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# Advances in CLOT Treatment (ACT)

## A Textbook of Cardiology

*Editors-in-Chief*

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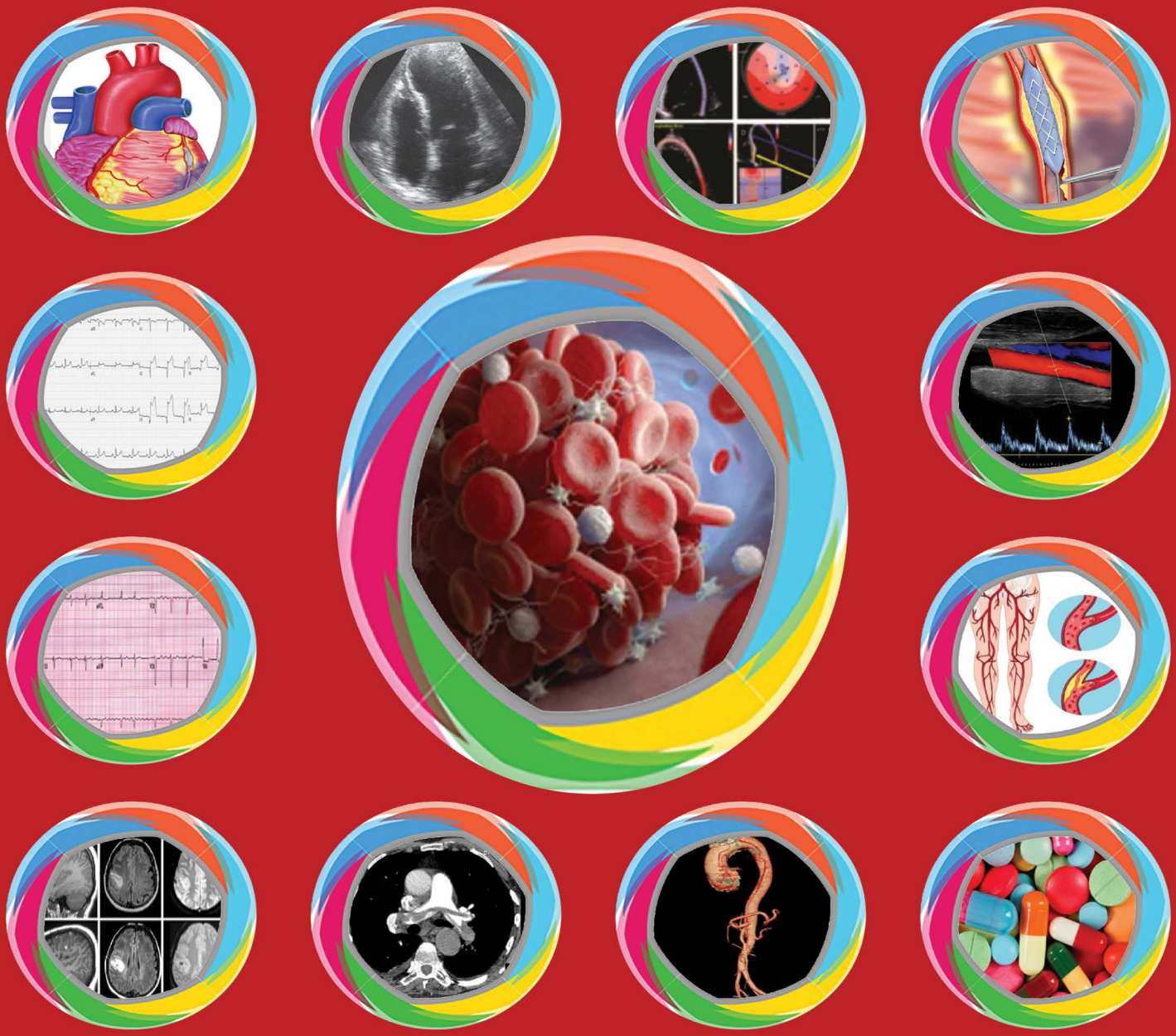

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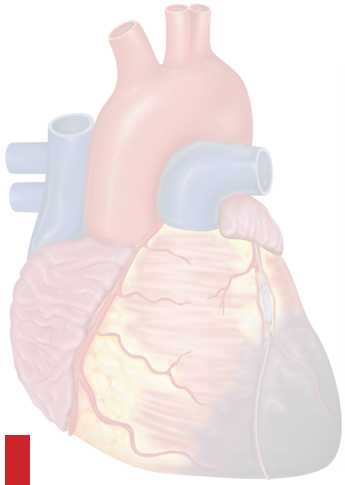

# American College of Cardiology/ American Heart Association and Heart Rhythm Society Guidelines on Anticoagulation in Atrial Fibrillation

*Akash Batta, GS Wander*

## INTRODUCTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia worldwide, and the prevalence is increasing owing to the aging population worldwide. It is strongly associated with other cardiovascular conditions, most notably coronary artery disease, heart failure, diabetes, hypertension, and valvular heart diseases.[1-3] Various theories have been hypothesized regarding the development of AF in these conditions, which include hemodynamic stress, neurohormonal alteration, microvascular dysfunction, atrial ischemia, and inflammation culminating in eventual atrial fibrosis and initiation of AF.[4]

Atrial fibrillation is associated with excess morbidity and mortality. It confers an increased risk of developing heart failure, acute coronary syndromes, cardiogenic shock, and thromboembolic manifestation.

Among thromboembolic manifestations, cerebrovascular accident (CVA) is the most feared and associated with significant morbidity and mortality. AF increases the risk of CVA by five times compared to those without AF. The risk is much higher in valvular AF patients.[1,2,4-6] Hence, prevention of thromboembolic CVA remains central to the treatment of AF. Accordingly, abundant research in recent years has been backed by guidelines which are periodically updated, thanks to the ever-increasing pool of evidence. The American Heart Association/American College of Cardiology (AHA/ACC) and Heart Rhythm Society (HRS) have incorporated the recent evidence from 2006. In this chapter, we will discuss about antithrombotic regimens from the recent AHA/ACC and HRS guidelines which were published in 2014.[5] We will further be emphasizing on the recent updates to the same, made in 2019.[6]

**TABLE 1:** Definitions of AF: Based on the duration of an episode.

| *Term* | *Definition* |
|---|---|
| Paroxysmal AF | AF that reverts spontaneously or with intervention <7 days of onset |
| Persistent AF | Continuous AF sustained >7 days |
| Long-standing AF | Continuous AF sustained >12 months |
| Permanent AF | A joint decision by the patient and physician to stop any attempts to sinus rhythm |
| Nonvalvular AF | AF in the absence of rheumatic heart disease, a repaired mitral valve, or any replaced heart valve |
| Valvular AF | AF in the presence of rheumatic heart disease with more than or equal to moderate mitral stenosis, a repaired mitral valve, or any replaced heart valve |

(AF: atrial fibrillation)

## DEFINITION OF ATRIAL FIBRILLATION

Atrial fibrillation refers to a supraventricular tachycardia that results from chaotic atrial activation and resultant ineffective atrial contraction. An irregular R-R interval and absence of discernable P wave are hallmarks on a 12-lead electrocardiogram.[6] AF is classified based on the duration of episodes as highlighted in **Table 1**.

## ANTITHROMBOTIC THERAPIES

As discussed earlier, the prevention of thromboembolic complications (mainly stroke) is the most important aspect in the management of AF patients. Stroke risk assessment is the initial step before tailoring anticoagulation therapy for a particular patient. The 2014 AHA/ACC/HRS guidelines updated the stroke risk assessment tools and recommended

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**TABLE 2:** Components of $CHA_2DS_2$–VASc score and the American Heart Association/American College of Cardiology/Heart Rhythm Society (AHA/ACC/HRS) recommendations.

| *Risk factor* | *Score* |
|---|---|
| Congestive heart failure | 1 point |
| Hypertension | 1 point |
| Age >75 years | 2 points |
| Diabetes | 1 point |
| Stroke/TIA/thromboembolism history | 2 points |
| Vascular disease (MI, PAD, aortic plaque) | 1 point |
| Age 64–74 years | 1 point |
| Sex category (female sex) | 1 point |
| *Recommendations for antithrombotic therapy* | |
| Nonvalvular AF with $CHA_2DS_2$–VASc score = 0 | No antithrombotic therapy |
| Nonvalvular AF with $CHA_2DS_2$–VASc score = 1 | No antithrombotic therapy or oral antithrombotic therapy |
| Any valvular AF<br>Nonvalvular AF with prior stroke, TIA, or $CHA_2DS_2$–VASc score ≥2 | Oral antithrombotic therapy |

(AF: atrial fibrillation; MI: myocardial infarction; PAD: peripheral arterial disease; TIA: transient ischemic attack)

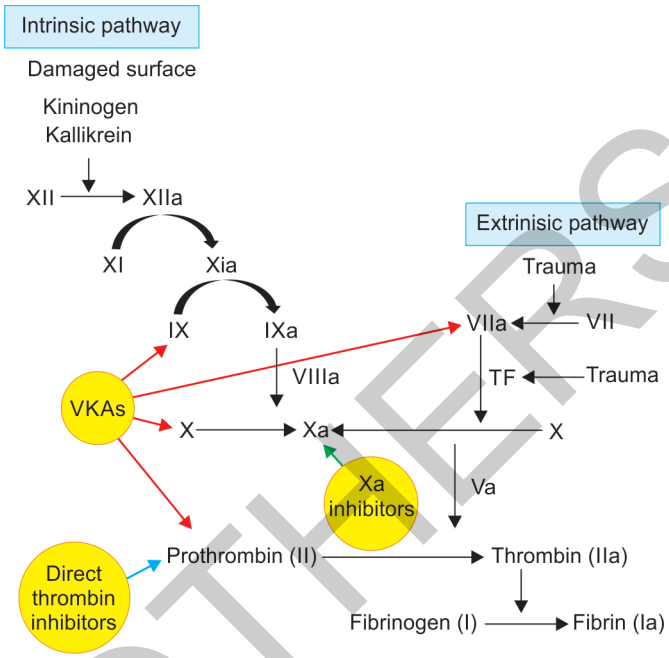


**Fig. 1:** Intrinsic and extrinsic coagulation pathways and the action of various oral anticoagulants. (TF: tissue factor; VKAs: vitamin K antagonists)

the use of $CHA_2DS_2$–VASc score instead of the earlier $CHADS_2$ score.[5] The components of $CHA_2DS_2$–VASc score are highlighted in **Table 2**. As a result, the shift from $CHADS_2$ score to $CHA_2DS_2$–VASc score has seen more people qualifying for oral antithrombotic therapy.

Antithrombotic therapy for prevention refers to therapeutic anticoagulation and not antiplatelet therapy. Large randomized controlled trials have clearly shown the superiority of oral anticoagulation in stroke prevention in AF patients compared to aspirin or clopidogrel alone or in combination.[7] Accordingly, recent updates recommend the use of oral anticoagulants instead of oral antithrombotic therapy to avoid confusion.[6] The oral anticoagulants available as of today are the conventional vitamin K antagonists (VKAs) and the newer oral anticoagulants (NOACs). The NOACs encompass both direct thrombin inhibitors (dabigatran) and factor Xa inhibitors (rivaroxaban, apixaban, and edoxaban). The mechanism of action on the anticoagulation pathways is depicted in **Figure 1**.

## Oral Anticoagulants

Vitamin K antagonist (warfarin) is the oldest available oral anticoagulation agent. As shown in **Figure 1**, it acts by inhibiting the coagulation cascade at various steps. It has shown superiority over placebo, aspirin, or clopidogrel alone or in combination. The absolute risk reduction of stroke is ~2.7% per year.[8] The benefit of VKAs has shown to be sustained across all age-groups, including >75 years, although the bleeding risks increase with advancing age. Despite these overwhelming benefits, warfarin is underused in today's clinical practice due to a number of limitations. These include a narrow therapeutic window, excess bleeding risk, multiple interactions with other drugs and food leading to erratic blood levels, and the need for periodic international normalized ratio (INR) monitoring. These limitations led to a search for an ideal oral anticoagulant which retains the therapeutic properties but with reduced adverse event profiles.[5,6]

Dabigatran (direct thrombin inhibitor) was the first NOAC approved for stroke prevention in AF patients. The approval came after the RE-LY (Randomized Evaluation of Long-Term Anticoagulation Therapy) trial, which demonstrated comparable efficacy of dabigatran compared to warfarin, but with reduced intracranial bleeding in both the 110 and 150 mg dabigatran groups.[9] Dabigatran is recommended in patients with estimated glomerular filtration rate (eGFR) >30 mL/min/$m^2$ with a reduction in dose to 75 mg twice a day in those with eGFR 15–30 mL/min/$m^2$.

Next in line were the Xa inhibitors. Rivaroxaban was the first to be approved in this category after the ROCKET AF trial, which again demonstrated the comparable efficacy of rivaroxaban compared to warfarin, but with reduced intracranial and fatal bleeding.[10] Rivaroxaban is recommended at a dose of 20 mg/day with a reduction in dose to 15 mg/day in patients with eGFR >30–49 mL/min/$m^2$. Apixaban was the next approved agent following the ARISTOTLE (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation) trial demonstrating the net superiority of apixaban in both stroke prevention and lesser bleeding risk compared to warfarin.[11] Apixaban is recommended at a dose of 5 mg twice daily with a reduction to 2.5 mg twice daily in those aged >80 years, body weight <60 kg, and a serum creatinine of >2.5 mg/dL. Edoxaban at a dose of 60 mg/day is the last of these agents, which has received recommendation in the 2019 focused update of the guidelines following the

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ENGAGE AF-TIMI (Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation-Thrombolysis in Myocardial Infarction) trial.[12]

### *Choosing an Oral Anticoagulant*

Overall, all NOACs offer an efficacy profile similar to warfarin in terms of stroke reduction with a reduced risk of major bleeding. Reduced drug and food interactions, stable blood levels, and little need for periodic monitoring are some of the points which render NOACs' use more favorable compared to warfarin. However, the efficacy of NOACs has not been established in patients with a mechanical heart valve or significant rheumatic mitral stenosis and those with end-stage renal disease necessitating the use of VKAs in these situations with close monitoring.[5,6]

Deciding antithrombotic therapy for a patient with AF is complex and involves the participation of both the physician and the patient, keeping in mind the absolute risk and benefit of antithrombotic therapies and individual patient preferences. Antithrombotic therapy initiation is based on individuals' risk of stroke as determined by the $CHA_2DS_2$–VASc score and not on the pattern of AF. Valvular AF (mainly rheumatic mitral stenosis) is associated with a much greater risk of stroke in AF patients compared to nonvalvular AF (20× in mitral stenosis compared to 5× increased risk of stroke in nonvalvular AF compared to general population). The salient antithrombotic recommendations for various scenarios are listed in **Table 3**.

## Other Recommendations

- In patients who are initiated on VKAs, it is recommended that the INR should be monitored at least weekly during initiation of antithrombotic therapy and monthly when INR is in a stable range.
- The management of AF is complex and requires a periodic reassessment of a patient's need for anticoagulation and the stroke and bleeding risk in the given individual.
- Use of NOACs is not recommended in patients with a mechanical heart valve or those with nonvalvular AF and end-stage renal disease on dialysis.

For individuals undergoing coronary stenting, anticoagulation should be interrupted prior to the procedure to avoid local site complications related to arterial puncture. Following stenting with drug-eluting or bare-metal stents, in patients with a $CHA_2DS_2$–VASc score ≥2, using clopidogrel with an oral anticoagulant agent with or without aspirin is recommended.

**TABLE 3:** Selecting appropriate anticoagulation for varied clinical scenarios.

| *Clinical setting* | *Recommendation* |
|---|---|
| AF with mechanical heart valve<br>• Mitral valve<br>• Aortic valve | • Oral VKAs<br>• Target INR 2.5–3.5<br>• Target INR 2–3 |
| AF with mechanical heart valve undergoing surgical procedure | Bridging with low molecular weight heparin or unfractionated heparin |
| Valvular AF (uncorrected rheumatic heart disease) | Oral VKAs with target INR 2–3 |
| Nonvalvular AF with prior stroke, TIA, or $CHA_2DS_2$–VASc score ≥2 | Oral VKAs (target INR 2–3) or NOACs |
| Nonvalvular AF $CHA_2DS_2$–VASc score ≥2 and underlying CKD (eGFR >15 mL/min/$m^2$) | Oral VKAs (target INR 2–3) or reduced dosage of NOACs, adjusted according to eGFR |
| Nonvalvular AF $CHA_2DS_2$–VASc score ≥2 and underlying CKD on dialysis (eGFR <15 mL/min/$m^2$) | Oral VKAs (target INR 2–3) |
| For patients unable to maintain therapeutic INR on VKAs | Switching to NOACs |

(AF: atrial fibrillation; CKD: chronic kidney disease; eGFR: estimated glomerular filtration rate; INR: international normalized ratio; NOACs: newer oral anticoagulants; TIA: transient ischemic attack; VKAs: vitamin K antagonists)

## NONPHARMACOLOGICAL STROKE PREVENTION

Nonpharmacological means to prevent stroke are percutaneous procedures and open surgical options. Around 90% of all micro- and macrothrombi are formed in the left atrial appendage (LAA); hence, occlusion or exclusion of LAA should result in stroke prevention.[13] Among the percutaneous options, LAA offers an effective treatment option for those who are unable to receive therapeutic oral anticoagulation due to medical contraindications or are intolerant to oral anticoagulation. Watchman and Lariat devices are two such options for percutaneous closure of LAA. Surgical excision or occlusion of LAA is seldom performed as a stand-alone procedure but mainly at the time of cardiac surgery for other diseases.

Besides anticoagulation, control of other risk factors including hypertension, diabetes, dyslipidemia, and obesity also reduced the risk of stroke. Though anticoagulation use is associated with reduction in thromboembolic events, it comes at the expense of increased bleeding tendencies, which need to be balanced in everyone. The use of $CHA_2DS_2$–VASc and HAS-BLED scores guides the risk of thromboembolism and bleeding in a patient, and the physician needs to weigh in on both thromboembolic and bleeding risk before initiating antithrombotic therapy.

An important consideration is patient adherence to the chosen anticoagulation regimen. Recent studies have shown that patient compliance to both VKAs and NOACs is poor and achieved only in about half to two-thirds of all patients on anticoagulation.[14-16] Achieving a satisfactory patient adherence percentage is an unmet need in patient management.

## 2019 UPDATES TO THE AMERICAN HEART ASSOCIATION/AMERICAN COLLEGE OF CARDIOLOGY AND HEART RHYTHM SOCIETY 2014 GUIDELINES

A focused update to the earlier guidelines after incorporating the evidence from large, randomized controlled trials during

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this time period was released in January 2019. The salient alterations included are discussed below.

## Anticoagulation Selection

Firstly, the word "antithrombotic" was changed to "anticoagulant" to avoid confusion and intention of treatment of patients with a higher $CHA_2DS_2$–VASc score. NOACs are now the preferred agents over VKAs due to comparable or superior stroke prevention and reduced major bleeding. However, patients with mechanical heart valves or moderate–severe rheumatic mitral stenosis are excluded in whom VKAs are still preferred. Next, the emphasis on female sex, which was earlier believed to be a risk factor for stroke, is now reduced. Accordingly, the recommendation for starting oral anticoagulation includes a $CHA_2DS_2$–VASc score ≥2 in males and a $CHA_2DS_2$–VASc score ≥3 in females. Female as in isolation is no longer considered a relevant risk factor. In addition to the previously recommended NOACs in 2014 guidelines, edoxaban is also a first-line agent for prevention of stroke in AF patients. Periodic assessment of renal and hepatic function is recommended for those on NOACs, at least annually. The role of aspirin is reduced in the update, and it is no longer recommended for those with a $CHA_2DS_2$–VASc score <2. Instead, the physician may decide on NOAC prescription in this group on a case-to-case basis.

The other modification pertains to life-threatening bleeding in patients on NOACs.

Patients who develop bleeding on NOACs can be given antidotes as these are available now. Idarucizumab is recommended for those on dabigatran and andexanet alfa for those on Xa inhibitors.

## Nonpharmacological Stroke Prevention

Left atrial appendage occlusion is recommended for those having contraindications to long-term oral anticoagulation.

## Anticoagulation Regimen during Cardioversion

Therapeutic anticoagulation is recommended for those having AF or flutter >48 hours who are being considered for cardioversion (pharmacological or electrical). The anticoagulation should be initiated for a period of 3 weeks prior and to be continued for 4 weeks after successful cardioversion regardless of the $CHA_2DS_2$–VASc score.

## Acute Coronary Syndromes Complicating Atrial Fibrillation

For patients of AF with concomitant acute coronary syndrome, undergoing coronary stenting, double therapy (clopidogrel + rivaroxaban/dabigatran/VKAs) is reasonable to triple therapy (aspirin + clopidogrel + rivaroxaban/dabigatran/VKAs) in those at higher bleeding risk. For others initiating triple therapy for a duration of 4-6 weeks, subsequent transition to dual therapy is recommended. Besides these, stress has been placed on weight loss which is associated with improved outcomes even in those with a normal range body mass index.

## CONCLUSION

In summary, AF is strongly associated with stroke which is associated with excess morbidity and mortality in these patients. Hence, prevention of stroke is central to the successful management of AF patients. Deciding antithrombotic therapy for a patient with AF is complex and involves active participation of both the physician and the patient, keeping in mind the absolute risk and benefit of antithrombotic therapies. The use of $CHA_2DS_2$–VASc and HAS-BLED scores determines the risk of thromboembolism and bleeding in a patient and guides decision-making.

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