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Original Article

Remote magnetic catheter navigation versus conventional ablation in atrial fibrillation ablation: Fluoroscopy reduction

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Background: Percutaneous transcatheter radiofrequency ablation of atrial fibrillation with remote controlled magnetic navigation (RMN) has been shown to reduce radiation exposure to patients and physicians compared with conventional manual (MAN) ablation techniques.
Methods: Catheter ablation for atrial fibrillation was performed utilizing RMN in 214 consecutive patients and MAN ablation techniques in 229 patients. We compared the fluoroscopy and procedural times between RMN and MAN catheter ablation of atrial fibrillation. Secondary objectives included comparing acute procedural success and short-term complication rates between both ablation strategies.
Results: Fluoroscopy time was significantly shorter in the RMN group than the MAN group (53.5 $\pm$ 30.1 vs 68.1 $\pm$ 27.6 min, respectively; $p < 0.01$); however, the total procedural time was longer in the RMN group (280.2 $\pm$ 74.4 min vs 213.1 $\pm$ 64.75, respectively; $p > 0.001$). Further subgroup analysis of the most recent 50 ablations each from the RMN and MAN groups, to attenuate the RMN learning curve effect, showed an even greater difference in fluoroscopy time (RMN vs MAN: 53.5 $\pm$ 30.1 vs 68.1 $\pm$ 27.6 min), though a consistently longer procedure time with RMN (249.5 $\pm$ 65.5 vs 186.3 $\pm$ 65.6 min, respectively). The acute procedural success rate was comparable between the groups (98.6% vs 95.6%, respectively; $p = 0.07$). The rates of acute complications were similar in both groups (2.3% vs 4.8%, respectively; $p = 0.16$).
Conclusions: In radiofrequency ablation of atrial fibrillation, RMN appears to significantly reduce fluoroscopy time compared with conventional MAN ablation, though at a cost of increased total procedural time, with comparable acute success rates and safety profile. A reduction in procedure and fluoroscopy times is possible with gaining experience.

1. Introduction

Percutaneous transcatheter radiofrequency ablation has shown superiority in rhythm control compared with antiarrhythmic drugs and has become an established standard of care for the invasive management of drug refractory atrial fibrillation [1–6]. The complexity of the procedure invariably results in long procedural time and significant fluoroscopic use [7]. Remote controlled magnetic navigation (RMN) theoretically lowers the risk of cardiac perforation compared with conventional catheters, thus, allowing reduction of fluoroscopy time during catheter maneuvering [8–14].

The primary objective of this study was to compare fluoroscopy and total procedural times between RMN and conventional manual (MAN) ablation of atrial fibrillation. Secondary objectives were to compare the efficacy and safety of both ablation techniques.

2. Material and methods

In total, 443 consecutive patients undergoing pulmonary vein isolation between 2009 and 2014 were reviewed in a retrospective case control analysis. The patients were divided into 2 groups: an RMN group and a MAN group. We compared their procedural times, fluoroscopy times, baseline characteristics, and acute success and short-term complication rates.

2.1. Ablation technique

After pre-procedural transesophageal echocardiograms to exclude left atrial clot, vascular access was obtained via the femoral veins, and multipolar catheters were placed in the coronary sinus and

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selectively in the right ventricle. Transseptal punctures were performed fluoroscopically and depending on the physician's preference, with intracardiac ultrasound guidance. SL0 or SL1 sheaths (St. Jude Medical Inc., St. Paul, MN, USA) were advanced into the left atrium. Heparin was administered upon left atrial access and an activated clotting time of 250–400 s was the target for anticoagulation throughout the procedure.

2.2. Remote magnetic navigation ablation

A 3.5-mm irrigated magnetic mapping and ablation catheter (Navistar RMT Thermocool, Biosense-Webster Inc., Diamond Bar, CA, USA) and multipolar deflectable catheter (Lasso, Biosense-Webster Inc.) were advanced through the sheaths. Advancement and retraction of the Navistar RMT ablation catheter were achieved utilizing a motorized catheter drive system (Cardiodrive, Stereotaxis Inc., St. Louis, MO, USA), and vector alignment was achieved through a magnetic remote navigation system (Niobe II Stereotaxis magnetic navigation system, Stereotaxis Inc.). Electroanatomic mapping was done utilizing the CARTO3 3-dimensional (3D) non-fluoroscopic navigation system (CARTO3, Biosense Webster Inc.).

Ablation was performed remotely with a workstation (Navigant II workstation, Stereotaxis Inc.) allowing precise control of the catheter movements (1-mm steps and 1-degree precision). The ablation catheter tip temperature and ablation power was limited to 40 °C and 40 W, respectively.

2.3. Conventional ablation

For the MAN group, ablation was done by standard technique utilizing open irrigated ablation and mapping catheters (3.5 mm Navistar thermocool, Biosense-Webster Inc./Flexibility, St. Jude Medical Inc./Tacticath, St. Jude Medical Inc.) and multipolar deflectable catheters (Lasso, Biosense-Webster Inc. or Inquiry Optima Plus, St. Jude Medical Inc.). The two 3D electroanatomic mapping system used were the Carto3 (Biosense-Webster Inc.) as described above or the Ensite NavX system (St. Jude Medical Inc.). Briefly, the Ensite NavX system uses impedance measurements between individual catheter electrodes and external patches placed on the chest to project a 3D image of the catheters. Temperature control settings were similar to the remote magnetic navigation group.

2.4. Ablation end points

All patients underwent pulmonary vein antral ablation. Further ablations were carried out on the superior vena cava, cavotricuspid isthmus, complex fractionated atrial electrograms, and other sites as deemed necessary by the attending proceduralist. The end point and acute procedural success of ablations was defined as electrical isolation of all pulmonary veins with sinus rhythm at the end of the procedure.

Table 1
Baseline characteristics of the RMN and MAN groups.

	Whole cohort ($n=443$)	RMN ($n=214$)	MAN (n=229)	p Value
Age (years)	54.2 ± 10.1	54.9 ± 10.4	54.0 ± 9.3	0.39
Male sex	298 (75.8)	150 (74.6)	148 (77.1)	0.63
CHA_2DS_2Vasc	1.18 ± 1.13	1.18 ± 1.16	1.18 ± 1.11	0.99
Initial ablation	364 (82.2)	177 (82.7)	187 (81.7)	0.51
Repeat ablation	79 (17.8)	42 (18.3)	37 (17.3)	
Paroxysmal AF	315 (71.1)	161 (75.2)	154 (67.2)	0.06
Persistent AF	128 (28.9)	53 (24.8)	75 (32.8)	
Atrial flutter ablation	189 (42.7)	108 (50.5)	81 (35.4)	0.04

Data are presented as mean ± SD or n (%).
Abbreviations: AF, atrial fibrillation; MAN, manual; RMN, remote controlled magnetic navigation.

Table 2
Comparison of fluoroscopy and procedural times between the RMN and MAN groups excluding abandoned procedures and acute success and complication rates of the RMN and MAN groups among the whole cohort.

	RMN ($n=213$)	MAN ($n=228$)	p Value
Fluoroscopy time (min)	53.5 ± 30.1	68.1 ± 27.6	< 0.01
Procedure time (min)	276.9 ± 75.0	208.3 ± 61.6	< 0.01
	RMN ($n=214$)	MAN ($n=229$)	
Acute success	211 (98.6)	219 (95.6)	0.065
Acute complications	5 (2.3)	11 (4.8)	0.16
Catheter-related complications	1 (0.5)	2 (0.9)	0.60

Data are presented as mean ± SD or n (%).
Abbreviations: MAN, manual; RMN, remote controlled magnetic navigation.

Table 3
Comparison in primary, secondary end points, and baseline characteristics of the 50 most recent ablations performed in each group.

	RMN ($n=50$)	MAN ($n=50$)	p Value
Age (years)	55.5 ± 9.0	56.0 ± 8.4	0.92
CHA_2DS_2Vasc score	1.24 ± 1.29	1.14 ± 1.03	0.50
Initial ablation	43 (86.0)	38 (76.0)	0.20
Repeat ablation	7 (14.0)	12 (24.0)	
Paroxysmal AF	36 (72.0)	38 (76.0)	0.65
Persistent AF	14 (28.0)	12 (24.05)	
Atrial flutter ablation	21 (42.0)	33 (66.0)	0.03
Acute success	50 (100)	48 (96.0)	0.15
Acute complications	1 (2)	1 (2)	1.00
Fluoroscopy time (min)	35.4 ± 13.9	61.2 ± 32.6	< 0.01
Procedure time (min)	249.5 ± 65.5	186.3 ± 65.6	< 0.01

Data are presented as mean ± SD or n (%).
Abbreviations: AF, atrial fibrillation; MAN, manual; RMN, remote controlled magnetic navigation.

2.5. Statistical analysis

Categorical variables are expressed as percentages and continuous variables described as mean ± standard deviation (SD). Characteristics between the two cohorts (RMN and MAN groups) were compared using Pearson χ^2 test or Fisher's exact test for categorical variables, and continuous variables were compared using the student's t-test. All statistical tests were performed with SPSS software version 17.0 (SPSS Institute Inc., Chicago, IL, USA).

3. Results

A total of 443 patients were included in our study. The RMN group and MAN group included 214 (48.3%) and 229 (51.7%) patients, respectively.

Baseline demographic and clinical characteristics are shown in Table 1. There were no significant differences in age and sex between the two groups. Both groups had a comparable proportion of initial procedures (RMN vs MAN: 82.7% vs 81.7%) and repeat procedures (17.3% vs 18.3%, respectively). The composition of paroxysmal and persistent atrial fibrillation in both groups was also similar (RMN: Paroxysmal 75.2%, Persistent 24.8% vs MAN: Paroxysmal 67.2%, Persistent 32.8%). There was a significantly greater proportion of atrial flutter ablations in the RMN group than the MAN group (50.5% vs 35.4%, respectively; $p=0.001$).

The mean procedural and fluoroscopy times are shown in Table 2. These results excluded 2 patients (1 from each group) whose procedures were abandoned midway through, which would have resulted in shorter fluoroscopy and procedural times. Our results showed significantly lower fluoroscopy times in the RMN group than the MAN group (53.5 ± 30.1 vs 68.1 ± 27.6 min; $p < 0.001$). This was despite the higher proportion of atrial flutter ablations in the RMN cohort. Total procedure times were longer in the RMN cohort (276.9 ± 75.0 vs 208.3 ± 61.6 min, $p < 0.001$).

However, as the above results included patients who underwent RMN ablation during its introduction to our center when physicians were still in the process of familiarization, we proceeded to compare fluoroscopy and procedural times in the most recent 50 patients undergoing ablation in each cohort. This was to eliminate the learning curve effect where physicians had yet been able to garner full radiation reduction benefits during their initial experience with RMN. This yielded an even greater magnitude of fluoroscopy time reduction in the RMN group vs MAN group (35.4 ± 13.9 vs 61.2 ± 32.6 min, respectively; $p < 0.001$).

A summary of the ablation outcomes among the two cohorts is shown in Table 2. Both acute procedural success rates (RMN vs MAN: 98.6% vs 95.6%, respectively; $p=0.065$) and complication rates (2.3% vs 4.8%, respectively; $p=0.16$) were comparable (Table 3).

Of note, both groups had one patient each where the development of pericardial effusions necessitated mid-procedural abandonment, for which they were also considered failed procedures. Among patients in the MAN group, 2 patients (0.87%) developed significant pericardial effusions during ablation and required emergency pericardiocentesis. The third patient who had tamponade suffered right atrial perforation during a difficult trans-septal puncture and was not catheter related. Two patients (0.8%) in the MAN group suffered significant hematomas prolonging inpatient stay because of difficult groin access, 1 patient (0.4%) had an intra-procedural air embolism, and another patient (0.4%) had a deep vein thrombosis post procedure. The other documented complications included post procedure stroke, access site bleeding with partial thrombosis, and a pulmonary venous infarction from an occluded lingular branch of the pulmonary vein in a patient that presented with hemoptysis.

The complications among patients in the RMN group included 1 patient (0.47%) who developed pericardial tamponade whilst attempting trans-septal access and whose procedure was abandoned. The remaining 4 patients consisted of 1 patient (0.47%) with ablation-related pericardial effusion that did not require drainage, 1 patient (0.47%) with a branch retinal vein occlusion, 1 patient (0.47%) with an infected groin hematoma, and another (0.47%) with a groin pseudoaneurysm.

4. Discussion

Our results show that the RMN system helps reduce the fluoroscopy time in comparison with MAN techniques for atrial fibrillation ablation. Comparable acute success and complication rates were seen with RMN and MAN ablation.

4.1. Advantages of remote magnetic navigation

Fluoroscopy times were significantly lower in the RMN group of the present study, consistent with current literature [13,15–19]. This reduction in fluoroscopy time may be attributed to the lower risk of intracardiac trauma because of the atraumatic flexible tip of the magnetic catheter in comparison with the stiff conventional ablation catheter. Decreased reliance on fluoroscopy for intracardiac navigation limits radiation exposure. This may be the solution to perforation concerns which make near zero-fluoroscopy hard to achieve. Admittedly, the use of fluoroscopy can vary greatly between physicians, with factors such as ablation technique and use of adjunct imaging modalities such as intracardiac ultrasound. Our results still mirror the current literature which shows a consistent lower need for fluoroscopy with RMN.

Besides radiation burns having been reported to occur from atrial fibrillation ablation, there is also increased risk of fatal malignancy related to radiation exposure which has been estimated at 0.15% to 0.21% in patients undergoing atrial fibrillation ablation [20–24]. Furthermore, it is not uncommon for patients to require repeat procedures which further compound such radiation risks. Owing to the combination of dose-dependent and non-dose dependent effects, the As Low As Reasonably Achievable principle was proposed by the United States National Council on Radiation Protection and Measurements as there is no known baseline threshold of radiation exposure that can be deemed entirely safe [25]. The lower mean fluoroscopy time in the RMN group supports the radiation safety benefit of RMN to patients. Looking at the initial whole RMN cohort, fluoroscopy times were considerably high overall and did not differ greatly from that of the MAN group. These data, however, included patients undergoing atrial fibrillation ablation with RMN when it was first introduced and when physicians were still in the familiarization phase. Studies have documented longer fluoroscopy times while overcoming the initial learning curve of RMN atrial fibrillation ablation [23]. The RMN fluoroscopy time in our cohort decreased as more procedures were performed. The mean fluoroscopy time of the overall RMN cohort was 53.5 ± 30.1 min compared with 35.4 ± 13.9 min in the last 50 RMN ablations performed. A similar trend was seen in total procedural time which was 276.9 ± 75.0 min for the whole cohort compared with 249.5 ± 65.5 min for the corresponding subset cohort. These findings indicated the presence of a learning curve [26–28]. The lower mean fluoroscopy time demonstrated in our subanalysis of the most recent ablations from each cohort then showed an even greater difference between the RMN group (35.4 ± 13.9 min) and the MAN group (61.2 ± 32.6 min). This may be a better reflection of the fluoroscopic reduction potential of RMN. Although fluoroscopy time as well as other factors such as equipment settings, the use of collimation, filters, and patient factors have been shown to not accurately predict the radiation dose, fluoroscopy time still remains a major component contributing to the total radiation dose. We note that the fluoroscopic times documented in our study may not have been as low in the RMN and MAN groups compared with those in more recent studies. This could be attributed to individual differences in ablation technique for atrial fibrillation, us not practicing zero fluoroscopy techniques during this study period, and the use fluoroscopy during trans-septal access with some physicians not utilizing intracardiac echocardiogram to aid transseptal access. Other contributory factors were the teaching nature of our hospital with the participation fellows in the procedure, and that most of the manual ablations were performed without contact force catheters which would have accorded a measure of force at the catheter tip to reduce perforation risk and thus less reliance on visualization of catheter buckling/movement patters. Ideally we might have measured fluoroscopy time during the actual ablation process itself to exclude fluoroscopy time for catheter placement and trans-septal access but this was not recorded. Despite this, these results still collectively indicate the potential for fluoroscopic reduction with RMN.

The benefits of RMN extend to physicians and laboratory staff to an even greater degree. Electrophysiologists constitute a large proportion of medical staff categorized as receiving the highest annual radiation exposure, with the median lifetime professional exposure at 54 mSV. This translates to an estimated lifetime attributable malignancy risk of 1 in 200 [29]. The ability to perform ablations away from the radiation source with RMN significantly attenuates radiation exposure and is one of the great strengths of the RMN system. Beyond radiation risks alone, the use of radiation protection gear can be associated with orthopedic complications of chronic back and hip problems among interventional cardiologists and other medical staff [30,31]. RMN ablation, which does not require constant use of heavy radiation protection gear, may aid in reducing this and operator fatigue [16].

4.2. Acute procedural success rates and safety

The results of our analysis revealed a comparable success rate in patients undergoing RMN assisted ablation and MAN catheter ablation. This is consistent with current published literature [16,19,26,27,32]. The flexible catheter used for remote magnetic navigation theoretically facilitates electroanatomic mapping by having a "lighter" tissue touch and thus decreasing distortion of the endocardial border at the catheter tip site. Precise control of the catheter also aids complex ablation procedures by overcoming the difficulty of ablating hard-to-access sites as compared with conventional curvature catheter ablation (commonly the right lower pulmonary vein in atrial fibrillation ablation) [32]. Although the lack of contact force and charring of the catheter tip in the era of solid tip remote magnetic navigation catheters resulted in a higher rate of procedural failure initially, this is rarely seen nowadays with the utilization of irrigated tip catheters.

One of the major assets of the magnetic navigation catheter is its flexibility which limits the maximum force exerted at the catheter tip resulting in a much lower risk of perforation in more vulnerable anatomical areas such as the appendage [27]. Consistent with this, catheter/ablation-related complications were low in the remote magnetic navigation cohort.

4.3. Disadvantages of remote magnetic navigation

Despite reduction in fluoroscopy times, total procedural times were longer in patients in the RMN cohort. This has been attributed to several reasons. First, the flexible catheter design has been known to limit contact force during ablation, thus necessitating longer radiofrequency ablation times for certain regions such as the cavotricuspid isthmus [27]. Second, complexity in the set-up of remote navigation prolongs procedural time as evident in our study cohorts [33]. Another disadvantage is that the learning curve associated with RMN may prove to be an impediment to its utilization as an entirely new navigation technique using a mouse and keyboard has to be acquired. Being in a separate room from the patient also limits the response time in the event of an emergency or clinical deterioration, and healthcare staff should take this into consideration. With utilization of newer and more advanced technology, increased cost may also be a concern.

4.4. Limitations

This study was a non-randomized retrospective case control study, and the patient population may be heterogeneous. The data included our experience in the early phases of remote navigation utilization, and the overall calculated mean fluoroscopy time was higher than expected. All patients included in this study had their ablations performed prior to the introduction of contact force catheters at our center which have been associated with improved ablation success outcomes [34–37]. These data were pooled from atrial fibrillation ablations at our center by various physicians, which would have led to differences in ablation technique and fluoroscopy dependence. Physicians naturally have different preferences toward tools utilized and hence did not perform equal numbers of RMN and MAN ablations within this cohort. Air kerma area and dose area products were not collected as measures of radiation dose. However, in radiofrequency ablation, cineradiography sequences are less commonly used compared with percutaneous coronary.

5. Conclusions

RMN in radiofrequency ablation of atrial fibrillation appears to significantly reduce radiation exposure to both patient and physician compared with conventional MAN ablation techniques, even more so when experience is gained. This, however, is at a cost of increased total procedural time. Acute complication and success rates were comparable between both ablation strategies.

Conflict of interest

None.

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