Antiplatelet and anticoagulation update

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No Conflicts or Disclosures
Introduction

Oral antiplatelet/anticoagulation has become very complicated!

2009: ASA, clopidogrel, warfarin. 8 permutations

2017: ASA, clopidogrel, prasugrel, ticagrelor, vorapaxar, warfarin, dabigatran, rivaroxaban, apixaban, edoxaban

160 permutations!
Introduction

Individualizing treatment is key, taking into account ischemic risks and bleeding risks.

Resident: “What do you give your ACS patients?”

Me: “Depends on the patient.”

90-year old 40 kg woman with chest pain who is ruling out for MI gets ASA 81 mg ONLY.

55-year old 150 kg man with atrial fibrillation, elevated troponin, abnormal EKG, ongoing chest pain gets EVERYTHING!
OVERVIEW

1. **What is the Optimal antiplatelet and anticoagulant therapy in patients with oral anticoagulation and coronary Stenting (WOEST)**

2. Why prasugrel or ticagrelor over clopidogrel?

3. Left atrial appendage closure. Does it ever make sense?
1. **First randomized trial** to address the optimal antiplatelet therapy in patients on OAC undergoing coronary stenting

2. In this study which was specifically designed to detect bleeding events, the **bleeding rate** was higher than expected

3. **Primary endpoint was met**: OAC plus clopidogrel causes less bleeding than triple antithrombotic therapy, but now shown in a randomized way

4. **Secondary endpoint was met**: with double therapy there is no excess of thrombotic/thromboembolic events: stroke, stent thrombosis, target vessel revascularisation, myocardial infarction or death

5. **Less all-cause mortality** with double therapy
Primary Endpoint: Total number of TIMI bleeding events

Cumulative incidence of bleeding

- **Triple therapy group**
  - 44.9%

- **Double therapy group**
  - 19.5%

**p<0.001**

**HR=0.36  95%CI[0.26-0.50]**

Days

<table>
<thead>
<tr>
<th>n at risk:</th>
<th>284</th>
<th>210</th>
<th>194</th>
<th>186</th>
<th>181</th>
<th>173</th>
<th>159</th>
<th>140</th>
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<tbody>
<tr>
<td></td>
<td>279</td>
<td>253</td>
<td>244</td>
<td>241</td>
<td>241</td>
<td>236</td>
<td>226</td>
<td>208</td>
</tr>
</tbody>
</table>
All-Cause Mortality

- Triple therapy group
- Double therapy group

Cumulative incidence of death

- HR=0.39  95%CI[0.16-0.93]
- p=0.027

Days

Cumulative incidence of death

- 0 %
- 2.5 %
- 5 %
- 7.5 %

n at risk:

- 284 281 280 280 279 277 270 252
- 279 278 276 276 276 275 274 256
WOEST – My Take

1. Dual anti-platelet therapy is VERY POTENT. Combining this with an anticoagulant is extremely aggressive treatment.

2. Contemporary “second-generation” or “third-generation” drug-eluting coronary stents are far safer than Cypher/Taxus (off the market).

3. The association of bleeding and mortality shouldn’t be surprising – this has been shown in multiple settings.
A 78-year woman with paroxysmal atrial fibrillation and a CHA2DS2-VASc score of 4 undergoes coronary stent implantation for progressive angina. An everolimus-eluting 3 mm x 12 mm stent was placed in the mid left anterior descending coronary artery. She tolerates the procedure without complications. She does not have any significant bleeding risk factors or bleeding history.

Which of the following anticoagulation/antiplatelet strategies would you recommend for this patient?

A. Warfarin with goal INR 2.0-3.0, ASA 325 mg daily, clopidogrel 75 mg daily

B. Warfarin with goal INR 2.0-3.0, clopidogrel 75 mg daily

C. Warfarin with goal INR 1.5.-2.5, prasugrel 10 mg daily

D. ASA 81 mg daily, clopidogrel 75 mg daily
Question 1 – Answer

• B. Warfarin with goal INR 2.0-3.0, clopidogrel 75 mg daily

WOEST showed a significant reduction in the primary endpoint of bleeding events, the secondary endpoint of death, MI, revascularization, stroke, stent thrombosis, and even the endpoint of all-cause mortality for patients receiving a coronary stent who require anticoagulation.

• Answer A is incorrect because triple therapy that includes high-dose ASA is not indicated. Answer C is incorrect because prasugrel is contraindicated in patients over 75 years. Also the lower warfarin goal of 1.5-2.5 is not established as effective. Answer D is incorrect because it does not include anticoagulation therapy to prevent stroke in this patient with significant stroke risk.
Question 2 – Audience Response

An 80-year old woman is admitted to the hospital with acute onset of chest discomfort. She has ischemic-appearing EKG changes and mild elevation in her troponin.

Coronary angiography shows a high-grade “culprit lesion” in a diagonal branch (too small for stent) and medical management is recommended.

• Which of the following antiplatelet strategies would you recommended for this patient to be in accordance with AHA guidelines?

• A. Prasugrel 10 mg daily, ASA 81 mg daily.

• B. Ticagrelor 90 mg twice daily, ASA 81 mg daily.

• C. ASA 81 mg daily

• D. Clopidogrel 75 mg daily
Question 2 – Audience Response

• B. Ticagrelor 90 mg twice daily, ASA 81 mg daily.

• Prasugrel is contraindicated in this woman who is over 75 years of age and was only studied in a population of patients who received PCI. Dual anti-platelet therapy is recommended for 12 months as a Class I recommendations and so ASA alone or clopidogrel alone are not recommended.
Ruptured Vulnerable Plaque
Prasugrel (Effient)

Triton TIMI-38 study. High-risk ACS patients receiving stents.

Reduction in MACCE (12.1% to 9.9%) primarily non-fatal MI reduction (NNT 50). Stent thrombosis reduced from 2.4% to 1.1%.

Excessive bleeding risk in patients with previous TIA/stroke, >75 years, < 60 kg.
Prasugrel (Effient)

% Pli Inhibition

Hours

Prasugrel 60 mg

Clopidogrel 600 mg

*** P<0.0001
Ticagrelor (Brilinta)

PLATO study, 18,000 patients. ACS patients either stents or medical management.

Reduction in MACCE (11.7% to 9.8%) primarily non-fatal MI reduction (NNT 50).

Mortality reduction: 5.9% to 4.5%

Contraindicated if previous intracranial bleed.
Ticagrelor/Brilinta

Graph showing the time (hour) on the x-axis and the percentage on the y-axis for Ticagrelor 180 mg, Clopidogrel 600 mg, and Placebo.
Potent antiplatelet medicines (prasugrel, ticagrelor)

1. Great advantages for “loading doses” in the cath lab or hospital. Much less expensive and less dangerous than IV antiplatelet meds.

2. Number needed to treat to benefit compared to clopidogrel is high, especially after the first 30 days.

3. Would avoid use of prasugrel/ticagrelor with oral anticoagulants.
80-year old woman with non-valvular atrial fibrillation.

AV Node ablation and pacing for rapid, chronic atrial fibrillation
Hip replacements, should use a walker but refuses (too proud!)
Takes aspirin for CAD and PAD
Hypertension
Renal insufficiency GFR 38
“I really don’t want to take that rat poison and can’t afford expensive medicines!”
CHA$_2$DS$_2$-VASc = 5

<table>
<thead>
<tr>
<th>Condition/Risk Factor</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>C Congestive heart failure</td>
<td>1</td>
</tr>
<tr>
<td>H Hypertension</td>
<td>1</td>
</tr>
<tr>
<td>A Age $\geq$75 years</td>
<td>2</td>
</tr>
<tr>
<td>D Diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>S$_2$ Previous stroke or TIA</td>
<td>2</td>
</tr>
<tr>
<td>V Vascular disease</td>
<td>1</td>
</tr>
<tr>
<td>A Age 65-74 years</td>
<td>1</td>
</tr>
<tr>
<td>Sc Sex (female gender)</td>
<td>1</td>
</tr>
</tbody>
</table>

### Table:

<table>
<thead>
<tr>
<th>CHA$_2$DS$_2$VASc Score</th>
<th>Risk of Stroke</th>
<th>Annual Risk of Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>15.2%</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>9.6%</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>9.8%</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>6.7%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>4.0%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3.2%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2.2%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1.3%</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.0%</td>
<td></td>
</tr>
</tbody>
</table>

1 Lip GY et al, *Chest*. 2010;137(2):263–72
HAS-BLED = 3 (possibly 4)

- Hypertension (SBP>160 mm Hg)
- Abnormal:
  - Kidney function: creat > 2.26
  - Liver function: Bili >2x ULN and LFTs > 3x LN
- Stroke history
- Bleeding history or predisposition
- Labile INRs: TTR < 60%
- Elderly > 65 years
- Drugs:
  - ETOH abuse
  - ASA or NSAID use

<table>
<thead>
<tr>
<th>HAS-BLED Score</th>
<th>Annual Bleed Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.9 - 1.1</td>
</tr>
<tr>
<td>1</td>
<td>1.0 – 3.4</td>
</tr>
<tr>
<td>2</td>
<td>1.9 – 4.1</td>
</tr>
<tr>
<td>3</td>
<td>3.7 – 5.8</td>
</tr>
<tr>
<td>4</td>
<td>8.7 – 9.1</td>
</tr>
</tbody>
</table>

- HAS-BLED does not fully account for fall risk
- Annual risk of stroke & bleeding multiplies quickly

## Direct Oral Anticoagulants (DOACs)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>1 Year Drug Discontinuation</th>
<th>Major Bleeding (rate/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivaroxaban¹</td>
<td>24%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Apixaban²</td>
<td>25%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Dabigatran³</td>
<td>21%</td>
<td>3.3%</td>
</tr>
<tr>
<td>(150 mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edoxaban⁴</td>
<td>33% / 34%</td>
<td>2.8% / 1.6%</td>
</tr>
<tr>
<td>(60 mg / 30 mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warfarin¹⁻⁴</td>
<td>17 – 28%</td>
<td>3.1 – 3.6%</td>
</tr>
</tbody>
</table>

### Notes:

1 Connolly, S. NEJM 2009; 361:1139-1151 – 2 yrs follow-up (Corrected)
2 Patel, M. NEJM 2011; 365:883-891 – 1.9 yrs follow-up, ITT
3 Granger, C NEJM 2011; 365:981-992 – 1.8 yrs follow-up,

**Convenient & reduced hemorrhagic stroke**

**Persistent rate of major bleeding and intolerance**

**Elderly & bleeding risk patients are not represented in clinical trials**
Use of OACs in AF Patients peaks at < 60%, Use declines with increasing risk & age
Question 3 – Audience Response

Which of the following would you recommend for stroke prevention in this 80-year old woman with atrial fibrillation who refuses to take warfarin?

• A. Clopidogrel 75 mg daily.
• B. Dabigatran 150 mg twice daily
• C. ASA 81 mg daily
• D. Apixaban 5 mg twice daily
Question 3 – Audience Response

• D. Apixaban 5 mg twice daily.

• Anti-platelet medicines alone are not effective for stroke prevention.

• Dabigatran carried excessive bleeding risk in this elderly woman with renal insufficiency.
Primary Outcome
Stroke (ischemic or hemorrhagic) or systemic embolism

- Apixaban: 212 patients, 1.27% per year
- Warfarin: 265 patients, 1.60% per year

P (non-inferiority)<0.001
21% RRR
Major Bleeding

- **Apixaban**: 327 patients, 2.13% per year
- **Warfarin**: 462 patients, 3.09% per year

31% RRR

**Graph Details**
- **X-axis**: Months
- **Y-axis**: Percent with Event
- **Lines**:
  - Orange line: Warfarin (462 patients, 3.09% per year)
  - Green line: Apixaban (327 patients, 2.13% per year)

**Legend**
- **Warfarin**
- **Apixaban**

**Note**: Intermountain Heart Institute logo is present on the page.
Connection Between NVAF-Related Stroke and the Left Atrial Appendage

AF Creates Environment for Thrombus Formation in Left Atrium

- Stasis-related LA thrombus is a predictor of TIA\(^1\) and ischemic stroke\(^2\).
- In non-valvular AF, >90% of stroke-causing clots that come from the left atrium are formed in the LAA\(^3\).

U.S. LAA CLOSURE 2017

Watchman: FDA Approved, CMS Covered

Device Implant

- warfarin & aspirin (45 Days)
- plavix & aspirin
- aspirin alone
45 days post-implant
# LAA Closure Pivotal Trials

<table>
<thead>
<tr>
<th></th>
<th>PROTECT AF</th>
<th>CAP Registry</th>
<th>PREVAIL</th>
<th>CAP2 Registry</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enrolled</strong></td>
<td>800</td>
<td>566</td>
<td>461</td>
<td>579</td>
<td>2406</td>
</tr>
<tr>
<td><strong>Randomized</strong></td>
<td>707</td>
<td>---</td>
<td>407</td>
<td>---</td>
<td>1114</td>
</tr>
<tr>
<td><strong>Device:</strong> warfarin (2:1)</td>
<td>463 : 244</td>
<td>566</td>
<td>269 :138</td>
<td>579</td>
<td>1877: 382</td>
</tr>
<tr>
<td><strong>Mean Follow-up (years)</strong></td>
<td>5.0</td>
<td>3.7</td>
<td>2.2</td>
<td>0.58</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Patient-years</strong></td>
<td>2717</td>
<td>2022</td>
<td>860</td>
<td>332</td>
<td>5931</td>
</tr>
</tbody>
</table>

PROTECT AF
4-Year (2621 Pt Yr) Analysis

LAA Closure Demonstrated Statistical Noninferiority and Superiority for the Primary Composite Endpoint Compared to Warfarin

<table>
<thead>
<tr>
<th>Event</th>
<th>Device Group (n = 463)</th>
<th>Warfarin Group (n = 244)</th>
<th>Device/Warfarin Rate Ratio (95% Credible Interval)</th>
<th>Posterior Probabilities, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events/Patient-Years</td>
<td>Observed Rate$^a$</td>
<td>Events/Patient-Years</td>
<td>Observed Rate$^a$</td>
</tr>
<tr>
<td>Primary efficacy endpoint$^b$</td>
<td>39/1720.2</td>
<td>2.3 (1.7-3.2)</td>
<td>34/900.8</td>
<td>3.8 (2.5-4.9)</td>
</tr>
<tr>
<td>Stroke</td>
<td>26/1720.7</td>
<td>1.5 (1.0-2.2)</td>
<td>20/900.9</td>
<td>2.2 (1.3-3.1)</td>
</tr>
<tr>
<td>Ischemic</td>
<td>24/1720.8</td>
<td>1.4 (0.9-2.1)</td>
<td>10/904.2</td>
<td>1.1 (0.5-1.7)</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>3/1774.2</td>
<td>0.2 (0.0-0.4)</td>
<td>10/916.2</td>
<td>1.1 (0.5-1.8)</td>
</tr>
<tr>
<td>Disabling$^c$</td>
<td>8/1771.3</td>
<td>0.5 (0.2-0.8)</td>
<td>11/912.7</td>
<td>1.2 (0.6-1.9)</td>
</tr>
<tr>
<td>Nondisabling$^c$</td>
<td>18/1723.7</td>
<td>1.0 (0.7-1.7)</td>
<td>9/907.7</td>
<td>1.0 (0.4-1.7)</td>
</tr>
<tr>
<td>Systemic embolization</td>
<td>3/1773.6</td>
<td>0.2 (0.0-0.4)</td>
<td>0/919.5</td>
<td>0</td>
</tr>
<tr>
<td>Cardiovascular or unexplained death</td>
<td>17/1774.3</td>
<td>1.0 (0.6-1.5)</td>
<td>22/919.4</td>
<td>2.4 (1.4-3.4)</td>
</tr>
<tr>
<td>Primary safety endpoint$^d$</td>
<td>60/1666.2</td>
<td>3.6 (2.8-4.6)</td>
<td>27/878.2</td>
<td>3.1 (2.0-4.3)</td>
</tr>
</tbody>
</table>

## Ischemic Stroke Across Pivotal Studies Similar to Contemporary Warfarin Trials

### Table 17: Ischemic Stroke and Systemic Embolism Across WATCHMAN Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>WATCHMAN Events (rate per 100 pt-yrs)</th>
<th>Control Events (rate per 100 pt-yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ischemic Stroke</td>
<td>Systemic Embolism</td>
</tr>
<tr>
<td>PREVAIL-only</td>
<td>13 (2.30)</td>
<td>1 (0.17)</td>
</tr>
<tr>
<td>PROTECT AF</td>
<td>24 (1.3)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>CAP</td>
<td>24 (1.2)</td>
<td>1 (0.05)</td>
</tr>
<tr>
<td>CAP2</td>
<td>9 (2.7)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Total across all studies</td>
<td><strong>70 (1.5)</strong></td>
<td><strong>6 (.12)</strong></td>
</tr>
</tbody>
</table>

Stroke in Contemporary Warfarin Trials

Table 26: Event Rates in Warfarin Control groups across anticoagulation trials (FDA analysis)

<table>
<thead>
<tr>
<th>Event Rate per 100 pt-ys, (Events/total pt-ys), (95% CI*)</th>
<th>All Stroke</th>
<th>Ischemic Stroke</th>
<th>Hemorrhagic Stroke</th>
<th>Systemic Embolism</th>
<th>Cardiovascular Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIVE W</td>
<td>1.40</td>
<td>1.00 (42/4200)</td>
<td>0.36 (15/4166.7)</td>
<td>0.10 (4/4000)</td>
<td>2.52 (106/4206.3)</td>
</tr>
<tr>
<td></td>
<td>(59/4214.3)</td>
<td>(0.72, 1.35)</td>
<td>(0.20, 0.59)</td>
<td>(0.03, 0.25)</td>
<td>(2.06, 3.05)</td>
</tr>
<tr>
<td>BAFTA</td>
<td>1.6</td>
<td>0.8 (10/1250)</td>
<td>0.5 (6/1200)</td>
<td>0.1 (1/1000)</td>
<td>3.1 (41/1322.6)</td>
</tr>
<tr>
<td></td>
<td>(21/1312.5)</td>
<td>(0.38, 1.47)</td>
<td>(0.18, 1.09)</td>
<td>(0.003, 0.56)</td>
<td>(2.22, 4.21)</td>
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<tr>
<td>RELY</td>
<td>1.57</td>
<td>1.20 (142/11833)</td>
<td>0.38 (45/11842)</td>
<td>-</td>
<td>2.69 (317/11784)</td>
</tr>
<tr>
<td></td>
<td>(187/11910.83)</td>
<td>(1.01, 1.41)</td>
<td>(0.28, 0.51)</td>
<td></td>
<td>(2.40, 3.00)</td>
</tr>
<tr>
<td>ROCKET AF</td>
<td>2.2</td>
<td>1.6 (241/10954.6)</td>
<td>0.4</td>
<td>0.2</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>(241/10954.6)</td>
<td>(1.93, 2.50)</td>
<td></td>
<td></td>
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<tr>
<td>ARISTOTLE</td>
<td>1.51</td>
<td>1.05 (175/16666.7)</td>
<td>0.47 (78/16595.7)</td>
<td>0.10 (17/17000)</td>
<td>2.02</td>
</tr>
<tr>
<td></td>
<td>(250/16556.3)</td>
<td>(0.90, 1.22)</td>
<td>(0.37, 0.59)</td>
<td>(0.06, 0.16)</td>
<td></td>
</tr>
<tr>
<td>ENGAGE AF</td>
<td>1.69</td>
<td>1.25 (235/18800)</td>
<td>0.47 (90/19148.9)</td>
<td>0.12 (23/19166.7)</td>
<td>3.17 (611/19274.5)</td>
</tr>
<tr>
<td></td>
<td>(317/18757.4)</td>
<td>(1.10, 1.42)</td>
<td>(0.38, 0.58)</td>
<td>(0.08, 0.18)</td>
<td>(2.92, 3.43)</td>
</tr>
<tr>
<td>PROTECT AF</td>
<td>2.2</td>
<td>1.1 (10/932.8)</td>
<td>1.1 (10/945.6)</td>
<td>0.0</td>
<td>2.3 (22/948.9)</td>
</tr>
<tr>
<td></td>
<td>(20/929.4)</td>
<td>(0.51, 1.97)</td>
<td>(0.51, 1.94)</td>
<td></td>
<td>(1.45, 3.51)</td>
</tr>
<tr>
<td>PREVAIL-only</td>
<td>1.00</td>
<td>0.34 (1/298.1)</td>
<td>0.67 (2/300.1)</td>
<td>0.0</td>
<td>2.33 (7/300.2)</td>
</tr>
<tr>
<td></td>
<td>(3/299)</td>
<td>(0.008, 1.869)</td>
<td>(0.081, 2.407)</td>
<td></td>
<td>(0.937, 4.804)</td>
</tr>
</tbody>
</table>

*The 95% CI calculations are performed assuming Poisson distribution.

# Imputed Placebo Analysis

## Table 28: Imputed Placebo versus Observed WATCHMAN Ischemic Stroke Rate

<table>
<thead>
<tr>
<th>Study (Date of Dataset Lock)</th>
<th>Average CHADS2 Score WATCHMAN Patients</th>
<th>Imputed Untreated Control Event Rate</th>
<th>Observed WATCHMAN Ischemic Stroke Rate (95% CI)</th>
<th>Relative Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROTECT AF (3/3/2014)</td>
<td>2.2</td>
<td>5.6 to 5.7</td>
<td>1.3 (0.9, 2.0)</td>
<td>77% (64%, 84%)</td>
</tr>
<tr>
<td>CAP (3/7/2014)</td>
<td>2.5</td>
<td>6.4</td>
<td>1.1 (0.8, 1.7)</td>
<td>83% (73%, 88%)</td>
</tr>
<tr>
<td>PREVAIL only (4/18/2014)</td>
<td>2.6</td>
<td>6.6 to 6.7</td>
<td>2.5 (1.5, 4.3)</td>
<td>62% (35%, 77%)</td>
</tr>
</tbody>
</table>
Figure 18: PROTECT AF: Freedom from Cardiovascular/Unexplained Death - Kaplan-Meier Curves at 2621 Patient-Years

Watchman: FDA Approved 3/2015

Indications for Use

The Watchman device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHADS$_2$ or CHA$_2$DS$_2$-VASc scores and are recommended for anticoagulation therapy;

- Are deemed by their physicians to be suitable for warfarin; and

- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.
A. The device has received Food and Drug Administration (FDA) Approval (PMA) for that device’s FDA-approved indication and meet all of the conditions specified below:

- A CHADS2 score $\geq 2$ or CHA2DS2-VASc score $\geq 3$
- Suitable for short-term warfarin but deemed unable to take long term oral anticoagulation.
- Formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF.
Yes. I agree that LAA closure would be appropriate for him. Would you mind dictating a note documenting that you have participated in a formal shared decision making interaction using an evidence-based decision tool on oral anticoagulation and concluded that the patient may take short term anticoagulation but is unable to take chronic oral anticoagulation and LAA closure is being offered as second line therapy.
Audience Response Question 4

Which of the following patients may be appropriate for on-label, CMS-reimbursed left atrial appendage closure?

A. 80-year old woman with non-valvular atrial fibrillation hospitalized 1 week ago for major GI bleed on warfarin.

B. 85-year old woman with non-valvular atrial fibrillation who refuses to ever take warfarin.

C. 65-year old man with atrial fibrillation who received an LAD stent, prefers to take aspirin and prasugrel only.

D. 85-year old man with subdural hematoma on warfarin one year ago with CHADS-VASC score of 6, OK to resume warfarin per PCP and neurologist judgment.
Audience Response Question 4

Which of the following patients may be appropriate for on-label, CMS-reimbursed left atrial appendage closure?

D. 85-year old man with subdural hematoma on warfarin one year ago with CHADS-VASC score of 6, OK to resume warfarin.

This man is at increased risk for stroke or systemic embolism, is “suitable for warfarin” but has a rationale for a non-pharmacologic alternative to warfarin (previous subdural hematoma).
Take-Home Messages

1. Individualize your treatment choices

2. Use formal risk assessment tools

3. Avoid “triple” therapy

4. Consider LAA closure for patients at very high stroke risk who have bled on warfarin or DOAC
Thank you! Questions?

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