Stroke Prevention in Atrial Fibrillation

Gregory Albers, M.D.
Director Stanford Stroke Center
Professor of Neurology and Neurological Sciences

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www.strokecenter.org
### Age Distribution of People with Atrial Fibrillation

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The Bad News - Atrial Fibrillation Increases Stroke Risk

The Bad News:
atrial fibrillation increases stroke risk

- 2 million U.S. adults with AF
- AF prevalence increases with age
  > age 60, 1 AF person in 25
  > age 80, 1 AF person in 10
- Expert physicians recommend anticoagulation therapy for AF
- Less than 50% of eligible patients get needed therapy
The Good News - Anticoagulation Therapy Reduces Stroke

**The Good News:**
anticoagulation therapy reduces stroke

- Proper anticoagulation treatment prevents > 40,000 strokes per year
- Treatment can save > $600 million each year
Atrial Fibrillation Electrocardiogram

**Atrial Fibrillation**
**Electrocardiogram**

Baseline coarsely or finely irregular; P waves absent. Ventricular response (QRS) irregular, slow or rapid


**Notes:**
Atrial fibrillation is diagnosed using electrocardiography. On the ECG atrial fibrillation is demonstrated by the absence of discrete atrial activity (or P waves), an irregular undulating baseline, and a variable R-R interval.
Emboli of Cardiac Origin

Notes:
Nonvalvular atrial fibrillation is the most common cause of thromboembolism from cardiac origin.
Notes:
Altered blood flow in atrial fibrillation may lead to stasis and formation of a cardiac thrombus, which can embolize.
Left Atrial Appendage

Notes:
Left atrial appendage is the most common site for thrombus formation in patients with AF.
Left Atrial Appendage Thrombus

Notes:
The left atrial appendage of a woman with atrial fibrillation who suffered a thromboembolic event is shown. Organized 5mm thrombi are apparent. A 5mm thrombus can completely occlude the middle cerebral artery.

Figure reproduced with permission.

Reference 8, figure 1
Cardiac Embolism to a Cerebral Artery

Notes:
A small thrombus from the left atrium can embolize to the brain and occlude a major intracranial artery.
Notes:
A thrombus can embolize from the left atrium or atrial appendage, and occlude a cerebral artery.
Notes:
The CT scan demonstrates a thromboembolic event in the left hemisphere of the brain. The patient presented with right hemiplegia.
Notes:
The thromboembolic events in control patients from three prospective trials (AFASAK, SPAF and BAATAF) are combined and classified as cerebral or systemic (non-CNS). Most thromboembolic events associated with atrial fibrillation involve the brain.

“Intention-to-treat” results are shown. Thromboembolic events represent all such events regardless of suspected etiology. Transient ischemic attacks and intracerebral hemorrhages are not included. Control represents placebo in all studies except BAATAF where 46% of the “control” patients received aspirin and 54% received no treatment. SPAF data are from group I only.
Thromboembolic Stroke - Severity of Intracranial Events in Atrial Fibrillation

Notes:
The thromboembolic events in control patients from three prospective trials (AFASAK, SPAF and BAATAF) are combined and classified by severity. The thromboembolic complications associated with atrial fibrillation carry significant morbidity and mortality.

Intracranial events include all strokes and intracranial hemorrhages. Transient ischemic attacks and systemic emboli are not included. Control represents placebo in all studies except BAATAF where 46% of the “control” patients received aspirin and 54% received no treatment. Mild represents minimal or no disability. Moderate/severe represents moderate to severe disability. SPAF data are from group I only.
# Atrial Fibrillation and Risk of Stroke

## Notes:
The risk of stroke associated with atrial fibrillation (AF) is substantial. The relative risk is fairly similar in these 4 epidemiological studies done in 4 different countries. Stroke rates (shown here as % per year) varied between studies because of differences in population characteristics, especially age.

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean age (Yrs)</th>
<th>Stroke*</th>
<th>Relative risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framingham, USA</td>
<td>70</td>
<td>4.1</td>
<td>0.74</td>
</tr>
<tr>
<td>Shibata, Japan</td>
<td>65</td>
<td>5.0</td>
<td>0.90</td>
</tr>
<tr>
<td>Reykjavik, Iceland</td>
<td>52</td>
<td>1.6</td>
<td>0.23</td>
</tr>
<tr>
<td>Whitehall, UK</td>
<td>60</td>
<td>1.8</td>
<td>0.26</td>
</tr>
</tbody>
</table>

*Stroke risk shown is % per yr
Age and Risk of Stroke in Atrial Fibrillation

Notes:
The risk of stroke associated with atrial fibrillation increases with age. The stroke rates are adjusted for other factors putting patients at risk of stroke (cardiac failure, coronary heart disease, and hypertension). The excess of strokes with AF is significant in all age groups.
Notes:
The prevalence of atrial fibrillation begins to increase after age 40 and rises rapidly after age 65.

Framingham = The Framingham Study
CHS = Cardiovascular Health Study
Rochester = Mayo Clinic Study, Rochester, Minnesota
Western Australia = Busselton, Western Australia

Reprinted from Feinberg et al.
Notes:
The prevalence of AF is associated with advancing age.
## Major Clinical Trials

### Trials for Stroke Prevention in Atrial Fibrillation

| AFASAK | Copenhagen Atrial Fibrillation, Aspirin, Anticoagulation Study. Lancet 1989; 171–175 |
| SPAF II | Stroke Prevention in Atrial Fibrillation Study II. Lancet, 1994; 343:637-691 |
Notes:
Over the last several years, multiple randomized multi-center trials have investigated the safety and efficacy of oral anticoagulant therapy for primary stroke prevention in AF patients (4–8). The target range for the intensity of anticoagulation and the use of aspirin varied between trials. The international normalized ratio (INR) range recommended by the Fourth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy is also shown.
Risk Factors for Stroke and Efficacy of Antithrombotic Therapy in Atrial Fibrillation

Archives of Internal Medicine
July 11, 1994
Methods

- Pooled individual data from 5 studies
  - AFASAK
  - SPAF I
  - BAATAF
  - CAFA
  - SPINAF
- Patient-specific data files
  - baseline characteristics
  - outcome events
  - analyzed on intention-to-treat basis

Notes:
A collaborative analysis was performed by the investigators from the five original AF stroke prevention studies. Their database is the most powerful source for assessment of risk factors for stroke in AF patients.
Baseline Characteristics of Patients

<table>
<thead>
<tr>
<th></th>
<th>Control (n=1236)</th>
<th>Warfarin (n=1225)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td>Gender, % male</td>
<td>73</td>
<td>75</td>
</tr>
<tr>
<td>History of, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hypertension</td>
<td>46</td>
<td>45</td>
</tr>
<tr>
<td>diabetes</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>prior stroke/TIA</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>peripheral vascular disease</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>CHF</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>angina</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>MI</td>
<td>14</td>
<td>13</td>
</tr>
</tbody>
</table>

Notes:
The baseline characteristics of the warfarin and control groups were well matched for stroke risk factors.
“The patients were elderly and had numerous comorbid conditions such as a history of hypertension, diabetes, heart failure, and coronary artery disease, and the estimates of the efficacy of antithrombotic therapy are likely generalizable to most patients with atrial fibrillation.”

Atrial Fibrillation Investigators

- Atrial Fibrillation Investigators
- Arch Intern Med 1995;1446–57

Notes:
The AF patient characteristics are described by the Atrial Fibrillation Investigators.
Efficacy of Warfarin

Notes:
A stroke risk reduction of 69% attributable to warfarin was seen when the data from five studies were combined in the pooled analysis. All analyses represented for individual studies are done on an “intention-to-treat” basis.

Strokes represent all strokes regardless of suspected etiology. Transient ischemic attacks, systemic emboli and intracranial hemorrhages are not included. Control represents placebo in all studies except BAATAF where 46% of “control” patients received aspirin and 54% received no treatment.
“The confidence limits around the estimate of benefit are sufficiently narrow (50%–79%) to reassure clinicians that patients with a substantial risk of stroke will indeed benefit from anticoagulation.”

Atrial Fibrillation Investigators

Notes:
The results of these trials may still underestimate the true efficacy of warfarin because eight of the 27 patients who suffered a stroke were not taking the drug at the time of the event.
Patients Assigned to Warfarin in ATF Trials

**Notes:**
The intensity of anticoagulation at the time of stroke in AF patients assigned to warfarin is illustrated. The majority of strokes that were documented in the “warfarin groups” of the original five trials occurred in patients who were not taking anticoagulant therapy at the time of the event 21-26. The shaded area illustrates the ACCP recommended range of INR 2.0–3.019.
Major Bleeding Events - Annual Frequency

**Major Bleeding Events**

**Annual Frequency**

- Patients receiving placebo or control: 1.0%
- Warfarin-treated patients: 1.3%
- Aspirin-treated patients: 1.0%

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**Notes:**

Major Bleeding: A bleeding episode is usually classified as major if meets at least one of the following criteria:

- intracranial or retroperitoneal
- led directly to death
- resulted in hospitalization or transfusion
Notes:
Four clinical features were identified by multivariate analysis of the pooled data that independently identified individuals who were at increased stroke risk. Patients in the control group with any of these risk factors had an annual stroke risk of at least 4% per year.
**Predicting Stroke Risk in AF**

**Who Benefits Most?**

<table>
<thead>
<tr>
<th>Clinical Risk factors</th>
<th>Stroke rate (%/yr)</th>
<th>Relative risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>No risk factors*</td>
<td>1.3</td>
<td>—</td>
</tr>
<tr>
<td>No RF except CHF</td>
<td>3.6</td>
<td>2.8 x</td>
</tr>
<tr>
<td>No RF except CAD***</td>
<td>4.6</td>
<td>3.5 x</td>
</tr>
</tbody>
</table>

*no Hx of stroke or TIA, HTN, diabetes, age>80, CAD or CHF  
**CAD=previous MI or angina

---

**Notes:**

Associated cardiac disorders were also shown to influence stroke risk. Patients whose only stroke risk factor was congestive heart failure or coronary artery disease (angina or myocardial infarction) had stroke rates approximately three times higher than the patients without any risk factors.
Notes:
The pooled analysis looked at annual embolic event rates per age groups with or without risk factors. In the control group, patients between 65–75 years old with risk factors carried a 5.7% rate of risk of suffering an embolic event. The cohort of patients over 75 with risk factors carried an annual risk of 8.1% of suffering an event.
Notes:
In the warfarin-treated cohorts, the patients with or without risk factors had an annual event rate, irrespective of the age group, of no greater than 1.7%.
Notes:
Comparing data according to risk factors in the warfarin and control arms shows a distinct advantage among the anticoagulated patients at risk of an event.
**Notes:**
This collaborative analysis yielded new, clinically useful information about the prevention of stroke in women with AF.

---

**Stroke Prevention with Warfarin**

<table>
<thead>
<tr>
<th></th>
<th>Risk Reduction vs. Control</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>68%</td>
<td>(50–79%)</td>
</tr>
<tr>
<td>Men</td>
<td>60%</td>
<td>(35–76%)</td>
</tr>
<tr>
<td>Women*</td>
<td>84%</td>
<td>(55–95%)</td>
</tr>
</tbody>
</table>

*approximately 25% of study population were women*
Notes:
To further investigate the efficacy and safety of aspirin and warfarin, the SPAF II study continued to follow patients who had been randomized to aspirin or warfarin in the original SPAF trial. They also re-randomized patients originally on placebo and recruited 419 new patients (most older than 75 years) and randomized these patients to receive warfarin or aspirin. The group that was over 75 years of age was followed for a mean of 2.0 years, while the less than 75 year-old group was followed for a mean of 3.1 years.
Notes:
In SPAF II warfarin appeared to be more effective than aspirin for prevention of ischemic stroke in both age groups; however, most of this benefit was lost because of a higher rate of intracranial hemorrhage in the warfarin groups, especially in the group that was over 75 years of age. In addition, the younger patients.
Intracranial Hemorrhage in AF Trials

Analysis for patients > 75 years on warfarin

<table>
<thead>
<tr>
<th>Mean Age</th>
<th>N</th>
<th>ICH (%/yr)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPAF II</td>
<td>80</td>
<td>197</td>
<td>1.8</td>
</tr>
<tr>
<td>Other 4 trials*</td>
<td>80</td>
<td>223</td>
<td>0.3</td>
</tr>
</tbody>
</table>

* pooled data from AFASAK, BAATAF, CAFA and SPINAF

Notes:
Compared to the SPAF II data, the rate of intracranial hemorrhage in elderly patients (>7 years of age) was lower in the pooled data from the other four primary prevention trials. SPAF I patients were excluded from these pooled data because they are included in SPAF II.
Patients Assigned to Warfarin in AF Trials

Intensity of Anticoagulation When ICH Occurred

<table>
<thead>
<tr>
<th>PT ratio (ISI 2.4)</th>
<th>INR ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8</td>
<td>4.0</td>
</tr>
<tr>
<td>1.7</td>
<td>3.0</td>
</tr>
<tr>
<td>1.6</td>
<td>2.0</td>
</tr>
<tr>
<td>1.5</td>
<td>1.0</td>
</tr>
</tbody>
</table>

- ACCP recommendations: INR 2.0-3.0
- Mean PT for 13 events
- Target range for individual study

Notes:
Although the intensity of anticoagulation documented at the time of the intracranial hemorrhage appeared to be within the range for their study, most had relatively high values (PTR>.5 or INR>.0). Therefore, although more data are needed, it appears that very elderly individuals are at increased risk for anticoagulant-associated brain hemorrhage, especially if excessively anticoagulated.
Notes:
The European Atrial Fibrillation Trial (EAFT) was a randomized comparison of anticoagulation, aspirin and placebo in AF patients who had suffered a recent stroke or TIA. This study provided an opportunity to compare the effectiveness of aspirin with both oral anticoagulants and placebo and to help determine whether the lack of aspirin response in the AFASAK trial was related to the lower dose of aspirin used in that study. Mean duration of follow up was 2.3 years.
European Atrial Fibrillation Trial Results

Notes:
The EAFT documented a mild but statistically not significant benefit of aspirin (300mg/day) for prevention of stroke, which was very similar to the degree of aspirin benefit in AFASAK. EAFT also provided a direct comparison of the efficacy of aspirin vs. anticoagulation. The study also confirmed that AF patients with a recent stroke/TIA are at a substantial stroke risk (??%/yr). Furthermore, no patient on anticoagulants in EAFT suffered a documented intracranial hemorrhage.

www.strokecenter.org
Efficacy of Aspirin Compared with Control

Efficacy of Aspirin Compared with Control

<table>
<thead>
<tr>
<th></th>
<th>No. of Events</th>
<th>Patient-years</th>
<th>Risk Reduction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFASAK</td>
<td>35</td>
<td>807</td>
<td></td>
</tr>
<tr>
<td>SPAF</td>
<td>65</td>
<td>1457</td>
<td></td>
</tr>
<tr>
<td>EAFT</td>
<td>130</td>
<td>838</td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>230</td>
<td>3102</td>
<td></td>
</tr>
</tbody>
</table>

*Total risk reduction for all 3 studies combined is 21%

Notes:
The results of the three AF trials that directly compared aspirin to placebo are summarized. Although the AF trials all have wide confidence intervals, in aggregate they suggest an approximately 20% to 25% stroke risk reduction attributable to aspirin with no clear relationship to aspirin dose.
The SPAF III study evaluated a more “user-friendly” approach to stroke prevention in atrial fibrillation. For high risk patients, a fixed dose of warfarin (initially titrated to an INR of 1.2–1.5) in combination with a 325 mg dose of aspirin. Low risk patients were assigned to aspirin 325 mg per day.
### SPAF III Results

**Event Rate Per Year**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Warfarin (INR 2–3)</th>
<th>Warfarin (INR 1.2–1.5) + Aspirin (325 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke/systemic emboli</td>
<td>1.9%</td>
<td>7.9%*</td>
</tr>
<tr>
<td>Intracranial hemorrhage</td>
<td>0.5%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Major hemorrhage</td>
<td>2.1%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

*(*p=0.0001)*

**Notes:**

Unfortunately, the combination therapy was inadequate to prevent stroke in high risk patients and this part of the study was stopped early by the safety monitoring committee. Results from the low risk aspirin cohort are not yet available.
Guidelines and Treatment Approaches

Fourth ACCP Consensus Conference on Antithrombotic Therapy

Fourth ACCP Consensus Conference on Antithrombotic Therapy
CHEST Supplement: October, 1995
ACCP Recommendations 1995
Risk Factors for Stroke in Patients with AF

- Previous TIA or stroke
- Hypertension
- Heart failure
- Diabetes
- Clinical CAD
- Mitral stenosis
- Prosthetic heart valves
- Thyrotoxicosis
ACCP Recommendations for Stroke Prevention in Atrial Fibrillation

<table>
<thead>
<tr>
<th>Age</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;65 y</td>
<td>ASA or nothing</td>
</tr>
<tr>
<td>no risk factors</td>
<td>warfarin INR 2–3</td>
</tr>
<tr>
<td>risk factors</td>
<td></td>
</tr>
<tr>
<td>65–75 y</td>
<td>warfarin or ASA</td>
</tr>
<tr>
<td>no risk factors</td>
<td>warfarin INR 2–3</td>
</tr>
<tr>
<td>risk factors</td>
<td></td>
</tr>
<tr>
<td>&gt;75 y</td>
<td>warfarin INR 2–3</td>
</tr>
</tbody>
</table>

Notes:
These recommendations resulted from the Fourth ACCP Consensus Conference on Antithrombotic Therapy.
**PORT Study Findings**

**THE WALL STREET JOURNAL**

**Increased Use of Blood-Thinning Drug Could Prevent 40,000 Strokes a Year**

**By Ron Winslow**

*Staff Reporter of The Wall Street Journal*

Health researchers said that increased use of a common blood-thinning drug by patients with erratic heartbeats could prevent 40,000 strokes in the U.S. a year and save $600 million.

“...people will die needlessly from a stroke, a highly preventable condition,” said Clifton R. Gaus, administrator of the agency. In addition, he said, “researchers found that getting the right treatments to the right people could actually save the health-care system at least $600 million each year.”

**Notes:**
The study was funded by the US agency for Healthcare Policy and Research.
Notes:
Recently, the Secondary and Tertiary Prevention of Stroke Patient Outcome Research Team (PORT) study findings reported that stroke in atrial fibrillation patients is as preventable as myocardial infarction—if patients are appropriately treated with anticoagulant therapy. However, it appears that about 75% of AF patients are not treated appropriately. Clinical data have demonstrated that warfarin can prevent 50% of the strokes caused by AF. The findings of this Duke University study indicate that warfarin therapy can prevent 40,000 strokes and save $600 million in healthcare costs annually. Although clinical trials have shown that warfarin prevents stroke in AF patients, the fear of major bleeding complications has inhibited some clinicians from using anticoagulant therapy in this setting. The analysis reported in the PORT study found that when properly administered, warfarin prevents 20 strokes for every major bleeding complication it causes.
Notes:
As depicted in this graphic, clinical events associated with thrombosis (thromboembolic stroke, venous thrombosis, cardiac thromboembolism) decrease with increasing intensity of anticoagulation (as expressed by the INR—International Normalized Ratio). Conversely, with increasing intensity of anticoagulation, clinical events associated with hemorrhage increase.

The therapeutic “window” can be defined as the range of intensity of anticoagulation over which there is protection from thromboembolic events with a minimal risk of hemorrhagic events.

This therapeutic “window” has been established from the results of numerous multicenter randomized clinical trials, and recent case-control studies.
Optimal Intensity for Warfarin Therapy

Notes:
Recently, Hylek et al. evaluated the efficacy of different intensities of anticoagulation in a case-control study. They found that an intensity of anticoagulation below an INR of 2.0 was associated with a higher risk of stroke.
Hylek, et al, studied the risk of intracranial hemorrhage in outpatients treated with warfarin. They determined that an intensity of anticoagulation expressed as a prothrombin time ratio (PTR) above 2.0* resulted in an increase in the risk of bleeding.

* roughly corresponding to an INR of 3.7 to 4.3
Recommended Range for Warfarin Therapy

For Patients in Atrial Fibrillation

Effective Range:
INR 2.0–3.0*

*An INR of 2.0–3.0 corresponds to a PT ratio of:
1.3–1.5 (QSI = 2.8)
1.4–1.6 (QSI = 2.5)
1.5–1.8 (QSI = 1.8)

Notes:
The Fourth ACCP Consensus Conference on Antithrombotic Therapy recommends that an INR of 2.0 to 3.0 be used in patients with atrial fibrillation.
Notes:
The use of the International Normalized Ratio (INR) in the monitoring of oral anticoagulant therapy allows for a more accurate comparison between laboratories, and with recommended INR ranges in the literature. The Prothrombin Time (PT) ratio can vary between laboratories, and with time in the same laboratory as a different batch of thromboplastin reagent is used.

The formula and the nomogram show how the INR and PT ratio are related. The INR can be calculated when the ISI of the laboratory’s thromboplastin reagent is known.33 An analogy can be made when purchasing a pair of shoes in a foreign country. You will pay in a foreign currency (PT), which will vary depending on point in time and country. If you know the exchange rate (ISI), you can always convert back to a price in dollars (INR).
Guidelines for Initiating Warfarin Therapy

- Start low
- Stabilize
- Monitor and adjust
Guidelines for Initiating Warfarin Therapy - Continued

Guidelines for Initiating Warfarin Therapy

- Start low
  - Initiate outpatients on 2-5 mg daily doses
  - Use up to 10 mg daily doses for inpatients on heparin
  - Determine INR within 1-3 days of initiation
  - Begin patient education
Guidelines for Initiating Warfarin Therapy - Continued

Guidelines for Initiating Warfarin Therapy

- Stabilize
  - Titrate dose for INR 2.0 - 3.0
  - Determine INR every week
    until values are in-range and stable
  - Check INR more often if < 1.4 or > 4.0
Guidelines for Initiating Warfarin Therapy - Continued

Guidelines for Initiating Warfarin Therapy

- Monitor and adjust
  - Check INR monthly for stable patients
  - Adjust dosage in small increments, i.e. 5-20% of total weekly dose
  - Monitor INR daily, weekly, or biweekly depending on post-adjustment values
Atrial Fibrillation and Cardioversion

It is strongly recommended that warfarin therapy (INR 2.0–3.0) be given for 3 weeks before elective cardioversion of patients who have been in AF for more than 2 days and be continued until normal sinus rhythm has been maintained for 4 weeks.
## Reimbursement for Monitoring

<table>
<thead>
<tr>
<th>Category</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary diagnosis, e.g. AF</td>
<td>427.31</td>
</tr>
<tr>
<td>Long-term anticoagulation</td>
<td>V58.61</td>
</tr>
<tr>
<td>Low level office visit</td>
<td>99211</td>
</tr>
<tr>
<td>Lab PT and INR report</td>
<td>85610</td>
</tr>
</tbody>
</table>
Medical Benefits of Anticoagulation Clinics

- Reduced incidence of bleeding episodes
- Lower number of thromboembolic events
- INR levels in proper 2.0-3.0 range more often

Reported in *Cardiology World News*, May-June, 1996, p. 8
Financial Benefits of Anticoagulation Therapy

- Cost savings due to stroke prevention and reduction of urgent care
- Cost savings from lowered risks of therapy
- Practice benefit by reimbursement for anticoagulation services provided
Legal Benefit of Meeting Standard of Care

Reduced risk exposure

A physician, if a general practitioner, must exercise the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession.

Threat of Strokes

So small a thrombus can dehumanize stroke victims
stealing their language, movement, and thoughts.

Like a blow torch to the Mona Lisa, so does the
unthinking heart wreck nature’s penultimate miracle.

Jonathan Halperin, M.D.
Case Study 1
Family physician’s perspective

- 72 year-old female
  - Hypertension controlled since 1982
  - BP 140/80
  - Complaints of heart palpitations, shortness of breath on stair-climbing
Case Study 2
New family practice resident’s perspective

- 71 year-old male
  - Paroxysmal AF since 1980
  - CAD, angioplasty in 1983
  - Smoker
  - Echo: enlarged LA and LV
decrease in LV function
  - BP 160/80, HR 76, ECG AF
## Sample Dosing Protocol

<table>
<thead>
<tr>
<th>INR</th>
<th>Adjustment</th>
<th>Revisit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 - 1.4</td>
<td>↑ TWD 10 - 20%</td>
<td>1 week</td>
</tr>
<tr>
<td>1.5 - 1.9</td>
<td>↑ TWD 5 - 10%</td>
<td>2 weeks</td>
</tr>
<tr>
<td>2.0 - 3.0</td>
<td>No change</td>
<td>4 weeks</td>
</tr>
<tr>
<td>3.1 - 3.9</td>
<td>↓ TWD 5 - 10%</td>
<td>2 weeks</td>
</tr>
<tr>
<td>4.0 - 5.0</td>
<td>Hold dose for 1 - 2 days, ↓ TWD 10 - 20%</td>
<td>1 week</td>
</tr>
<tr>
<td>&gt; 5.0</td>
<td>Stop warfarin and monitor until INR 3.0 is reached. Resume therapy at 20 - 50% lower TWD</td>
<td>next day as needed</td>
</tr>
</tbody>
</table>
Case Study 3
Nursing home physicians’ perspective

- 82 year-old female
  - AF for 8 yrs
  - Digoxin for rate control
  - Warfarin therapy
  - Unstable INR for > 3 mos (1.1 - 3.9)
  - BP 140/80, HR 84, ECG AF
Case Study 4
Internal medicine/cardiology perspective

- 73 year-old male
  - Paroxysmal AF
  - 4 mg warfarin/day with INR stable for 2 yrs
  - Seeks cardiology consult for heart palpitations
  - Amiodarone prescribed at 400 mg/day
  - Patient calls internist with complaint of large hematoma on leg
Issues for Stroke Prevention in AF Patients

- **Primary Prevention**
  - Stop smoking
  - Lose weight
  - Lower blood pressure

- **Medical care**
  - Anticoagulation therapy
  - Heart rate control
  - Cardioversion
  - Anti-arrhythmia therapy
Why Change AF Care Strategy?

- Practice preventive medicine
- Improve outcomes
- Apply new technologies and processes
- Contain medical costs
- Changing age demographics in U.S.
Issues for Stroke Prevention in AF Patients

New approaches

- Enhance professional and patient education
- Improve access to anticoagulation
Clinical Pathway for Management of Atrial Fibrillation

Clinical pathway for management of atrial fibrillation

**Initial screening**

- Conduct exams
  - Focused physical exam
  - Health history interview
  - Review health records
- Conduct lab tests
  - ECG to confirm diagnosis
  - Electrolytes, magnesium, TSH

**Consider lab tests**
- Echocardiogram to screen for left ventricular dysfunction
- Stress test to screen for CAD
- Blood Count and INR
Clinical pathway for management of atrial fibrillation

Initial Screening

Is ventricular response controlled?

Yes
- No AV blocking drug
  * Is AV Node normal

On AV blocking drug
  * Continue on AV blocking drug

NO
- Start AV blocking drug
  * Consider cardiology consult
Clinical pathway for management of atrial fibrillation

Initial Screening
Consider risk vs. benefit with warfarin therapy

Is warfarin contraindicated?
- Pregnancy
- Alcoholism
- Risk for bleeding (e.g., trauma)
  - Observe or aspirin

Is stroke risk moderate?
- Over age 65 and no other risk factors
  - Aspirin or warfarin

Is stroke risk high?
- Over age 75 or
- Any age with risk factors
  - Previous stroke/TIA
  - Diabetes
  - Hypertension
  - CAD
  - Begin warfarin therapy
  - Target INR 2-3
Clinical Pathway for Management of Atrial Fibrillation - Continued

Clinical pathway for management of atrial fibrillation

Initiate warfarin therapy

- Evaluate for indication
- Order INR

Patient education by nurse (30 min.)
- Explain AF and therapy
- Discuss importance of regular INRs
- Review drug interactions

Instruct patient on starting, stopping or changing dosage and medication
- Discuss lifestyle changes and limits

Patient consultation with physician (15 min.)
- Review current medications
- Consult drug interaction table and anticipate effects on warfarin
- Prescribe warfarin

Monitor coagulation status
- Office/Clinic based service
- Laboratory based service
Clinical pathway for management of atrial fibrillation

Initial screening (16-20) minutes

Is stroke risk low?
Patient under age 65 with "lone" AF?

Yes
Observe or aspirin

No
Consider risks versus benefits of warfarin therapy
Clinical pathway for management of atrial fibrillation

- Continue treatment and monitor anticoagulation status

  - Initially monitor coagulation every 1-3 days until INR appears stable (2-3) range
  - Monitor coagulation weekly if INR not stable
  - Routinely monitor INR every 4 weeks to maintain therapy

  - Check INR within 3 days of starting or stopping medication known to interact with warfarin
  - Check INR if patient reports bleeding signs or symptoms
Clinical Pathway for Management of Atrial Fibrillation - Continued

Clinical pathway for management of atrial fibrillation

Consider correction of arrhythmia

Would patient benefit from conversion to sinus rhythm?

- Yes
  - Warfarin for 34 weeks, then drug or electrical cardioversion
  - Continue warfarin indefinitely

- No
  - Leave in AF, control ventricular rate, and continue warfarin

Is sinus rhythm attained?

- No
  - Try other drugs to terminate rhythm
  - AV node ablation + or - pacemaker
  - AF surgery

- Yes
  - Continue warfarin therapy for 4 weeks after sinus rhythm is attained
  - Evaluate risks-benefits of continued anti-arrhythmic therapy
Stroke Prevention in Atrial Fibrillation

Stroke prevention in AF
Risk reduction by warfarin therapy

Risk reduction, %

Total  Men  Women

www.strokecenter.org