



Remote Magnetic versus Manual Catheter Navigation in the Ablation of Accessory Pathways in Adults

Gregory P. Siroky^{1,2,*}, Ameesh Isath^{3,4,*}, Hieu Huynh², Mena Yacoub², Asad Mohammad², Seth Keller², Ranjit Suri², Patrick Lam², Davendra Mehta²

¹St. Francis Hospital and Heart Center, Arrhythmia Center, Roslyn, NY

²Department of Cardiology, Division of Electrophysiology, Mount Sinai Morningside, Icahn School of Medicine at Mount Sinai, New York, NY

³Department of Medicine, Mount Sinai Morningside and West, Icahn School of Medicine at Mount Sinai, New York, NY

⁴Department of Cardiology, Westchester Medical Center, New York Medical College, Valhalla, NY

*Dr. Siroky and Dr. Isath contributed equally to this manuscript

Abstract

Introduction: There is a paucity of data comparing remote magnetic navigation (RMN) to manual catheter navigation (MCN) in the ablation of accessory pathways (AP) in adult patients.

Methods: A retrospective analysis of AP ablations performed in adults (>18 years old) at our institution was conducted from January 2015 to June 2020.

Results: Over the five-and-a-half-year study period, there were 114 patients with a total of 132 APs ablated. Of the 114 patients, 14 required a second ablation and 2 required a third ablation. Of the 132 AP ablations, 114 were performed using MCN and 18 were performed using RMN. The mean age among all patients was 38.1 ± 14.5 years ($p = 0.984$) with 53.8% being male ($p = 0.172$). Mean follow up was 459.9 ± 435.4 days with no statistical difference between groups. The acute success of all ablations was 84.1% (111/132) with a significant difference in favor of the RMN group (100% vs 81.6%; $p = 0.047$). Number of lesions (RMN 12, IQR 5-17 vs MCN 7.5, IQR 3-13; $p = 0.016$), ablation time (RMN 368 sec, IQR 215-572 vs MCN 259 sec, IQR 133.5-461.25; $p = 0.031$), and procedure time (RMN 230.89 \pm 79.42 vs MCN 183.26 \pm 64.88; $p = 0.006$) as well as the cost per procedure (RMN \$8,915 \pm \$2,552.11 vs MCN \$6,675.35 \pm \$1,737.31; $p = 0.001$) were all significantly higher in the RMN group compared to the MCN group. Of the redo ablations, 100% (6/6) were successful using RMN while only 83.3% (10/12) were successful using MCN.

Conclusion: Compared to manual navigation, remote magnetic navigation was more successful in first time and redo accessory pathway ablations.

Introduction

Ablation of cardiac arrhythmias requires precise manipulation and stability of the ablation catheter at the area of interest for success. A particular challenge which may arise with manually navigated/

Key Words

Accessory Pathway, Wolf-Parkinson-White Syndrome, Atrioventricular Reciprocating Tachycardia, Manual Navigation

Corresponding Author

Gregory P. Siroky,
St. Francis Hospital and Heart Center
Arrhythmia Center 100 Port Washington Boulevard Roslyn, NY 11576

manipulated catheters includes lack of stability in certain areas of the heart. In addition, complications as a result of manipulating a relatively stiff, deflectable catheter can occur which include hematoma, thrombotic events, atrioventricular block/conduction system damage, and cardiac perforation¹. The introduction of the Niobe system (Stereotaxis, Inc., St. Louis, MO), a remote magnetic navigation (RMN) system, using a soft tipped catheter ameliorated many of these potential risks and complications. It uses a motor drive advancement system (Cardiodrive) to manipulate/navigate the ablation catheter in a remotely controlled directional magnetic field. The safety and feasibility of using this system has been demonstrated very thoroughly.^{2,3,4} RMN has been shown to be safe and effective in the ablation of all cardiac

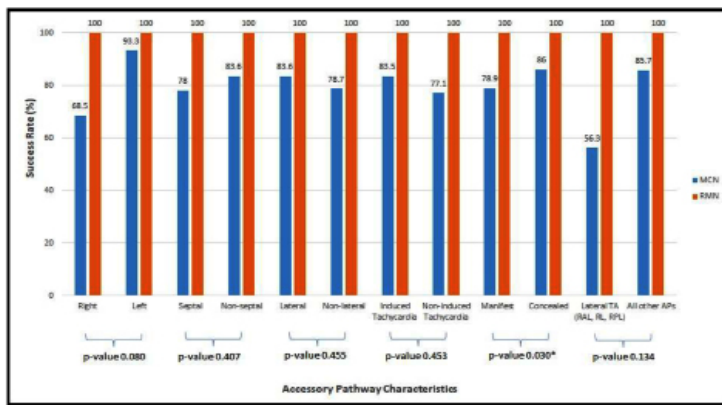


Figure 1: Success rates between remote and manual catheter navigation based on specific AP characteristics.

MCN = manual catheter navigation; RMN = remote magnetic navigation; TA = tricuspid annulus; AP = accessory pathway.

arrhythmias, including atrial fibrillation^{5,6,7}, ventricular tachycardia^{8,9}, and supraventricular tachycardias (SVT)^{1,4,7}.

Atrioventricular (AV) accessory pathways (AP) can be challenging to ablate as there tends to be less stability of the catheter tip at the level of the tricuspid and mitral valve annuli. RMN has been shown to be safe and effective in the ablation of APs in adults^{1,10,11} and children¹², but there is a paucity of data comparing the success of this modality of navigation to conventional manual catheter navigation (MCN) in adults. We therefore aim to elucidate the success of RMN compared to MCN in the ablation of APs in adults by performing a retrospective analysis of data at our institution.

2. Methods

2.1 Data Collection

A retrospective collection of data from our electronic medical records on all AP ablations was performed at our institution. Patient records were reviewed with the approval of the Institutional Review Board at Mount Sinai Morningside Hospital. Patients over the age of 18 who underwent ablation of an AP between January 2015 and June 2020 were included in the data analysis. All first time and redo ablations were included as well. Manifest APs were identified from the surface ECG and concealed APs during electrophysiology study. Demographic and procedural data including patient age, gender, co-morbidities, AP location, AP characteristics, procedure time, ablation time, fluoroscopy time, acute procedural success, acute complications, and the navigation modality was collected.

2.2 Procedure Description

Patients underwent electrophysiology study and ablation via femoral access under conscious sedation. Quadripolar catheters (Abbott, St Paul, MN) were placed in the high right atrium, His, and right ventricular apical positions. A deflectable decapolar catheter was placed in the coronary sinus (Bard Electrophysiology, Lowell, MA or Biosense Webster, Diamond Bar, CA). Ablation catheters were driven either remotely via a magnetically tipped catheter or manually. RMN was performed using the Niobe system (Stereotaxis, St. Louis, MO). This system consists of two laterally placed magnets that apply a 0.08-0.10 Tesla magnetic field across the patient and a separate drive system

which advances and retracts the catheter (Cardiodrive, Stereotaxis, St. Louis, MO). Magnetic elements in the catheter tip cause the catheter to align and be steered by the magnetic field⁴. MCN ablation was performed with conventional hand-held, deflectable, open irrigated, uni- or bidirectional, ablation catheters. Both RMN and MCN ablation were performed with the use of an electroanatomic mapping (EAM) system (CARTO 3, Biosense Webster, Diamond Bar, CA or EnSite NavX (Abbott, St. Paul, MN). The choice of navigation modality (magnetic or manual) was left to the discretion of the operator.

2.3 Ablation and Catheters

Ablation was performed at 30-40 W maximum for up to 60-120 seconds per lesion using a 3.5mm tip open-irrigated catheter (Navistar Thermocool RMT) for RMN and Smart Touch Thermocool (Biosense Webster, Diamond Bar, CA) or TactiCath (EnSite NavX, Abbott, St. Paul, MN) for MCN.

2.4 Procedural Endpoint

Procedural success was defined as the absence of antegrade and/or retrograde AP conduction on repeat electrophysiology testing after a 30-minute waiting period at the conclusion of ablation as well as freedom from repeat ablation.

2.5 Statistics

Cases were stratified by navigation type and analyzed for potential differences in total procedure time, ablation time, fluoroscopy time, and acute procedural success. Statistical analysis was performed using SPSS ver. 23 (SPSS Inc.). Continuous data is presented as mean with standard deviations or median with interquartile range. Categorical data is presented as frequency of occurrence "N" with percentage. Comparison of continuous data was performed using the unpaired two-tailed Student's t-test or the Mann-Whitney test for normally and non-normally distributed data, respectively. Chi-Square or Fisher's exact test analysis was performed to determine the relationship between categorical variables as appropriate. A 'p value' ≤ 0.05 was deemed as statistically significant.

Table 1: Patient demographic and medical characteristics.

Variable	All Patients	RMN	MCN	p-value
Age (Median, IQR)	34 (26-50)	32 (26.5-52)	36.5 (26-50.3)	0.984
Gender, Male (N, %)	71 (53.8%)	7 (38.9%)	64 (56.1%)	0.172
HTN (N, %)	32 (24.2%)	1 (5.6%)	31 (27.2%)	0.045*
HLD (N, %)	23 (17.4%)	1 (5.6%)	22 (19.3%)	0.153
CAD (N, %)	4 (3%)	0 (0%)	4 (3.5%)	0.420
EF % (Median, IQR)	60 (56-60)	57.5 (48.75-60)	60 (60-60)	0.080
Prior Arrhythmias (N, %)	17 (12.9%)	5 (27.8%)	12 (10.5%)	0.048*
Prior Ablation (N, %)	35 (26.5%)	12 (66.7%)	23 (20.2%)	0.0001*
DM (N, %)	12 (9.1%)	0 (0%)	12 (10.5%)	0.149
CKD (GFR<60) (N, %)	3 (2.3%)	0 (0%)	3 (2.6%)	0.489
COPD/Asthma (N, %)	8 (6.1%)	1 (5.6%)	7 (6.1%)	0.923

RMN = remote magnetic navigation; MCN = manual catheter navigation; HTN = hypertension; HLD = hyperlipidemia; CAD = coronary artery disease; EF = ejection fraction; DM = diabetes mellitus; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease.

Table 2: Distribution of patient symptoms.

Symptom	All Patients	RMN	MCN	p-value
Palpitations (N, %)	126 (95.5%)	17 (94.4%)	109 (95.6%)	0.825
Chest pain/discomfort (N, %)	32 (24.2%)	5 (27.8%)	27 (23.7%)	0.706
Dyspnea (N, %)	19 (14.4%)	2 (11.1%)	17 (14.9%)	0.669
Syncope (N, %)	10 (7.6%)	2 (11.1%)	8 (7.0%)	0.542
Dizziness (N, %)	30 (22.7%)	5 (27.8%)	25 (21.9%)	0.582
Other * (N, %)	6 (4.5%)	1 (5.6%)	5 (4.4%)	0.212

RMN = remote magnetic navigation; MCN = manual catheter navigation.
 * Other symptoms - nausea, vomiting, weakness, diaphoresis.

3. Results

3.1 Patients

Over the five-and-a-half-year study period, 114 patients underwent ablation of their APs with a total of 132 APs ablated (includes redo ablations). Of the 114 patients, 14 required a second ablation and 2 required a third ablation. Of the 132 AP ablations, 114 were performed using MCN and 18 were performed using RMN. The mean age among all patients was 38.1 ± 14.5 years with 53.8% male and without a significant difference between the 2 groups (p = 0.984 and 0.172, respectively) (Table 1). Mean follow up was 459.9 ± 435.4 days with no statistical difference between groups. Regarding co-morbidities (HLD, CAD, DM, COPD/asthma, CKD), there were no significant differences between the two groups except for hypertension in which the MCN was significantly higher (27.2% vs 5.6%; p = 0.045). In addition, there was no significant difference between the groups with respect to ejection fraction (p = 0.080). As a majority of the RMN group underwent redo ablations, there was a significant difference between prior arrhythmias (27.8% vs 10.52%; p = 0.048) and prior ablations (66.7% vs 20.2%; p = 0.0001) when compared to the MCN group.

3.2 Symptoms

Symptoms reported by patients included palpitations, chest pain/discomfort, dyspnea, pre-syncope/syncope, dizziness, nausea/vomiting, diaphoresis, and weakness. There was no significant difference between groups for any symptom (table 2).

3.3 Accessory Pathway Characteristics

Of the 132 APs, 67 (50.76%) were left sided and there was no significant difference between the RMN and MCN group (38.9% vs 52.63%; p = 0.278). In addition, there was no difference in manifest pre-excitation (66.7% vs 62.3%; p = 0.720). Most of the ablations were performed using the CARTO electroanatomic mapping system (97.7%)(table 3). Figure 1 displays success rates between navigation types based on certain AP characteristics. There was a trend towards higher success of ablating APs using RMN around the tricuspid annulus (100% vs 68.5%) as well as for lateral tricuspid annulus APs compared to all other APs (100% vs 56.3%). There was a statistically significant difference found in favor of RMN when comparing ablation of manifest and concealed APs (p = 0.030).

3.4 Procedural Characteristics

Accessory pathway success rates by location and navigation type are displayed in figure 2. The acute success of all ablations was 84.1% (111/132) with a significant difference in favor of the RMN group

(100% vs 81.6%; p = 0.047). The number of lesions given (RMN 12, IQR 5-17 vs MCN 7.5, IQR 3-13; p = 0.016), ablation time (RMN 368 sec, IQR 215-572 vs MCN 259 sec, IQR 133.5-461.25; p = 0.031), and procedure time RMN (230.89 ± 79.42 vs MCN 183.26 ± 64.88; p = 0.006) were all significantly higher in the RMN group compared to the MCN group. In addition, the cost per procedure (RMN \$8,915 ± \$2,552.11 vs MCN \$6,675.35 ± \$1,737.31; p = 0.001) was significantly more expensive for the RMN compared to the MCN group (table 4). Lastly, there were no complications in either group.

3.5 Redo Ablations

There was a total of 18 redo ablations. 100% (6/6) were successful using RMN while only 83.3% (10/12) were successful using MCN. In addition, the redo RMN cases were shorter in duration (195.3 min ± 61.4 min) as compared to the de novo RMN cases (248.7 min ± 83.7 min).

Discussion

This study specifically compares acute success rates of accessory pathway ablations in adults between RMN and MCN. The main finding is that the acute success rate of AP ablations in adults is higher when utilizing RMN compared to MCN, however, RMN was associated with a larger number of lesions given, higher ablation times, and higher cost.

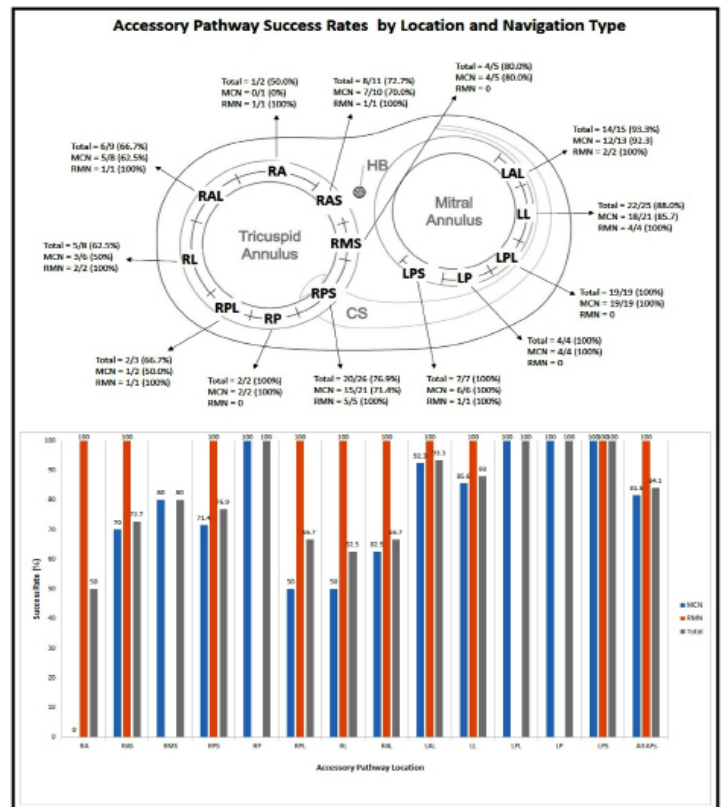


Figure 2: Accessory pathway success rates by location and navigation type.

HB = His bundle; CS = coronary sinus; RAL = right anterolateral; RA = right anterior; RAS = right anteroseptal; RMS = right mid septal; RPS = right posteroseptal; RP = right posterior; RPL = right posterolateral; RL = right lateral; LAL = left anterolateral; LL = left lateral; LPL = left posterolateral; LP = left posterior; LPS = left posteroseptal.

One of the major advantages of a magnetically driven ablation catheter system, aside from a reduction in major complications due to its flexible, nontraumatic design, is its increased stability, specifically on highly mobile and precise locations within the heart. Davis et al. suggested increased stability of RMN in comparison to MCN based on lower mean temperature, earlier time to junctional tachycardia, and less variability of temperature when ablating the slow pathway in atrioventricular reentrant tachycardia (AVNRT)¹³. Similarly, in a case report by the same authors, they demonstrated better precision and stability of RMN in ablation of a concealed parahisian AP which was previously unsuccessful using MCN¹⁴. Ernst et al. also reported their success in the mapping and ablation of two parahisian APs when utilizing RMN¹⁰.

Two prior studies have compared RMN to MCN in the ablation of SVTs, including AVNRT, atrioventricular reciprocating tachycardia (AVRT)/Wolf-Parkinson-White syndrome, and atrial tachycardia^{15, 16}. Woods et al. analyzed a total of 17 AP ablations, 5 via MCN and 12 via RMN, without a significant difference in acute success¹⁵. Similarly, Kim et al. presented results of 33 AP ablations (7 via MCN and 26 via RMN) with only a difference (non-statistically significant) in success among right free wall APs¹⁶, akin to our findings. Additionally, in a recent publication by Noten et al, they observed a higher long term success rate in the ablation of AVNRT and AVRT using RMN compared to MCN in a pediatric population¹⁷.

Right free wall/lateral APs have been shown to have the worst ablation outcomes via conventional, manual ablation due to anatomic features of the tricuspid annulus^{16, 18}. As such, the increased stability of the magnetically driven catheter on the highly mobile tricuspid and mitral annuli could be responsible for improved acute success rates with RMN, in not only right lateral APs but all APs ablation. Related to easy maneuverability RMN catheter is specifically useful when ablation is to be performed on the ventricular side of accessory pathway under the mobile tricuspid leaflets.

We attempted to elucidate any potential AP characteristics that would predict an increased rate of success based on navigation type. We demonstrated that the ablation of APs with manifest pre-excitation was statistically associated with an increased rate of success. One potential explanation is that manual manipulation of the ablation catheter increases the risk of mechanical trauma to the AP, thereby increasing the risk of failure¹⁹. Additionally, An aforementioned factor which increases the acute success rate when using RMN is location of the AP, specifically on the lateral aspect of the tricuspid annulus, as the flexibility/maneuverability of the magnetic catheter allows the operator to easily position it underneath the tricuspid valve if needed for greater stability.

Previous studies have reported a reduction in fluoroscopy times, ablation times, and lesions delivered when using RMN for ablation^{15, 20}. We showed no difference in the amount of fluoroscopy used, but a higher number of lesions delivered and increased ablation time. Increased procedure time in the RMN group compared to the MCN group is likely related to longer ablation times for prior failed procedures requiring more detailed mapping for pathway locations and often attempting to ablate the right sided pathways under the

tricuspid valve. Among the RMN group, procedure times of the de novo ablations were longer than the redo ablations, likely as a result of the more detailed electrophysiology study in the de novo cases.

Finally, using RMN for AP ablations was statistically more expensive in comparison to MCN. The added cost of the procedure comes from the drive system used to manipulate the magnetic catheter as well as the costs inherent of the stereotaxis system. There were a total of 18 repeat ablations, all of which were failed MCN ablations, and ultimately cost the hospital system more than if the initial ablation performed was successful. It can be stipulated that if RMN was the initial navigation modality utilized, then repeat ablations would not have been required given the analyzed success rate thus leading to an overall lower cost.

There are a few limitations in the current analysis. Firstly, the small number of RMN cases that were performed during the study period. Secondly, due to the retrospective design of the study, there are inherent challenges in data collection, relying solely on documentation of the performing physician(s) as well as lack of randomization in each group. Lastly, as discussed by Kim et al (12), experience discrepancies amongst fellows, supervised by attending physicians, based on navigation modalities are not accounted for affecting success rates, despite likely improvement over time with resultant higher success rates.

Conclusion

To our knowledge, this is the first relatively large study specifically comparing acute success rates between RMN and MCN in the ablation of accessory pathway in adults. We demonstrate that the acute success rate of AP ablations in adults was higher when utilizing RMN compared to MCN.

Table 3: Accessory pathway characteristics.

	All Patients	RMN	MCN	p-value
AP Sidedness- left; (N, %)	67 (50.76%)	7 (38.9%)	60 (52.63%)	0.278
Baseline Pre-excitation (manifest AP); (N, %)	83 (62.9%)	12 (66.7%)	71 (62.3%)	0.720
AP Conduction				
Antegrade (N, %)	29 (22.0%)	5 (27.8%)	24 (21.1%)	0.476
Retrograde (N, %)	46 (34.8%)	7 (38.9%)	39 (34.2%)	
Both (N, %)	56 (42.4%)	5 (27.8%)	51 (44.7%)	
EAM System				
CARTO (N, %)	129 (97.7%)	18 (100%)	111 (97.4%)	0.486
NAVX (N, %)	3 (2.3%)	0 (0.0%)	3 (2.6%)	
Inducible tachycardia				
ORT (N, %)	74 (56.1%)	8 (44.4%)	66 (57.9%)	0.213
ART (N, %)	6 (4.5%)	0 (0.0%)	6 (5.3%)	
Both (N, %)	7 (5.3%)	0 (0.0%)	7 (6.1%)	
TCL (ms); (Mean±SD)	332.47 ± 54.851	328.25 ± 54.631	332.96 ± 55.25	0.820

RMN = remote magnetic navigation; MCN = manual catheter navigation; SD = standard deviation; AP = accessory pathway; EAM = Electroanatomical mapping; ORT = orthodromic reciprocating tachycardia; ART = antidromic reciprocating tachycardia; ERP = effective refractory period; FRP = functional refractory period; TCL = tachycardia cycle length

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Table 4: Procedural characteristics.

	All Patients	RMN	MCN	p-value
Ablation energy, RF (N, %)	129 (97.7%)	18 (100%)	111(97.4%)	0.785
Number of lesions; Median (IQR)	8 (4-14)	12 (5-17)	7.5 (3-13)	0.016*
Ablation time (sec); Median (IQR)	266 (149-506)	368 (215-572)	259 (133.5-461.25)	0.031*
Fluoroscopy time (min); Median (IQR)	15.3 (10-27.15)	19.3 (9.42-42.8)	15 (10.3-25.5)	0.403
Procedure time (min) (Mean ± SD)	189.76 ± 68.69	230.89 ± 79.42	183.26 ± 64.88	0.006*
Cost (\$) (Mean ± SD)	6,968.22 ± 2,000.73	8,915 ± 2,552.11	6,675.35 ± 1,737.31	0.0001*
Redo Ablations Performed#	18/132 (13.6%)	6/18 (33.3%)	12/18 (66.7%)	0.75
Time to Redo ablation (days)	224.5 ± 312.9	0	224.5 ± 312.9	-
Lost to follow up\$	53/132 (40.2%)	10/53 (18.9%)	43/53 (81.1%)	0.120
Follow-up after initial/last ablation (days)*	459.9 ± 435.4 (10 - 1876)	372.0 ± 398.9 (10 - 1015)	472.0 ± 442.5 (22 - 1876)	0.714
Acute Success of Redo Ablations	16/18 (88.9%)	6/6 (100%)	10/12 (83.3%)	0.289
Complications	0 (0)	0 (0)	0 (0)	1.00
Acute success (N, %)	111/132 (84.1%)	18/18 (100%)	93/114 (81.6%)	0.047*

RMN = remote magnetic navigation; MCN = manual catheter navigation; IQR = interquartile range; SD = standard deviation; RF = radiofrequency.

Redo ablations performed via the specific navigation type.

\$ Number of patients lost to follow up after initial or redo ablation (only seen the day after ablation).

*Follow up = ≥ 7 days. Does not include patients lost to follow up and first and/or second ablation of patients who underwent redo ablations. Number in parentheses represents the range.

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