Changes in Guidelines for Atrial Fibrillation

A Small Feeding of the Mind

Kelly Evans Hullinger, MD, FACP

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CLINICAL PRACTICE GUIDELINE: FOCUSED UPDATE

2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society

Developed in Collaboration With the Society of Thoracic Surgeons

Highlights from the 2019 update

- Anticoagulation recommendations
- Bridging for procedures
- Left atrial appendage occlusion
- Recommendations on triple therapy (DAPT+AC)

CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — **Benefit >>> Risk**

Suggested phrases for writing recommendations:

- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE) — **Benefit >> Risk**

Suggested phrases for writing recommendations:

- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK) — **Benefit ≥ Risk**

Suggested phrases for writing recommendations:

- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE) — **Benefit = Risk**

(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:

- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG) — **Risk > Benefit**

Suggested phrases for writing recommendations:

- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A

- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R (Randomized)

- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR (Nonrandomized)

- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD (Limited Data)

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO (Expert Opinion)

Consensus of expert opinion based on clinical experience

Anticoagulation

I B

4. In patients with AF (except with moderate-to-severe mitral stenosis or a mechanical heart valve), the CHA_2DS_2-VASc score is recommended for assessment of stroke risk (S4.1.1-5-S4.1.1-7).
MODIFIED: Exclusion criteria are now defined as moderate-to-severe mitral stenosis or a mechanical heart valve. Patients with AF with bioprosthetic heart valves are addressed in the supportive text. (Section 4.1. in the 201

Definition and scores for $CHADS_2$ and
$CHADS_2$ acronym
Congestive HF
Hypertension
Age ≥75 years
Diabetes mellitus
Stroke/TIA/TE
Maximum score
CHA_2DS_2-VASc acronym
Congestive HF
Hypertension
Age ≥75 years
Diabetes mellitus
Stroke/TIA/TE
Vascular disease (prior MI, PAD, or aortic plaqu
Age 65 to 74 years
Sex category (ie, female sex)
Maximum score

$CHADS_2$ acronym	Unadjusted ischemic stroke rate (% per year)*
0	0.6%
1	3.0%
2	4.2%
3	7.1%
4	11.1%
5	12.5%
6	13.0%
CHA_2DS_2-VASc acronym	**Unadjusted ischemic stroke rate (% per year)***
0	0.2%
1	0.6%
2	2.2%
3	3.2%
4	4.8%
5	7.2%
6	9.7%
7	11.2%
8	10.8%
9	12.2%

Anticoagulation

Recommendations for Selecting an Anticoagulant Regimen—Balancing Risks and Benefits
Referenced studies that support new or modified recommendations are summarized in Online Data Supplements 1 and 2.

COR	LOE	RECOMMENDATIONS
I	A	1. For patients with AF and an elevated CHA_2DS_2-VASc score of 2 or greater in men or 3 or greater in women, oral anticoagulants are recommended. Options include: ■ Warfarin (LOE: A) (S4.1.1-5-S4.1.1-7) ■ Dabigatran (LOE: B) (S4.1.1-8) ■ Rivaroxaban (LOE: B) (S4.1.1-9) ■ Apixaban (LOE: B) (S4.1.1-10), or ■ Edoxaban (LOE: B-R) (S4.1.1-11) MODIFIED: This recommendation has been updated in response to the approval of edoxaban, a new factor Xa inhibitor. More precision in the use of CHA_2DS_2-VASc scores is specified in subsequent recommendations. The LOEs for warfarin, dabigatran, rivaroxaban, and apixaban have not been updated for greater granularity as per the new LOE system. (Section 4.1. in the 2014 AF Guideline) The original text can be found in Section 4.1 of the 2014 AF guideline. Additional information about the comparative effectiveness and bleeding risk of NOACs can be found in Section 4.2.2.2.
	B	
	B	
	B	
	B-R	

Anticoagulation

2. NOACs (dabigatran, rivaroxaban, apixaban, and edoxaban) are recommended over warfarin in NOAC-eligible patients with AF (except with moderate-to-severe mitral stenosis or a mechanical heart valve) (S4.1.1-8-S4.1.1-11).
NEW: Exclusion criteria are now defined as moderate-to-severe mitral stenosis or a mechanical heart valve. When the NOAC trials are considered as a group, the direct thrombin inhibitor and factor Xa inhibitors were at least noninferior and, in some trials, superior to warfarin for preventing stroke and systemic embolism and were associated with lower risks of serious bleeding.

"There have been 4 RCT's comparing NOACs with warfarin. There was consistent evidence of at least noninferiority for the combined endpoint of stroke or systemic embolism. When combined with a superior safety profile, they are recommended as firstline therapy for eligible patients."

Cost Comparison

Medication/Service	Estimated Cost
Dabigatran *(Pradaxa 150mg #60)*	**$530** ($418 w discount)
Rivaroxaban *(Xarelto 20mg #30)*	**$511** ($449 w discount)
Apixaban *(Eliquis 5mg #60)*	**$487** ($445 w discount)
Edoxaban *(Savaysa 60mg #30)*	**$436** ($366 w discount)
Warfarin *(warfarin 5mg #30)*	**$20**
PT/INR *(lab)*	**$59**
Nurse visit INR check	**$116**

30 days warfarin + 2 INR checks = max $252/month

*Drug prices from goodrx.com

Bridging

Recommendations for Interruption and Bridging Anticoagulation
Referenced studies that support new or modified recommendations are summarized in Online Data Supplement 3.

COR	LOE	RECOMMENDATIONS
I	C	1. Bridging therapy with unfractionated heparin or low-molecular-weight heparin is recommended for patients with AF and a mechanical heart valve undergoing procedures that require interruption of warfarin. Decisions on bridging therapy should balance the risks of stroke and bleeding.
I	B-R	2. For patients with AF without mechanical heart valves who require interruption of warfarin for procedures, decisions about bridging therapy (unfractionated heparin or low-molecular-weight heparin) should balance the risks of stroke and bleeding and the duration of time a patient will not be anticoagulated (S4.3-1). MODIFIED: LOE was updated from C to B-R because of new evidence. (Section 4.1. in the 2014 AF Guideline)

Perioperative Bridging Anticoagulation in Patients with Atrial Fibrillation

James D. Douketis, M.D., Alex C. Spyropoulos, M.D., Scott Kaatz, D.O., Richard C. Becker, M.D., Joseph A. Caprini, M.D., Andrew S. Dunn, M.D., David A. Garcia, M.D., Alan Jacobson, M.D., Amir K. Jaffer, M.D., M.B.A., David F. Kong, M.D., Sam Schulman, M.D., Ph.D., Alexander G.G. Turpie, M.B., et al., for the BRIDGE Investigators*

August 27, 2015
N Engl J Med 2015; 373:823-833
DOI: 10.1056/NEJMoa1501035

Abstract

Triple Therapy

IIa	B-NR

4. If triple therapy (oral anticoagulant, aspirin, and $P2Y_{12}$ inhibitor) is prescribed for patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone percutaneous coronary intervention (PCI) with stenting for ACS, it is reasonable to choose clopidogrel in preference to prasugrel (S7.4-4, S7.4-5).
NEW: New published data are available.

IIa	B-R

5. In patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone PCI with stenting for ACS, double therapy with a $P2Y_{12}$ inhibitor (clopidogrel or ticagrelor) and dose-adjusted vitamin K antagonist is reasonable to reduce the risk of bleeding as compared with triple therapy (S7.4-3, S7.4-6-S7.4-8).
NEW: New RCT data and data from 2 registries and a retrospective cohort study are available.

IIa	B-R

6. In patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone PCI with stenting for ACS, double therapy with $P2Y_{12}$ inhibitors (clopidogrel) and low-dose rivaroxaban 15 mg daily is reasonable to reduce the risk of bleeding as compared with triple therapy (S7.4-2).
NEW: New published data are available.

IIa	B-R

7. In patients with AF at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) who have undergone PCI with stenting for ACS, double therapy with a $P2Y_{12}$ inhibitor (clopidogrel) and dabigatran 150 mg twice daily is reasonable to reduce the risk of bleeding as compared with triple therapy (S7.4-1).
NEW: New published data are available.

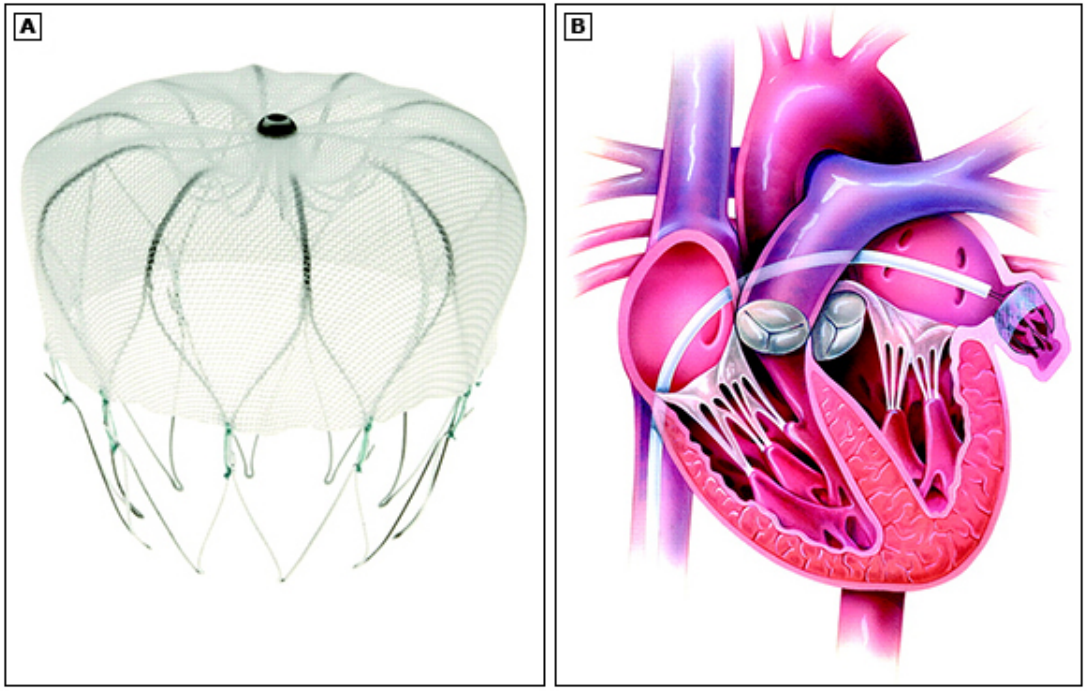
IIb	B-R

8. If triple therapy (oral anticoagulant, aspirin, and $P2Y_{12}$ inhibitor) is prescribed for patients with AF who are at increased risk of stroke (based on CHA_2DS_2-VASc risk score of 2 or greater) and who have undergone PCI with stenting (drug eluting or bare metal) for ACS, a transition to double therapy (oral anticoagulant and $P2Y_{12}$ inhibitor) at 4 to 6 weeks may be considered (S7.4-9, S7.4-10).
NEW: New published data are available.

Left Atrial Appendage Occlusion

Recommendation for Percutaneous Approaches to Occlude the LAA
Referenced studies that support the new recommendation are summarized in Online Data Supplement 4.

COR	LOE	RECOMMENDATION
IIb	B-NR	1. Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (S4.4.1-1-S4.4.1-5). NEW: Clinical trial data and FDA approval of the Watchman device necessitated this recommendation.



Comments and Questions