Management of Atrial Fibrillation

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University of Colorado
Disclosures

• Educational and Research Grants:
  – Medtronic, Boston Scientific

• Consulting:
  – Boston Scientific, Medtronic, St Jude Medical
Road Map

• AFFIRM Clarified
• Stroke Associated with Atrial Fibrillation
  – Left Atrial Appendage Occlusion
• Antiarrhythmic Drugs
• Ablation of Atrial Fibrillation
  – New Techniques
• Summary
• Patients with atrial fibrillation have a higher mortality compared to those without atrial fibrillation
Correlation and Causation

• Is AF resulting in increased mortality?
  – Rhythm control will improve mortality

• Is AF merely a result of other causes of increased mortality (HF, HTN, et c.)
  – Rhythm control will have no effect
Correlation and Causation

Example: Global Warming Correlation

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of EPs</th>
<th>Global Temperature (Celsius)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1890</td>
<td>1</td>
<td>13.5 (Eintohoven)</td>
</tr>
<tr>
<td>1920</td>
<td>124</td>
<td>14</td>
</tr>
<tr>
<td>1940</td>
<td>259</td>
<td>14.5</td>
</tr>
<tr>
<td>1960</td>
<td>587</td>
<td>15</td>
</tr>
<tr>
<td>1980</td>
<td>1267</td>
<td>15.5</td>
</tr>
<tr>
<td>2000</td>
<td>2345</td>
<td>16</td>
</tr>
<tr>
<td>2020</td>
<td>6732</td>
<td>16.5</td>
</tr>
</tbody>
</table>
Correlation and Causation

(Relationship between Surface Area of Women’s Undergarments and Global Warming)
AFFIRM – Study Overview

• Randomized comparison of two treatment strategies
  – Rate control + anticoagulation
  – Rhythm control +/- anticoagulation
• Subjects without symptoms, but with risk factors for stroke
• Enrollment 1995 – 1999
Primary Endpoint: All-Cause Mortality

Rhythm

Rate

$p = 0.078$

<table>
<thead>
<tr>
<th>Time (Years)</th>
<th>Rhythm N:</th>
<th>Rate N:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2033</td>
<td>2027</td>
</tr>
<tr>
<td>1</td>
<td>1932</td>
<td>1926</td>
</tr>
<tr>
<td>2</td>
<td>1807</td>
<td>1827</td>
</tr>
<tr>
<td>3</td>
<td>1316</td>
<td>1329</td>
</tr>
<tr>
<td>4</td>
<td>780</td>
<td>774</td>
</tr>
<tr>
<td>5</td>
<td>255</td>
<td>236</td>
</tr>
</tbody>
</table>
Secondary Endpoint - Death, Disabling Stroke or Anoxic Encephalopathy, Major Bleed, or Cardiac Arrest

$p = 0.33$

Rhythm N: 2033, 1895, 1746, 1260, 719, 231
Rate N: 2027, 1890, 1761, 1264, 723, 208
Atrial Fibrillation: Follow-up Investigation of Rhythm Management

Time dependent, on treatment, Multivariate Analysis of Survival

<table>
<thead>
<tr>
<th>HR (99%)</th>
<th>Factor</th>
</tr>
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<tbody>
<tr>
<td>1.06 (1.05–1.08)</td>
<td>Age (per year)</td>
</tr>
<tr>
<td>1.56 (1.20–2.04)</td>
<td>CAD</td>
</tr>
<tr>
<td>1.57 (1.18–2.09)</td>
<td>CHF</td>
</tr>
<tr>
<td>1.56 (1.17–2.07)</td>
<td>Diabetes</td>
</tr>
<tr>
<td>1.78 (1.25–2.53)</td>
<td>Smoking</td>
</tr>
<tr>
<td>1.70 (1.24–2.33)</td>
<td>Stroke/TIA</td>
</tr>
<tr>
<td>0.74 (0.55–0.98)</td>
<td>Normal LVEF</td>
</tr>
<tr>
<td>1.36 (1.03–1.80)</td>
<td>Mitral Regurg</td>
</tr>
<tr>
<td>0.50 (0.37–0.69)</td>
<td>Warfarin</td>
</tr>
<tr>
<td>1.42 (1.09–1.86)</td>
<td>Digoxin</td>
</tr>
<tr>
<td>0.53 (0.39–0.72)</td>
<td>Sinus Rhythm</td>
</tr>
<tr>
<td>1.49 (1.11–2.01)</td>
<td>AA drug</td>
</tr>
</tbody>
</table>

Better vs Worse
Limitations of AFFIRM

• Patients with any symptoms of AF were not enrolled
• The mean follow-up of 3.5 years is not long-term.
  – AF begets AF – this makes cross-over to rhythm control difficult
  – AF symptoms could develop over time
• AFFIRM did not evaluate CHADS 0 patients.
The Case for Rhythm Control within AFFIRM

• Rhythm control arm was only apparently successful at sinus rhythm maintenance 60% of the time
  – Not truly a comparison of strategies
  – Actually, there was significant survival benefit in those patients able to maintain sinus rhythm

• The apparent increase in stroke and mortality risk in the rhythm control arm is entirely explained by lack of anticoagulation

Rate control is an acceptable strategy for treatment of asymptomatic AF

Anticoagulation should be continued in patients with risk factors for stroke – even in those who appear to maintain sinus rhythm

Patients with any symptoms attributable to AF should be treated with a rhythm control strategy
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Prevalence of AF and Impact of Strokes attributable to AF

• 35% of patients with AF will have a stroke in their lifetime. (Stroke 22:938,991)

• Strokes related to AF are big
  • Higher Rate of Mortality
  • Higher Rate of Major Disability

Risk Stratification and annual stroke risk for patients with AF.

<table>
<thead>
<tr>
<th>CHADS(2) Score</th>
<th>CHADS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congestive heart failure</td>
<td>+1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>+1</td>
</tr>
<tr>
<td>Age 75&gt;</td>
<td>+1</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>+1</td>
</tr>
<tr>
<td>Stroke or History of Cerebral Ischemia</td>
<td>+2</td>
</tr>
</tbody>
</table>

**Annual Stroke Risk for Patients with AF**

```
<table>
<thead>
<tr>
<th>CHADS Score</th>
<th>Stroke Risk</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>0.8%</td>
</tr>
<tr>
<td>1</td>
<td>2.2%</td>
</tr>
<tr>
<td>2</td>
<td>4.5%</td>
</tr>
<tr>
<td>3</td>
<td>8.6%</td>
</tr>
<tr>
<td>4</td>
<td>10.9%</td>
</tr>
<tr>
<td>5</td>
<td>12.3%</td>
</tr>
<tr>
<td>6</td>
<td>13.7%</td>
</tr>
</tbody>
</table>
```

# CHA$_2$DS$_2$ VASc Score

<table>
<thead>
<tr>
<th>CHA$_2$DS$_2$ VASc Risk Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior stroke or TIA</td>
<td>2</td>
</tr>
<tr>
<td>Age &gt; 75</td>
<td>2</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>1</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>1</td>
</tr>
<tr>
<td>Vascular Disease</td>
<td>1</td>
</tr>
<tr>
<td>Age 65 - 74</td>
<td>1</td>
</tr>
<tr>
<td>Sex category</td>
<td>1</td>
</tr>
</tbody>
</table>

Camm AJ. *EHJ* 2010
Targets for novel anticoagulants in the coagulation pathway
Prevention of AF Related Stroke with Dabigatran

Connolly SJ. NEJM 2009
• Source of Strokes: Left Atrial Appendage
Caution: Investigational device restricted by federal law to investigational use only. Not for sale.
Caution: Investigational device restricted by federal law to investigational use only. Not for sale.
PROTECT-AF Trial

- Prospective Randomized trial comparing closure of the LAA with long-term warfarin therapy
- 800 patients from 59 enrolling centers (US & Europe)
- Randomized in a device-to-control ratio of 2:1
Protect-AF Trial

• Patients Included:
  – documented nonvalvular atrial fibrillation who could take long-term warfarin (could have not have any indication that would require warfarin)
  – CHADS2 scores had to be ≥1;
    • 65% of patients in the trial ultimately were CHADS 1 or 2, relatively low risk, but all had been referred because their physician had recommended they go on warfarin treatment
PROTECT-AF RESULTS

• The device was successfully implanted in 90.9% (408/449) of attempts.

• 32% reduction in the primary endpoint of all events
  — the combined rate of stroke (ischemic and hemorrhagic) and cardiovascular death was 3.4% in the device group versus 5.0% in the warfarin group.
PROTECT-AF Results: Reduction in Strokes

- **26%** reduction for all strokes
- **91%** decrease in hemorrhagic stroke
  - The hemorrhagic stroke in the device group occurred 15 days post implant (patient still on Coumadin)
- **39%** decrease in mortality
  - All as a result in reduction in stroke
Competition
Amplatzer Cardiac Plug

Caution: Investigational device restricted by federal law to investigational use only. Not for sale.
Mechanism of Action

- Lobe placed in landing zone
- Disc deployed at LAA orifice
- Independent of LAA shape
- Not attempting to “fill” the LAA
Anatomy of the Normal Left Atrial Appendage
A Quantitative Study of Age-Related Changes in 500 Autopsy Hearts: Implications for Echocardiographic Examination
John P. Veinot, MD; Phillip J. Harrity, MD; Federico Gentile, MD; Bijoy K. Khandheria, MBBS; Kent R. Bailey, PhD; Jeffrey T. Eickholt, BS; James B. Seward, MD; A. Jamil Tajik, MD; William D. Edwards, MD
Endothelialization: Progression over time

- After implant
- 2 days
- 1 month
- 3 months

Pre-Clinical Canine Study
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The rate of sinus rhythm maintenance with antiarrhythmic medication in patients with persistent atrial fibrillation is:

- 1) >70%
- 2) 60%
- 3) 50%
- 4) 25%
- 5) <10%
Audience Response Question

• The rate of sinus rhythm maintenance with antiarrhythmic medication in patients with persistent atrial fibrillation is:
  - 1) >70%
  - 2) 60%
  - 3) 50%
  - 4) 25%
  - 5) <10%
Figure 3. Percentages of Patients without Atrial Fibrillation and Atrial Flutter in the Absence of Antiarrhythmic-Drug Therapy.

Patients in the control group who had recurrent atrial fibrillation and subsequently underwent circumferential pulmonary-vein ablation or resumed amiodarone therapy for recurrent atrial fibrillation were considered to have remained in atrial fibrillation for the remainder of the study. Therefore, the total number of patients randomly assigned to each study group was used as the denominator in calculating the proportions for the respective study groups.
Vaughn-Williams Antiarrhythmic Drug Classification
Vaughn-Williams Antiarrhythmic Drug Classification

Vince Vaughn

Robin Williams
Number Needed to Treat to Prevent AF for 1 year

Lafuente CL. Archives of Internal Medicine 2006
Amiodarone Toxicity

- Hypothyroidism ~ 7%
- Hyperthyroidism ~ 2%
- Liver Function Abnormalities ~ 10%
  - Fulminate Hepatic Necrosis – Rare
  - Optic Neuropathy – blindness
- Sinus bradycardia – Pacemaker 5%
- Photosensitivity
- Constipation/Loss of appetite
- Headaches
- Insomnia
- Tremor
- Alopecia/Other rashes
PACERONE®
(Amiodarone HCl)
Tablets

DESCRIPTION
Pacerone® (Amiodarone HCl) Tablets are a member of a new class of antiarrhythmic drugs with predominantly Class III (Vaughan Williams’ classification) effects. Pacerone® Tablets are available in three strengths, containing 100 mg, 200 mg, and 400 mg amiodarone hydrochloride, for oral administration. The 100 mg tablets are white tablets with the following inactive ingredients: anhydrous lactose, colloidal silicone dioxide, corn starch, magnesium stearate and povidone. The 200 mg tablets are pink, scored tablets with the following inactive ingredients: lactose monohydrate, magnesium stearate, povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid, FD&C Red 40 and FD&C Yellow 6. The 400 mg tablets are light yellow, scored tablets with the following inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone and D&C Yellow 10 Aluminum Lake.

Amiodarone hydrochloride, the active ingredient in Pacerone® Tablets, is a benzofuran derivative: 2-butyl-3-benzofuranyl 4-[2-(diethylamino)-ethoxy]-3,5-diiodophenyl ketone hydrochloride. It is not chemically related to any other available antiarrhythmic drug.

The structural formula is as follows: 

\[
\text{OCH}_3
\]
PRECAUTIONS
Impairment of Vision
Optic Neuropathy and/or Neuritis
Cases of optic neuropathy and optic neuritis have been reported (see “WARNINGS”).

Corneal Microdeposits
Corneal microdeposits appear in the majority of adults treated with amiodarone. They are usually discernible only by slit-lamp examination, but give rise to symptoms such as visual halos or blurred vision in as many as 10% of patients. Corneal microdeposits are reversible upon reduction of dose or termination of treatment. Asymptomatic microdeposits alone are not a reason to reduce dose or discontinue treatment (see “ADVERSE REACTIONS”).

Neurologic
Chronic administration of oral amiodarone in rare instances may lead to the development of peripheral neuropathy that may resolve when amiodarone is discontinued, but this resolution has been slow and incomplete.

Photosensitivity
Amiodarone has induced photosensitization in about 10% of patients; some protection may be afforded by the use of sun-barrier creams or protective clothing. During long-term treatment, a blue-gray discoloration of the exposed skin may occur. The risk may be increased in patients of fair complexion or those with excessive sun exposure, and may be related to cumulative dose and duration of therapy.

Thyroid Abnormalities
Amiodarone inhibits peripheral conversion of thyroxine (T₄) to triiodothyronine (T₃) and may cause increased thyroxine levels, decreased T₃ levels and increased levels of inactive reverse T₃ (rT₃) in clinically euthyroid patients. It is also a potential source of large amounts of inorganic iodine. Because of its release of inorganic iodine, or perhaps for other reasons, amiodarone can cause either hypothyroidism or hyperthyroidism. Thyroid function should be monitored prior to treatment and periodically thereafter.
The following side-effect rates are based on a retrospective study of 241 patients treated for 2 to 1,515 days (mean 441.3 days).

**The following side effects were each reported in 10 to 33% of patients:**
- Gastrointestinal: Nausea and vomiting.

**The following side effects were each reported in 4 to 9% of patients:**
- Dermatologic: Solar dermatitis/photosensitivity.
- Neurologic: Malaise and fatigue, tremor/abnormal involuntary movements, lack of coordination, abnormal gait/ataxia, dizziness, paresthesias.
- Gastrointestinal: Constipation, anorexia.
- Ophthalmologic: Visual disturbances.
- Hepatic: Abnormal liver-function tests.
- Respiratory: Pulmonary inflammation or fibrosis.

**The following side effects were each reported in 1 to 3% of patients:**
- Thyroid: Hypothyroidism, hyperthyroidism.
- Neurologic: Decreased libido, insomnia, headache, sleep disturbances.
- Cardiovascular: Congestive heart failure, cardiac arrhythmias, SA node dysfunction.
- Gastrointestinal: Abdominal pain.
- Hepatic: Nonspecific hepatic disorders.
- Other: Flushing, abnormal taste and smell, edema, abnormal salivation, coagulation abnormalities.
What is the most important information I should know about Pacerone® Tablets?
Pacerone® Tablets can cause serious side effects that can lead to death including:
• lung damage
• liver damage
• worse heartbeat problems
• thyroid problems

Call your doctor or get medical help right away if you have any symptoms such as the following:
• shortness of breath, wheezing, or any other trouble breathing; coughing, chest pain, or spitting up of blood
Cumulative Incidence (%) vs Days

- Placebo
- Dronedarone

Hazard ratio, 0.75 (95% CI, 0.65 to 0.87)
P<0.001

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Dronedarone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>409</td>
<td>828</td>
</tr>
<tr>
<td>60</td>
<td>192</td>
<td>450</td>
</tr>
<tr>
<td>120</td>
<td>156</td>
<td>389</td>
</tr>
<tr>
<td>180</td>
<td>133</td>
<td>347</td>
</tr>
<tr>
<td>270</td>
<td>112</td>
<td>307</td>
</tr>
<tr>
<td>360</td>
<td>90</td>
<td>262</td>
</tr>
</tbody>
</table>
Adverse Events (Dronaderone v. Placebo)

- Hyperthyroid (8.4% vs. 14.1%; P=0.002)
- Hypothyroid (5.5% vs. 3.5%; P=0.15)
- Pulmonary (3.3% vs. 3.7%; P=0.74)
- Abnormal LFT (12.2% vs. 13.6%; P=0.52)
- Dermatologic (0.7% vs 0.2%; P=0.44)

- Although not as effective as Amiodarone, Dronedarone does not have the side effects

Singh BN. et al. NEJM 2007
Summary of Dronedarone

• Modestly Effective
  – A little better than Tylenol

• 2010 Safe – Most Important Aspect of the Drug

• 2011 Not Safe??
  – Recent question of rare but serious liver toxicity
  – Not safe in patients with severe heart failure
  – Not safe in persistent AF
AF Guidelines
(Focused Update 2011)

• Developments since last update in 2006
  – Dabigatran
  – Dronedarone
  – Catheter Ablation

Wann SL. *Heart Rhythm* 2011
## Dabigatran

<table>
<thead>
<tr>
<th>2011 Focused Update Recommendation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
<td><strong>New recommendation</strong></td>
</tr>
<tr>
<td>1. Dabigatran is useful as an alternative to warfarin for the prevention of stroke and systemic thromboembolism in patients with paroxysmal to permanent AF and risk factors for stroke or systemic embolization who do not have a prosthetic heart valve or hemodynamically significant valve disease, severe renal failure (creatinine clearance &lt;15 mL/min) or advanced liver disease (impaired baseline clotting function) (3). <em>(Level of Evidence: B)</em></td>
<td></td>
</tr>
</tbody>
</table>

Wann SL. *Heart Rhythm* 2011
<table>
<thead>
<tr>
<th>2011 Focused update recommendations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class IIa</strong></td>
<td></td>
</tr>
<tr>
<td>1. Dronedarone is reasonable to decrease the need for hospitalization for cardiovascular events in patients with paroxysmal AF or after conversion of persistent AF. Dronedarone can be initiated during outpatient therapy.(^{29}) \textit{(Level of Evidence: B)}</td>
<td>New recommendation</td>
</tr>
<tr>
<td><strong>Class III–Harm</strong></td>
<td></td>
</tr>
<tr>
<td>1. Dronedarone should not be administered to patients with class IV heart failure or patients who have had an episode of decompensated heart failure in the past 4 weeks, especially if they have depressed left ventricular function (left ventricular ejection fraction (\leq 35%)).(^{30}) \textit{(Level of Evidence: B)}</td>
<td>New recommendation</td>
</tr>
</tbody>
</table>
Atrial Specific Antiarrhythmic Drugs
(Maybe Later in 2011)
Atrial Specific Antiarrhythmic Drugs

• Vernakalant
  – Phase 3 study: 47% acute cardioversion rate in 90 minutes compared to 14% in the placebo group (P<0.01)
  – No prolongation of QT interval observed

• AVE-0118
  – Phase 2 studies demonstrated safety
  – Phase 3 soon

• AZD-7009
  – Phase 3 studies on hold because of QT prolongation – unknown clinical significance
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  - New Guidelines in Europe (2010) and America (2011)
- Ablation of Atrial Fibrillation
  - New Techniques
- Summary
# Updated Guidelines on Catheter Ablation

<table>
<thead>
<tr>
<th>Class I</th>
<th>2011 Focused update recommendations</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Catheter ablation performed in experienced centers* is useful in maintaining sinus rhythm in selected patients with significantly symptomatic, paroxysmal AF who have failed treatment with an antiarrhythmic drug and have normal or mildly dilated left atria, normal or mildly reduced LV function, and no severe pulmonary disease.(^{38-51}) (Level of Evidence: A)</td>
<td>Modified recommendation (class of recommendation changed from IIa to I, wording revised, and level of evidence changed from C to A).</td>
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</table>

<table>
<thead>
<tr>
<th>Class IIa</th>
<th>2011 Focused update recommendations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Catheter ablation is reasonable to treat symptomatic persistent AF.(^{38,48,55-64}) (Level of Evidence: A)</td>
<td>New recommendation</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Class IIb</th>
<th>2011 Focused update recommendations</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Catheter ablation may be reasonable to treat symptomatic paroxysmal AF in patients with significant left atrial dilatation or with significant LV dysfunction.(^{38,48,55-64}) (Level of Evidence: A)</td>
<td>New recommendation</td>
</tr>
</tbody>
</table>

Wann SL. *Heart Rhythm* 2011
ESC Guidelines with Ablation

Camm AJ. *EHJ* 2010
What is an AF Ablation?
Identification of an AF trigger

- Blocked PAC
- Resets Sinus Node
- Same PAC Initiates AF
Catheter position for triggers
Left PV ectopy and AF
Isolation of Left Pulmonary Veins
Transseptal
Real Time Identification of Venous Anatomy
PV with Lasso
PV with RFA Catheter
1. Wire Targeted Vein
2. Inflate and Position
3. Occlude and Ablate
Properties of Cryoablation

- Removes heat from the tissue
- Leads with a wave of hypothermia
- Ablates at the point of balloon contact
STOP-AF Trial

CRYO 69.9% (114 / 163)

OR = 29.5 (12.0 – 72.2) p < 0.001

DRUG 7.3% (6 / 82)

Blanked for Detectable AF
HRS 2011 Late-Breaker: FIRM

- Novel Technique to Identify Focal AF Drivers
  - Focal Impulse and Rotor Modulation (FIRM)
- AF Terminated in Persistent AF in 7 +/- 5 minutes with FIRM
- Randomized trial demonstrated improved success compared to PVI only (84% vs. 50%)
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Summary

• Symptomatic AF Should be Treated
• AF Patients at Risk for Stroke Need Protection – New Methods
  – Anticoagulation (Dabigatran)
  – Left Atrial Appendage Occlusion
• Antiarrhythmic Drugs Have Low Efficacy
• AF Ablation has Expanded Indications
  – New techniques available with unclear safety and efficacy results compared to point to point ablation
Thank You