Oral anticoagulant therapy for stroke prevention in patients with atrial fibrillation undergoing ablation: results from the First European Snapshot Survey on Procedural Routines for Atrial Fibrillation Ablation (ESS-PRAFA)

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The European Snapshot Survey on Procedural Routines in Atrial Fibrillation Ablation (ESS-PRAFA) is a prospective, multicentre snapshot survey of patients undergoing atrial fibrillation (AF) ablation, conducted to collect patient-based data on current clinical practices in AF ablation in context of the latest AF Guidelines and contemporary oral anticoagulant therapies. The EP Research Network Centres were asked to prospectively enrol consecutive patients during a 6-week period (September/October 2014). Data were collected via the web-based case report form. We present the results pertinent to the use of antithrombotic therapies. Thirteen countries prospectively enrolled 455 eligible consecutive patients [mean age 59 ± 10.8 years, 131 (28.8%) females]. The mean CHA2DS2-VASc score was 1.12 ± 1.06 [137 patients (30.1%) had a score of ≥ 2]. Before ablation, 443 patients (97.4%) were on anticoagulant therapy [143 (31.4%) on non-vitamin K antagonist oral anticoagulants (NOACs) and 264 (58.0%) on vitamin K antagonists (VKAs)]. Of the latter, 79.7% underwent ablation without VKA interruption, whilst a variety of strategies were used in patients taking NOAC. After ablation, most patients (89.3%) continued the same anticoagulant as before, and 2 (0.4%) were not prescribed any anticoagulation. At discharge, 280 patients (62.2%) were advised oral anticoagulation for a limited period of mean 3.8 ± 2.2 months. On multivariate analysis, CHA2DS2-VASc, AF duration, prior VKA use, and estimated AF ablation success were significantly associated with the decision on short-term anticoagulation. Our results show the increasing use of NOAC in patients undergoing AF ablation and emphasize the need for more information to guide the periprocedural use of both NOACs and VKAs in real-world setting.

Keywords

Atrial fibrillation • Oral anticoagulation • Ablation • Periprocedural anticoagulant therapy • Stroke prevention • Survey

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Introduction

Increasing number of patients with atrial fibrillation (AF) are undergoing catheter ablation, and recent reports from the real-world AF ablation registries suggest significant variability in procedural strategies.1,2 Adequate thromboprophylaxis with oral anticoagulant (OAC) therapy, either vitamin K antagonists (VKAs) or non-vitamin K antagonist oral anticoagulants (NOACs), is recommended for all AF patients with one or more stroke risk factors, including those undergoing AF ablation.3,4

Given the diversity of available treatment strategies regarding both the AF ablation procedure and the use of OAC, especially since the introduction of NOACs, the European Heart Rhythm Association (EHRA) Scientific Initiative Committee (SIC) designed the multicentre, prospective European Snapshot Survey on Procedural Routines in Atrial Fibrillation Ablation (ESS-PRAFA) in order to collect patient-based data on routine practice related to AF ablation in the context of the latest AF Guidelines and contemporary OAC therapies. We present the ESS-PRAFA results pertinent to the use of antithrombotic therapies in patients undergoing AF ablation in current real-world clinical practice in Europe.

Methods

Study design and data collection

The ESS-PRAFA is a prospective, multicentre snapshot survey of consecutive patients undergoing AF ablation, designed by the EHRA SIC and conducted over a 6-week period from 12 September to 27 October 2014.

The ESS-PRAFA was announced by the invitation letter, which was sent to the Electrophysiology (EP) Research Network Centres. Participation was also facilitated via the contact with the EHRA SIC members, Chairpersons of the National Working groups on Arrhythmias and the Regional EHRA Coordinators. The ESS-PRAFA was approved by the national and/or local Institutional Review Board, or the need for approval was waived according to the regulations in the respective country. Where requested by the local policy, a signed informed consent was obtained from patients before enrolment.

There was no pre-specified protocol or recommendation regarding the indications for AF ablation, ablation procedure, technique, equipment, and treatment before, during, and after the procedure, which were all left to the discretion of responsible physician. Data were collected using a web-based case report form (CRF) developed by the EHRA SIC to obtain the following information for each enrolled patient:

- **Centre parameters:** the centre type (i.e. university, non-university, private, or other hospital), annual number of AF ablations, and number of physicians performing the procedure in the centre.
- **Patient baseline characteristics:** age, gender, race, height, weight, clinical type of AF (i.e. paroxysmal, persistent, long-standing persistent, permanent), concomitant cardiac or other diseases, and medication (i.e. rhythm or rate control and upstream therapies).
- **Pre-, intra-, and post-procedural anticoagulant therapy:** the use of VKAs, NOACs, low molecular weight heparins (LMWHs), or unfractionated heparin (UFH) prior to, during and post AF ablation, as well as the choice of further antithrombotic strategy post discharge.
- **Procedure-related data:** the type of AF ablation (i.e. first-time procedure as a first-line therapy, first-time procedure following the antiarrhythmic drug(s) trial, or a re-do procedure), the AF ablation strategy (e.g. pulmonary vein isolation, linear ablation of the left atrium, etc.), the ablation energy source, equipment and technique, procedural endpoints, procedure-related parameters (e.g. ablation time, X-ray time, etc.), and complications recorded until discharge.

Owing to the short duration of the ESS-PRAFA systematic monitoring of centres was not performed. Participating centres and the national/regional co-ordinators were the guarantors of the consecutiveness of enrolment, authenticity, accuracy, and completeness of data and protection of safety and rights of subjects. The CRF, patient files (paper or database), tracings of investigations, and the questionnaire served as source documents.

Statistical analysis

Following a test of statistical normality, continuous variables were presented as mean (± SD), or with a skewed distribution as median with interquartile range (IQR, 25th to 75th quartile). Categorical variables were reported as counts with percentages. The Student’s t test was used for comparison of continuous variables with normal distribution, and Mann–Whitney test for continuous variables with skewed distribution. Differences in categorical variables were tested by χ² test.

Univariate and multivariate logistic regression analyses were used to investigate the associations of the centre parameters, patient baseline characteristics, and pre-procedural antithrombotic strategies with the choice of post-procedural OAC strategy. The c-statistic, a measure of the area under the receiver-operator characteristic curve, was used to quantify the predictive validity of the multivariable models identifying independent predictors of persistent or limited-duration OAC therapy post AF ablation. All statistical analyses were performed using SPSS 20.0 software package (SPSS Inc., Chicago, IL, USA). A two-sided P-value of < 0.05 was considered statistically significant.

Results

Participating countries and patient enrolment

During the 6-week snapshot survey period, 13 countries submitted a total of 466 patients undergoing AF ablation (Figure 1). After excluding 11 submissions (3 duplicates and 8 empty submissions), 455 patients were entered into further analyses.

Most patients were recruited from university hospitals (n = 385, 84.6%), whilst 35 patients (7.7%) each were from non-university hospitals or private hospitals; 267 patients (58.7%) were from the centres performing 100–299 AF ablations per year, 129 patients (28.4%) from the centres performing ≥ 300 AF ablations per year, and 59 patients (12.9%) were included from the centres performing < 100 AF ablations annually.

Baseline characteristics

Patient baseline characteristics are shown in Table 1. Most patients were Caucasians (423, 93.0%) and relatively young (the median age was 61, IQR: 53–68 years); 318 patients (69.9%) had a CHA2DS2-VASC score of 0–1, and only 9 patients (2.0%) had a HASBLED score of 3 (none of the patients had a HASBLED of 4 or more).

Anticoagulant therapy prior to ablation

Overall, 443 patients (97.4%) received OAC therapy prior to AF ablation (Table 1) for at least 3 weeks before ablation. Of those, 264 patients (58.0%) were taking a VKA. Of 143 patients (31.4%) taking a NOAC, only 6 patients (1.3%) were subjected to specific adherence follow-up strategies, such as everyday reporting system,
dosage labelled package, etc. Of 12 patients (2.6%) who were not taking any anticoagulant therapy prior to AF ablation, all had paroxysmal AF and a CHA2DS2-VASc score of 0 or 1 (10 and 2 patients, respectively). Only 1 patient had a HASBLED score of 2 (in other 11 patients the score was 0).

To exclude a thrombus in the left atrial appendage, 201 patients (44.3%) underwent transoesophageal echocardiography (TOE), 58 (12.8%) computed tomography (CT) of the chest, and 145 patients (31.9%) underwent both diagnostic procedures, whilst 50 patients (11.0%) were subjected to neither TOE nor CT for the purpose of thrombus detection (data are missing for one patient). Of the latter, 16 patients (32.0%) had a CHA2DS2-VASc score of 0, 19 (38.0%) had a CHA2DS2-VASc score of 1, whilst 15 patients (30.0%) had a CHA2DS2-VASc score of ≥ 2. Of 12 patients who were not taking any anticoagulant therapy prior to AF ablation, 4 patients underwent the procedure without prior TOE or CT examination.

**Oral anticoagulant therapy during ablation**

Along with intraprocedural parenteral anticoagulation which was used in line with the local AF ablation protocols, a total of 240 patients (54.7% of 443 patients taking OAC) underwent AF ablation under uninterrupted VKA with a therapeutic international normalized ratio (INR) of mean 2.4 ± 0.6 (range of 1.0–4.0) and median INR value of 2.0, IQR: 2.0–3.0 (INRs were available for 183 patients). Bridging with heparin (either UFH or LMWH) was used in a minority of patients (n = 60, 13.6%), and in four patients a VKA was interrupted 24 h prior to AF ablation and no bridging was used.

Of 264 patients who were taking a VKA before AF ablation, data on the intraprocedural OAC strategy were available for 261. Of these, 208 (79.7%) underwent AF ablation under uninterrupted VKA with therapeutic INR value.

Of 125 patients (27.7%) treated with NOAC, the procedure was performed under uninterrupted NOAC therapy in 17 patients (3.9%), with a brief NOAC interruption (1–2 doses) in 66 patients (15.0%), whilst NOAC was interrupted ≥ 2 days prior to AF ablation in 42 patients (9.6%), and bridging with LMWH was used in 3 of these patients (Table 2A).

**Oral anticoagulant therapy after ablation**

Following AF ablation, most patients were prescribed the same OAC drug as before the procedure (n = 402, 89.3%), and only two patients (0.4%) were not prescribed any OAC (Table 2B and Figure 2). Overall, the use of VKAs after the procedure was significantly associated with the CHA2DS2-VASc score (OR 1.21; 95% CI, 1.02–1.46, P = 0.033) and AF clinical type (OR 1.58; 95% CI, 1.12–2.21, P = 0.009), whilst
Oral anticoagulation for AF ablation

Table 1: Baseline characteristics of the ESS-PRAFA study population, including anticoagulant therapy and other medications prior to AF ablation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Range</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>CHA2DS2-VASc components</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>25–88</td>
<td>59.5 ± 10.8</td>
<td>61.0</td>
<td>HF or LVEF &lt; 40%</td>
<td>47</td>
<td>10.3</td>
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<tr>
<td>Body mass index</td>
<td>18.6–43.2</td>
<td>27.1 ± 4.1</td>
<td>26.4</td>
<td>Hypertension</td>
<td>176</td>
<td>38.7</td>
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<tr>
<td>CHA2DS2-VASc</td>
<td>0–5</td>
<td>1.12 ± 1.06</td>
<td>1.00</td>
<td>Diabetes mellitus</td>
<td>33</td>
<td>7.3</td>
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<tr>
<td>HASBLED</td>
<td>0–3</td>
<td>0.60 ± 0.75</td>
<td>0.00</td>
<td>Prior stroke/TIA</td>
<td>19</td>
<td>4.2</td>
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<td>CHA2DS2-VASc by category</td>
<td>n</td>
<td>Percentage</td>
<td></td>
<td></td>
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<tr>
<td>0</td>
<td>148</td>
<td>32.5</td>
<td></td>
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<tr>
<td>1</td>
<td>170</td>
<td>37.4</td>
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<tr>
<td>2</td>
<td>90</td>
<td>19.8</td>
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<td>4–5</td>
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<tr>
<td>AF clinical type</td>
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<td>Percentage</td>
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<tr>
<td>Paroxysmal</td>
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<td>66.5</td>
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<td>Persistent</td>
<td>129</td>
<td>28.4</td>
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<td>Long-standing persistent</td>
<td>23</td>
<td>5.1</td>
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<tr>
<td>Anticoagulant therapy prior to AF ablation</td>
<td>n</td>
<td>Percentage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VKAs</td>
<td>264</td>
<td>58.0</td>
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<tr>
<td>A NOAC</td>
<td>143</td>
<td>31.4</td>
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<tr>
<td>Dabigatran</td>
<td>51</td>
<td>11.2</td>
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<tr>
<td>Rivaroxaban</td>
<td>75</td>
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<td>Apixaban</td>
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<td>LMWH</td>
<td>8</td>
<td>1.7</td>
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<tr>
<td>Other (e.g. aspirin, etc.)</td>
<td>18</td>
<td>4.0</td>
<td></td>
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<tr>
<td>No anticoagulant</td>
<td>12</td>
<td>2.6</td>
<td></td>
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<tr>
<td>The LAA occlusion</td>
<td>0</td>
<td>0.0</td>
<td></td>
<td></td>
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<tr>
<td>Other medication prior to AF ablation</td>
<td>n</td>
<td>Percentage</td>
<td></td>
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<tr>
<td>ACEi/ARB</td>
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<td>36.0</td>
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<td>Beta blocker</td>
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<tr>
<td>Ca-channel blocker</td>
<td>38</td>
<td>8.4</td>
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<tr>
<td>Digitalis</td>
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<td>3.1</td>
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<td>Amiodarone</td>
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<td>22.9</td>
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<td>Dronedarone</td>
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<td>Other AAD</td>
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<td>Diuretic</td>
<td>52</td>
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<td>Statin</td>
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<td>22.4</td>
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<tr>
<td>NSAIDs</td>
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<td>2.2</td>
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</tbody>
</table>

SD, standard deviation; AF, atrial fibrillation; AADs, antiarrhythmic drugs; HF, heart failure; LVEF, left ventricular ejection fraction; TIA, transient ischaemic attack; MI, myocardial infarction; PAD, peripheral artery disease; VKA, vitamin K antagonist; NOAC, non-vitamin K antagonist oral anticoagulant; LMWH, low molecular weight heparin; LAA, left atrial appendage; NSAID, non-steroidal anti-inflammatory drug; ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

aData available for 417 patients.

bOne patient is missing.

There were no significant relationships between the use of NOACs and patient baseline characteristics.

Most patients (n = 280, 62.2%) were advised OAC for a limited period of time (1–12 months, mean 3.8 ± 2.2, median 3, IQR: 3–3 months) during the follow-up, whilst 168 patients (37.3%) were prescribed continuous OAC (Figure 3). None of the patients were prescribed aspirin or a P2Y12 inhibitor at discharge. Factors influencing the physician’s decision on OAC duration post AF ablation were: the stroke risk as estimated by the CHA2DS2-VASc score (in 407 patients, 89.5%), the estimated risk of AF recurrence (n = 82, 18.0%), the estimated success of AF ablation (n = 108, 23.7%), the patient’s preference (n = 5, 1.1%), or other (n = 37, 8.1%).

Factors associated with the prescription of continuous OAC post AF ablation are shown in Table 3. On univariate analysis, the centre type, annual number of AF ablations per centre, the CHA2DS2-VASc and HASBLED scores, AF clinical type, the use of VKAs and NOACs prior to AF ablation, and the estimated success of AF ablation were all significantly associated with the prescription of persistent OAC therapy post AF ablation.

On multivariate analysis, the CHA2DS2-VASc score, AF clinical type, the use of a VKA before AF ablation, and the estimated success of the procedure were independent predictors of the continuous OAC therapy post AF ablation (Table 3), with a very good model predictive ability (model c-statistic 0.82, 95% CI, 0.78–0.86, P < 0.001).

Regarding the single components of the CHA2DS2-VASc score, the following were significantly associated with continuous OAC therapy post AF ablation on univariate analysis (OR; 95% CI): age (2.84; 1.91–4.22, P < 0.001), heart failure or reduced left ventricular ejection fraction (6.03; 3.03–11.99, P < 0.001), hypertension (2.39; 1.61–3.54, P < 0.001), diabetes mellitus (2.18; 1.07–4.44, P = 0.033), and previous myocardial infarction (8.17; 3.28–20.41, P < 0.001), whilst the association was non-significant for prior stroke/transient ischaemic attack (2.44; 0.96–6.20, P = 0.060), peripheral artery disease (2.31; 0.51–10.44, P = 0.277), and female gender (1.41; 0.93–2.14, P = 0.102).
The same parameters were also associated with the prescription of limited duration of OAC therapy post AF ablation, but the associations were mostly in the opposite direction compared with the persistent OAC prescription (Table 2).

In general, the use of VKAs was more likely in patients with a higher CHA2DS2-VASc score (OR 1.22; 95% CI, 1.02–1.46) and in those with non-paroxysmal AF (OR 1.58; 95% CI, 1.12–2.21) than in those with paroxysmal AF. Hypertension was the most prevalent comorbidity. Similar to patients in other AF ablation registries, our patients were relatively young, at low stroke and bleeding risk and mostly with paroxysmal AF. Hypertension was the most prevalent comorbidity.

Nearly one-third of the ESS-PRAFA patients were on a NOAC before AF ablation, which is most likely a reflection of increasing availability and uptake of NOACs in Europe. However, only a minority of these patients were subjected to a strategy for monitoring the adherence to NOAC therapy before AF ablation. In contrast to VKAs, there was a larger variety of intraprocedural approaches when NOACs were used in the ESS-PRAFA survey, including uninterrupted therapy, temporary NOAC discontinuation at variable time points before AF ablation, or even NOACs discontinuation with heparin bridging (Table 2). This is comparable with a recent report describing current European practices in acute coronary syndrome, which reflects the lack of valid recommendations for NOAC in this setting. Indeed, available data on the safety of the periprocedural use of NOACs in AF ablation (namely, dabigatran...
and rivaroxaban) are to some extent limited, and ongoing randomized clinical trials of periprocedural anticoagulation for AF ablation will better inform daily clinical practice.\textsuperscript{13–20}

In line with current recommendation,\textsuperscript{3,4,7} essentially all ESS-PRAFA patients were prescribed OAC post AF ablation, and almost two-thirds were advised to take OAC for a limited period of time. Independent factors influencing such decision were the patient’s risk of stroke as estimated by the CHA\textsubscript{2}DS\textsubscript{2}–VASc score, AF clinical type, the prior use of a VKA, and the estimated success of AF ablation. Indeed, available data suggest that the thrombo-embolic risk is greatest during the first 4 weeks after AF ablation, whilst the use of OAC beyond 3 months from the procedure was associated with slightly lower rates of thrombotic events and increased rates of major bleeding.\textsuperscript{21} Interestingly, 65% of patients from the AF Ablation Pilot Registry\textsuperscript{4} were still on OAC 1 year after the procedure, including \textasciitilde 50% of patients with a CHA\textsubscript{2}DS\textsubscript{2}–VASc score of 0, whilst as many as 25% of patients with a CHA\textsubscript{2}DS\textsubscript{2}–VASc score \textasciitilde 2 were not taking any OAC. This emphasizes the need for more high-quality data to guide daily clinical practice.

In our survey, most patients underwent TOE, whilst both TOE and CT were performed in 32% of patients. However, \textasciitilde 30% of patients with a CHA\textsubscript{2}DS\textsubscript{2}–VASc score \textasciitilde 2 and 30% of patients who were not on OAC before AF ablation were not subjected to either TOE or CT for thrombus detection, in contrast to current recommendation.\textsuperscript{4} More data are also needed to better define and implement optimal diagnostic assessment for left atrial thrombus detection in patients undergoing AF ablation.

**Limitations**

The ESS-PRAFA Snapshot Survey provides a general idea of current clinical practice regarding procedural routines in patients undergoing

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**Figure 2** Oral anticoagulant therapy before and after AF ablation.

**Figure 3** Long-term strategy for OAC therapy post AF ablation.
AF ablation in Europe. Participation in the snapshot was voluntary which might have resulted in selection bias and other limitations inherent to this type of studies. Owing to a short duration of the ESS-PRAFA survey, a relatively small number of patients were enrolled and caution is needed when interpreting the results. In addition, most patients were recruited from university hospitals, and therefore, the ESS-PRAFA Survey may not fully reflect ‘real-world’ clinical practice.

**Conclusion**

Our results show increasing use of NOACs in patients undergoing AF ablation. A diversity of NOAC strategies in patients undergoing AF ablation emphasizes the need for trials to identify the optimal periprocedural use of NOACs for stroke prevention in patients undergoing AF ablation in real-world setting and to inform the AF ablation guidelines. More data are also needed to guide the decision on post-procedural OAC duration.

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**Conflict of interest:** none declared.

**References**


exants in a real-world cohort of patients undergoing catheter ablation of atrial fibrilla-


