



Research article

Real world risk of discontinuing oral anticoagulation after successful catheter ablation for atrial fibrillation

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ABSTRACT

Background: Many patients with atrial fibrillation (AF) discontinued oral anticoagulation (OAC) therapy after successful catheter ablation. We aimed to determine the real-world risks and consequences of discontinuing OAC use after catheter ablation for AF.

Methods: Patients who underwent successful catheter ablation for AF from January 2004 to December 2020 were divided into continued long-term OAC (On-OAC, n = 1062) and discontinued (Off-OAC, n = 1055) groups. The long-term outcomes including thromboembolic events, major bleeding, all-cause mortality and major adverse cardiovascular events (MACE), were compared between the two groups.

Results: The CHA2DS2-VASc score was 3.44 ± 1.12 . After a mean follow-up of 37.09 months, thromboembolism risk was higher and major bleeding risk was lower in the Off-OAC than in the On-OAC group (Both log-rank $P < 0.001$). CHA2DS2-VASc score-stratified subgroup analysis showed similar cumulative event rates between the two groups in men and women with scores of 2 and 3 (intermediate risk for stroke), respectively, ($P > 0.05$), except for a higher major bleeding rate in the On-OAC group ($P = 0.002$). Patients at high risk for stroke (men and women with scores ≥ 3 and ≥ 4) had better non-thromboembolic and non-MACE results (Both log-rank $P < 0.05$).

Conclusion: Men with a CHA2DS2-VASc score of 2 and women with a score of 3 had a relatively low incidence of stroke events after successful catheter ablation for AF and may be safe for anticoagulation cessation. Greater benefits from long-term OAC were observed in men with CHA2DS2-VASc score ≥ 3 and women with score ≥ 4 .

1. Introduction

Atrial fibrillation (AF) is the most common persistent arrhythmia and a public health burden associated with increased risk of stroke [1,2]. Catheter ablation is an important strategy for the treatment of AF and is being increasingly accepted [3]. Current guidelines recommend the continuation of oral anticoagulant (OAC) therapy for men and women with a CHA2DS2-VASc score ≥ 2 and ≥ 3 , respectively, after catheter ablation [3,4]. However, real-world clinical data showed that approximately 70 % of patients with AF

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Abbreviations and acronyms

AF	atrial fibrillation
NVAF	nonvalvular atrial fibrillation
OAC	oral anticoagulation
NOAC	novel oral anticoagulant
LAAC	left atrial appendage closure
ECG	electrocardiogram
AT	atrial tachycardia
CI	confidence interval
HR	hazard ratio
IS	ischemic stroke
GIH	gastrointestinal hemorrhage
ICH	intracranial hemorrhage
ATT	antiplatelet drug
MACE	major adverse cardiovascular events
TEE	transesophageal echocardiogram
TIA	transient ischemic attack

discontinue OAC use after successful ablation [5–8]. In this study, we retrospectively analyzed the clinical data from patients with nonvalvular atrial fibrillation (NVAF) after successful catheter ablation for AF at our center and explored the real-world risk of discontinuing OAC after ablation.

2. Methods

All patients with paroxysmal or persistent AF who underwent AF ablation between January 2004 and December 2020 in our center were included in the study, in the absence of exclusion criteria which were as follows: (1) age < 18 years, (2) valvular heart disease or hyperthyroidism, (3) left atrial appendage closure (LAAC), (3) low stroke risk (CHA₂DS₂-VASc < 2 in males or < 3 in females), (5) thromboembolic events, major bleeding events, or OAC discontinuation within the initial 3 months post-catheter ablation, or (6) incomplete data or loss to follow-up.

A total of 2117 eligible patients were enrolled (Fig. 1). The study protocol was approved by the Ethics Committee of Xinhua Hospital Affiliated with Shanghai Jiao Tong University School of Medicine. The requirement for informed consent was waived because of the retrospective nature of the study.

Patients were followed up at 3 and 6 months after the procedure, and every 6 months thereafter by outpatient or telephone until December 2022. Follow-up data, including cardiac rhythm, anticoagulation regimen, and endpoints, were recorded.

AF recurrence was defined as the occurrence of AF, atrial flutter, or atrial tachycardia (AT) lasting > 30 s after ablation. The rhythm was monitored using the following three methods: (1) electrocardiogram (ECG) records during regular follow-ups in the outpatient clinic, (2) ECG records triggered by symptoms, and (3) opportunistic screening wherein ECG was obtained for other reasons (e.g., as a routine preoperative examination for surgery).

After the exclusion of contraindications, all patients received OAC for at least 3 months post-ablation, and long-term maintenance of OAC therapy was recommended. Patients were divided into the anticoagulation continuation (On-OAC) and discontinuation (Off-

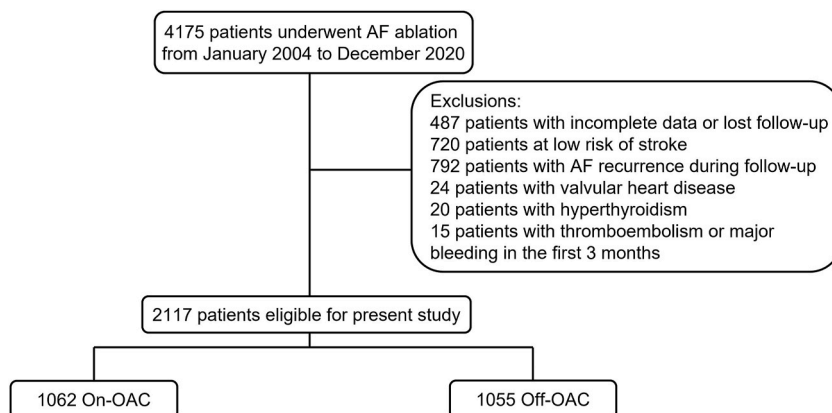


Fig. 1. Study flowchart. AF, atrial fibrillation; OAC, oral anticoagulation; low risk of stroke, CHA₂DS₂-VASc score < 2 in males or < 3 in females.

OAC) groups based on continuation throughout follow-up. The On-OAC status was confirmed by asking patients during follow-up. Patients who had an event after brief discontinuation were included in the Off-OAC group, while those who had an event during OAC treatment were included in the On-OAC group.

The study outcomes were as follows: (1) ischemic stroke (IS), transient ischemic attack (TIA), or systemic embolism; (2) major bleeding events, defined as incidents of gastrointestinal or intracranial hemorrhage (GIH/ICH), or hemothorax requiring hospitalization, resulting in a decrease of more than 2 g/dL in hemoglobin levels and/or necessitating a blood transfusion; (3) all-cause mortality; (4) a composite endpoint consisting of ischemic and hemorrhagic stroke, myocardial infarction, hospitalization for heart failure, and cardiogenic death, represented as a major adverse cardiovascular event (MACE).

SPSS Statistics software (IBM, version 25.0) was used for data analysis. Continuous variables are presented as means and standard deviations, and categorical variables are presented as counts and percentages. Independent sample t-tests (comparison of means between groups) or chi-square tests (comparison of rates) were used to analyze differences between groups and time-points. Hazard ratios (HRs) were adjusted for age and sex between groups using a Cox hazard regression model. The Kaplan–Meier method and log-rank test were used for survival analysis. Cox hazard regression analysis was used to identify risk factors associated with the clinical outcomes. Statistical significance was set at $P < 0.05$.

3. Results

A total of 2117 patients included in the study were divided into the On-OAC ($n = 1062$) and Off-OAC ($n = 1055$) groups. The mean follow-up was 37.09 ± 13.35 months. The mean age of the patients was 68.94 ± 9.21 years. Of all included patients, 45.0 % were female, and 43.0 % had persistent AF. Hypertension (1531,72.3 %), diabetes (545,25.7 %), and congestive heart failure (507,23.9 %) were common comorbidities.

During follow-up, 674 patients (63.5 %) in the On-OAC group were treated with warfarin with a median international normalized ratio of 2.4 (interquartile range: 2.1–3.0), and 388 patients (36.5 %) were treated with novel oral anticoagulants (NOAC). ECG at follow-up showed no AF recurrence, and patients were in apparent sinus rhythm, suggesting that AF recurrence had a low impact on the results. In the Off-OAC group, 334 patients (31.7 %) were switched to antiplatelet drugs (ATT), and the remaining 721 patients (68.3 %) did not receive any ATT. The baseline patient characteristics did not differ significantly between the two groups (Table 1). All patients received anticoagulant therapy before discharge. Most patients who discontinued OAC after successful ablation did not have an absolute contraindication to anticoagulation, but discontinued for subjective factors, including an unwillingness to receive long-term anticoagulation therapy (13.3 %), poor medication compliance (7.3 %), minor bleeding (29.6 %), the belief that there was no need to continue anticoagulation therapy after "disappearance" of AF after ablation (42.7 %), and other subjective factors (7.1 %). Over half of the patients in the off-OAC group discontinued anticoagulation treatment within the first 6 months postoperatively. The anticoagulation discontinuation timeline after ablation in the off-OAC group is depicted in Supplementary Fig. S1. A total of 37.9 % of the patients adopted long-term use of antiarrhythmic drugs.

During the follow-up period, thromboembolic events occurred in 35 patients (26 ISs and 9 others) in the On-OAC group, with an incidence rate of 1.05/100 patient-years (24 warfarin and 11 NOAC). A total of 53 cases of mortality (1.59/100 patient-years) and 76 cases of major bleeding (2.29/100 patient-years), including 22 ICHs (0.66/100 patient-years) and 43 GIHs (1.30/100 patient-years), were reported with OAC use. Subgroup analysis showed that compared with warfarin, NOAC showed similar efficacy for stroke and MACE prevention (stroke: HR, 0.807; 95 % CI, 0.377–1.728; $P = 0.581$; MACE: HR, 0.942; 95 % CI, 0.590–1.503; $P = 0.801$) and similar rates of major bleeding (HR, 0.772; 95 % CI, 0.458–1.300; $P = 0.330$). Tabular data detailing descriptive statistics for each group is presented in Table 2. In the Off-OAC cohort, 76 thromboembolisms occurred (2.36/100 patient-years; 58 ISs, 18 others; 22 ATT, 54 no ATT), along with 51 deaths (1.58/100 patient-years) and 30 major bleeding events (0.93/100 patient-years) which includes 8 ICHs (0.25/100 patient-years) and 14 GIHs (0.43/100 patient-years). Thirty patients in the Off-OAC group and 15 in the On-OAC group had previous ischemic stroke/TIA.

Table 1
Baseline characteristics of the study population.

	General (2117)	On-OAC (1062)	Off-OAC (1055)	P
Age (years)	68.94 ± 9.21	69.29 ± 9.05	68.60 ± 9.35	0.083
Female	952 (45.0)	491 (46.2)	461 (43.7)	0.241
Persistent AF	911 (43.0)	465 (43.8)	446 (42.3)	0.483
CHA2DS2-VASc score	3.44 ± 1.12	3.47 ± 1.12	3.41 ± 1.12	0.231
HAS-BLED score	2.53 ± 0.71	2.55 ± 0.74	2.50 ± 0.68	0.136
Hypertension	1531 (72.3)	763 (71.8)	768 (72.8)	0.625
Diabetes mellitus	545 (25.7)	281 (26.5)	264 (25.0)	0.450
Previous stroke/TIA/TE	560 (26.5)	279 (26.3)	281 (26.6)	0.849
Coronary artery disease	863 (40.8)	433 (40.8)	430 (40.8)	0.995
Heart failure	507 (23.9)	268 (25.2)	239 (22.7)	0.164
LAD (mm)	42.30 ± 5.77	42.24 ± 5.79	42.37 ± 5.75	0.602
LVEF (%)	63.10 ± 6.34	63.18 ± 6.20	63.02 ± 6.48	0.563
Follow-up time	37.09 ± 13.35	37.51 ± 14.23	36.67 ± 12.39	0.147

AF, atrial fibrillation; CA, catheter ablation; OAC, oral anticoagulation; TIA, transient ischemic attack; TE, thromboembolism; LAD, left atrial diameter; LVEF, left ventricular ejection fraction.

Table 2
Relative risk of the clinical endpoints for NOAC patients.

Outcomes	Warfarin users (382)		NOAC users (365)	
	Cumulative incidence [n (%)]	Incidence rates (per 100 patient-years)	Cumulative incidence [n (%)]	Incidence rates (per 100 patient-years)
Thromboembolism	10 (2.6)	0.84	15 (4.1)	1.95
Major bleeding	26 (6.8)	2.17	9 (2.5)	1.04
All-cause death	18 (4.7)	1.50	12 (3.3)	1.69
MACE	26 (6.8)	2.17	20 (5.5)	2.46

NOAC, novel oral anticoagulant; MACE, major adverse cardiovascular events.

Kaplan–Meier survival analysis revealed that discontinuing OAC after AF ablation was associated with thromboembolic events (Log-rank $P < 0.001$), whereas maintaining OAC after ablation was associated with major bleeding events (Log-rank $P < 0.001$). In addition, long-term OAC use post-ablation was not associated with a significant reduction in all-cause mortality or MACE (Both log-rank $P > 0.05$; Fig. 2).

Subgroup analysis further showed that women [HR, 0.612; 95 % confidence interval (CI), 0.397–0.945; $P = 0.027$], patients ≥ 75 years of age (HR, 0.590; 95 % CI, 0.379–0.920; $P = 0.020$), and patients with high risk for stroke (HR, 0.705; 95 % CI, 0.504–0.987; $P = 0.041$) tended to benefit from long-term OAC use (Fig. 3).

A CHA2DS2-VASc score of 2 for men and 3 for women was associated with a relatively low cumulative incidence of adverse events, which did not differ significantly between the two groups (On-OAC vs. Off-OAC: thromboembolic events: 2.6 % vs. 4.1 %; all-cause mortality: 4.7 % vs. 3.6 %; MACE: 6.8 % vs. 5.2 %; all comparisons $P > 0.05$) except for the higher major bleeding rate in the On-OAC group (6.8 % vs. 2.2 %, $P = 0.002$). The Kaplan–Meier analysis indicated a similar composite endpoint rate in the On-OAC and Off-OAC groups (Log-rank $P = 0.479$; Fig. 4). The HR values of each clinical endpoint for Off-OAC patients with intermediate stroke risk before and after adjustment are presented in Table 3.

Although patients with high stroke risk had a higher incidence of major bleeding while maintaining long-term OAC post-ablation (Log-rank $P = 0.002$), they were more likely to benefit from the reduction of thromboembolic events and MACE (log-rank $P < 0.05$ for

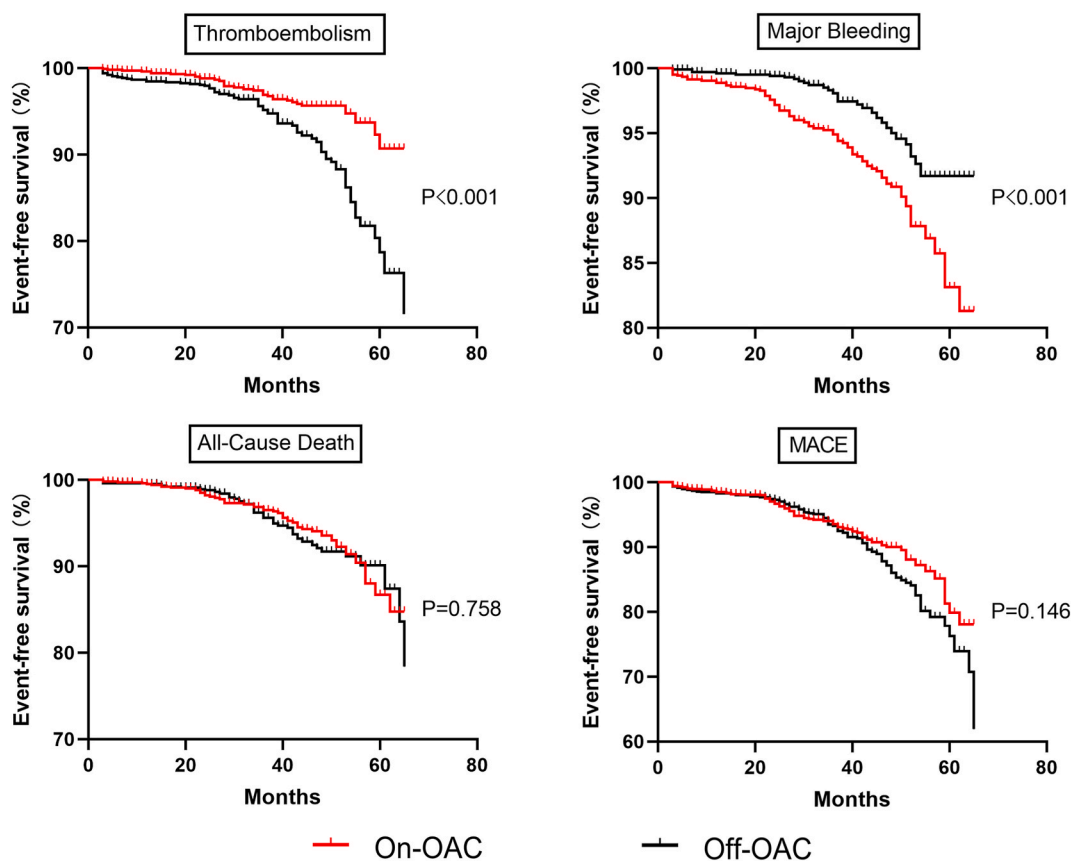


Fig. 2. Kaplan–Meier curves for freedom from endpoint events of the two groups. Event-free survival of thromboembolisms, major bleeding events, all-cause mortality and MACEs. OAC, oral anticoagulation; MACEs, major adverse cardiovascular events.

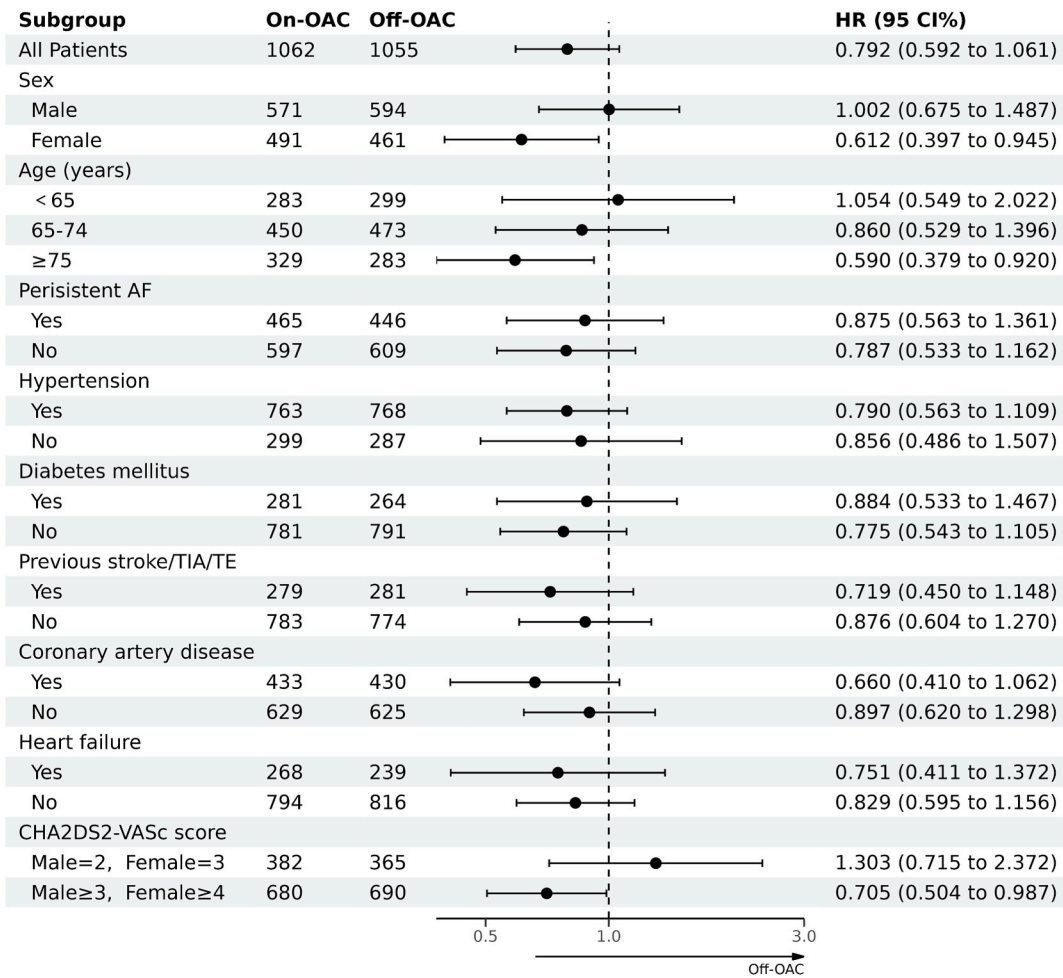


Fig. 3. Subgroup analysis. AF, atrial fibrillation; OAC, oral anticoagulation; TIA, transient ischemic attack; TE, thromboembolism; HR, hazard ratio; CI, confidence interval.

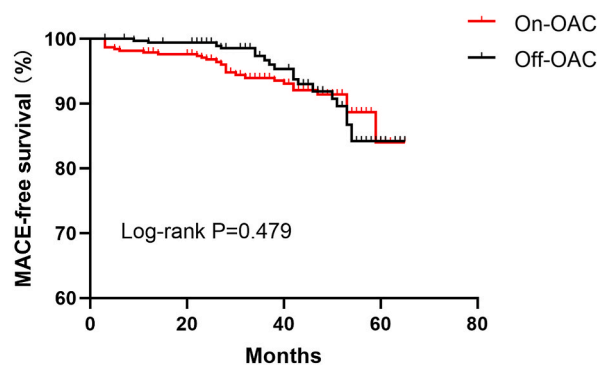


Fig. 4. Kaplan–Meier curves for freedom from endpoint events between groups in men with a CHA2DS2-VASc score = 2, and women with a CHA2DS2-VASc score = 3. OAC, oral anticoagulation; MACEs, major adverse cardiovascular events.

both; [Supplementary Fig. S2](#)). This represented a 59 % and 26 % relative risk reduction for thromboembolic events and MACE, respectively ([Supplementary Fig. S3](#)). Cox regression analysis revealed that age (HR, 1.048; 95 % CI, 1.027–1.070; $P < 0.001$) and history of thromboembolism (HR, 1.913; 95 % CI, 1.359–2.693; $P < 0.001$; [Table 4](#)) were independent risk factors for MACE events.

Table 3
Relative risk of the clinical endpoints for Off-OAC patients.

Outcomes	On-OAC (382)		Off-OAC (365)		Unadjusted		Adjusted	
	Cumulative incidence [n (%)]	Incidence rates (per 100 patient-years)	Cumulative incidence [n (%)]	Incidence rates (per 100 patient-years)	HR (95 % CI)	P value	HR (95 % CI)	P value
Thromboembolism	10 (2.6)	0.84	15 (4.1)	1.95	1.344 (0.596–3.028)	0.476	1.275 (0.558–2.916)	0.565
Major bleeding	26 (6.8)	2.17	9 (2.5)	1.04	0.324 (0.146–0.720)	0.006*	0.335 (0.150–0.749)	0.008*
All-cause death	18 (4.7)	1.50	12 (3.3)	1.69	0.885 (0.431–1.821)	0.741	0.877 (0.423–1.815)	0.723
MACE	26 (6.8)	2.17	20 (5.5)	2.46	0.768 (0.422–1.398)	0.388	0.728 (0.398–1.332)	0.303

HRs were calculated based on cumulative incidence. HR adjustment for age and sex was performed with the use of a Cox hazard regression model. HR (95 % CI), hazard ratio (95 % confidence interval); OAC, oral anticoagulation; MACE, major adverse cardiovascular events. *P < 0.05.

Table 4
Individual risk factors associated with MACE after AF ablation.

Variable	Univariate		Multivariate	
	HR (95 % CI)	P-value	HR (95 % CI)	P-value
OAC discontinuation	0.807 (0.603–1.079)	0.148		
Age	1.042 (1.024–1.060)	< 0.001*	1.048 (1.027–1.070)	< 0.001*
Female	1.079 (0.809–1.440)	0.604		
Persistent AF	1.006 (0.753–1.345)	0.966		
Congestive heart failure	0.884 (0.629–1.244)	0.481		
Hypertension	1.057 (0.763–1.466)	0.737		
Diabetes mellitus	1.377 (1.031–1.871)	0.041*	1.366 (0.991–1.885)	0.057
Previous stroke/TIA/TE	1.717 (1.278–2.307)	< 0.001*	1.913 (1.359–2.693)	< 0.001*
Coronary artery disease	0.827 (0.615–1.112)	0.209		
CHA2DS2-VASc score	1.286 (1.143–1.447)	< 0.001*	1.047 (0.896–1.223)	0.564
HAS-BLED score	1.289 (1.064–1.563)	0.010*	0.886 (0.696–1.127)	0.324
LAD	1.009 (0.985–1.034)	0.453		

HR adjustment was performed with the use of a Cox hazard regression model. HR (95 % CI), hazard ratio (95 % confidence interval); AF, atrial fibrillation; MACE, major adverse cardiovascular events; CA, catheter ablation; OAC, oral anticoagulation; TIA, transient ischemic attack; TE, thromboembolism; LAD, left atrial diameter; LVEF, left ventricular ejection fraction. *P < 0.05.

4. Discussion

In this study, we analyzed real-world follow-up data from patients who underwent successful catheter ablation for AF and found that nearly half of the patients with AF and a CHA2DS2-VASc scores ≥ 2 in men and ≥ 3 in women discontinued OAC therapy after successful catheter ablation. Further, cessation of anticoagulation therapy after ablation increased the risk of thromboembolism but did not significantly increase the risk of all-cause mortality and MACE, whereas long-term OAC therapy continuation after ablation was associated with increased major bleeding. Finally, anticoagulation therapy discontinuation after successful ablation may be considered safe in patients with intermediate stroke risk owing to the low stroke incidence rate.

Catheter ablation for AF can restore sinus rhythm and improve patient quality of life [4]. However, studies have suggested that the risk of stroke is higher in patients with AF after ablation than in those without AF. Noseworthy et al. [6] analyzed the long-term anticoagulation status of 6886 patients with AF for 10 years after catheter ablation and found that the 12-month OAC discontinuation rates of patients with CHA2DS2-VASc scores of 0–1 and ≥ 2 were 82 % and 62.5 %, respectively, whereas patients with a score ≥ 2 had an increased risk of thrombosis when warfarin administration was terminated after ablation. The CABANA trial [8] also showed that catheter ablation did not reduce the risk of thromboembolism in patients with AF. The main reasons for this are as follows: first, the recurrence of asymptomatic AF [9,10]; second, left atrial ablation injury may increase the risk of thromboembolism [11]; third, improving ablation is difficult in poor and the presence of atrial cardiomyopathy [12,13]; fourth, in addition to AF, stroke risk factors, such as old age and associated comorbidities, persist for a long time.

Notably, some studies, have reported contradicting results. A prospective, real-world, observational registry study conducted in China (n = 4512) found a lower risk of thromboembolism and major bleeding events in patients who discontinued OAC therapy, weighing the risk-benefit ratio in favor of OAC therapy discontinuation [7]. Large-scale studies based on data from Denmark's and Sweden's AF management registries also reported a low stroke risk with OAC discontinuation after AF ablation [14,15]. These inconsistencies in the findings across studies may be due to differences in the patients' race/ethnicity, baseline characteristics, follow-up duration, or recurrence rates.

The present study aimed to identify the real-world risk of OAC discontinuation after successful catheter ablation for AF. As

anticoagulant therapy is not recommended for low-risk stroke patients in the current guidelines, low stroke risk patients were not included in this study. As expected, our data showed that long-term anticoagulation therapy after successful ablation of AF in patients with a high risk of stroke significantly reduced stroke events, however, it also increased the risk of major bleeding. The incidence of stroke events in men and women with a CHA2DS2-VASc score of 2 and 3, respectively, was low and the benefit of long-term OAC was limited considering the risk of major bleeding, all-cause mortality, and MACE events; therefore, discontinuing long-term OAC in these patients may be reasonable.

Our cohort included a mix of patients using warfarin and DOACs. The superior bleeding profile of DOACs over warfarin has been documented in previous studies [16]; [17] however, the bleeding event induced by the two kinds could not be defined in our cohort due to the small patient numbers. Further studies are required to clarify this issue.

In practice, approximately 70 % of patients with AF discontinue anticoagulation therapy after successful ablation, and nearly 40 % of these patients are at a high risk of stroke [6], [7,18] which is consistent with our follow-up results. This highlights the importance of patient health education and long-term follow-ups. The results of this study further emphasize the importance of long-term OAC use after successful catheter ablation for AF in men with a CHA2DS2-VASc score ≥ 3 and women with a score ≥ 4 .

We agree that strict monitoring of rhythm status is crucial in deciding to stop anticoagulation after 'successful' catheter ablation, however, this procedure is not always followed in real world clinical practice. LAAC, a possible alternative to anticoagulation for AF, provides an alternative for stroke prevention in patients with a high risk of bleeding. Recent ongoing studies at our center have compared the efficacy and safety of left atrial appendage occlusion after ablation for AF with those of OAC to determine whether combined occlusion is a reasonable and safe alternative to anticoagulation for stroke prevention in high-risk patients after successful ablation.

5. Limitation

The single-center retrospective nature of the current study, moderate sample size, and moderate follow-up duration may have led to selection bias and bias in the results. Since strict monitoring of rhythm status by Holter was not applied to each patient in our study, asymptomatic AF recurrence could not be ensured; this is a significant study limitation of our study. Strict inclusion criteria resulted in the exclusion of a significant number of patients, which may present a bias. In the Cox models, adjustment was made only for age and sex, as no significant differences in baseline characteristics were observed. However, this resulted in a remarkable potential for differences in unmeasured characteristics to serve as confounders. Although subgroup analysis found that the benefit of long-term OAC was more in men with a CHA2DS2-VASc score ≥ 3 and women with a score ≥ 4 . Notably, the results of the subgroup analysis must be interpreted with caution as selection bias could not be avoided and given the small sample size and number of events, the results have less reliability. The presented subgroup analysis results are described for descriptive reasons only. We aim to conduct a multicenter randomized controlled prospective study to further verify the results of our study.

6. Conclusion

Men with CHA2DS2-VASc score 2 and women with score 3, showed reduced stroke incidence after successful AF catheter ablation, permitting safe long-term OAC discontinuation. Greater OAC benefits were seen in men with CHA2DS2-VASc score ≥ 3 and women with score ≥ 4 . Strict monitoring of rhythm status is crucial in the decision to discontinue anticoagulation after successful catheter ablation. Future long-term prospective studies are needed to corroborate our findings.

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Ethics declarations

The study protocol was approved by the Ethics Committee of Xinhua Hospital Affiliated with Shanghai Jiao Tong University School of Medicine (No. XHEC-D-2024-026). The requirement for informed consent was waived because of the retrospective nature of the study.

Data availability statement

The study data were not deposited in publicly available repositories but will be made available upon request.

CRedit authorship contribution statement

Zhen-Tao Fei: Writing – original draft, Validation, Resources, Methodology, Investigation, Data curation. **Peng-Cheng Yao:** Writing – original draft, Formal analysis, Data curation. **Mu Chen:** Validation, Software, Investigation, Conceptualization. **Yu-Dong Fei:** Software, Project administration, Investigation, Funding acquisition. **Wei Li:** Writing – review & editing, Validation, Methodology, Formal analysis. **Peng-Pai Zhang:** Writing – review & editing, Resources, Investigation, Data curation. **Jian Sun:** Visualization,

Validation, Methodology, Investigation, Formal analysis. **Qun-Shan Wang:** Writing – review & editing, Validation, Methodology, Conceptualization. **Yi-Gang Li:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Funding acquisition.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that AI and AI-assisted technologies were not used in the writing process.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2024.e32516>.

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