Comparison of Magnetic Navigation System and Conventional Method in Catheter Ablation of Atrial Fibrillation: Is Magnetic Navigation System 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.5

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.6

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
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 electrophysiological study. Double trans-septal puncture was performed using the Brockenbrough 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 mGy/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, Siemens, 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 Navigator II workstation, when used in conjunction with the Cardiowire 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 de-
mographics, 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.

### 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, atrial flutter, or atrial tachycardia.

| 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

| 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
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. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. Our significant pericardial effusion occurred in the MNS group. 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fusion rate was high in the conventional group compared to previously reported data but the MNS was able to significantly reduce this rate. 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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