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Comparison of Magnetic Navigation System and Conventional Method in Catheter Ablation of Atrial Fibrillation: Is Magnetic Navigation System Is More Effective and Safer Than Conventional Method?

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ABSTRACT

Background and Objectives: Although there have been so many reports of catheter ablation of atrial fibrillation (AF) with magnetic navigation system (MNS), it is not necessarily obvious that MNS is more effective than conventional ablation. We performed AF ablation with MNS and compared the clinical outcomes and radiofrequency ablation parameters with those of conventional ablation. **Subjects and Methods:** One hundred eleven consecutive patients (conventional group, n=70 vs. MNS group, n=41) undergoing catheter ablation of AF were enrolled. We compared and analyzed the procedural parameters, namely fluoroscopic time, procedural time, acute procedural success and 3 months success rate of both groups. **Results:** The MNS group was associated with slightly larger left atrial size (43.7±6.3 mm vs. 41.2±6.3 mm, p=0.04), significantly longer total procedure time (352±50 minutes vs. 283±75 minutes, p<0.0001), and shorter total fluoroscopic time (99±28 minutes vs. 238±45 minutes, p<0.0001) than the conventional group. The MNS and conventional group did not differ with respect to acute procedural success, AF recurrence, atrial flutter/atrial tachycardia recurrence, or total arrhythmia recurrence. While no complications were observed in the MNS group, eight cases of significant pericardial effusion occurred in the conventional group. **Conclusion:** The MNS system seems to be effective and safe in the catheter ablation of AF, particularly in the population of patients with persistent AF and slightly dilated left atria. **(Korean Circ J 2011;41:248-252)**

KEY WORD: Atrial fibrillation.

Introduction

Remote catheter manipulation is a major technological advancement for ablation procedure. Since its first published report in humans in 2002,[1] its efficacy in the treatment of various arrhythmias has been demonstrated.[2-4] It may also reduce radiation exposure and physical stress to the operator and could thus theoretically enhance the safety and efficacy of the procedure due to the unrestricted and more precise catheter movement.[6]

Although previous studies have shown remote magnetic navigation to be feasible for atrial fibrillation (AF), the benefits of this navigation modality relative to conventional manual technique remain unclear.[5]

The aim of this study is to compare overall fluoroscopy time and procedural duration of the magnetic navigation system (MNS) with conventional ablation and to report our initial short term clinical outcomes of magnetic ablation in AF.

Subjects and Methods

Patient population

One hundred eleven consecutive patients (mean age: 56±11 years, M : F=84 : 27) undergoing AF ablation were enrolled

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in this study. All patients were drug refractory symptomatic AF patients. Patients with contraindications for the use of MNS were excluded.

Electrophysiological study

After informed consent was obtained, the patients were studied in the fasting state and all antiarrhythmic drugs were ceased at least five half-lives prior to procedure. Continuous sedation and analgesia was achieved by intravenous bolus administration of midazolam (2.5-5 mg) and administration of fentanyl (30-50 mg). One multipolar (5 Fr) and two decapolar (6 Fr) catheters were introduced via the right internal jugular vein and the left femoral vein, respectively. The catheters were positioned in the right atrium, coronary sinus, his bundle and right ventricle for the diagnostic electrophysiologic study. Double trans-septal puncture was performed using the Brokenbrough needle and two sheaths (SL1, Saint-Jude Medical, Minnetonka, MN, USA and Multipurpose, Biosense Webster, Diamond Bar, CA, USA) were used for left atrium access. A circular Lasso catheter (30 mm to 45 mm or variable sized, Biosense Webster, Diamond Bar, CA, USA) was positioned at each pulmonary antrum and used to assess electrical conductivity. To reduce radiation exposure, we set fluoroscopy at 6 nGy/p with a pulse rate of 10/sec.

Magnetic navigation system

The MNS (Niobe, Stereotaxis, St-Louis, MO, USA) consists of two permanent magnets, each weighing 1.8 tons, positioned at either side of the fluoroscopy table (Axiom Artis, Simens, Germany) to create a magnetic field vector (0.1 T) approximately 15 cm inside the chest of the patient, that can be manipulated remotely.

The soft magnetic catheters are equipped with three magnets near its distal tips which align to the orientation of the magnetic field. All magnetic field vectors can be stored and reapplied in order to facilitate accurate navigation. A computer-controlled catheter advancement system is used to allow remote advancement and retraction of the catheter. The Navigant II workstation, when used in conjunction with the Cardiodrive unit, allows the operator to control the catheter's position with 1 mm step and at 1° angle precision.

The MNS was used with the CARTO mapping system to produce 3-D anatomical maps which were then integrated with 3D CT images using CARTO-Merge. The system is controlled remotely by mouse and joystick from a radiation-shielded control room.

Catheter ablation

Left atrial access was achieved by the trans-septal approach. The irrigated magnetic mapping and ablation catheter (3.5 mm Navistar thermocool RMT, Biosense-webster, Diamond Bar, CA, USA) was introduced manually into the left atrium, and radiofrequency catheter ablation was performed in a temperature controlled mode (maximum temperature 39°C, maximum duration 120 seconds, maximum 40 W).

Conventional ablation was accomplished by standard technique using 4 mm ablation and mapping catheter (3.5 mm Navistar thermocool, Biosense-webster, Diamond Bar, CA, USA) in a temperature controlled mode (maximum temperature 39°C, maximum duration 120 seconds, maximum 35 W).

For paroxysmal AF interventions, electrical isolation was achieved by antral ablation with carina, roof and posterior lines. Posterior line was defined as linear line connecting posterior lower portion of both antral lines. For persistent AF interventions, the operator produced an anterior ablation line which connected roof line and anterior mitral annulus through the medial side of the left atrial appendage. Electrical block was confirmed by measuring electrical potentials at the left atrial appendage, using the Lasso catheter.

We defined complete antral isolation as a lack of PV potential recorded by a small Lasso placed in the ipsilateral upper and lower PVs, after same side antral ablation. Acute success was defined as non-inducibility of AF, atrial flutter, or tachycardia during rapid atrial pacing between 250 ms and 200 ms, with less than 5 μgm/min of isoproterenol. Total procedure time is defined from arrival of patient to electrophysiology room to sheath out time. Total arrhythmia recurrence is defined as the sum of AF and atrial flutter/atrial tachycardia recurrence.

Immediately following ablation, the operator checked, with echocardiography, for evidence of pericardial effusion. Significant pericardial effusion was defined as more than 5 mm of newly developed effusion with a 6-10 mmHg drop in systolic blood pressure.

Follow up of patients

During the three months following the initial ablation procedure, all patients underwent monthly follow-up with EKG and ambulatory electrocardiogram monitoring as needed. All patients were instructed to report symptomatic palpitations during this period. Mid-term success was defined as a lack of electrocardiographically evident atrial tachycardia or AF.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) for Windows, version 15.0 (Chicago, IL, USA) was used for all analysis. Continuous variables are presented as mean values±standard deviation and were compared using unpaired Student's t-tests. A p of less than 0.05 was considered statistically significant.

Results

A total of 111 patients were included in the study. Patient demographics, procedural characteristics and clinical outcomes are presented in Table 1.

These groups did not differ significantly with respect to age, sex, body mass index (BMI), or underlying disease (including hypertension, diabetes, and coronary artery disease) (Table 1). Left atrial diameter was observed to be mildly enlarged and ejection fraction (EF) was normal.

Total procedure time was significantly longer (352±50 minutes vs. 283±75 minutes, p<0.0001) and total fluoroscopy time was significantly shorter (99±28 minutes vs. 238±45 minutes, p<0.0001) in the MNS group compared to the conventional group. Although not statistically significant, acute procedural success rate was lower in the MNS group than in the manual group (85% vs. 90%, p=0.08).

In the conventional group, eight cases of cardiac tamponade occurred, five of which required pericardiocentesis. One patient in the conventional group suffered a transient ischemic attack (TIA). No cardiac tamponade, stroke, or TIA occurred in the MNS group (Table 2).

The two groups did not differ in terms of AF, atrial flutter/atrial tachycardia, or total arrhythmia recurrence rates at 3 month follow-up (Table 2).

This total population was divided into paroxysmal (n=67) and persistent (n=44) AF subgroups.

Table 1. Baseline patient characteristics

	Conventional (n=70)	MNS (n=41)	p
Age (years)	55±11	57±11	0.55
Male, n (%)	54 (77)	31 (75)	0.97
BMI (kg/cm²)	25.0±3.7	25.0±5.5	0.49
LAD (mm)	41.2±6.3	43.7±6.3	0.04
EF (%)	60.3±6.6	59.9±6.6	0.99
HTN (%)	30 (42)	15 (36)	0.78
DM (%)	9 (13)	6 (14)	0.70
CAD (%)	7 (10)	4 (9)	0.99

MNS: magnetic navigation system, BMI: body mass index, LAD: left atrial diameter, HTN: hypertension, CAD: coronary artery disease

Table 2. Procedure parameters and acute/midterm procedural success

	Conventional (n=70)	MNS (n=41)	p
Total procedure time (minute)	283±75	352±50	<0.0001
Total fluoroscopic time (minute)	238±45	99±28	<0.0001
Acute procedural success, n (%)	63 (90)	34 (85)	0.28
Significant PE, n (%)	8 (11)	0 (0)	NA
Stroke/TIA, n (%)	1 (1)	0 (0)	NA
Total arrhythmia recurrence, n (%)	12 (17)	7 (17)	0.99
AF recurrence, n (%)	5 (7)	4 (10)	0.79
AFL/AT recurrence, n (%)	7 (10)	3 (7)	0.64

MNS: magnetic navigation system, PE: pericardial effusion, AF: atrial fibrillation, AFL: atrial flutter, AT: atrial tachycardia, NA: not applicable

Paroxysmal atrial fibrillation

A total of 67 patients with paroxysmal AF underwent catheter ablation with conventional (n=43) and MNS (n=24) navigation. These groups did not differ significantly with respect to age, sex, BMI, or underlying disease (including hypertension, diabetes, and coronary artery disease) (Table 3). Left atrial diameter was not statistically different and EF was normal.

Total procedure time was significantly longer (321±52 minutes vs. 273±74 minutes, p=0.03) and total fluoroscopy time was significantly shorter (105±28 minutes vs. 234±53 minutes, p<0.0001) in the MNS group compared to the conventional group. Although not statistically significant, acute procedural success rate was lower in the MNS group than in the manual group (79% vs. 90%, p=0.19).

In the conventional group, five cases of significant pericardial effusion occurred, three of which required pericardiocentesis. One patient in the conventional group suffered a TIA. No cardiac tamponade, stroke, or TIA occurred in the MNS group (Table 4). The two groups did not differ in terms of AF,

Table 3. Baseline patient characteristics in paroxysmal atrial fibrillation

	Conventional (n=43)	MNS (n=24)	p
Age (years)	54±12	56±12	0.52
Male, n (%)	32 (74)	19 (79)	0.67
BMI (kg/cm²)	25.0±2.3	26.0±4.4	0.49
LAD (mm)	40.2±6.2	41.4±6.9	0.59
EF (%)	61.0±5.5	61.3±4.9	0.99
HTN (%)	13 (30)	10 (41)	0.35
DM (%)	7 (16)	3 (12)	0.68
CAD (%)	6 (13)	2 (8)	0.50

MNS: magnetic navigation system, BMI: body mass index, LAD: left atrial diameter, HTN: hypertension, CAD: coronary artery disease

Table 4. Procedure parameters and acute/midterm procedural success in paroxysmal atrial fibrillation

	Conventional (n=43)	MNS (n=24)	p
Total procedure time (minute)	273±74	321±52	0.03
Total fluoroscopic time (minute)	234±53	105±28	<0.0001
Acute procedural success, n (%)	39 (90)	19 (79)	0.19
Significant PE, n (%)	5 (12)	0 (0)	NA
Stroke/TIA, n (%)	1 (1)	0 (0)	NA
Total arrhythmia recurrence rate, n (%)	5 (11)	3 (13)	0.93
AF recurrence, n (%)	2 (4)	1 (4)	0.94
AFL/AT recurrence, n (%)	3 (6)	2 (8)	0.84

MNS: magnetic navigation system, PE: pericardial effusion, AF: atrial fibrillation, AFL: atrial flutter, AT: atrial tachycardia, NA: not applicable

Table 5. Baseline patient characteristics in persistent atrial fibrillation

	Conventional (n=27)	MNS (n=17)	p
Age (years)	58±11	59±6	0.60
Male, n (%)	22 (81)	12 (70)	0.46
BMI (kg/cm^2)	26.0±2.4	26.0±2.1	0.93
LAD (mm)	43.2±6.1	46.5±4.3	0.07
EF (%)	58.4±8.0	56.8±8.2	0.59
HTN (%)	17 (62)	5 (30)	0.07
DM (%)	2 (7)	3 (18)	0.28
CAD (%)	1 (3)	2 (12)	0.11

MNS: magnetic navigation system, BMI: body mass index, LAD: left atrial diameter, HTN: hypertension, CAD: coronary artery disease

Table 6. Procedure parameters and acute/midterm procedural success in persistent atrial fibrillation

	Conventional (n=27)	MNS (n=17)	p
Total procedure time (minute)	294±77	358±54	0.01
Total fluoroscopic time (minute)	234±75	98±46	<0.0001
Acute procedural success, n (%)	24 (88)	15 (88)	0.92
Significant PE, n (%)	3 (11)	0 (0)	NA
Stroke/TIA, n (%)	0 (0)	0 (0)	NA
Total arrhythmia recurrence rate, n (%)	7 (26)	4 (24)	0.82
AF recurrence, n (%)	3 (11)	3 (18)	0.59
AFL/AT recurrence, n (%)	4 (15)	1 (5)	0.36

MNS: magnetic navigation system, PE: pericardial effusion, AF: atrial fibrillation, AFL: atrial flutter, AT: atrial tachycardia, NA: not applicable

atrial flutter/atrial tachycardia, or total arrhythmia recurrence rates at 3 month follow-up (Table 4).

Persistent atrial fibrillation

A total of 44 patients with persistent AF underwent catheter ablation with either conventional (n=27) or magnetic (n=17) navigation. These groups did not differ significantly with respect to age, sex, BMI, or underlying disease (including hypertension, diabetes, and coronary artery disease) (Table 5). Left atrial diameter was observed to be mildly enlarged and EF was normal.

Total procedure time was significantly longer (358±54 minutes vs. 294±77 minutes, p=0.01) and total fluoroscopy time was significantly shorter (98±46 minutes vs. 234±75 minutes, p<0.0001) in the MNS group compared to the conventional group. The MNS group did not differ significantly from the conventional group with respect acute success rate (88% vs. 88%, p=0.92).

In the conventional group, four cases of significant pericardial effusion occurred, two of which required pericardiocentesis. No cardiac tamponade, stroke, or TIA occurred in the MNS group (Table 2). The two groups did not differ in terms of AF, atrial flutter/atrial tachycardia, or total arrhythmia recurrence rates at the 3 month follow-up (Table 6).

Discussion

Our initial experience with the MNS demonstrates that the system is effective for ablation of both paroxysmal and persistent AF, with outcomes comparable to what is observed with manual technique. The results support the safety of the MNS, which was not found to be associated with any complications or incidents of significant pericardial effusion.

Acute procedural success rates were similar in both groups and were consistent with previously published data. AF ablation is a complex and operator dependent procedure. Although Papone et al. reported that MNS-guided AF ablation was simple and did not require a long learning curve. We found that MNS procedures were significantly longer for patients with both paroxysmal and persistent AF.[6] Our results, however, support the observation of Di Biase et al.[7] in that fluoroscopy times are reduced with use of MNS. Frequent dislodgment of the Lasso catheter may account for our longer fluoroscopy times.

Di Biase et al.[7] reported low rates of acute success for MNS-guided AF ablation and attribute these results to the unavailability of irrigated tip catheters. As expected, the present study demonstrates a remarkable improvement in procedural success compared to previously reported data as a result of the incorporation of irrigated tip magnetic catheters following their commercial release. Despite the stability of magnetic catheters, an energy delivery of 40 watts was usually necessary to overcome the system's soft contact force.

The MNS provides precise and stable catheter positioning which gives it the potential to improve the efficacy of ablation procedures. We found, however, that catheter navigation in the small atrium was more difficult than in the large atrium due to limitations of the fixed curvature of the catheter's distal tip. Our study has shown that MNS is more effective at achieving acute procedural success in persistent AF. Based on this observation, we speculate that the large atrium is more suitable for catheter navigation with the MNS. In a deviation from manual technique, during magnetic procedure the sheath was usually positioned in the lower inferior vena cava following a more anterior septal puncture. This facilitated access to the anterior aspect of the right-sided pulmonary vein.

Additionally, we took advantage of the magnetic vector-storing capabilities of the MNS to reapply previously used vectors. This allowed us to more easily obtain points in the electro-anatomic mapping portion of the procedure and to decrease ablation time.

Consistent with previous reports, no acute complications occurred in the MNS group. Our significant pericardial effusion rate was high in the conventional group compared to previously reported data but the MNS was able to significantly reduce this rate.[8] Inadvertent pericardial access during trans-septal puncture by an inexperienced trainee and cardiac damage during ablation procedure with a stiff conventional catheter may explain our results. No evidence of char formation or embolic complication was observed with the irrigated tip catheters.

The main limitation of this study is its nonrandomized design. Nevertheless, our data is representative of the daily practice of an operator experienced in manual technique. Furthermore, we acknowledge that our results represent the initial experience of the operator and, consequently, all data should be cautiously interpreted as they may incorporate initial learning curve biases associated with the adoption of magnetic navigation technology.

Conclusions

The MNS seems to be effective for catheter ablation of AF. The system's benefits are particularly evident in the treatment of patients with persistent AF and a slightly dilated left atrium. Although several complications were encountered in the manual group, none were evident in MNS procedures.

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