

Catheter ablation versus medical therapy for atrial fibrillation with prior stroke history: a prospective propensity score-matched cohort study

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ABSTRACT

BACKGROUND Patients with atrial fibrillation (AF) and prior stroke history have a high risk of cardiovascular events despite anticoagulation therapy. It is unclear whether catheter ablation (CA) has further benefits in these patients.

METHODS AF patients with a previous history of stroke or systemic embolism (SE) from the prospective Chinese Atrial Fibrillation Registry study between August 2011 and December 2020 were included in the analysis. Patients were matched in a 1:1 ratio to CA or medical treatment (MT) based on propensity score. The primary outcome was a composite of all-cause death or ischemic stroke (IS)/SE.

RESULTS During a total of 4.1 ± 2.3 years of follow-up, the primary outcome occurred in 111 patients in the CA group (3.3 per 100 person-years) and in 229 patients in the MT group (5.7 per 100 person-years). The CA group had a lower risk of the primary outcome compared to the MT group [hazard ratio (HR) = 0.59, 95% CI: 0.47–0.74, $P < 0.001$]. There was a significant decreasing risk of all-cause mortality (HR = 0.43, 95% CI: 0.31–0.61, $P < 0.001$), IS/SE (HR = 0.73, 95% CI: 0.54–0.97, $P = 0.033$), cardiovascular mortality (HR = 0.32, 95% CI: 0.19–0.54, $P < 0.001$) and AF recurrence (HR = 0.33, 95% CI: 0.30–0.37, $P < 0.001$) in the CA group compared to that in the MT group. Sensitivity analysis generated consistent results when adjusting for time-dependent usage of anticoagulants.

CONCLUSIONS In AF patients with a prior stroke history, CA was associated with a lower combined risk of all-cause death or IS/SE. Further clinical trials are warranted to confirm the benefits of CA in these patients.

Atrial fibrillation (AF) is the leading arrhythmic disease posing a significant health burden globally.^[1] AF substantially increases the risk of cardiovascular morbidity and mortality including cardiovascular death, heart failure (HF), acute coronary syndrome, and stroke.^[2] Stroke is the most common comorbidity with AF, and around 25% of these patients also have AF.^[3,4] Previous publications show AF patients with a prior stroke history maintain an increased risk of recurrent stroke, occurring in up to 21% of

these patients in five-year follow-up, together with increased risk of long-term cardiovascular death and worsening HF.^[5] Under current guidelines, besides management of cardiovascular risk factors, oral anticoagulation is recommended for the prevention of stroke in AF patients.^[6] However, even with anticoagulant use, the AF population with stroke history is still associated with a higher recurrence of stroke, indicating that interventions beyond anticoagulation were warranted for these people.^[7]

In 2020, the Early Treatment of Atrial Fibrillation for Stroke Prevention Trial (EASTAFNET 4) showed that early rhythm control strategy significantly reduced stroke and cardiovascular risk in patients with recent AF,^[8] and its benefit could extend to those with prior stroke history.^[9] As an important therapy for rhythm control, catheter ablation (CA) has shown its superiority over anti-arrhythmic drugs (AAD) due to its lower AF recurrence and improvement in quality of life.^[10] However, its effect on stroke or cardiovascular risk remains uncertain, especially in patients with previous stroke history who were excluded in the latest randomized clinical trial that compared CA to medical treatment (MT) on patients' outcomes.^[11-13]

Using data from the Chinese Atrial Fibrillation (China-AF) Registry, we investigated the efficacy of CA in comparison to MT for AF patients with previous stroke history and provided evidence for its further impact on cardiovascular risk in these patients.

METHODS

Study Population

The China-AF Registry is a prospective, multicenter, and ongoing study of AF patients recruited from 19 tertiary and 12 non-tertiary hospitals in Beijing, China. Data collected between August 2011 and December 2020 were used for analyses. The rationale and design of the study were published previously.^[14] This study was conducted in line with the Declaration of Helsinki and was approved by the Ethics Committee of Beijing Anzhen Hospital, Capital Medical University, Beijing, China. Informed consent was collected from all study participants.

Inclusion and Exclusion Criteria

Patients fulfilling the following criteria were included in the study: (1) AF patients with age ≥ 18 years; and (2) with a previous history of thromboembolism including ischemic stroke (IS) or systemic embolism (SE). We excluded patients with the following conditions from the analysis: patients with valvular AF or those who withdrew before the end of follow-up. If a patient received more than one CA, we anchored the date of the first ablation and used it as the index date. For the MT group, we identified patients who were not treated with CA at any time but were treated with MT (AAD or rate control drugs).

Catheter Ablation and Medical Treatment

The CA strategy utilized among participating centers was previously described, as circumferential pulmonary vein isolation was routinely performed for paroxysmal AF patients and three additional linear ablations at the left atrial roof, cavotricuspid and mitral isthmus were performed for persistent AF patients. The procedural endpoint was to achieve circumferential pulmonary vein isolation and bidirectional conduction block of the additional linear lesion.

Long-term oral anticoagulant therapy was recommended in all patients without absolute contradiction for oral anticoagulant in both groups. This recommendation persists even after a successful ablation procedure since all included patients had CHA₂DS₂-VASc score ≥ 2 and with a high risk for stroke recurrence. The choice of anticoagulant relied on the joint decision made by patients and physicians. AAD prescription for AF was decided by physicians.

Follow-up and Outcome

Patients enrolled in the registry were followed by telephone interviews or via outpatient clinics on the 3rd, 6th, 12th, and every 6 months thereafter. During each follow-up, information on patients' status, symptoms, drug treatment, electrocardiogram (ECG) and 24-hour Holter results was collected. Additional ECG or 24-hour Holter was performed if symptoms took place.

The primary outcome was a composite of all-cause death or IS/SE. The secondary outcome was as follows: all-cause death, IS/SE, cardiac death, cardiovascular hospitalization, and AF recurrence. AF recurrence was defined as atrial tachyarrhythmia ≥ 30 s confirmed by a 12-lead ECG or 24-hour Holter monitoring after a three-month blanking period from the initiation in both groups.

Statistical Analysis

Continuous and ordinal variables were described as mean $\pm$ SD or medians (interquartile range) depending on whether the data were normally distributed, while categorical variables were described as counts (percentages). The two-sample *t*-tests and the Pearson's chi-squared tests were used for continuous variables and categorical variables, respectively.

Patients with and without CA were matched 1:1 using propensity score matching (PSM) to minimize potential bias thanks to the uneven distribution of baseli-



ne covariate. PSM calculations were based on the main variables including age, sex, body mass index, AF duration, type of AF, smoking status, drinking status, and comorbidity. The 0.1 was considered as a caliper for the PSM method. Kaplan-Meier analysis was used to compare the results of the primary outcome between groups. Cox regression analyses were applied to assess the association between CA and outcomes. Two-tailed *P*-value < 0.05 were designated to be nominally significant.

In our sensitivity analysis, potential time-varying confounders influenced by anticoagulant drugs were adjusted to investigate the effect of CA on primary and secondary outcomes. We also performed subgroup analyses and multivariable Cox regression analyses to examine the comparative effect of CA on the primary outcome

and all-cause death stratified by variable baseline characteristics.

RESULTS

Patient Selection and Baseline Characteristics

Of 30,174 patients enrolled in the China-AF Registry between August 2011 and December 2020, 3563 patients met the inclusion criteria (supplemental material, Figure 1S). Of these, 1230 patients were treated with CA and 2333 patients were treated without CA (Table 1). Before PSM, the CA group tended to be younger, more male, shorter AF duration, lower CHA₂DS₂-VAsC score, lower prevalence rates of congestive HF, hypertension, di-

Table 1 Baseline characteristics of AF patients with and without ablation before and after propensity score matching.

Characteristics	Before matching			After matching		
	Ablation (n = 1230)	Non-ablation (n = 2333)	<i>P</i> -value	Ablation (n = 905)	Non-ablation (n = 905)	<i>P</i> -value
Age, yrs	64.3 ± 9.4	71.5 ± 9.8	< 0.01	66.4 ± 8.7	67.2 ± 9.3	0.06
Female	396 (32.2%)	991 (42.5%)	< 0.01	323 (35.7%)	335 (37.0%)	0.56
Body mass index, kg/m ²	25.6 ± 3.2	25.2 ± 3.4	0.51	25.5 ± 3.3	25.5 ± 3.5	0.78
AF type			< 0.01			0.25
Newly diagnosed	22 (1.8%)	181 (7.8%)		18 (2.0%)	38 (4.2%)	
Paroxysmal	694 (56.4%)	1039 (44.5%)		494 (54.6%)	450 (49.7%)	
Persistent	514 (41.8%)	1113 (47.7%)		393 (43.4%)	417 (46.1%)	
AF duration, yrs	3.8 ± 5.0	5.2 ± 7.1	0.01	4.5 ± 6.1	4.1 ± 5.2	0.75
Smoking	134 (10.9%)	216 (9.3%)	0.12	89 (9.8%)	89 (9.8%)	1.00
Drinking	129 (10.5%)	201 (8.6%)	0.07	92 (10.2%)	94 (10.4%)	0.88
Comorbidity						
Congestive heart failure	103 (8.4%)	664 (28.5%)	< 0.01	94 (10.4%)	87 (9.6%)	0.58
Hypertension	839 (68.2%)	1844 (79.0%)	< 0.01	656 (72.5%)	671 (74.1%)	0.43
Diabetes mellitus	319 (25.9%)	776 (33.3%)	< 0.01	254 (28.1%)	252 (27.8%)	0.92
Vascular disease	206 (16.8%)	644 (27.6%)	< 0.01	166 (18.3%)	169 (18.7%)	0.86
Chronic kidney disease, eGFR ≤ 60 mL/min per 1.73 m ²	86 (7.0%)	425 (18.2%)	< 0.01	81 (9.0%)	67 (7.4%)	0.23
Bleeding history	78 (6.3%)	184 (7.89%)	0.09	63 (7.0%)	68 (7.5%)	0.65
CHA ₂ DS ₂ -VAsC	4.1 ± 1.3	5.2 ± 1.6	< 0.01	4.36 ± 1.3	4.46 ± 1.3	0.06
Medication						
Oral anticoagulant	1191 (96.8%)	1181 (50.6%)	< 0.01	866 (95.7%)	868 (95.9%)	0.81
Warfarin	546 (45.8%)	1046 (88.5%)	< 0.01	419 (46.3%)	753 (83.2%)	< 0.01
Direct oral anticoagulant	645 (54.1%)	136 (11.5%)	< 0.01	447 (49.4%)	115 (12.7%)	< 0.01
Anti-arrhythmic drugs	532 (43.3%)	374 (16.0%)	< 0.01	406 (44.9%)	142 (15.7%)	< 0.01
Rate control	345 (28.1%)	1512 (64.8%)	< 0.01	277 (30.6%)	540 (59.7%)	< 0.01
Angiotensin-converting enzyme inhibitor/Angiotensin receptor blocker	396 (32.2%)	1040 (44.6%)	< 0.01	303 (33.5%)	352 (38.9%)	0.02
Statin	586 (47.6%)	1260 (54.0%)	0.03	451 (49.8%)	459 (50.7%)	0.71

Data are presented as means ± SD or *n* (%). AF: atrial fibrillation.



abetes mellitus (DM), vascular disease, chronic kidney disease, more often medication use including anticoagulant agents, AAD, and less often medication use such as rate control drugs, statin, and angiotensin-converting enzyme inhibitor/angiotensin receptor blocker. After 1:1 PSM, 905 patients in each group were included for analysis. Baseline differences between the two groups were significantly reduced. However, despite PSM, a statistically significant difference remained in terms of medication use, as the CA group tended to have more often use of direct oral anticoagulant (DOAC), and AAD, and less use of warfarin, rate control drugs and angiotensin-co-

nverting enzyme inhibitor/angiotensin receptor blocker.

Outcomes

During a total of 4.1 ± 2.3 years of follow-up, the primary outcome occurred in 111 patients in the CA group (3.3 per 100 person-years) and 229 patients in the MT group (5.7 per 100 person-years). CA was associated with a reduction in the composite outcome of all-cause mortality or IS/SE during follow-up [hazard ratio (HR) = 0.59, 95% CI: 0.47–0.74, $P < 0.001$] in Figure 1 and Table 2. Besides, CA was associated with a lower risk

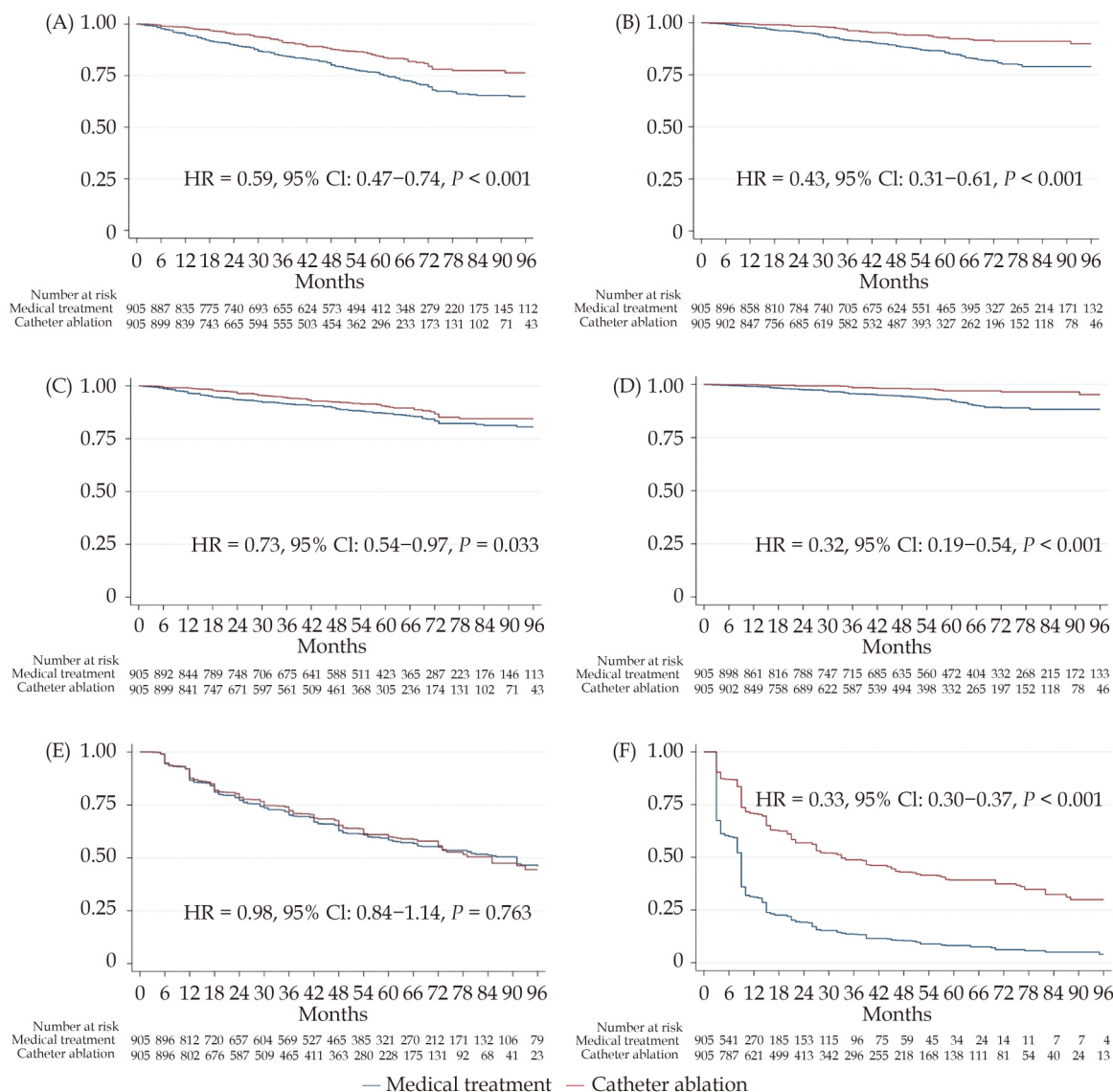


Figure 1 Kaplan-Meier curves for outcomes in the catheter ablation and medical treatment groups during follow-up for atrial fibrillation patients with prior stroke history. (A): The cumulative event of all-cause mortality or ischemic stroke/systemic embolism; (B): all-cause mortality; (C): ischemic stroke/systemic embolism; (D): cardiovascular mortality; (E): cardiovascular hospitalization; and (F): atrial fibrillation recurrence.



Table 2 The primary and secondary outcomes analysis for atrial fibrillation patients with and without ablation after propensity score matching.

Outcome	Medical treatment (n = 905)		Catheter ablation (n = 905)		Hazard ratio (95% CI)	$P_{\text{interaction}}$ -value
	Event/100 person-years	Event number during follow-up	Event/100 person-years	Event number during follow-up		
Primary outcome*	5.7	230	3.3	111	0.59 (0.47–0.74)	< 0.001
All-cause mortality	3.2	136	1.3	47	0.43 (0.31–0.61)	< 0.001
Ischemic stroke	2.9	119	2.1	71	0.73 (0.54–0.97)	0.033
Cardiovascular hospitalization	10.8	375	10.7	311	0.98 (0.84–1.14)	0.763
Cardiovascular mortality	1.6	72	0.5	18	0.32 (0.19–0.54)	< 0.001
Atrial fibrillation recurrence	78.1	792	22.2	478	0.33 (0.30–0.37)	< 0.001

*Refers to the cumulative event of all-cause mortality or ischemic stroke/systemic embolism.

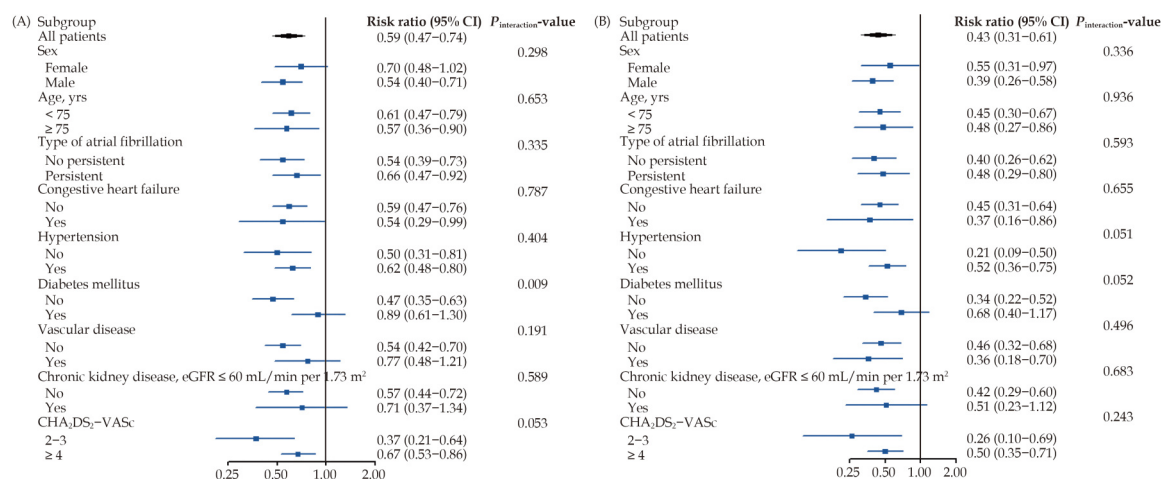
for all-cause mortality (HR = 0.43, 95% CI: 0.31–0.61, $P < 0.001$), IS/SE (HR = 0.73, 95% CI: 0.54–0.97, $P = 0.033$), cardiovascular mortality (HR = 0.32, 95% CI: 0.19–0.54, $P < 0.001$) and AF recurrence (HR = 0.33, 95% CI: 0.30–0.37, $P < 0.001$). The risk for cardiovascular hospitalization between the MT and CA groups was insignificant (HR = 0.98, 95% CI: 0.84–1.14, $P = 0.763$).

Subgroup and Sensitivity Analysis

To test the reliability of our results, subgroup analysis was further performed based on patients' baseline information, including sex, age, type of AF, comorbidity and CHA₂DS₂-VASc score, to investigate the impact of these factors on the primary outcome and all-cause mortality. The results of the primary outcome and all-cause mortality remained robust in most prespecified subgroups (Figure 2). Patients without DM seemed to ben-

efit more from CA ($P_{\text{interaction}} < 0.01$).

The proportions of patients receiving anticoagulation therapy during each follow-up interval are shown in Figure 3. In general, anticoagulants used over time in the CA group were lower than those in the MT group. Time-dependent analysis was performed to adjust the use of anticoagulant drugs in different groups. Primary and secondary outcomes remained robust (supplemental material, Table 1S). We also performed multivariable Cox regression to adjust the drug use at baseline with significant differences between the two groups after PSM. Results remained consistent as CA was associated with a lower risk for all-cause mortality or stroke (HR = 0.57, 95% CI: 0.44–0.75, $P < 0.001$), all-cause mortality (HR = 0.42, 95% CI: 0.29–0.62, $P < 0.001$), cardiovascular mortality (HR = 0.33, 95% CI: 0.18–0.59, $P < 0.001$), and AF recurrence (HR = 0.33, 95% CI: 0.30–0.37, $P < 0.001$).

**Figure 2** Subgroup analysis for outcomes during follow-up. (A): The cumulative event of all-cause mortality or ischemic stroke/systemic embolism; and (B): all-cause mortality.

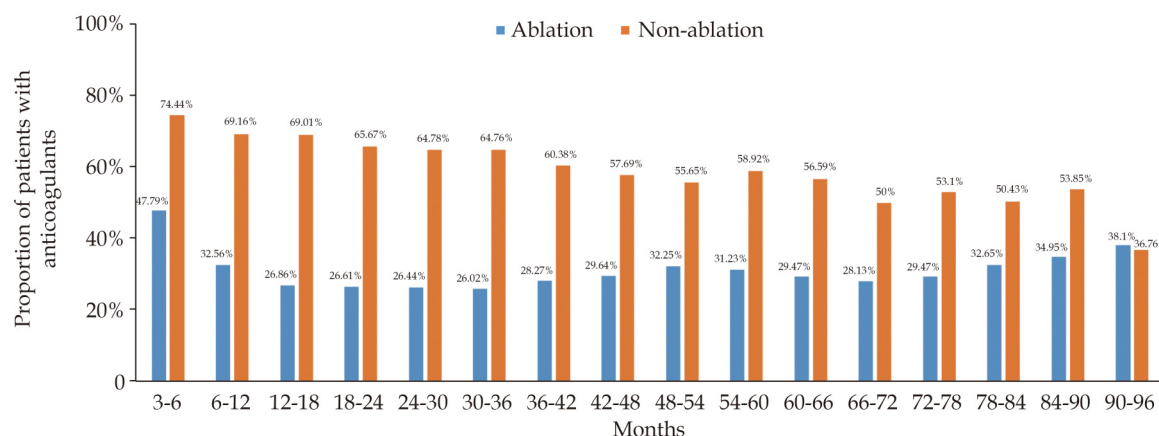


Figure 3 The proportion of anticoagulant exposure during follow-up intervals.

0.001), IS/SE (HR = 0.69, 95% CI: 0.49–0.99, $P = 0.044$) and AF recurrence (HR = 0.38, 95% CI: 0.33–0.44, $P < 0.001$) after the adjustment.

DISCUSSION

In this prospective, multicenter China-AF Registry, AF patients with prior stroke history, CA, compared to MT, were associated with a lower risk of the composite event of all-cause death and IS/SE, all-cause mortality, cardiovascular mortality, IS/SE, and AF recurrence.

Prior stroke is a well-established risk factor for future recurrent stroke and cardiovascular events in patients with AF. Previous randomized clinical trials have proven that DOACs were more effective and safer than warfarin for thromboembolism prevention in AF patients.^[15] However, with routine usage of anticoagulants, 7% of AF patients with prior stroke history underwent recurrent stroke in one year,^[7] and almost half of AF patients died of cardiac reasons (sudden cardiac death, HF, and myocardial infarction), showing unmet medical need still existing for patients with AF and prior stroke history.^[16]

Post hoc of EASTAFNET 4 indicated that early rhythm control therapy was associated with a lower risk of the composite outcome of cardiovascular death, stroke, or cardiovascular hospitalization compared to usual care, which is in line with the result from a retrospective analysis in the real-world datasets.^[9,17] However, in these two studies, less than 8% and 4%, respectively, of total patients in the early rhythm control group underwent CA. As an important technique for early rhythm control, large real-world studies showed the superiority of CA

over MT in the reduction of all-cause mortality, cardiac outcome, stroke and major bleeding risk.^[18,19] The CABANA (Catheter Ablation vs Antiarrhythmic Drug Therapy for Atrial Fibrillation) trial did not show a significant difference between CA and MT in terms of death, disabling stroke, serious bleeding, or cardiac arrest. However, its results were largely impacted by treatment crossovers between the two groups. Our result is consistent with the findings of the previous study showing that CA is associated with lower rates of mortality, stroke, major bleeding, and cardiac arrest than MT for patients with a prior thromboembolic history, indicating the additional benefit of CA beyond stroke prevention among these patients.^[20] Data from the subgroup study indicated that patients with DM seemed to benefit less from ablation when it comes to the reduction of the risk of all-cause mortality or stroke. DM has been well-recognized as an independent risk factor of cardiovascular mortality with or without other comorbidities like AF.^[21] Besides, diabetic patients are commonly comorbid with hypertension, hyperlipidemia and coronary heart disease, and these risk factors further increase the mortality risk. Therefore, in patients with DM, the effect of CA might be diminished by the pre-existing risks caused by DM or DM-associated comorbidities. Comprehensive management including regulation of AF comorbidities might be required for these patients.^[22] The continuation of anticoagulation among patients undergoing CA is still highly debated. Previous findings indicated that continuation DOAC among patients with $\text{CHA}_2\text{DS}_2\text{-VASc} \geq 2$ after CA was associated with a significant reduction of thromboembolic risk, whereas no benefit was observed among patients with $\text{CHA}_2\text{DS}_2\text{-VASc} \leq 1$.^[23,24] Despite



the benefits of continuation of DOAC after AF ablation, up to 30% of patients withdrew DOAC therapy during the first year. A recent study from a Chinese AF cohort demonstrated that the proportion of AF patients who started DOAC therapy after new-onset stroke was still low, as more than 40% discontinued DOAC therapy within two years after stroke.^[25] In our study, only 26% of patients in the CA group and 69% of patients in the MT group continued DOAC after a year. However, despite the proportion of patients with anticoagulant therapy in the MT group being significantly higher than in the CA group, CA still showed superiority over MT in terms of most outcomes, especially recurrent stroke events over the course of follow-up. These results were in line with a previous study showing that CA was associated with lower rates of recurrent stroke than MT for patients with a prior stroke in five-year follow-up.^[20] However, in that study, the baseline antithrombotic therapy usage was much higher in AF ablation patients (AF patients with ablation: 56.0%, AF patients without ablation: 14.3%, no AF participants: 1.4%, $P < 0.01$), making the results of alleviating effect of CA on stroke recurrence less credible. In addition, although baseline covariates in that study were adjusted by PSM, limited by the size and quality of the data sample, there were still significant differences among those covariates, like comorbidities and drug choices between ablation and non-ablation groups. In our study, after adjustment by PSM, the baseline differences between the two groups were largely reduced as only two parameters out of twelve remain different. Besides, the preventive effect of anticoagulant drugs is driven by therapy continuation over time, as more than 40%–50% of AF patients discontinued oral anticoagulant therapy after prescription in the previous study.^[26] Thus, as a potential time-dependent confounder, the usage of anticoagulants for patients with or without CA might change over time. To our knowledge, no previous studies have considered that. Therefore, accounting for baseline and time-varying confounders, we found that all results remained persistent after adjustment.

A series of randomized clinical trials and meta-analysis demonstrated that CA compared to MT was associated with reductions in AF recurrence, with no difference in major adverse events.^[11–13] Being consistent with these findings, our results illustrated the superiority of CA over MT in terms of AF recurrence reduction. Rec-

ent guidelines suggest CA can result in better symptoms and quality of life for AF patients, and the recommendations range from class I to IIA depending on whether patients with comorbidities like HF or whether AAD use was unsuccessful or intolerant.^[6] Some trials and large cohort studies showed that CA may be associated with lower mortality and stroke risk beyond improving quality of life.^[18,27] But no guideline up to now suggests performing ablation to reduce major adverse cardiovascular events. Our subgroup study found that CA showed significant superiority of primary outcome and all-cause mortality reduction over MT for AF patients with different characteristics including sex, age, type of AF, congestive HF, and hypertension. Further investigations are warranted.

LIMITATIONS

There are several limitations that must be noted. Firstly, residual confounders of uncalculated factors, including variation in comprehensive consideration by patients and physicians were unmeasured. Although we tried to eliminate these confounders through PSM, baseline variates like medication preferences remained unbalanced for several parameters after adjustment. Secondly, this study relied on admission data to stratify baseline characteristics and clinical outcomes, which might lead to misclassification. However, it is almost impossible to systematically ascertain the difference between two treatment groups, and thus, the misclassification should be non-differential. Last but not least, the anticoagulant treatment was not optimal in our study, as more than 30% of patients in the MT group and 70% of patients in the CA group discontinued usage of the anticoagulant during the follow-up. However, the sensitivity analysis suggested our primary and secondary outcomes remained robust after the time-varying adjustment of anticoagulant usage, indicating that CA still had a lower risk of the outcomes even under a higher rate of anticoagulant discontinuation. We also performed the multivariable Cox regression to adjust the use of drugs to reduce the bias related to the differences in drug use between the two groups. The results remained consistent, as ablation was still associated with a lower risk of all-cause mortality, cardiovascular mortality, stroke, or AF recurrence in these patients.



CONCLUSIONS

In AF patients with prior stroke history, CA was associated with a lower combined risk of all-cause death or IS/SE. Further clinical trials are warranted to confirm the benefits of CA in these patients.

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