Remote Magnetic Navigation-Guided Pulmonary Vein Isolation: A Single Center Experience

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ABSTRACT. Background: The present study was designed to evaluate whether anatomic remote magnetic navigation (RMN) catheter ablation alone is sufficient to achieve pulmonary vein isolation (PVI) and the role of pulmonary vein (PV) anatomy on acute success of PVI with both standard and RMN approaches. Methods: We examined 91 consecutive patients with atrial fibrillation (AF) who underwent PVI from June 1 2010 to January 1 2011 with standard (n = 61) and RMN-guided (n = 30) irrigated tip catheter ablation. RMN and standard PVI groups were compared regarding clinical characteristics, fluoroscopy, ablation, and procedure time. The acute anatomic RMN and anatomic standard isolation rate for each individual PV and all four PV (complete PVI) were determined. Results: The respective acute success rates of anatomic RMN-guided PVI for each individual PV was right superior PV (RSPV) 78.5%, left inferior PV (LIPV) 69%, right inferior PV (RIPV) 57.6%, and left superior PV (LSPV) 46.4%. When compared to acute isolation rates with anatomic only standard ablation (RSPV 53.4%, RIPV 64.2%, LSPV 43.8%, LIPV 57.1%) the RSPV was isolated significantly more often with anatomic RMN ($\chi^2$ 5.04, p = 0.025). Complete PVI was only achieved in 40% of RMN patients after an anatomic-only ablation strategy compared to a final complete PVI rate of 86.7% after circular mapping catheter (CMC)-guided ablation. RMN-guided PVI was associated with significantly longer procedure time (240.6 min versus 201.8 min, p = 0.006) and radiofrequency ablation (61.0 versus 50.2 min, p = 0.012) times without a difference in fluoroscopy time (43.8 versus 47.4, p = 0.15). Conclusion: Suboptimal success in isolating all four pulmonary veins using anatomic RMN ablation alone suggests that additional CMC-guided ablation is necessary to improve the overall success of PVI.

KEYWORDS. atrial fibrillation, pulmonary vein isolation, remote magnetic navigation.

Introduction

Pulmonary vein isolation (PVI) via radiofrequency (RF) catheter ablation is an effective treatment for selected patients with symptomatic atrial fibrillation (AF). Remote magnetic navigation (RMN) catheter ablation has been shown to be a feasible and safe technique to achieve PVI with long-term effectiveness.2–9 RMN offers the advantage of reduced radiation exposure to the operator compared with conventional RF ablation.4,6–8 In addition, RMN allows improved catheter stability and endocardial contact during RF application with a reduced risk of complications secondary to the atraumatic design of the RMN ablation catheter.6

The overall success rates of acute PVI of all four pulmonary veins with RMN is variable, with reported success rates between 66% and 90%.2,7–8 The rate of isolation of individual pulmonary veins following wide area circumferential ablation (WACA) has not been previously described. We hypothesize that there are different isolation rates for the individual pulmonary veins due to the anatomic structures surrounding the
PVs; more specifically that the LSPV will prove more difficult to acutely isolate secondary to the ridge between it and the left atrial appendage. Further, we seek to study if there are any clinical predictors of complete PVI, which would make the use of additional circular mapping catheter (CMC)-guided ablation unnecessary.

Specific aims of the study were to determine the following: 1) if differential isolation rates are present for individual pulmonary veins utilizing standard and RMN PVI approaches; 2) the technical success rate of achieving complete PVI utilizing an anatomic RMN versus anatomic standard PVI approach; and 3) the effect of RMN on fluoroscopy, ablation, and procedure time.

**Methods**

We conducted a retrospective chart review using an electrophysiology electronic procedure database to identify a cohort of 91 consecutive adult (>18 years of age) patients who underwent ablation for AF between June 1 2010 and January 1 2011 at the University of Rochester Medical Center, Rochester, NY. The Research Subject Review Board at the University of Rochester Medical Center approved this study. Experienced high-volume operators at our institution trained in both RMN-guided and standard PVI performed all procedures. The decision to use of RMN-guided PVI or standard PVI was at the operator’s discretion. Patients with contraindications for magnetic navigation such as pacemakers, defibrillators, or other implants that precluded the use of magnetic fields were excluded. We collected data regarding patient demographics, clinical baseline characteristics, medications, and type of AF using the patient’s electronic medical records. Procedure details including acute PVI rates, procedure time, duration of ablation, and fluoroscopy time were also collected.

**Definitions of outcomes and covariates**

Paroxysmal AF was defined as episodes of AF that are self-terminating and do not require chemical or electrical cardioversion. Persistent AF was defined as episodes of AF that require chemical or electrical cardioversion for termination or episodes that persist for more than 7 days. Longstanding persistent AF was defined as episodes of AF that have persisted for more than 1 year. Successful PVI was defined as proof of both entrance and exit block and/or evidence of dissociated PV potentials seen on a circular mapping catheter. Acute success of PVI was defined as PVI achieved with RMN-guided or standard WACA alone, and the final success of PVI was defined as PVI achieved at the end of the procedure with or without additional circular mapping catheter-guided ablation. Total procedure time was defined as time in the procedure room to completion of the procedure. Acute procedural complications included tamponade, cerebrovascular events, or hemorrhage requiring transfusion.

**Procedure methods**

All patients gave written informed consent for the procedure. Left atrial appendage thrombus was ruled out via transesophageal echocardiogram. All ablation procedures were performed under general anesthesia. An esophageal temperature probe was placed in all patients and moved during the procedure to mirror the anatomical location of the ablation catheter as closely as possible. An octopolar diagnostic catheter (Steerocath-Dx, Boston Scientific, Natick, MA) was placed in the coronary sinus from the right femoral vein. Transseptal puncture was performed under intracardiac echo guidance (Intracardiac Echo Catheter, Boston Scientific) with a transseptal needle (Baylis Medical, Montreal, CA) introduced through a non-steerable sheath (SWARTZ SLO, St. Jude Medical Inc, Minnetonka, MN). A 3.5-mm irrigated tip ablation catheter (Navistar RMT, Biosense Webster, Diamond Bar, CA) was utilized for ablation in all patients.

The tilting Niobe II magnetic navigation system (Stereotaxis, St. Louis, MO) was used for remote magnetic ablation in all patients who received RMN-guided PVI. The details of the remote magnetic-guided navigation system have been described in detail previously. The ablation catheter was advanced and retracted by a computer-controlled catheter advancer system (Catheter Advancing System User Interface, Stereotaxis) which was placed on the anterior thigh. An electroanatomical map (CARTO 3, Biosense Webster) of the left atrium and PVs was created utilizing the ablation catheter. For patients with a prior history of AF ablation, documentation of baseline electrical isolation was performed (dissociation between atrial and PV potentials) with only non-isolated veins included in the analysis.

WACA was performed initially with either RMN guidance or with standard ablation, insuring that all RF lesions were delivered at least 5 mm outside the venous ostia, except anterior to the left pulmonary veins where the lesions were delivered either on top of the ridge between the veins and appendage or at the anterior ostium of the vein. A power setting of 40 watts was used on the anterior wall, which was decreased to 35 watts on the posterior wall with a flow rate of 30 mL/min. Maximum catheter temperature tip was 40°C. Ablation was immediately stopped for any esophageal temperature rise of greater than or equal to 0.5°C. Following anatomic WACA in every patient, a 20-pole CMC (Lasso, Biosense Webster) was placed sequentially in each PV via additional transseptal access. If a vein was proved to be isolated, demonstrating both entrance (pacing from ablation catheter to CMC) and exit (pacing from CMC to ablation catheter) block with high output pacing, no further ablation was performed. In those veins that were not isolated following anatomical WACA, further electrogram-guided ablation was performed with both the CMC and ablation catheter in the left atrium. Ablation was performed at the sites of earliest atrial activation as recorded on the CMC until complete PVI was achieved.
Statistical methods

Data were reported as percentage or mean ± standard deviation. The characteristics of study subjects were compared using the Wilcoxon rank-sum test for continuous variables and the $\chi^2$ of Fisher’s exact test, as appropriate, for categorical variables. The rate of electrical isolation following anatomic RMN and standard PVI were compared for each individual PV using $\chi^2$ analysis. Differential rates of isolation between PVs within each modality were also compared utilizing $\chi^2$ analysis. Two-sided $p<0.05$ was considered to declare statistical significance. SAS statistical software package, version 9.2 (SAS Institute, Cary, NC) was used for analyses.

Results

A total of 91 patients were included in the present study. Baseline characteristics are listed in Table 1. The mean age was 58.8 years, and 79% of the patients were male. Permanent or persistent AF was present in 56%, with paroxysmal AF making up the remainder at 44%. Standard PVI had previously been performed in 20% of the RMN patients and 16.6% of standard ablation patients. Baseline PVI in patients with previous standard ablation was noted in n=5 (25%) right superior PV (RSPV), n=5 (31.2%) right inferior PV (RIPV), n=6 (37.5%) left superior (LSPV), and n=6 (37.5%) left inferior (LIPV), and were not included in the analysis. The mean left ventricular ejection fraction ± SD was 53.0 ± 10.4% without significant difference between the RMN (51.3%) and standard ablation groups (53.5%, $p=0.37$). The mean left atrial volume was 91.5 ± 30.6 ml without any difference between the RMN (95.4 ml) and the standard PVI group (90.3 ml, $p=0.49$). In terms of prior drug therapy for AF, 83% of the patients were on antiarrhythmic drugs, 79% on beta-blockers, and 46% on angiotensin converting enzyme inhibitors or angiotensin receptor blockers.

In contrast, there were significant baseline differences between the RMN and standard PVI patient groups. Patients referred for RMN-guided PVI were more likely to have persistent or permanent AF (76.7 % versus 52.6 %, $p=0.013$), and conversely standard PVI patients were more likely to have paroxysmal AF (47.4 % versus 23.3 %, $p=0.013$). No significant procedural complications were noted with either standard or RMN-guided PVI.

RMN versus standard PVI

The acute PVI success rate for individual PVs with an anatomic RMN-guided versus anatomic standard PVI ablation is depicted in Figure 1. With RMN the acute success rate was highest for the RIPV (78.5%) followed by the LIPV (69%), RSPV (57.6%), and lowest for the LSPV (46.4%). The difference in acute isolation rate between the RSPV and LSPV in this group was statistically significant yielded ($\chi^2$ of 2.72, $p=0.099$) with all other comparisons not approaching statistical significance. In the standard ablation group acute isolation rates in the respective PVs were 53.4%, 64.2%, 43.8%, and 57.1% with no difference between individual veins. When comparing the acute PVI rates for individual veins in the RMN and standard PVI groups, RSPV isolation was significantly greater in the RMN group ($\chi^2$ 5.04, $p=0.025$) with no difference in acute isolation of the other pulmonary veins.

Rates of complete acute isolation (all four veins isolated with anatomic WACA) differed significantly between the RMN (40%) and standard PVI (12%, $p=0.007$) groups. Given the small size of the two complete acute isolation groups (RMN=12, standard PVI=7), clinical predictors of such were not able to be determined. Moreover, the rates of final PVI for the individual PVs for RMN and standard PVI approaches were similar (86.7% versus 89.8% respectively, $p=0.67$ (Figure 2)) making the differences in acute isolation likely related to procedure technique and not patient-specific factors.

Table 1: Baseline clinical characteristics of the study population dependent on ablation method

<table>
<thead>
<tr>
<th>Clinical characteristic</th>
<th>All patients</th>
<th>RMN PVI</th>
<th>Standard PVI</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.6 ± 9.4</td>
<td>57.7 ± 8.8</td>
<td>59.2 ± 9.7</td>
<td>0.51</td>
</tr>
<tr>
<td>Male</td>
<td>79.2</td>
<td>86.7</td>
<td>75.4</td>
<td>0.18</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>215 ± 65.5</td>
<td>240.6 ± 59.0</td>
<td>201.8 ± 65.3</td>
<td>0.006</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>46.2 ± 12.5</td>
<td>43.8 ± 10.0</td>
<td>47.4 ± 13.5</td>
<td>0.15</td>
</tr>
<tr>
<td>Ablation time (min)</td>
<td>53.7 ± 22.7</td>
<td>61.4 ± 14.7</td>
<td>50.2 ± 25.1</td>
<td>0.012</td>
</tr>
<tr>
<td>Paroxysmal AF</td>
<td>42.8</td>
<td>20.0</td>
<td>54.1</td>
<td>0.001</td>
</tr>
<tr>
<td>Persistent AF</td>
<td>57.2</td>
<td>76.7</td>
<td>52.6</td>
<td>0.013</td>
</tr>
<tr>
<td>Prior AF Ablation</td>
<td>17.7</td>
<td>20.0</td>
<td>16.7</td>
<td>0.70</td>
</tr>
<tr>
<td>LVEF</td>
<td>53.3 ± 9.9</td>
<td>51.3 ± 9.8</td>
<td>53.5 ± 10.7</td>
<td>0.37</td>
</tr>
<tr>
<td>LA diameter (cm)</td>
<td>4.6 ± 0.71</td>
<td>4.8 ± 0.85</td>
<td>4.5 ± 0.67</td>
<td>0.21</td>
</tr>
<tr>
<td>LA volume (ml)</td>
<td>91.2 ± 32.8</td>
<td>95.4 ± 33.2</td>
<td>90.3 ± 30.0</td>
<td>0.49</td>
</tr>
<tr>
<td>Digoxin</td>
<td>10.5</td>
<td>13.3</td>
<td>9.1</td>
<td>0.57</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>77.3</td>
<td>70.0</td>
<td>81.5</td>
<td>0.25</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>45.2</td>
<td>46.7</td>
<td>44.4</td>
<td>0.84</td>
</tr>
<tr>
<td>AAD</td>
<td>84.5</td>
<td>90.0</td>
<td>81.5</td>
<td>0.27</td>
</tr>
</tbody>
</table>

Data are presented as percentage or mean ± standard deviation. LVEF: left ventricular ejection fraction; AAD: antiarrhythmic drug; ACEI/ARB: ACE inhibitor or angiotensin receptor blocker use.

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The effect of RMN on fluoroscopy, procedure, and ablation times

When compared with standard PVI, RMN-guided PVI was associated with significantly longer procedure (240.6 min versus 201.8 min, p = 0.006) and RF ablation (61.0 min versus 50.2 min, p = 0.012) times. However, only a non-significant reduction in fluoroscopy time was seen with RMN (43.8 min versus 47.4 min, p = 0.15).

Discussion

The present study is the first to examine the PVI success rate for the individual PVs with RMN-guided anatomic WACA in patients with AF. We have shown that higher acute isolation rates with an anatomic RMN versus anatomic standard PVI technique may exist for the RSPV and for complete PVI of all four veins. However, with RMN-guided anatomic WACA alone, complete isolation of all four veins is achieved only 40% of the time based on our experience. This suggests that anatomic WACA alone is not sufficient, and additional CMC-guided ablation is necessary following RMN-guided anatomic WACA to achieve complete PVI.

The differential acute isolation rate for the RSPV with RMN should support a shift in focus from the traditionally difficult to isolate right-sided PVs during standard PVI toward the left-sided PVs during RMN-guided PVI. We also found the final PVI rates to be similar between RMN-guided and standard PVI approaches, indicating parity between the two in achieving the procedural endpoint of complete PVI. RMN did not appreciably reduce fluoroscopy time but was associated with significantly longer ablation and total procedure time.

Although somewhat novel in its examination of successful isolation of individual pulmonary veins, this study is not the first to support the idea that pulmonary vein location plays a role in how difficult it is to electrically isolate. Pappone et al.\textsuperscript{5} noted that the right superior and right inferior PVs required significantly less ablation time with RMN than standard conventional...
ablation. However, the ablation time was similar for both right- and left-sided veins with RMN guidance. Our study suggests that following RMN-guided anatomic WACA, PVI was most successful in the right superior PV, with a lower success rate in the left superior PV. The explanation for this difference lies with the differing advantages of RMN-guided compared with standard PVI. Enhanced catheter flexibility with the RMN ablation catheter allows for configurations and stability not possible with standard ablation catheters, likely resulting in improved access to the right PVs. Given the difficult nature of standard right-sided PVI, a focus on right-sided ablation to achieve PVI may have persisted into the anatomic RMN-guided PVI approach resulting in the higher acute isolation rates seen in the RSPV. This focus would be easily displayed if differential ablation times were present between left- and right-sided PVs. However, we are not currently able to assess such a bias as ablation times are not available for individual PVs. Further study is required to definitively assess differential ablation times for each PV during both standard and RMN-guided PVI.

The use of a CMC after anatomic approach appears necessary regardless of the navigation technique. With such, our rate of final complete RMN-guided PVI (all four PVs) is 86% and similar to that reported by Luthje et al. (90%), Choi et al. (88%), and Bauernfind et al. (94%) without appreciable difference from the standard PVI group. Such consistency between our study and those currently available strengthens our conclusions and their applicability.

In contrast to existing literature, we did not see a significant reduction in fluoroscopy time with RMN compared with standard PVI. Previous data have supported increased fluoroscopy use in the learning phase of RMN with significantly lower fluoroscopy use with mastery of the RMN technology than standard PVI. As the RMN and standard PVI procedures in our study were performed by high-volume operators, the RMN fluoroscopy times were lower than the studies showing longer RMN fluoroscopy times (43.3 ± 10.4 min versus 58 ± 24 min), and the standard PVI times were shorter than those reporting fluoroscopy reduction with RMN (47.2 ± 11 min versus 238 ± 45 min). However, the preponderance of persistent or permanent AF within the RMN group may have acted to increase the fluoroscopy time for the RMN group compared with predominantly paroxysmal AF in the standard PVI group. As no difference in fluoroscopy time was seen and no serious complications noted with RMN guidance, we are left to conclude that RMN-guided anatomic PVI combined with CMC-guided ablation is a safe and efficacious approach to PVI.

Figure 2: Final individual pulmonary vein isolation rates for remote magnetic navigation and standard ablation techniques. LSPV: left superior pulmonary vein; LIPV: left inferior pulmonary vein; RSPV: right superior pulmonary vein; RIPV: right inferior pulmonary vein.
Study limitations
The present study is limited with regard to its size, lack of follow-up, and significant baseline differences between non-randomized groups. However, the differential isolation rates for individual PVs should not be affected directly by these limitations, with the findings of this study remaining sound.

Conclusions and clinical implications
During anatomic RMN-guided PVI, isolation of the LSPV is significantly more difficult than for the RSPV, indicating that additional focus on isolation of the LPSV is necessary if an anatomic RMN-guided only approach to PVI is taken. As anatomic RMN-guided PVI alone was only successful at achieving complete PVI less than half of the time, routine use of the CMC is necessary to achieve acceptable complete PVI rates, making anatomic only RMN PVI not advisable.

References