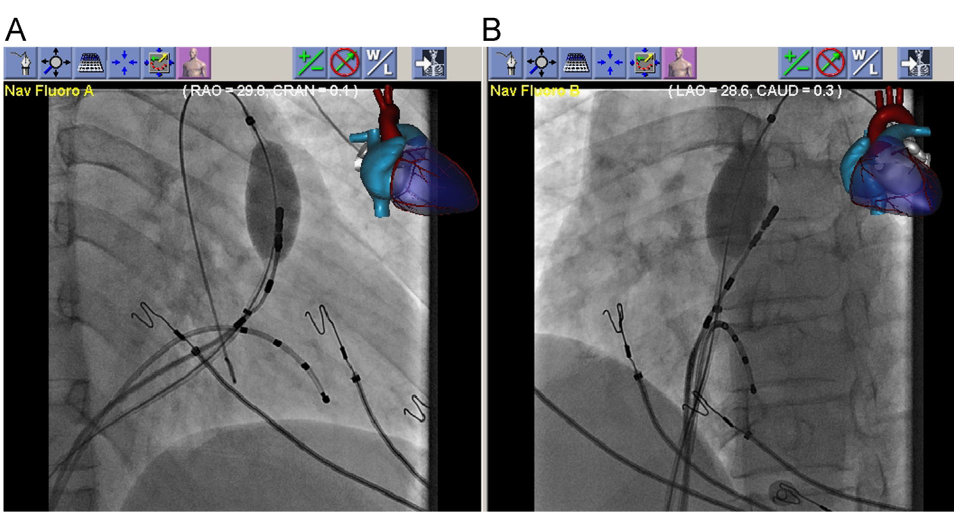

Figure 1 The multielectrode array can be seen within the right ventricular outflow tract with a quadripolar right ventricular catheter. The magnetically enabled catheter has been navigated to a more anteroseptal position. The magnetic Navigant screen shows the 2 radiographic views. **A:** Right anterior oblique (RAO). **B:** Left anterior oblique (LAO).

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