Assessment of Thromboembolic Risk of Cessation of Oral Anticoagulation Post Catheter Ablation in Patients with and without Atrial Fibrillation Recurrence

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Abstract

Instruction Cessation of oral anticoagulation (OAC) is common after the first 3 months of catheter ablation of atrial fibrillation (AF); however, thromboembolic risk has not been defined in patients with and without AF recurrence (RAF vs. NRAF) post ablation

Methods and Results We identified 796 patients who discontinued OAC at 3 months post AF ablation from January 2015 to May 2018 in our center. Regular follow-up was performed to detect RAF, collect medication management and thromboembolic and major bleeding events. CHA_2DS_2-VASc score was 1.79±1.50; 547 (68.7%) patients were at intermediate and high risk (i.e. CHA_2DS_2-VASc score ^{3}1 in male patients, or ^{3}2 in female patients); 169 (21.2%) were RAF. During 29.2±12.2 months follow-up, the incidence rate of thromboembolism was 1.62 per 100 patient-year (7 in 431 years) in RAF, 0.33 per 100 patient-year (5 in 1503 years) in NRAF. After adjusting for potential confounding factors, RAF was associated with more 3.5-fold higher rate of thromboembolism compared with NRAF (adjusting HR, 4.488; 95%CI, 1.381-14.586). Rate of thromboembolism was even higher in patients with intermediate and high risk (2.16 per 100 patient-year [7 in 323 years] versus 0.38 per 100 patient-year [4 in 1043 years], aHR, 5.807; 95%CI, 1.631-20.671). In multivariate logistic regression analysis, RAF was the only independent predictor of thromboembolism (4.837 [1.498-15.621], P=0.008).

Introduction

Atrial fibrillation (AF), the most common arrhythmia, is associated with an approximately fivefold increased risk of stroke.[1]Catheter ablation is effective as rhythm control strategy in AF patients.[2] Use of long-term oral anticoagulation (OAC) treatment, i.e., after the first 3 months post ablation of AF, remains controversial. Although studies have reported a low incidence rate of thromboembolism after ablation in patients discontinuing OAC compared with those continuing OAC,[3,4] the thromboembolic risk has been inconsistent particularly among studies including patients with and without AF recurrence.[5-8] Cessation of OAC is common (from 30% to 95%) in AF patients undergoing or not undergoing catheter ablation,[3,9-12] although guidelines have recommended that OAC should follow general anticoagulation recommendations regardless of the presumed rhythm outcome after catheter ablation.[1,13,14] The diversity of approaches in clinical practice might be secondary to low level evidence and absence of data about the risk of thromboembolism.

In patients with versus those without AF recurrence (RAF vs. NRAF) after ablation, the incidence rate and hazard risk of thromboembolism after OAC discontinuation remains unclear. We therefore reviewed data on efficacy and complications after catheter ablation at our center to investigate the incidence rate

of thromboembolic events and to identify the risk factors for thromboembolism after cessation of OAC in patients with and without AF recurrence.

Methods

This study was approved by the local institutional Ethics Committee, and written informed consent was obtained from all participants. The present analysis of events of thromboembolism and major bleeding (MB) after cessation of OAC at 3 months post ablation was based on data from a prospective observational study (Chinese Clinical Trial Registry: ChiCTR-OCH-14004674) with three-year follow-up of patients who underwent ablation for AF at our center. The study collected data on the efficacy of radiofrequency and cryogenic catheter ablation, pharmacotherapy, and complications including death, thromboembolism, MB and rehospitalization. All patients undergoing AF catheter ablation between January 2015 and May 2018 were consecutively included in the study unless they met any of the following exclusion criteria: (i) valvular heart disease; (ii) follow-up for <12 months; or (iii) thromboembolic or MB events during the first 3 months after ablation.

Baseline data were collected before procedure. CHA_2DS_2-VASc score was used to stratify thromboembolic risk. CHA_2DS_2-VASc scores of 0, 1, [?] male patients and 1, 2, [?] female patients were considered to correspond to low, intermediate and high risk of thromboembolism, respectively. As recommended,[14] HAS-BLED score was used to evaluate bleeding risk; no score points were given for use of nonsteroidal anti-inflammatory drugs (except antiplatelet drugs) or labile international normalized ratio values because of incomplete information.

Postprocedural management and follow-up strategy

Medical management during the first 3 months after ablation has been previously described.[15] After discharge, patients underwent heart rhythm evaluation by electrocardiography (ECG) and 24-hour Holter monitoring at 1, 3, and 6 months and every 6 months thereafter. If the patient did not show up for scheduled follow-up monitoring visits, within one month our follow-up office would call the patient to collect information on recurrence and complications. Atrial tachyarrhythmia recurrence was defined as developing atrial tachyarrhythmia lasting at least 30 seconds after the 3-months observation window after ablation.

After the 3-months observation period post ablation, OAC use in patients without AF recurrence was determined in conjunction with the electrophysiologist; OAC use was encouraged in the high-risk RAF patients.

Primary outcome events

Study primary outcomes included rates of thromboembolism and MB events. Thromboembolism events included ischemic stroke, transient ischemic attack, and systemic embolism, which were diagnosed based on symptoms and computerized tomography or magnetic resonance imaging. MB events included intracranial hemorrhage and any other bleeding events requiring hospitalization. Timing and outcome of primary events were recorded during follow-up.

Statistical analysis

Data analysis was performed using SPSS 25.0 (IBM Corp.), and the significance level was set at P <0.05. The Kolmogorov-Smirnov test was used to check for normality of distribution of continuous variables, which are expressed as mean ± standard deviation (SD) and were compared using the t test or Fisher's test, while categorical variables are expressed as numbers with percentage and were compared using the chi-square test.

Crude incidence rates of thromboembolic events were expressed as rates per 100 patient-years. Cumulative survival free from thromboembolic outcome is presented as Kaplan-Meier curve. Cox hazard regression analysis was used to calculate the hazard ratio of the thromboembolic risk between RAF and NRAF groups, both overall and for intermediate- and high-risk patients. Potential confounders, including RAF, age, sex, AF type, all factors in CHA_2DS_2-VASc score, smoking, alcohol consumption, left atrium diameter [?], and obesity (body mass index[?]28.0).

Factors associated with thromboembolism during follow-up were analyzed using uni- and multivariable logistic regression analyses in RAF and NRAF of overall or intermediate- and high-risk patients (significance level set at P <0.10 for inclusion into model). All factors in CHA_2DS_2-VASc score were analyzed, with age as continuous variable, and AF type, smoking, alcohol consumption, left atrium diameter [?], and obesity as categorical variables.

Results

As shown in Figure 1, of the 871 consecutive patients who underwent catheter ablation between January 2015 and May 2018, 796 patients were included in the present analysis and underwent 826 catheter ablation procedures (average 1.04 per patient). Mean CHA_2DS_2-VASc score was 1.79+-1.50; 547 (68.7%) patients were at intermediate and high risk. Mean HAS-BLED score was 0.76+-0.76. Follow-up duration was 29.2+-12.2 months. During follow-up, all patients had at least one ECG or 24h Holter evaluation after 3 months post ablation, while only 479 (60.2%) had 24h Holter recording; 154 (19.3%) were on antiplatelet drugs continuously, and 219 (27.5%) on antiarrhythmic drugs, with the proportion being much higher in RAF versus NRAF group. Three patients died of cancer, fatal stroke, and myocardial infarction, respectively, after 12 months post ablation. 169 (21.2%) patients developed atrial tachyarrhythmia after the 3-month observational period, 24 (14.2%) developed persistent AF, and 14 (8.3%) were asymptomatic. Comparison of baseline and follow-up data between RAF and NRAF are presented in Table 1. Overall, CHA_2DS_2-VASc score was higher in RAF vs. NRAF (P <0.05).

Primary outcome events

Overall, 12 patients experienced thromboembolic events (Table 2) and 1 patient suffered an MB event (subarachnoid hemorrhage in patient without AF recurrence). No patient on continuous OAC experienced a thromboembolic or MB event. The rate of sequela was numerically higher in RAF vs. NRAF (4/7 versus 1/5). The incidence rate of thromboembolic events was 0.33 per 100 patient-year (5 in 1503 patient-years) in NRAF, and 1.62 per 100 patient-year (7 in 431 patient-years) in RAF. In patients at intermediate and high risk, the incidence rate of thromboembolic events was 0.38 per 100 patient-year (4 in 1043 patient-years) in NRAF, and 2.16 per 100 patient-year (7 in 323 patient-years) in RAF. Compared with NRAF, after adjusting potential confounders, RAF had significantly higher incidence rate of thromboembolic events (overall: aHR, 4.488; 95%CI, 1.381-14.586, P =0.013) and (intermediate and high risk: aHR, 5.807; 95%CI, 1.631-20.671, P =0.007) (Table 3 and Supplementary Table S1). The Kaplan-Meier curves demonstrated higher cumulative survival rate free from thromboembolism in overall, or intermediate and high risk patients NRAF vs. RAF (P =0.002 and 0.001, respectively, Figure 2); events happened post 6 months after ablation, and happened post the first recording episode of recurrent AF in RAF (6/7, Table 2).

Risk factors associated with thromboembolic events

As listed in Table 4, in univariable logistic regression analysis, CHA_2DS_2-VASc score was associated with thromboembolic events in patients overall and in RAF, but not in NRAF (Supplementary Table S2). No other factors were associated with thromboembolic events in this investigation. In multivariable logistic regression analysis, after adjustment for age and sex, CHA_2DS_2-VASc score was not an independent predictor, in patients overall or in RAF (1.406 [0.920-2.147], P =0.115; and 1.592 [0.977-2.594],P =0.062 respectively). If adding AF recurrence as potential factor, in multivariable logistic regression analysis, AF recurrence was the strong predictor in all patients (4.837 [1.498-15.621], P =0.008).

Discussion

The present study, which to the best of our knowledge is the first to compare the thromboembolic risk of cessation of OAC in RAF and NRAF after catheter ablation documented: (i) a low rate of thromboembolic events after successful catheter ablation; (ii) an approximately 3.5-fold higher incidence rate of thromboembolic events in RAF vs. NRAF; and (iii) that the CHA_2DS_2-VASc score may still predict thromboembolic risk in RAF but not in NRAF in whom OAC had been discontinued.

Cessation of OAC after catheter ablation and risk of thromboembolism

Catheter ablation has been associated with improvement in structural remodeling, hemodynamic function of the left atrium (LA) and intra-LA blood stasis in NRAF, which would decrease risk for thrombogenesis.[16] Results from a large prospective real-world observational registry study of Chinese patients with AF (n=4512) indicated that compared with patients continuing long-term OAC after successful ablation, the thromboembolic risk was low in patients discontinuing long-term OAC (0.54 vs. 0.86 per 100 patient-years), as was risk for MB events (0.19 vs. 0.35 per 100 patient-years).[3] Similarly, for patients who had undergone successful ablation, Themistoclakis *et al.* [4] reported that the incidence rate of ischemic stroke and MB events was lower in patients off OAC than in those on OAC (0.07% vs. 0.45%, P =0.06; 0.04% vs. 2%,P <0.0001). In the present study, in NRAF, the incidence rate of thromboembolism was 0.33 or 0.38 per 100 patient-year in the overall or intermediate and high risk populations. The annual incidence of stroke events for general Chinese population was 377 per 100,000 in 2013.[17] Therefore, consistent with study by Yang*et al.* ,[3] for NRAF, thromboembolic risk was low and similar to the general population.

Some studies have reported on thromboembolic risk for RAF vs. NRAF. Bunch *et al.* [6] reported that across all $CHADS_2$ scores and ages, AF patients who underwent ablation had a similar long-term risk of stroke to that of patients without AF but lower than that of patients who did not undergo ablation. Another study based on Danish administrative registries[7] reported similar thromboembolic incidence rates in patients on and off OAC, even in those at high-risk (CHA_2DS_2-VASc score [?]2). In contrast, in the Swedish catheter ablation register,[5] patients with CHA_2DS_2-VASc score [?]2 and off warfarin treatment had a higher rate of ischemic stroke compared with those on warfarin treatment (1.6% vs. 0.3% per year, P =0.046). A meta-analysis in 2017 including 9 observational studies reported that the overall rate of thromboembolism was not significantly different between patients on or off OAC, however, the incidence of total bleeding events was higher among patients continuing OAC patients.[18] The inconsistency in results may result from differences in race/ethnicity, proportion of complications, follow-up duration, and incidence of recurrence. Indeed, in this study, AF recurrence was significantly associated with increased thromboembolic risk in univariate model,[7] and in the Swedish catheter ablation register[5] or Taiwanese ablated patients,[19] 8 of 11 patients with ischemic stroke events had suffered AF recurrence, which may indicate that it is not proper to evaluate the thromboembolic risk in mixed patient populations with and without AF recurrence. In the present study, the incidence rate of thromboembolic events was much higher in RAF vs. NRAF; in addition to worse outcomes in AF-related strokes, the sequelae of thromboembolism were more severe in RAF. In a single-center study, the estimated 5-year stroke incidence was 3% for patients discontinuing OAC after successful ablation compared with 23% for patients with AF recurrence remaining on warfarin.[20] The latter results suggest that it is reasonable to use a differential strategy in RAF vs. NRAF. Noteworthy, consistent with previous studies,[4,5] in present study, all thromboembolic events happened post 6 months after ablation if cessation of OAC, which were mostly post the time of the first recording AF recurrence providing the practicable space to take timely intervention of OAC. However, the temporal association between the AF episode and need for OAC still needs further confirmation.

Potential factor associated with post catheter ablation thromboembolism

Many potential factors associated with thromboembolism in general AF patients may still be suitable for predicting the risk of thromboembolism after catheter ablation, such as abnormal clotting function, low velocity of intra-atrial flow, atrial myopathy, and cardiovascular diseases.[1,14] Reportedly, atrial myopathy, assessed by cardiac magnetic resonance, bipolar voltage mapping, may have a relationship with stroke.[21] While in present study, because of some restrictions, we did not always record the data of bipolar voltage mapping and not regularly assess fibrosis by cardiac magnetic resonance.

CHA_2DS_2-VASc score was significantly associated with increased thromboembolic risk (Table 4), as had been previously reported.[10] Of note, in the present study, CHA_2DS_2-VASc score was the only predictor of thromboembolism incidence in RAF but not in NRAF. In previous studies of patients who had undergone successful ablation or in mixed populations, previous thromboembolism was the only independent predictor among components of CHA_2DS_2-VASc score associated with thromboembolic events.[3,5,7] While in multiple analysis, CHA_2DS_2-VASc score was not an strong predictor; if adding AF recurrence as a potential factor,

AF recurrence was the strong predictor, which implies the performance of catheter ablation is a crucial factor for prognosis of AF patients after catheter ablation as previous publish reported (174 ablated patients, 47 +- 23 months).[19]

As per the latest recommendations (2019 AHA/ACC/HRS, 2017 HRS/EHRA/ECAS/APHRS /SOLAECE expert consensus, 2016 ESC),[1,13,14] long-term continuation of OAC after 2 months post ablation should be based on the patient's stroke risk profile (i.e. CHA_2DS_2-VASc score), and not on the efficacy of ablation. However, the published results have been inconsistent which may underlie the variety of approaches seen in clinical practice. The ratio of benefits to risks for OAC and economic reasons also underlie the high proportion of cessation of OAC after the first 3 months post ablation.[9] Although the present study was a single-center observational study, its results underscore the need for differential management between patients with versus those without AF recurrence after ablation, which may translate into better outcomes.

Limitations

The present study has the limitations inherent to its single-center observational design which may introduce selection bias; large-scale randomized studies are warranted to provide high-level evidence, such as the OCEAN trial.[22] AF recurrence may have been underestimated because of how the events were captured during follow-up which may have affected mostly the observed incidence rate of thromboembolism in AF free patients. It would be better with extended ECG monitoring, like long-term daily life ECG or implantable loop recorders, to detect heart rhythm, build the relationship between AF burden and thromboembolic events, and improve medical care timely.[23-25] Moreover, the small sample size might underlie the lack of achievement of statistical significance in multivariate analysis for CHA_2DS_2-VASc score as a predictor of thromboembolic events. Finally, missing data for the components of the HAS-BLED might have led to a lower score.

Conclusions

Discontinuation of OAC in patients who had undergone successful ablation may be reasonable with strict post-procedure monitoring; however, high level evidence is warranted. Patients who experience AF recurrence would appear to benefit from not discontinuing OAC if they have a high-risk stroke profile because of high incidence rate of thromboembolic events.

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Table 1. Baseline and follow-up information

Baseline data
Age, mean (SD), years
65 years, n(%)
75 years, n(%)
Male, n(%)
Persistent AF, n(%)
Congestive heart failure, n(%)
Hypertension, n(%)
Diabetes mellitus, n(%)
Prior stroke/TIA/systemic embolism, n(%)
Vascular disease, n(%)
CHA2DS2-VASc score, mean (SD)
HAS-BLED score, mean (SD)
Renal disease, n(%)
Liver disease, n(%)
Anemia, n(%)
Alcohol consumption, n(%)
Body mass index, mean (SD)
LAD [?] 40 mm, n (%)
Follow-up data
Follow-up duration, mean(SD), months
Antiplatelet drugs, n(%)
Antiarrhythmic drugs, n(%)
ACEI/ARB, n(%)
Statins, n(%)

Abbreviations: AF, atrial fibrillation; CHA2DS2-VASc, congestive heart failure, hypertension, age 75 years or older (double
P<0.05, compared with no recurrence in total patients; +P<0.05, compared with no recurrence in intermediate or high risk

Table 2. Characteristics of patients with thromboembolic events

Table 2. Characteristics of patients with thromboembolic events

Table 3. Univariable and multivariable Cox regression for the incidence of thromboembolic events in all patients (n=796)

Variable	
AF recurrence	
Age	
Female sex	
Persistent AF	
Congestive heart failure	
Hypertension	
Diabetes mellitus	
Prior stroke/TIA /systemic embolism	
Vascular disease	
CHA2DS2-VASc score	
Smoking	
Alcohol consumption	
LAD [?] 40 mm	
Obesity	

Abbreviations: AF, atrial fibrillation; CHA2DS2-VASc, congestive heart failure, hypertension, age 75 years or older (double

Table 4. Individual risk factors associated with thromboembolism after AF ablation in all and recurrent patients

Variable	Univaria
	HR(95%
Age	1.043(0.9
Female sex	1.178(0.3
Persistent AF	0.798(0.5
Congestive heart failure	0.483(0.0
Hypertension	2.193(0.0
Diabetes mellitus	2.132(0.5
Prior stroke/TIA /systemic embolism	2.140(0.4
Vascular disease	2.542(0.7
CHA2DS2-VASc score	1.399(1.0
Smoking	0.733(0.1
Alcohol consumption	0.899(0.2
LAD [?] 40 mm	1.683(0.5

Table 4. Individual risk factors associated with thromboembolism after AF ablation in all and recurrent patients	Table 4.
Obesity	0.935(0.

Table 4. Individual risk factors associated with thromboembolism after AF ablation in all and recurrent patients (continued
Variable
Age
Female sex
Persistent AF
Congestive heart failure
Hypertension
Diabetes mellitus
Prior stroke/TIA /systemic embolism
Vascular disease
CHA2DS2-VASc score
Smoking
Alcohol consumption
LAD [?] 40 mm
Obesity
Abbreviations: AF, atrial fibrillation; CHA2DS2-VASc, congestive heart failure, hypertension, age 75 years or older (double

Figure legends

Figure 1. Flowchart of study patients with atrial fibrillation. OAC, oral anticoagulation.

Figure 2. Kaplan-Meier curves for cumulative survival free from thromboembolic events in overall (A, P =0.002) and in intermediate and high risk (B, P =0.001) patient populations.

Figure 1

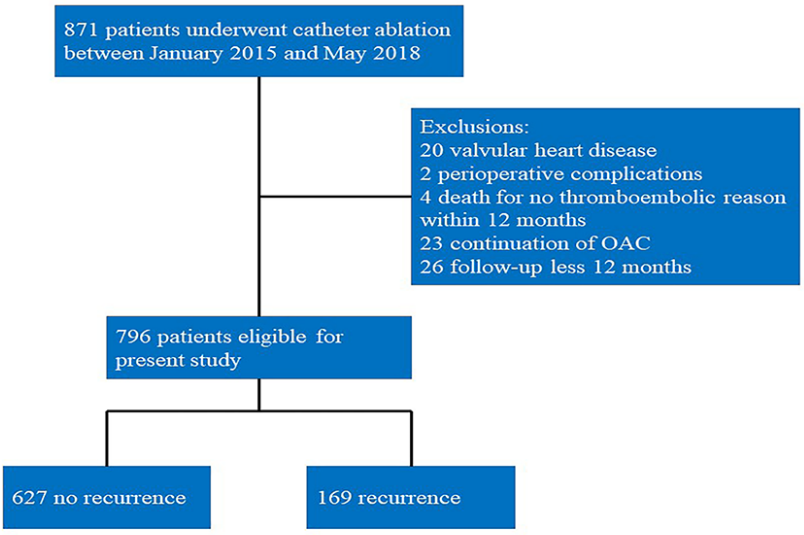

Figure 2