# Update on Anticoagulation

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## Disclosure

Consultant: Anthos; AstraZeneca; Bayer; Gilead; Perosphere; Regeneron

Research Grant: Inari; Regeneron



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# Learning Objectives

- Be able to apply the new guidelines to patients with atrial fibrillation
- Stop withholding anticoagulation in patients with high fall risk
- Consider treating sub-segmental pulmonary embolism

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# Update on Anticoagulation

Rapid Recap | Anticoagulation FORUM | ANTICOAGULATION Centers of Excellence

- I used AC Forum's Rapid Recaps to guide selection of papers
- Thanks to this team for providing such a useful and timely resource

## Editorial Board

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# Update on Anticoagulation

- Guidelines and retrospective cohort study: 'provoked' atrial fibrillation
- Atrial fibrillation and risk of falls, DOACs for older adults and falls, Things we do for no reason in older patients with atrial fibrillation and high risk of falls
- Systematic review: isolated sub-segmental pulmonary embolism
- Guideline: management of lower extremity peripheral artery disease
- Randomized trial: left atrial appendage closure after ablation for atrial fibrillation
- Periprocedural anticoagulation
  - Guideline: American Society of Regional Anesthesia (ASRA) and Pain Medicine
  - Randomized trial: PAUSE 2
  - Guideline: ACC/AHA/others perioperative cardiovascular management for noncardiac surgery
- Randomized trial: Prestige AF
- Cross sectional cohort: inappropriate DOAC dosing in atrial fibrillation

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# Case

- 68-year-old female with hypertension and diabetes admitted to ICU for sepsis
- First discovered atrial fibrillation
- Longest episode 18 hours with spontaneous conversion as sepsis improved
- Discharged without anticoagulation

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# Would You Start Anticoagulation?

A. Yes
B. No
C. Get cardiology consult

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## 2023 Guideline for Diagnosis and Management of Atrial Fibrillation

American College of Cardiology, American Heart Association, American College of Clinical Pharmacy and Heart Rhythm Society

- **Atrial fibrillation detected during acute medical illness or non-cardiac surgery**
  - DO: council patient of risk of recurrent atrial fibrillation if it occurs during an acute illness
  - DO: close outpatient follow up, risk stratification and surveillance for recurrent atrial fibrillation if occurs during acute illness or after non-cardiac surgery
  - DO/DON'T: uncertain benefit of anticoagulation for atrial fibrillation occurring during sepsis

**Recommendations for Acute Medical Illness or Surgery (Including AF in Critical Care)**
**Referenced studies that support the recommendations are summarized in the Online Data Supplement.**

| COR | LOE | RECOMMENDATIONS |
|---|---|---|
| 1 | B-NR | 1. Patients with AF who are identified in the setting of acute medical illness or surgery should be counseled about the significant risk of recurrent AF after the acute illness is resolved.[1-6] |
| 2a | B-NR | 2. In patients with AF who are identified in the setting of acute medical illness or surgery, outpatient follow-up for thromboembolic risk stratification and decision-making on OAC initiation or continuation, as well as AF surveillance, can be beneficial given a high risk of AF recurrence.[4-9] |
| 2b | B-NR | 3. In patients with AF who are identified in the setting of critical illness due to sepsis, the benefits of anticoagulation during critical illness for stroke prevention are uncertain.[10,11] |

Joglar JA. J Am Coll Cardiol. 2024 Jan 2;83(1):109-279. PMID: 38043043.

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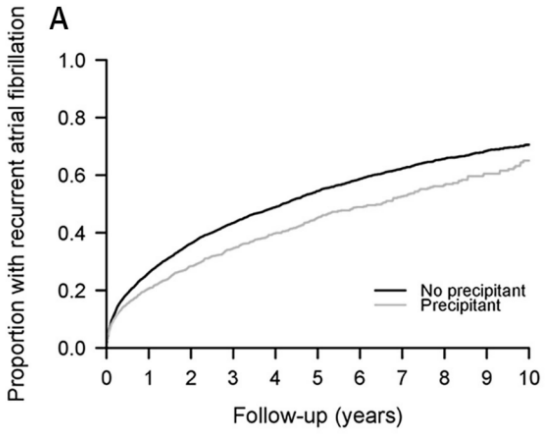
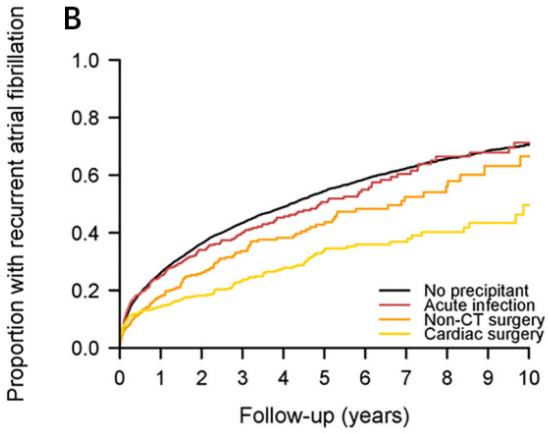
**FIGURE 27 Unadjusted Cumulative Risk of AF Recurrence**




| No. at risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No precipitant | 8634 | 5543 | 4042 | 2944 | 2149 | 1513 | 1070 | 705 | 496 | 347 | 245 |
| Precipitant | 2089 | 1352 | 966 | 683 | 490 | 356 | 244 | 177 | 121 | 86 | 55 |




| No. at risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Absent | 8634 | 5543 | 4042 | 2944 | 2149 | 1513 | 1070 | 705 | 496 | 347 | 245 |
| Acute infection | 637 | 367 | 235 | 163 | 112 | 82 | 54 | 37 | 25 | 21 | 15 |
| Non-CT surgery | 321 | 217 | 174 | 121 | 89 | 67 | 47 | 33 | 23 | 12 | 8 |
| Cardiac surgery | 459 | 348 | 279 | 216 | 164 | 116 | 81 | 60 | 40 | 29 | 15 |

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Joglar JA. J Am Coll Cardiol. 2024 Jan 2;83(1):109-279. PMID: 38043043.

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## 'Provoked' Atrial Fibrillation (AF) During Hospitalization

- Question: what is the risk of stroke of newly diagnosed atrial fibrillation during hospitalization for another cause?
- Design: population based retrospective cohort
- Patients: 20,639 patients ≥ 66 years old discharged after hospitalization with new atrial fibrillation in Ontario, Canada
- "Intervention": new AF, patients categorized as
  - Cardiac medical
  - Noncardiac medical
  - Cardiac surgical
  - Noncardiac surgical
- Outcomes:
  - Primary: hospitalization for stroke
  - Proportion of patients anticoagulated
- Timeframe: 1 year

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Abdel-Qadir H. Ann Intern Med. 2025 Apr 22. Epub ahead of print. PMID: 40258280.

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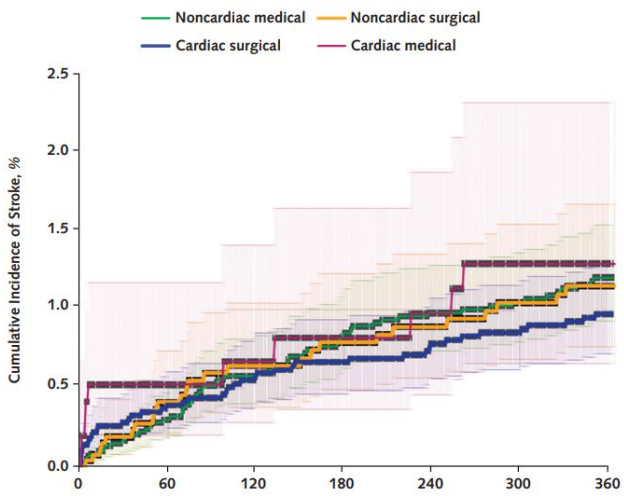
## 'Provoked' Atrial Fibrillation (AF) During Hospitalization Stoke Rate Without Anticoagulation




- **Cardiac medical : 1.3% (0.7-2.3)**
- **Noncardiac medical: 1.2% (0.9-1.5)**
- **Noncardiac surgical : 1.1% (0.8-1.7)**
- **Cardiac surgical: 1.0% (0.7-1.3)**

- **Less than ½ of patients discharged with new AF were anticoagulated**

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Abdel-Qadir H. Ann Intern Med. 2025 Apr 22. Epub ahead of print. PMID: 40258280.

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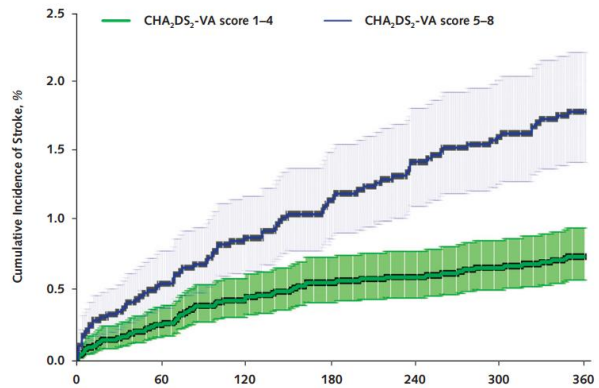
## 'Provoked' Atrial Fibrillation (AF) During Hospitalization Stoke Rate Without Anticoagulation




- $CHA_2DS_2$-VA used (without Sc, i.e. gender)
- Stroke rate at 1 year
  - $CHA_2DS_2$-VA 5-8: 1.8% (1.4-2.2)
  - $CHA_2DS_2$-VA 1-4: 0.7% (0.6-1.0)
- Dropping gender from risk stratification proposed by European Society of Cardiology (ESC) 2024 guideline

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Abdel-Qadir H. Ann Intern Med. 2025 Apr 22. Epub ahead of print. PMID: 40258280.
Van Gelder IC. Eur Heart J. 2024 Sep 29;45(36):3314-3414. PMID: 39210723.

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# 2023 Guideline for Diagnosis and Management of Atrial Fibrillation

American College of Cardiology, American Heart Association, American College of Clinical Pharmacy and Heart Rhythm Society

- **Device detected atrial high-rate episodes**
  - DO: consider anticoagulation for device detected atrial high-rate episodes lasting > 24 hours and CHADS-VASc ≥ 2
  - DO: consider for 5 minutes – 24 hours with shared decision making with CHADS-VASc ≥ 3
  - DON'T: anticoagulated for episodes < 5 minutes

| COR | LOE | RECOMMENDATIONS |
|---|---|---|
| 2a | B-NR | 1. For patients with a device-detected atrial high-rate episode (AHRE) lasting ≥24 hours[1] and with a $CHA_2DS_2$-VASc score ≥2 or equivalent stroke risk,[2] it is reasonable to initiate oral anticoagulation[3] within a SDM framework that considers episode duration and individual patient risk. |
| 2b | B-NR | 2. For patients with a device-detected AHRE lasting between 5 minutes and 24 hours and with a $CHA_2DS_2$-VASc score ≥3 or equivalent stroke risk,[2] it may be reasonable to initiate anticoagulation within a SDM framework that considers episode duration and individual patient risk. |
| 3: No Benefit | B-NR | 3. Patients with a device-detected AHRE lasting <5 minutes and without another indication for oral anti-coagulation should not receive oral anticoagulation.[4,5] |

Joglar JA. J Am Coll Cardiol. 2024 Jan 2;83(1):109-279. PMID: 38043043.

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# 2023 Guideline for Diagnosis and Management of Atrial Fibrillation

American College of Cardiology, American Heart Association, American College of Clinical Pharmacy and Heart Rhythm Society

- **Obesity**
  - DON'T: preclude patients with BMI > 40kg/m$^2$ from DOACs
  - DO: consider warfarin instead of DOAC in patients that have had bariatric surgery

| COR | LOE | RECOMMENDATIONS |
|---|---|---|
| 2a | B-NR | 1. In patients with AF and class III obesity (BMI ≥40 kg/m$^2$), DOACs are reasonable to choose over warfarin for stroke risk reduction.[1-5] |
| 2b | C-LD | 2. In patients with AF who have undergone bariatric surgery, warfarin may be reasonable to choose over DOACs for stroke risk reduction in view of concerns about DOAC drug absorption.[6,7] |

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Joglar JA. J Am Coll Cardiol. 2024 Jan 2;83(1):109-279. PMID: 38043043.

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- **Atrial fibrillation and risk of falls, DOACs for older adults and falls, Things we do for no reason in older patients with atrial fibrillation and high risk of falls**
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- Randomized trial: Prestige AF
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# Case

- 84-year-old female with atrial fibrillation, hypertension and coronary artery disease; CHADS-VASc = 5
- Laminectomy for lumbar spinal stenosis couple of years ago and uses a cane
- Creatinine = 0.77
- Clearance using actual body weight = 53 ml/min
- Weight 61 kg
- Hip arthroplasty, uses cane

# How Would You Treat?

A. No anticoagulation, fall risk too high
B. Apixaban 2.5 mg bid
C. Apixaban 5.0 mg bid
D. Rivaroxaban 15 mg qd
E. Rivaroxaban 20 mg qd



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December 2023

Table 1. Studies assessing anticoagulation safety in patients at risk of Falls.

| Study | Design | Population | Intervention/ Comparison | Key Findings |
|---|---|---|---|---|
| Steffel et al. [44] | Pre-specified sub-analysis of ENGAGE AF-TIMI 48 RCT | High falls risk patients 310 on high dose edoxaban vs 307 on warfarin | Edoxaban vs Warfarin | Safety was similar to those with low falls risk, with no significant treatment interaction. |
| Rao et al. [45] | Post-hoc subgroup analysis of ARISTOTLE RCT | Patients with falls within 1 year 386 on apixaban vs 367 on warfarin | Apixaban vs Warfarin | Safety was similar to those with low falls risk, with no significant treatment interaction. |
| Miao et al. [48] | Retrospective cohort | High falls risk patients 13,027 on NOAC 12,117 on warfarin | NOAC vs Warfarin | NOACs were associated with a 43% reduced hazard of intracranial haemorrhage compared with warfarin. |
| Fanning et al. [60] | Retrospective cohort | AF patients with dementia 1,013 on NOAC 1,386 on warfarin | NOAC vs Warfarin | NOACs were associated with lower risk of intracranial bleeding (IRR 0.27; $p$=0.02) but a higher risk of GI bleeding (IRR 2.11, $p$=0.003) and all-cause mortality (IRR 2.06, $p$<0.001) compared with warfarin. |
| Lip et al. [61] | Retrospective cohort | AF patients with frailty 87,332 on NOAC 63,155 on warfarin | NOAC vs Warfarin | Apixaban (HR 0.62, $p$<0.001) and Dabigatran (HR 0.79, $p$<0.001) were associated with reduced risk of major bleeding compared with warfarin. Rivaroxaban (HR 1.14, $p$<0.001) was associated with a higher risk of major bleeding. All three NOACs were associated with lower risk of intracranial bleeding compared with warfarin. |
| Wilkinson et al. [62] | Retrospective cohort | AF patients with frailty 43,228 patients on OAC<br>• 23.9% on NOAC<br>• 76.1% on VKA | NOAC vs VKA | NOACs and VKAs were associated with no significant increase in the hazard of major bleeding across three categories of frailty. |

- Narrative expert review
- For discontinuation of anticoagulation to be beneficial.
  - It is estimated that a patient taking
    - rivaroxaban would need to fall 45 times/year and
    - 450 times/year on apixaban

Latt NKZ,. Expert Opin Drug Saf. 2023 Jul-Dec;22(11):1041-1048. PMID: 37860853.

https://acforum-excellence.org/Resource-Center/resource_files/2139-2024-01-02-203122.pdf

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June 2024

- DOACs for Older Adults with AF and Falls: Results from the prospective single-center DOAFF study
- Purpose: This study aimed to evaluate the safety profile of DOACs in elderly patients with AF, stratified by occurrence of falls
- Design: Prospective study of 524 patients ≥65 years old who were starting a DOAC for atrial fibrillation. Fallers were defined as having at least one fall during a 2-year follow-up period

| Endpoint | Study cohort (n = 524) | Fallers (n = 148) | HR (95%CI) | HR (95%CI) |
|---|---|---|---|---|
| Major bleeding, n (%) | 49 (9.4) | 20 (13.5) | 1.46 (0.83–2.57) | 1.04 (0.58–1.85)[a] |
| Intracranial haemorrhage, n (%) | 15 (2.9) | 9 (6.1) | 2.64 (1.22–5.72) | 1.63 (0.69–3.80)[b] |
| CRNMB, n (%) | 196 (37.4) | 65 (43.9) | 1.37 (0.95–1.98) | 1.21 (0.83–1.76)[a] |
| All-cause death, n (%) | 31 (5.9) | 9 (9.1) | 2.24 (1.32–3.80) | 1.51 (0.85–2.69)[a] |

- This study suggests there was no difference in major bleeding, clinically relevant non-major bleeding, nor intracranial bleeding between fallers and non-fallers
- It aligns with existing guidance stating that increased risk of falls does not outweigh the benefits of appropriate anticoagulation in elderly patients with AF
- Furthermore, DOACs should only be dose reduced when clinical criteria are met

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https://acforum-excellence.org/Resource-Center/resource_files/2199-2024-06-19-104851.pdf

Catalani F. Thromb Res. 2024 Jun;238:78-84. PMID: 38678866.

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September 2024

- Things We Do for No Reason : Discontinuing anticoagulation in older patients with atrial fibrillation and a high risk of falls
- Background: Clinicians often consider AC discontinuation in fall-prone patients due to concerns regarding intracranial hemorrhage (ICH) and traumatic brain injury (TBI)
- Current literature and guidelines indicate fall history alone is NOT an independent risk factor for bleeding, and the benefit of AC outweighs the potential harm in many older patients with AF
- Literature Summary on risks vs. benefits of AC in fall-prone patients with AF:
  - **Patients would need to fall 35 to 295 times annually on warfarin, and**
  - **458 times annually on apixaban, for the risk of AC to outweigh the benefits**
- Outcomes of ICH/TBI post-fall are similar in patients on AC vs. not on AC
- Falls are not included in bleeding risk calculators (HAS-BLED, ORBIT, DOAC Score). These scores alone should not be used as a contradiction to AC
- Rapid Takeaway: The authors suggest against routinely discontinuing AC based on fall-risk alone in patients with AF and moderate to high stroke risk

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https://acforum-excellence.org/Resource-Center/resource_files/-2024-09-11-084212.pdf

Wang S. J Hosp Med. 2024 Jul 21. PMID: 39033419.

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| | | Off Lable *Low* Dose | | | | | Off Lable *High* Dose | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Stroke or Systemic Embolism | | | | | Stroke or Systemic Embolism | | | |
| Year | First Author | Number of studies | Hazzard ratio | Significant | $I^2$ | | Number of studies | Hazzard ratio | Significant | $I^2$ |
| 2022 | Caso | 6 | 1.01 | No | 38% | | 3 | 1.68 | No | 0% |
| 2021 | Zhang | 15 | 1.22 | Yes | 56% | | 7 | 1.26 | Yes | |
| 2023 | Shen | 18 | 1.03 | No | 57% | | 11 | 1.17 | Yes | 0% |
| 2021 | Liu | 8 | 1.29 | Yes | 39% | | 5 | 1.44 | Yes | 0% |
| 2023 | Joosten | 8 | 1.04 | No | | | | | | |
| 2022 | Pereira | 15 | 1.14 | No | 62% | | | | | |
| 2021 | Kong | 10 | 1.24 | Yes | 0% | | 3 | 1.71 | Yes | 0% |
| | | | | | | | | | | |
| | | Major Bleeding | | | | | Major Bleeding | | | |
| 2020 | Caso | 15 | 1.04 | No | 51% | | 7 | 1.41 | Yes | 41% |
| 2021 | Zhang | 14 | 0.95 | No | 71% | | 7 | 1.3 | Yes | |
| 2023 | Shen | 17 | 0.93 | No | 57% | | 11 | 1.18 | Yes | 0% |
| 2021 | Liu | 8 | 0.97 | No | 33% | | 5 | 1.99 | Yes | 0% |
| 2023 | Joosten | 8 | 1.1 | No | | | | | | |
| 2022 | Pereira | 14 | 1.02 | No | 44% | | | | | |
| 2021 | Kong | 8 | 1.18 | No | 87% | | 3 | 1.57 | No | 0% |
| | | | | | | | | | | |
| | | All Cause Mortality | | | | | All Cause Mortality | | | |
| 2020 | Caso | 11 | 1.28 | Yes | 70% | | 4 | 1.13 | No | 58% |
| 2021 | Zhang | 9 | 1.24 | Yes | 82% | | | | | |
| 2023 | Shen | 15 | 1.26 | Yes | 73% | | 8 | 1.19 | Yes | 0% |
| 2021 | Liu | | | | | | | | | |
| 2023 | Joosten | 4 | 1.22 | No | | | | | | |
| 2022 | Pereira | 9 | 1.27 | Yes | 71% | | | | | |
| 2021 | Kong | 7 | 1.58 | Yes | 88% | | 3 | 1.74 | Yes | 0% |

## Systematic Reviews of Off Label DOAC in Atrial Fibrillation

- Wrong low dose
  - Possible increase in stroke
  - No decrease in bleeding
  - ***Increase mortality***
- Wrong high dose
  - Increase in stroke
  - Increase in bleeding
  - ***Increase mortality***

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Caso V. Heart. 2023 Jan 11;109(3):178-185. PMID: 36316100
Zhang XL. Circ Cardiovasc Qual Outcomes. 2021 Dec;14(12):e007971. PMID: 34932377
Shen NN. Clin Appl Thromb Hemost. 2023 Jan-Dec;29:10760296231179439. PMID: 37264798
Liu X. Clin Cardiol. 2021 Apr;44(4):472-480. PMID: 33682184
Joosten LPT. Open Heart. 2023 May;10(1):e002197. PMID: 37169490
Pereira MQ. Int J Cardiol. 2022 Sep 1;362:76-82. PMID: 35513121
Kong X. Front Cardiovasc Med. 2021 Dec 23;8:774109. PMID: 35004891



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## Case

- 67-year-old with shortness of breath and elevated d-dimer in ED
- CT with 2 sub-segmental PE
- No right ventricular strain, normal troponin
- Normal lower extremity dopplers



## Would You Anticoagulated?

A. Yes
B. No

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February 2024

- Clinical Surveillance vs Anticoagulation Therapy for **Isolated Subsegmental Pulmonary Embolism (ISSPE)**: A Systematic Review of Clinical Outcomes
- Question: is there a difference in recurrent VTE, major bleeding or all-cause mortality at 90 days in patients with ISSPE with anticoagulation vs. surveillance?
- Design: systematic review of 3 prospective and 7 retrospective observational studies
- Patients: single (3 studies) or multiple (7 studies) ISSPE
  - Studies with high-risk patients such as those with malignancy excluded
- "Intervention": anticoagulation
- "Comparison": no anticoagulation and surveillance
- Outcomes
  - Recurrent VTE
  - Major bleeding
  - All-cause mortality
- Timeframe: 90 days

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https://acforum-excellence.org/Resource-Center/resource_files/2148-2024-02-13-195500.pdf

Chin B, Tweedie C. Am Surg. 2024 May;90(5):1089-1097. PMID: 38058129.

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## Clinical Surveillance vs Anticoagulation Therapy for Isolated Subsegmental Pulmonary Embolism: A Systematic Review of Clinical Outcomes

**Table 4.** 90-Day Outcomes for ISSPE Patients Who Underwent Clinical Surveillance.

Clinical Surveillance Group 90-Day Outcomes

| | Author (Year) | Recurrent VTE, n (%) | Major Bleeding, n (%) | All-Cause Mortality, n (%) |
|---|---|---|---|---|
| Patients with single ISSPE only | Castaner et al (2022) | 0 (0%) | 0 (0%) | 0 (0%) |
| | Li et al (2022) | 1 (3.2%) | 1 (3.2%) | 3 (9.7%) |
| | Mehta et al (2014) | 0 (0%) | 0 (0%) | 1 (8.3%) |
| Patients with single or multiple ISSPE | Dahan et al (2022) | 0 (0%) | NR | 7 (16.3%) |
| | Donato et al (2010) | 0 (0%) | 0 (0%) | 0 (0%) |
| | Eyer et al (2005) | 0 (0%) | NR | 5 (15.6%) |
| | Le Gal et al (2021) | 8 (3.0%) | 2 (.8%) | 4 (1.5%) |
| | Raslan et al (2018) | 0 (0%) | NR | 4 (44.4%) |

**167 in 6 studies**
**266 in Le Gal**

Abbreviations: NR = not Reported; VTE = venous thromboembolism; ISSPE = isolated subsegmental pulmonary embolism.

- Incidence of recurrent venous thromboembolism in Le Gal study
  - Single 2.1% (CI, 0.8% to 5.5%)
  - Multiple 5.7% (CI, 2.2% to 14.4%)

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Chin B, Tweedie C. Am Surg. 2024 May;90(5):1089-1097. PMID: 38058129.

Le Gal G,. Ann Intern Med. 2022 Jan;175(1):29-35. PMID: 34807722.

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July 2024

## 2024 Guideline for the Management of Lower Extremity Peripheral Artery Disease

*Watch the ACF Webinar on "Navigating the 2024 PAD Guidelines" and see the ACF Rapid Resource on Antithrombotic Therapy After PAD Revascularization!*

**Symptomatic PAD Treatment**

Rivaroxaban 2.5mg BID + Aspirin 81mg *(Level 1A)** - ↓MACE & MALE

Aspirin 75-325mg *(Level 1A)* or Clopidogrel 75mg *(Level 1B)* - ↓MACE

**Asymptomatic PAD Treatment:** SAPT *(Level 2A)* + CVD Risk Reduction

*Avoid in patients with high bleeding risk

**PAD Revascularization**

Rivaroxaban 2.5mg BID + Aspirin 81mg *(Level 1A)** - ↓MACE & MALE

DAPT: Low-dose Aspirin + P2Y12 Inhibitor for 1-6 months *(Level 2A/2B)*

Compelling AC indication (AF, VTE): Add SAPT *(Level 2A)*

**Claudication Symptoms:** Cilostazol *(Level 1)*

**All Patients**: Structured Exercise Program & CVD Risk Factor Reduction *(Level 1)*

**Contributors to Health Disparities**

*Race & Ethnicity (esp. Black, Hispanic, Native American), Geography (rural & ↓ access), Structural Racism, Implicit Bias, Social Determinants of Health*

**PAD Risk "Amplifiers":** *Age >75, Geriatric Syndromes, Diabetes, Smoking, CKD/ESRD, Poly- & Micro-vascular Disease, Depression*

https://acforum-excellence.org/Resource-Center/resource_files/2236-2024-07-23-104014.pdf

Gornik HL, Circulation. 2024 Jun 11;149(24):e1313-e1410. PMID: 38743805.

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# Update on Anticoagulation

- Guidelines and retrospective cohort study: 'provoked' atrial fibrillation
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# OPTION Trial

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December 2024

- Question: does left atrial appendage closure at time of atrial fibrillation ablation decrease major and clinically relevant non-major bleeding?
- Design: RCT
- Patients: 1600 patients from 106 sites in 10 countries undergoing ablation
- Intervention: watchman FLX with oral anticoagulation + aspirin for 90 days followed by aspirin alone until 12 months
- Comparison: oral anticoagulation, 59% apixaban, 27% rivaroxaban, 5% warfarin and others
- Outcomes:
  - Primary safety: superiority of non-procedural related major or clinically relevant non-major bleeding (ISTH)
  - Primary efficacy: non-inferiority (5% margin) of composite death from any cause, stroke, systemic embolism
- Timeframe: 36 months

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Wazni OM. N Engl J Med. 2024 Nov 16. PMID: 39555822.

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# OPTION Trial

| End Point | Analysis | Device Group (N=803) | Anticoagulation Group (N=797) | Difference (one-sided 97.5% upper confidence limit) | P Value |
|---|---|---|---|---|---|
| | | *no. of patients (%)* | | *percentage points* | |
| **Primary end points** | | | | | |
| Safety: non–procedure-related bleeding† | Superiority | 65 (8.5) | 137 (18.1) | — | <0.001 |
| Efficacy: death from any cause, stroke, or systemic embolism‡ | Noninferiority, with 5.0-percentage-point margin | 41 (5.3) | 44 (5.8) | −0.5 (1.8) | <0.001 |
| **Secondary end point** | | | | | |
| Major bleeding event§ | Noninferiority, with 5.25-percentage-point margin | 30 (3.9) | 38 (5.0) | −1.1 (1.0) | <0.001 |

- Watchman FLX superior with less non-procedural major and clinically relevant non-major bleeding at 36 months
  - Non-inferior all major bleeding (included procedure related bleeding)
- Non-inferior death from any cause, stroke or systemic embolism

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Wazni OM. N Engl J Med. 2024 Nov 16. PMID: 39555822.

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# Case

- 76-year-old female with atrial fibrillation, hypertension, diabetes, CHF undergoing elective hip replacement
- Apixaban (Eliquis) or rivaroxaban (Xarelto)
- Normal renal and liver function, no drug-drug interactions
- Planned spinal anesthesia



# How Would You Manage Anticoagulation Preop?

A. Hold for 2 days
B. Hold for 2 days with LMWH/heparin bridging
C. Hold for 72 hours
D. Hold for 72 hours with LMWH/heparin bridging
E. Hold for 72 hours and check DOAC level or anti-Xa level preoperatively

## American Society of Regional Anesthesia (ASRA) and Pain Medicine GuidelinesApixaban ***High*** Dose

- We suggest that a high dose of apixaban be discontinued at least 72 hours prior to neuraxial block or deep plexus/peripheral block
- Consider checking apixaban or anti-Xa plasma level if <72 hours (grade IIC)
  - Remarks: there is no change in this recommendation
  - We suggest that a residual apixaban plasma level <30ng/mL
  - or a residual anti-Xa activity plasma level ≤0.1 IU/mL … (grade IIC)
  - Remarks: this new recommendation includes acceptable plasma levels and aXa levels
- We suggest that needle placement/catheter removal occurs at least 24 hours prior to the first postoperative dose (grade IIC)
  - Remarks: this is a new recommendation in the setting of high dose administration
- Same suggestions for rivaroxaban

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Kopp SL. Reg Anesth Pain Med. 2025 Jan 29:rapm-2024-105766. PMID: 39880411.

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## American Society of Regional Anesthesia (ASRA) and Pain Medicine Guidelines Apixaban ***Low*** Dose

- We suggest that a low dose of apixaban be discontinued for at least 36 hours prior to neuraxial block or deep plexus/peripheral block
- Consider checking apixaban or anti-Xa plasma level if <36 hours (grade IIC)
  - For rivaroxaban, at least 24 hours (30 hours if CrCl < 30 mL/min)
  - Remarks: this is a new recommendation in the setting of low-dose administration
  - We suggest that a residual apixaban plasma level <30ng/mL or a
  - residual aXa activity plasma level ≤0.1IU/mL … (grade IIC)
  - Remarks: this new recommendation includes acceptable plasma levels and anti-Xa levels
- We suggest that needle placement/catheter removal occurs at least 6 hours prior to the first postoperative dose (grade IIC)
  - Remarks: there is no change in this recommendation

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Kopp SL. Reg Anesth Pain Med. 2025 Jan 29:rapm-2024-105766. PMID: 39880411.

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# PAUSE-2 Pilot Trial

- Question: are pre-procedure DOAC levels similar between the American Society of Regional Anesthesia (ASRA) and PAUSE trial interruption approach?
- Design: RCT, open-label
- Patients: 159 at 3 sites in Canada with atrial fibrillation and undergoing high-bleed-risk surgery or procedure and/or neuraxial anesthesia or deep nerve block with CrCL not less that 25 or 30 mL/min
  - 20% with neuraxial anesthesia
- Intervention: ASRA management
  - Pre: hold at least 72 **hours** before with *possibility* of heparin bridging (prophylactic dose LMWH or unfractionated heparin) and DOAC level measurement
  - Post: resume within 3 days or 72 hours
- Control: PAUSE management
  - Pre: hold 2 **days** before which equates to approximately 60-68 hours
  - Post: resume 2 to 3 days (at least 48 hours)
- Outcome: proportion of patients with DOAC levels <30 ng/mL

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Douketis JD. J Thromb Haemost. 2025 Mar 12:S1538-7836(25)00144-8. PMID: 40086754.

38

# PAUSE-2 Pilot Trial

| DOAC levels (ng/mL) all DOACs | ASRA, n=79 | PAUSE, n=80 | Standardized Difference† |
|---|---|---|---|
| Median (IQR) | 19 (19-24) | 20 (19-24) | -0.04 |
| DOAC level group, n (%) | | | 0.05 |
| <30 | 66 (95.6) | 68 (94.4) | |
| 30-50 | 1 (1.4)† | 2 (2.8)†† | |
| >50 | 2 (2.9)§ | 2 (2.8)¶ | |
| missing | 10 | 8 | |

Actual residual DOAC levels ≥30 ng/mL: †37; ††30,36; §57,92; ¶82,85

- Median (interquartile range) duration of pre procedure/surgery interruption
  - ASRA: 87 hours (84-92) ~ 7 half lives
  - PAUSE: 64 hours (63-72) ~ 5-6 half lives
- No explanation could be found for the 4 patients with levels > 50 ng/mL

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Douketis JD. J Thromb Haemost. 2025 Mar 12:S1538-7836(25)00144-8. PMID: 40086754.

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**PAUSE Management**

| DOAC | CrCl (mmol/L) | DOAC Interruption (no DOAC on shaded days) day -5 | -4 | -3 | -2 | -1 | Pre-op Blood Sample, No DOAC Day of Surgery | †DOAC Resumption (no DOAC on shaded days) Day+1 | +2 | +3 | +4 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| apixaban | *all* | | | | | | | | | | |
| dabigatran | *CrCl ≥50* | | | | | | | | | | |
| | *CrCl <50* | | | | | | | | | | |
| edoxaban | *all* | | | | | | | | | | |
| rivaroxaban | *all* | | | | | | | | | | |

**ASRA Management**

| DOAC | CrCl (mmol/L) | DOAC Interruption (no DOAC on shaded days) day -5 | -4 | -3 | -2 | -1 | Pre-op Blood Sample, No DOAC Day of Surgery | †DOAC Resumption (no DOAC on shaded days) Day+1 | +2 | +3 | +4 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| apixaban | *all* | | | | | | | | | | |
| dabigatran | *CrCl >80* | | | | | | | | | | |
| | *CrCl 50-80* | | | | | | | | | | |
| | *CrCl 30-49* | | | | | | | | | | |
| edoxaban | *all* | | | | | | | | | | |
| rivaroxaban | *all* | | | | | | | | | | |

Consider DOAC or anti-Xa measurement



# PAUSE-2 Pilot Trial

- ASRA management
  - Longer pre-procedure hold times
  - Possible DOAC measurement which is emphasized in 2025 update
  - At least 24 hours after needle placement/catheter removal
- Slide modified from bridging if high risk for thromboembolism to consider DOAC or anti-Xa measurement

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Douketis JD. J Thromb Haemost. 2025 Mar 12:S1538-7836(25)00144-8. PMID: 40086754.

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# Case

- 68-year-old with hypertension, diabetes and atrial fibrillation on direct oral anticoagulant (DOAC) mono therapy
- Normal renal and liver function
- Coronary stent 2 years ago and antiplatelet therapy stopped at 1 year
- Plan elective hip arthroplasty and spinal anesthesia

# What Would You Do Preoperatively?

A. Hold DOAC for 2 days
B. Hold DOAC for 72 hours
C. Hold DOAC for 2 days and start ASA when DOAC held
D. Figure out why ASA was held when patient has coronary stent
E. Consult cardiology



## 2020 ACC Expert Consensus Decision Pathway for Anticoagulant and Antiplatelet Therapy in Patients With Atrial Fibrillation or Venous Thromboembolism Undergoing Percutaneous Coronary Intervention or With Atherosclerotic Cardiovascular Disease

- For patients requiring indefinite [anticoagulant] AC therapy, we recommend that **APT be continued for 1 year post PCI**, as the safety and efficacy of an AC alone after a short duration of APT has not been tested.
- Thereafter, AC therapy **alone** could be used long-term

- Overall concept
  - –Very rarely need 'triple' therapy with anticoagulant and dual antiplatelet except acutely
  - –If 'dual" therapy needed, change ASA to clopidogrel

HENRY FORD HEALTH

Kumbhani DJ. J Am Coll Cardiol. 2021 Feb 9;77(5):629-658. PMID: 33250267.

## 2024 AHA/ACC/ACS/ASNC/HRS/SCA/SCCT/SCMR/SVM **Guideline for Perioperative Cardiovascular Management for Noncardiac Surgery:** A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

| 1 | B-NR |
|---|---|

9. In patients with prior PCI in whom OAC monotherapy must be discontinued before NCS, aspirin should be substituted when feasible in the perioperative period until OAC can be safely reinitiated.[27–29]

Thompson A. J Am Coll Cardiol. 2024 Nov 5;84(19):1869-1969. PMID:39320289.

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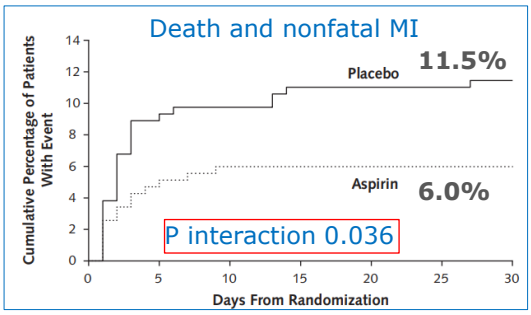
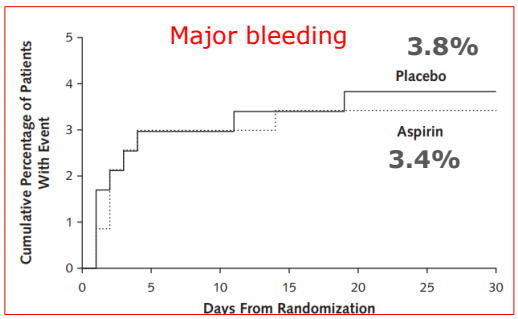
## POISE-2 Subgroup Analysis – Coronary Stents

- POISE-2 subgroup in 470 patients with history of coronary stent
  - 86% were on ASA and in the 'continuation' strata
  - Exclusion for overall trial: bare metal stent < 6 weeks, drug eluting stent < 12 months
  - Absolute increase major bleeding 0.8% in overall trial




HENRY FORD HEALTH Graham MM. Ann Intern Med. 2018 Feb 20;168(4):237-244. PMID: 29132159.

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# Assure-DES Trial

- Question: is it safe to interrupt ASA preoperatively in patients with coronary stents?
- Patients:
  - 1010 (926 in modified intention to treat analysis) from 30 sites in Korea, India and Turkiye
  - Drug eluting coronary stent > 1 year ago
  - ~ 40% ASA monotherapy, ~ 20% P2Y12 monotherapy, ~ 35% DAPT, ~ 3% no antiplatelet therapy
- Intervention: ASA monotherapy 5 days preop
- Control: antiplatelet therapy discontinued 5 days preop
- Outcome: composite of death from any cause, MI, stent thrombosis or stroke
- Timeframe: outcome between 5 days preop to 30 days postop

HENRY FORD HEALTH

Kang DY. J Am Coll Cardiol. 2024 Dec 10;84(24):2380-2389. PMID: 39217573.

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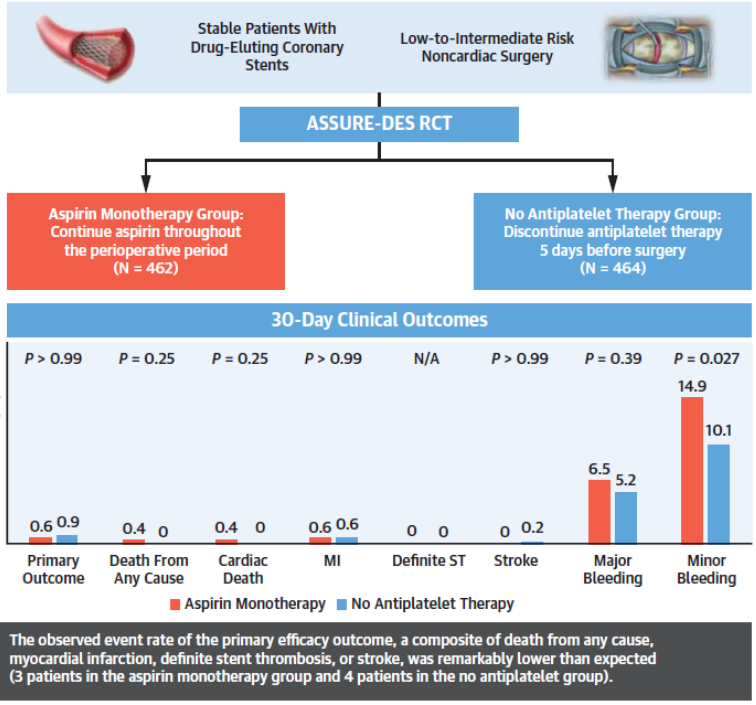


# Assure-DES Trial

- Event rate ~ 10-fold lower than predicted in sample size calculation
  - Study is underpowered
- Most patients of East-Asian decent and known to have lower CAD risk

Kang DY. J Am Coll Cardiol. 2024 Dec 10;84(24):2380-2389. PMID: 39217573.

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# PRESTIGE-AF Trial

- Question: in patients with intracerebral hemorrhage (ICH) and atrial fibrillation, do direct oral anticoagulants (DOAC) reduce the risk of ischemic events without substantially increasing the risk of recurrent ICH?
- Design: randomized trial, stratified by lobar/non-lobar, open-label, blinded adjudication committee, intention to treat
- Patients: 319 patients from 6 European countries between May 2019 and November 2023 with ICH (~ ¼ to 1/3 lobar) and atrial fibrillation (~ 84% anticoagulated), modified Rankin score $\leq$ 4
- Intervention: DOAC, time to enrollment 48 days (29-96)
- Comparison: No DOAC, time to enrollment 49 days (32-91)
- Outcomes:
  - Co-primary, efficacy (superiority, first hierarchy): ischemic stroke
  - Co-primary, safety (non-inferiority margin 1.735): recurrent ICH
- Timeframe: median follow up 1.4 years

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Veltkamp R. Lancet. 2025 Mar 15;405(10482):927-936. PMID: 40023176.

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| | DOAC group (n=158) | No anticoagulant group (n=161) | Unadjusted HR (95% or 90% CI)* | Adjusted HR† (95% or 90% CI)* |
|---|---|---|---|---|
| Ischaemic stroke | 1 | 20 | 0·05 (0·01–0·36) | 0·05 (0·01–0·38) |
| Recurrent intracerebral haemorrhage | 11 | 1 | 10·89 (1·95–60·72) | 11·2 (2·01–62·86) |

Data are number of events, unless otherwise specified. DOAC=direct oral anticoagulant. HR=hazard ratio. *95% CI for ischaemic stroke, 90% CI for intracerebral haemorrhage as the hypothesis for intracerebral haemorrhage endpoint was non-inferiority. †Adjusted for location of index intracerebral haemorrhage, sex, and age.

***Table 2:*** **Coprimary endpoints during follow-up**

PRESTIGE-AF Trial

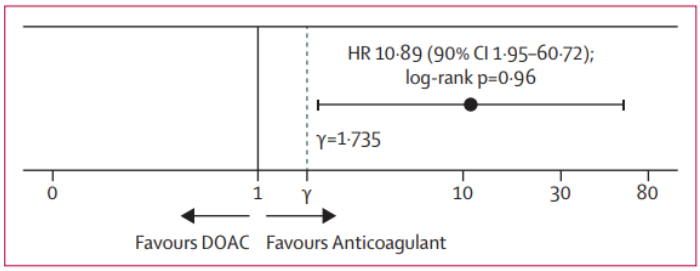


***Figure 4:*** **Intracerebral haemorrhage in relation to prespecified non-inferiority margin**

Veltkamp R. Lancet. 2025 Mar 15;405(10482):927-936. PMID: 40023176.

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# Off-label DOAC Dosing in Atrial Fibrillation (AF)

- Question: what is the proportion and factors associated with off-label DOAC dosing in outpatients with atrial fibrillation?
- Desing: cross sectional retrospective cohort using electronic medical records with natural language processing
- Population: 51,128 outpatients with AF on DOAC at 9 US healthcare systems
- Main measure: label-inconsistent dosing
- Timeframe: cross sectional

- Results
  - 9.8% label-inconsistent
    - 6.8% low
    - 3.0% high

HENRY FORD HEALTH DeLor B. J Gen Intern Med. 2025 Mar;40(4):828-837. PMID: 39424771

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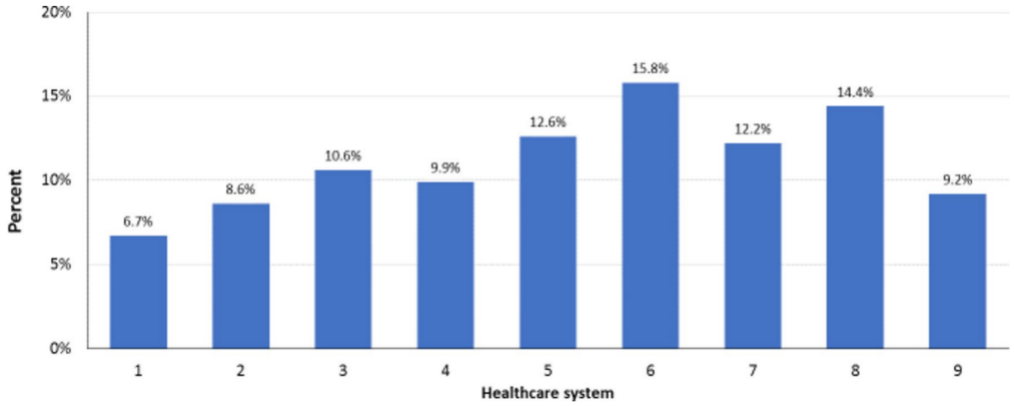
# Off-label DOAC Dosing in Atrial Fibrillation (AF)




- Compared to cardiologist or electrophysiologist, PCPs were more like to have off-label dosing
  - Lower dosing adjusted odds ratio 1.37
  - Higher dosing adjusted odds ratio 1.30

HENRY FORD HEALTH DeLor B. J Gen Intern Med. 2025 Mar;40(4):828-837. PMID: 39424771

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