The Hidden Threat: Nonadherence and Noncompliance Non-Valvular AF Patient
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The Hidden Threat
Adherence and Persistence in Patients with Atrial Fibrillation

Manish Shah MD, Program Director Cardiac Electrophysiology Training
MedStar Washington Hospital Center and MedStar Georgetown University Hospital
Case Presentation

• 66-year-old Male with prior history of stroke, atrial fibrillation s/p catheter ablation x 2. Diagnosed with bladder cancer managed with radiation and local chemotherapy. He is tolerating Apixaban 5mg po bid but has had hematuria with infusion of local chemotherapy. He wants to know more about WATCHMAN.
Adherence vs Persistence with NOAC usage

**Persistence**: whether a patient continues treatment after initiation (assessment years)

**Adherence**: whether a patient takes treatment as prescribed (Temporary Interruptions)
Double the Number of Strokes with Poor NOAC Compliance

- PDC < 90% is associated with a two-fold increase risk of Stroke or SE
- Patients with adequate Persistence still have temporary interruptions

PDC > 90% Reduces Stroke Risk

Kim et al. Europace (2020) 22, 547–557
Temporary Interruptions of NOAC’s are Inevitable

• Temporary Interruptions: (PDC<90)
  – Frequent: 8245 instances !! (Rocket-AF)
  – Mean duration: 6 days off OAC
  • Common Reasons:
    – Surgical Interventions 38%
    – Bleeding 16%
    – Adverse event 25%
    – Patient Confused 18%

Patel et al. JACC Vol. 61, No. 6, 2013 February 12, 2013:651–8
Case Presentation 2

• 82 year old gentleman with atrial fibrillation, hypertension, ischemic stroke and mild cognitive impairment. He is tolerating rivaroxaban 20mg po qhs but complains about the cost and periodically does not fill his prescription.

• Should we consider LAAC? If so when and how do we balance risk and benefit discussion?
Acute Stroke Admissions in NVAF Patients
n=6195 from 2018-2019 at 16 centers

Ischemic Strokes (n=5153, 83.2%)

- Previously known NVAF (77%)
- New NVAF Dx (23%)

On OAC (46%)

- No FDA Approved Prevention Measure (No OAC/LAAC) (54%)

Intracerebral Hemorrhage (n=1042, 16.8%)

- Known NVAF (82%)
- New NVAF Dx (18%)

- 71% on AC
- 15% on OAC

OAC failure

System Failure
Risk Stratification
Understanding of options
[(N)OAC vs LAAC]

OAC Failure
System Failure
Diagnosis
Risk Stratification

System Failure
Not Detecting
High Risk Features for ICH & Selecting LAAC

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Patients with AF who had Ischemic Strokes (n=5153)

Patients w/ previously known AF (77%)

- On Anticoagulant (46%)
  - DOAC (58%)
  - warfarin (40%)
  - heparin (2%)
- On Antiplatelet only (28%)
- Not on Antithrombotic (26%)

New AF Dx (23%)

- On Anticoagulant (10%)
  - On Antiplatelet only (38%)
- Not on Antithrombotic (52%)
Persistence of NOAC’s

N = 559,445
63% @ 5Y

Europace (2021) 23, 1722–1730

Kim et al. Europace (2020) 22, 547–557

PDC > 80%
Comparison with PINNACLE FLX
45-day Outcomes

Similar clinical outcomes in real-world & pivotal WATCHMAN FLX studies

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>SURPASS</th>
<th>PINNACLE FLX</th>
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<tbody>
<tr>
<td>Safety Endpoint</td>
<td>0.4</td>
<td>0.5</td>
</tr>
<tr>
<td>All Death</td>
<td>0.9</td>
<td>0.5</td>
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<tr>
<td>All Stroke</td>
<td>0.4</td>
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<tr>
<td>Ischemic Stroke</td>
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<tr>
<td>Device-Related Thrombus</td>
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Thank you

It’s how we treat people.
STROKE PREVENTION IN ATRIAL FIBRILLATION
74 year-old man with a history of HTN and paroxysmal AFib. Diagnosed with asymptomatic chronic myelomonocytic leukemia (CMML), with platelet counts of 70-100K. His CMML is being managed with supportive care alone. He has tolerated apixaban 5 mg BID. The degree of thrombocytopenia is expected to gradually worsen over time.
Case #2

77 year-old woman with a history of HTN, CKD-III (eGFR= 45), and CAD, s/p multivessel PCI in 2018. Atrial fibrillation, s/p ablation. She is managed with rivaroxaban 15 mg QD and clopidogrel 75 mg QD. Weight = 105 Lbs.
Bleeding Risk: Assess and Reduce

- Although the data on AC alone versus AC plus single antiplatelet therapy are limited for patients with stable CAD, there is more robust evidence that addition of antiplatelet therapy may have net clinical harm.

- Fewer antithrombotic meds is better.

- Independent risk factors for ICH in patients receiving antithrombotic therapy:
  - Advanced age
  - Lower body weight
  - CKD
  - Uncontrolled HTN
  - Other: active malignancy, falls, PAD, prior stroke, CAA


Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA
Nonadherence and Stroke in NVAF Patients: A Neurologist’s Perspective

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66 year old lady has 5 cryptogenic strokes!
Finally gets ILR and is soon diagnosed with AFib, so we start AC.
But then she has another ischemic stroke on OSH MRI.
She stopped the AC! Why? Bruises easily, falls on her face.

"Florida woman"

Extensive facial ecchymoses

Her message to us
“Florida woman”

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Finally gets ILR and is soon diagnosed with AFib, so we start AC.
But then she has another ischemic stroke on OSH MRI.
She stopped the AC! Why? Bruises easily, falls on her face.

Question: Do you restart anticoagulation?

A. Yes, stress compliance because AC is first-line therapy for AFib
B. Yes but get a followup CT-head first.
C. Later; when ready for LAAC implant and 45 days afterwards only.
D. No because she will not be compliant with her AC again.
E. No because resuming AC is too risky given falls.
“Florida woman”

66 year old lady has **5 cryptogenic strokes**!
Finally gets ILR and is soon diagnosed with AFib, so we start AC.
But then she has **another ischemic stroke** on OSH MRI.
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DOAC “Pseudo-failure” more likely than DOAC “True Failure” For AF patients with Ischemic Stroke: presented at ESOC 2019 (Milan, Italy)

• Background: For stroke prevention in AF, Direct Oral Anticoagulant (DOAC) use continues to rise, however some patients develop an ischemic stroke while prescribed this medication regardless.

  • **DOAC “True failure”** involves drug malabsorption, hypermetabolism, and clearance problems, while **DOAC “Pseudo-failure”** is from C.H.A.M.P. – (C)ompliance concerns, (H)ypertensive lacunar disease, (A)rterial atherosclerosis, (M)alignancy/hypercoagulable state, and (P)atent Foramen Ovale. The incidence of DOAC “True failure” vs “Pseudo-failure” is unknown.

• Methods: IRB-approved retrospective review at USF/TGH to identify AF patients who, between 2012 and 2017 developed an ischemic stroke, while prescribed DOAC.
DOAC “Pseudo-failure” more likely than DOAC “True Failure” for AF patients with Ischemic Stroke, presented at ESOC 2019

Compliance Concerns = top cause of Pseudofailure (49%)
Ischemic Stroke despite Oral Anticoagulant Therapy in Patients with Atrial Fibrillation

• **Results:** 5,413 Pts (median age = 78 years, NIHSS = 6, CHA$_2$DS$_2$-Vasc 5 [IQR = 4-6]) similar for OAC$_{\text{prior}}$ (n = 1,195) and OAC$_{\text{naive}}$ (n = 4,119, p = 0.103). During 6,128 patient-years of follow-up, 289 patients had AIS (4.7%/year). OAC$_{\text{prior}}$ was associated with an increased risk of AIS (HR = 1.6, 95% CI = 1.2-2.3, p = 0.005). OAC$_{\text{changed}}$ (n = 307) was not associated with decreased AIS risk (HR = 1.2, 95% CI = 0.7-2.1, p = 0.415) compared with OAC$_{\text{unchanged}}$ (n = 585).

• **Interpretation:** Patients with AF who have an ischemic stroke despite previous oral anticoagulation are at a higher risk for recurrent ischemic stroke despite a CHA$_2$DS$_2$-Vasc score similar to those without prior oral anticoagulation. Better prevention strategies are needed for this high-risk patient group.
