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ORIGINAL ARTICLE

Radiofrequency needle for transseptal puncture is associated with lower incidence of thromboembolism during catheter ablation of atrial fibrillation: propensity score-matched analysis

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Abstract

Atrial fibrillation (AF) ablation requires transseptal puncture to access the left atrium. Recently, a radiofrequency (RF) needle was developed. The purpose of this study was to compare the incidence of MRI-confirmed acute cerebral embolism (ACE) during AF ablation procedures performed with RF needle versus mechanical needle transseptal puncture. This study consisted of 383 consecutive patients who underwent catheter ablation for AF that required transseptal puncture with mechanical or radiofrequency transseptal needles. Of those, 232 propensity score-matched patients (116 with each needle type) were included in the analysis. All patients had cerebral MRI performed 1 or 2 days after the procedure. Baseline characteristics were similar between the two groups. Total procedure time was significantly shorter in Group RF than Group non-RF (167 ± 50 vs. 181 ± 52 min, $P = 0.01$). ACE was detected by MRI in 59 (25%) patients. All patients with ACE were asymptomatic. Incidence of ACE was lower in Group RF than Group non-RF (19 vs. 32%, $P = 0.02$). B-type natriuretic peptide level was higher in the patients with ACE as compared to those without ACE (65.2 ± 68.7 vs. 44.7 ± 55.1 pg/ml, $P = 0.02$). In multivariable analysis, the use of RF needle and BNP level was related to the incidence of ACE (OR = 0.499, 95% CI 0.270–0.922, $P = 0.03$ and OR = 1.005, 95% CI 1.000–1.010, $P = 0.03$). Use of RF needle for transseptal puncture was associated with lower total procedure time and risk of ACE during catheter ablation of AF.

Keywords Atrial fibrillation · Catheter ablation · Transseptal · Radiofrequency needle · Embolism

Introduction

The safety and effectiveness of catheter ablation (CA) as a treatment option for patients with symptomatic atrial fibrillation (AF) have been established. However, while one of the primary intentions of the procedure is to maintain sinus rhythm and thereby reduce the incidence of cerebral events, the procedure itself is not free of risk, with the periprocedural incidence rate of stroke in a large study reported to be 0.1% [1]. Further, these clinically manifest cerebral events appear to represent only a subset of total ischemic lesions generated during these procedures, with some studies reporting silent ischemic lesions in up to 40% of cases [2, 3]. This is of particular concern in light of some evidence of neuropsychological decline in the verbal memory domain in patients pursuant to catheter ablation treatment of AF [4].

Various risk factors for silent acute cerebral embolism (ACE) have been studied, but consensus on many of these is still lacking. Only recently, however, were the impacts of various approaches to accessing the heart considered in this context, with cerebral Doppler-confirmed microembolic signals demonstrating: (1) a significantly higher event rate in left-sided ablations than right-sided ablations, and (2) a higher event rate with the transseptal approach than with the transaortic approach [5].

Historically, transseptal puncture has been performed with a mechanical (non-RF) transseptal needle, but more recently radiofrequency (RF) transseptal needle technology has become available. Previous evidence comparing RF

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transseptal needles to mechanical needles indicated that the RF technology can improve clinical outcomes [6]. However, no clinical study to date has evaluated if the type of transseptal puncture needle used could impact the rate of ACE.

The objective of the current study was to compare the incidence of MRI-confirmed ACE during AF ablation procedures performed with RF needle versus mechanical needle transseptal puncture.

Methods

Study subjects

Between May 2011 and June 2014, 383 consecutive patients underwent an initial catheter ablation procedure for AF that required transseptal puncture. All of the patients underwent enhanced computed tomography (CT) prior to ablation to establish the anatomy of the LA and pulmonary veins (PVs). Antiarrhythmic drugs were discontinued for at least five half-lives prior to ablation. Transesophageal echocardiography was performed prior to the procedure to rule out LA thrombus. Paroxysmal AF was defined as AF that spontaneously terminated within 7 days. The studies and data collection were performed in accordance with protocols that had been approved by the Human Research Committee of the Jikei University School of Medicine.

Periprocedural anticoagulation

Strategy of periprocedural anticoagulation was previously described [7]. Anticoagulants were administered at least 3 months before the procedure. Warfarin was given in the evening and was continued at the adjusted doses throughout the periprocedural period. Direct-acting oral anti-coagulants were administered until the day before the procedure, discontinued on the day of the procedure, and restarted on the next morning after the procedure. Intravenous unfractionated heparin was administered immediately after the sheath insertion to the vein and maintained throughout the ablation procedure to keep the activated clotting time (ACT) ≥ 300 s. ACTs were monitored every 20 min. If the ACT fell < 300 s during the case, investigators were asked to give an additional bolus of heparin.

Catheter ablation of atrial fibrillation

Each patient provided their written informed consent. Pulmonary vein (PV) isolation was performed as described previously [8–10] An esophageal temperature probe (Sensitherm, St. Jude Medical, St. Paul, MN, or Esophastar, Japan Lifeline, Tokyo, Japan) was inserted throughout the ablation procedure to avoid esophageal injury.

A single transseptal puncture was performed using the non-RF (BRK, St. Jude Medical, St. Paul, MN, USA) or RF needle (Baylis Medical, Montreal, Quebec, Canada) and an 8-F long sheath (SL0, St. Jude Medical, St. Paul, MN). Direct visualization of all four PVs was performed using atriogram to show the venous anatomy. All four PVs were targeted to be electrically disconnected from the LA at their antrum using circular catheters (25 or 30 mm for the superior PVs, 20 or 25 mm for the inferior PVs). RF current ablation was performed as proximal to the antrum of the PV as possible. RF energy was delivered at the distal electrode of an open-irrigated ablation catheter with a power limit of 25–35 W for 30–60 s at each site. The endpoint of ablation was the establishment of a bidirectional conduction block between the LA and PV.

After waiting for at least 30 min after the final RF application of PV isolation, adenosine triphosphate (20 mg) was rapidly administered intravenously to induce dormant PV conduction under the continuous infusion of isoproterenol in all patients. If dormant PV conduction was provoked, additional RF was applied at the earliest transient PV activation site identified on the Lasso catheter to eliminate dormant PV conduction.

Additional ablation of persistent AF

Following PV antrum isolation, a linear (roof and mitral isthmus line) and/or electrogram-based ablation was performed in patients with persistent AF. The endpoint of linear ablation was achievement of bidirectional conduction block. The targeted areas included complex fractionated electrograms and continuous electrical activity during ongoing AF. The endpoint of this step was the elimination of these potentials in the LA. The decision to add the linear and/or electrogram-based ablation was dependent on operator preference.

Post-procedural MRI

Cerebral MRI is routinely performed following all AF catheter ablation procedures for safety monitoring purposes. These post-procedure images were, therefore, available for retrospective analysis in this study.

Cerebral MRI was performed using a 1.5-T scanner 1 or 2 day (usually 1 day) after the ablation procedure in all patients. The imaging protocol for all images consisted of a T2-weighted axial fluid-attenuated inversion recovery (FLAIR) and a diffusion-weighted imaging (DWI) sequence. Acute embolic cerebral embolism was defined as focal diffusion abnormalities (bright hyper-intense lesions) in diffusion-weighted imaging (DWI). For each DWI sequence, the apparent diffusion coefficient (ADC) map was obtained to rule out a shine through artifact. An acute embolic lesion was defined as a focal hyper-intense area detected by the DWI sequence with a corresponding hypo-intensity in the ADC map in a typical vascular pattern [11]. The presence/absence of acute embolism was evaluated by independent, blinded neuroradiologists. A systematic clinical neurological examination was performed by a certified neurologist or certified physician who had sufficient experience regarding neurological examinations and who was blinded to this study.

Statistical analysis

Propensity scores were calculated for each of the 383 patients based on a multivariable logistic regression model. A total of 14 characteristics hypothesized to be associated with the incidence of ACE were assessed for inclusion in the model as independent variables. All 14 characteristics were retained in the model with stepwise selection and subsequently used to generate propensity scores. The selection process used a *P* value cut-off of 0.05 for a characteristic to enter and remain in the model. In order of stepwise selection, the matching variables were as follows: sex, age, body mass index, left atrium diameter, left ventricular ejection fraction, estimated glomerular filtration rate, B-type natriuretic peptide (BNP), paroxysmal AF, history of AF, hypertension, old cerebral infarction, structural heart disease, CHADS2 score and use of direct-acting anti-coagulants. Based on their propensity score, the patients who underwent transseptal puncture with mechanical and RF needles were matched on a 1:1 basis with a nearest neighbor algorithm without replacement using a caliper width 1/5 logit of the standard deviation.

The continuous variables are expressed as the mean ± standard deviation. An unpaired Student's *t* test or the Mann–Whitney *U* test was used for continuous variables. The categorical variables, expressed as numbers or percentages, were analyzed using the Chi-squared test unless the expected values in any cells were less than 5, in which case Fisher's exact test was used. *P* values of <0.05 were considered to indicate statistical significance.

Multivariate analyses used logistic regression analysis to assess incidence of ACE. A 0.10 level of significance was used for variable entry and removal from the stepwise models. The following variables were included as candidates for entry into the stepwise models: use of RF needle, $CHADS_2$ score and total procedure time. All of the statistical analyses were performed using the SPSS software program (version 21.0.0; SPSS, Chicago, IL, USA).

Results

Study population

Of 383 patients who underwent AF ablation requiring transseptal puncture, 232 patients (116 with mechanical transseptal needle and 116 with RF transseptal needle) were selected by propensity score-matched analysis. The area under the receiver operating characteristic curve (c-statistic) of the propensity score model was 0.74. After the propensity score-matched analysis, there were no significant differences between the two groups with regard to the baseline patient characteristics (Table 1).

Table 1 Baseline patient characteristics

	All $N=232$	RF needle $N=116$	Non-RF needle $N=116$	*P* value
Sex (male)	210 (91%)	108 (93%)	102 (88%)	0.18
Age (years)	55.4 ± 9.3	55.8 ± 9.4	55.2 ± 9.3	0.64
Body mass index (kg/m^2)	23.9 ± 3.1	23.9 ± 3.4	24.0 ± 2.9	0.79
LA diameter (mm)	38.4 ± 5.6	38.4 ± 5.5	38.4 ± 5.8	0.94
LV ejection fraction (%)	63.1 ± 7.5	62.9 ± 7.7	63.3 ± 7.2	0.65
eGFR (ml/min/1.73 m^2)	73.9 ± 12.7	73.6 ± 12.3	74.2 ± 13.1	0.69
BNP (pg/ml)	49.9 ± 59.4	48.7 ± 59.5	51.2 ± 59.4	0.75
Paroxysmal AF	159 (69%)	77 (66%)	82 (71%)	0.48
History of AF (years)	4.8 ± 5.2	4.6 ± 4.9	4.9 ± 5.6	0.61
Hypertension	71 (31%)	34 (29%)	37 (32%)	0.67
Old cerebral infarction	11 (4.7%)	4 (3.4%)	7 (6.0%)	0.35
Structural heart disease	13 (5.6%)	5 (4.3%)	8 (6.9%)	0.39
$CHADS_2$ score	0.5 ± 0.8	0.5 ± 0.8	0.5 ± 0.8	0.39
Use of DOAC	176 (76%)	90 (78%)	86 (74%)	0.21

The data are presented as the mean ± SD or *n* (%)

RF radiofrequency, *LA* left atrium, *LV* left ventricle, *eGFR* estimated glomerular filtration rate, *BNP* B-type natriuretic peptide, *TEE* transesophageal echography, *DOAC* direct-acting oral anti-coagulant

Procedure results

The procedural details are summarized in Table 2. All PVs were successfully isolated from the LA in both groups. The total procedure time was significantly shorter in Group RF than Group non-RF (167 ± 50 vs. 181 ± 52 min, $P = 0.01$). No symptomatic cerebral infarction occurred. Incidence of cardiac tamponade was similar between the two groups ($P = 0.32$). The cardiac tamponade in the study occurred more than 2 h after puncturing the septum and was considered to be unrelated to the transseptal puncture: specifically, a delayed tamponade occurred after the patient returned to the hospital room, following PV isolation with cavotricuspid isthmus (CTI) line, roof line and mitral isthmus line ablation. Incidence of dormant PV conduction was higher in RF group than non-RF group ($P = 0.02$)

Post-procedural MRI

MRI detected ACE in 59 (25%) patients. All patients were asymptomatic. The incidence of ACE was significantly lower in Group RF than in Group non-RF (19 vs. 32%, $P = 0.02$, Fig. 1). The clinical variables were compared between the patients with and without ACE in Tables 3 and 4. Serum BNP level was higher (65.2 ± 68.7 vs. 44.7 ± 55.1 pg/ml, $P = 0.02$) in the patients with ACE than in those without ACE. According to a multivariable analysis, BNP and the use of RF needle were the factors independently associated with the presence of ACE (odds ratio = 1.005, 95% confidence interval 1.000–1.010, $P = 0.03$ and odds ratio = 0.499, 95% confidence interval 0.270–0.922, $P = 0.03$, Table 5).

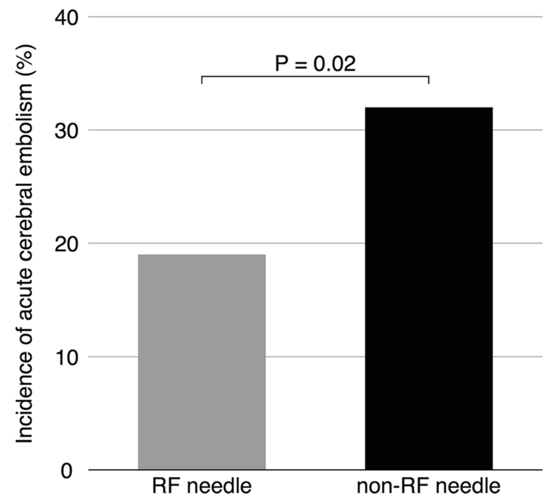

Fig. 1 Incidence of acute cerebral embolism (ACE) was less in the patients who underwent transseptal puncture using radiofrequency (RF) needle than those using non-RF needle

Discussion

This is the first clinical study to our knowledge that compares the association of different transseptal needle types with the MRI-confirmed incidence of ACE associated with catheter ablation treatment of AF. The results indicated that: (1) the use of a RF transseptal needle was associated with a significantly lower incidence of ACE than the non-RF needle, (2) BNP level was higher in patients with ACE, and (3) the total procedure time was significantly shorter in the RF needle group.

Table 2 Procedural details

	RF needle $N = 116$	Non-RF needle $N = 116$	P value
AF at entering operation room	39 (34%)	31 (27%)	0.25
Atrial angiography	114 (98%)	114 (98%)	1.00
Electrical cardioversion during procedure	53 (46%)	53 (46%)	1.00
Electrogram-based ablation	7 (6.0%)	11 (9.5%)	0.33
Roof line	31 (27%)	34 (29%)	0.66
Mitral isthmus line	30 (26%)	31 (27%)	0.88
Total procedure time (min)	167 ± 50	181 ± 52	0.01
Left atrial dwelling time (min)	129 ± 38	134 ± 38	0.24
Total radiofrequency energy (kJ)	4.8 ± 2.7	5.6 ± 2.8	0.12
Contact force sensing catheter	37 (32%)	28 (24%)	0.24
ATP injection test after PVI	101 (87%)	90 (78%)	0.06
Incidence of dormant conduction	48 (48%)	28 (31%)	0.02
Cardiac tamponade	1 (0.9%)	0 (0.0%)	0.32

The data are presented as the mean ± SD or *n* (%)

Abbreviations are the same as in the previous tables

ATP indicated adenosine triphosphate, *PVI* pulmonary vein isolation

Table 3 Comparison of patient characteristics between those with and without ACE

	ACE (−) $N=173$	ACE (+) $N=59$	P value
Sex (male)	154 (89%)	56 (95%)	0.18
Age (years)	55.0 ± 9.3	56.9 ± 9.2	0.16
Body mass index (kg/m^2)	24.1 ± 3.1	23.5 ± 3.1	0.25
LA diameter (mm)	38.4 ± 5.4	38.5 ± 6.5	0.85
LV ejection fraction (%)	62.9 ± 7.2	63.9 ± 8.1	0.35
eGFR (ml/min/1.73 m^2)	74.2 ± 12.2	72.8 ± 14.2	0.46
BNP (pg/ml)	44.7 ± 55.1	65.2 ± 68.7	0.02
Paroxysmal AF	119 (69%)	40 (68%)	0.88
History of AF (years)	4.8 ± 5.4	4.5 ± 4.8	0.65
Hypertension	51 (30%)	20 (34%)	0.53
Old cerebral infarction	10 (5.8%)	1 (1.7%)	0.20
Structural heart disease	9 (5.2%)	4 (6.8%)	0.65
$CHADS_2$ score	0.5 ± 0.8	0.5 ± 0.7	0.85
Use of DOAC	131 (76%)	45 (76%)	0.93

The data are presented as the mean ± SD or *n* (%)

Other abbreviations are the same as in the previous tables

ACE acute cerebral embolism

Table 4 Comparison of procedural details between with and without ACE

	ACE (−) $N=173$	ACE (+) $N=59$	P value
AF at entering operation room	50 (29%)	20 (34%)	0.47
Atrial angiography	170 (98%)	58 (98%)	0.98
Electrical cardioversion during procedure	78 (45%)	28 (48%)	0.75
Electrogram-based ablation	13 (7.5%)	5 (8.5%)	0.89
Roof line	48 (28%)	17 (29%)	0.88
Mitral isthmus line	45 (26%)	16 (27%)	0.87
Total procedure time (min)	171 ± 49	181 ± 59	0.15
Left atrial dwelling time (min)	130 ± 40	134 ± 32	0.22
Total radiofrequency energy (kJ)	5.4 ± 2.8	4.8 ± 2.8	0.13
Use of contact force sensing catheter	45 (26%)	20 (34%)	0.24
ATP injection test after PVI	142 (82%)	49 (83%)	0.87
Incidence of dormant conduction	55 (39%)	21 (43%)	0.61
Use of RF needle	94 (54%)	22 (37%)	0.02

The data are presented as the mean ± SD or *n* (%)

Abbreviations are the same as in the previous tables

Table 5 Multivariable analysis predicting ACE during AF ablation procedure

	Odds ratio	95% CI	P value
Use of RF needle	0.499	0.270–0.922	0.03
B-type natriuretic peptide	1.005	1.000–1.010	0.03

Abbreviations are the same as in the previous tables

While catheter ablation has been established as an important component of the treatment armamentarium for AF, it is known that the procedure carries with it, in addition to the clinically manifest complications such as stroke and TIA, the risk of silent ACE. This has been observed through MRI studies to occur at various rates of incidence up to approximately 40% of patients [2, 3]. While the exact clinical course and consequence of these silent ACE events is still being elucidated, they are generally and reasonably regarded as events that should be avoided, to the extent possible. An example of efforts to implement changes to workflow and technology to lower the rate of these events can be observed with the use of phased RF multi-electrode catheter (PVAC) technology. Early studies on PVAC demonstrated a consistently higher rate of silent embolic events than other catheter technologies, such as irrigated RF and cryoballoon catheters [3, 12]. However, by modifying the workflow to include ACT > 350 s with uninterrupted oral vitamin K antagonists, loading of the catheter into the introducer while submerged in saline, and deactivation of proximal or distal catheter electrode to prevent overlapping of electrodes, one study demonstrated an ACE incidence of 1.7% [13]. This example provides precedence for modifications to clinical workflow that may decrease the rate of ACE and thereby conceivably enhance the safety profile of catheter ablation procedures.

The results of a recent study demonstrated that the transseptal approach to the left heart produced a higher number of microembolic signals on transcranial Doppler than the transaortic approach, albeit without comparing needle types used for transseptal puncture [5]. Results of the current propensity score-matched analysis indicated an approximately 40% lower incidence of ACE in the RF needle group. These are the first results to suggest that physicians may consider use of an RF transseptal needle as an additional modification to clinical workflow to lower the incidence of ACE in patients undergoing catheter ablation of AF.

While additional research is needed to clarify a mechanistic basis for the lower incidence of ACE observed with the use of an RF needle, it is possible to speculate at present. Previous in vitro and preprocedural ex vivo experiments have demonstrated that advancement of sharp-tipped conventional mechanical (non-RF) needles through the dilator and sheath resulted in the production of visible plastic shavings, whereas the advancement of the blunt-tipped RF needle did not [6, 14]. It is conceivable that such particles generated by the sharp mechanical needles in this skiving process could translocate from the sheath/dilator apparatus into the left atrium of the heart during the transseptal puncture and catheterization processes, thereby delivering potentially embolic material into the body. Further, a more consistent transseptal puncture process with the RF needle, as compared to the mechanical needle, has been observed in studies, as characterized by: a shorter and more consistent amount of time required to puncture the septum; less need for repositioning of the needle prior to puncture; and, avoidance of transseptal failures seen with the mechanical needle due to multiple unsuccessful puncture attempts or safety concerns regarding applying excessive force or septal tenting [6, 15]. It is possible that the more unpredictable transseptal process with the mechanical needle, involving both increased time to puncture and increased interaction with septal tissue, could contribute to a more pro-embolic environment in the left heart. While the extent of tissue injury has been shown to be similar between the two needle types, it remains to be clarified how these puncture mechanisms would result in the expulsion of differing amounts of potentially embolic material into the left atrium [16].

It has been reported in the literature that AF ablation can be associated with post-operative cognitive dysfunction at 90-day follow-up in up to 20% of patients [17]. However, a direct correlation between silent ACE and cognitive dysfunction after AF ablation has not been evident in investigations, with authors speculating that particularly small lesions may evade detection on MRI and also that the observed decline in cognitive function could possibly be multifactorial [2, 4]. A study of the clinical course of ACE indicated that 94% of lesions were not detectable at a median follow-up of 3 months, but that some larger lesions did remain, which produced chronic glial scars, but without evidence of neurological symptoms [2]. It is important to acknowledge that, despite a currently incomplete understanding of the clinical course and consequence of silent ACE, it is widely regarded in the electrophysiology and AF ablation community as desirable to take efforts to help lower its incidence [18].

In the current study, a significantly lower procedure time was observed in the RF needle group. These time savings with the RF needle are likely due to a reduction in the time required to cross the septum and a more precise crossing of the septum at a desired location allowing optimized catheter contact with the targeted tissues. While needle type was determined at the discretion of the operator, the cases with the RF needle can be more recent. It is possible that development of operators' skill sets and lab practices may also have occurred over time.

It is interesting to consider that increased left atrial access time in AF ablation cases has been observed to be associated with post-operative neurocognitive dysfunction at 2- and 90-day following procedures [17]. And, at least one study has found a significant association between longer procedure times and increased incidence of silent embolism, although no association was found with left atrial procedure time [19]. This could suggest that shortening the duration of AF ablation procedures may yield clinical benefits to patients.

In addition to the clinical benefits afforded by shorter procedure times, the economic benefits can also be considered. Recently, the economic value of shorter procedure times on electrophysiology lab management was studied [20]. The results of the discrete event simulation model indicated that a mean reduction of 36 min seen with the use of cryoballoon, as compared with RF ablation procedures, translated into a 36.2% reduction in days with overtime, 92.7% fewer cumulative overtime hours, and a 46.7% increase in days with time available (at least 1 h) for additional electrophysiology lab use [20]. The lower mean time reported in the RF needle group in the current study suggests that improved EP lab efficiencies may also be achievable with its use.

Study limitations

Several limitations associated with the present study warrant mention. This study was a non-randomized single-center retrospective study. Exchanging catheters through a sheath, the numbers of flushes of the sheath and chronological state throughout the procedures may have an impact on the results of this study. In addition, because cerebral MRI imaging used in this study was generated through post-procedure routine safety monitoring of patients, there were no preprocedural images available for comparison. Even though patients were assessed for only ACE by independent, blinded neuroradiologists, we could not deny the possibility of events occurring immediately before the procedure. And, while the propensity score matching technique was used to attempt to reduce bias from potentially confounding variables, selective bias cannot be excluded. Further, no measurement of neurocognitive function was reported, limiting the ability to correlate the observed improvements in ACE and procedure time to patients' cognitive functioning. It is recommended that large-scale prospective studies be conducted to confirm the results of this study.

Conclusions

The results of the current study indicate that use of an RF needle for transseptal puncture is associated with a lower incidence of ACE and shorter procedure time during catheter ablation procedures for AF.

Compliance with ethical standards

Conflict of interest None.

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