Atrial Fibrillation: New Treatments and New Guidelines

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July 10, 2014

- No financial disclosures
**Epidemiology**

- Most common arrhythmia in clinical practice
  - Projected prevalence of more than 10 million by the year 2050
  - Accounts for 1/3 of all hospitalizations for cardiac rhythm disturbances
  - Increased prevalence with age: 8% in those older than 80 years

**Why Is This Important?**

- AF associated with an increased risk of stroke
  - Six-fold increase in rate of ischemic stroke
  - Rate of ischemic stroke in non-valvular AF approx 5%/year
  - AF accounts for 15% of all strokes
- Associated with increased CHF and all-cause mortality
- May be independently associated with MI

Atrial Fibrillation

- Work-Up
- Rate vs. Rhythm Control
- Treatment Options
- Anti-coagulation
- Future Treatment Options

Case I

- 55 yo woman being seen for a new patient visit. Asymptomatic.
- PMH: HTN (untreated)
- PE: 150/80, HR 125 Irregularly irregular
The EKG...

What Work-Up Does She Need?

- Complete history and physical
- PIRATES
Secondary Causes of AF

- PIRATES – secondary causes
  - Pericarditis
  - Pulmonary disease/pulmonary embolism
  - Ischemia
  - Rheumatic heart disease
  - Atrial myxoma
  - Thyrotoxicosis
  - Ethanol
  - Sepsis

Secondary Causes of AF

- Other Secondary Causes
  - Obesity – likely due to LA dilatation
  - ?Smoking
  - Familial
  - ?Inflammation
- Treat Underlying Etiology
What Work-Up Does She Need?

- Complete history and physical exam
  - Pulmonary disease/pulmonary embolism
  - Ischemia
  - Ethanol
  - Sepsis


What Work-Up Does She Need?

- ECHO
  - Rheumatic heart disease
  - Atrial myxoma
- The real reason...
  - LVH/LV size & function
  - Occult valvular disease
  - Occult pericardial disease

What Work-Up Does She Need?

- Complete history and physical exam
- EKG
- TTE
- Associated labs
  - TSH, renal and hepatic function
- Other tests based on history…ex: event monitor


Classification

- **Recurrent:** 2 or more episodes
  - **Paroxysmal:** arrhythmia terminates spontaneously or with treatment within 7 days of onset
  - **Persistent:** sustained beyond 7 days and is not self-terminating
- **Permanent:** cardioversion has failed (or been foregone)
- **Lone:** patients <60 years without clinical/EKG evidence of cardiopulmonary disease (incl htn)
Case I

- 55 yo woman being seen for a new patient visit.
  Asymptomatic.
- PMH: HTN (untreated)
- PE: 150/80, HR 125 Irregularly irregular

What is the Next Step for Our Case?

What should be our goal in treatment?
1) Convert her to sinus rhythm
2) Rate-control
3) Stroke prevention
4) #1 and #3
5) #2 and #3
Hemodynamic Consequences of AF

- Loss of atrial mechanical function - fibrosis
- Irregular ventricular response
- Elevated HR
- Results in:
  - Reduction in diastolic filling, stroke volume, CO
  - Risk of cardiomyopathy (chronic > 130 bpm)
  - Asymptomatic afib 12X more common

Rate or Rhythm?

- AFFIRM Study
  - Randomized 4070 patients with AF, F/U 3.5 years
    - Rate-control = coumadin
    - Rhythm-control = cardioversion/meds/coumadin
  - No difference in survival, stroke or QOL
    - Trend towards increased survival in rate-control (P = .08)
    - Pts ≥ 65 yrs and pts without h/o CHF had better outcomes with rate-control therapy
    - More thrombotic events in rhythm arm

AFFIRM Investigators, NEJM, 2002;347
Rate or Rhythm?

- AFFIRM Study…the Caveats…
  - No symptomatic patients
  - Average age of enrollees: 70 yrs
  - Only 63% of patients in control arm in sinus rhythm

AFFIRM Investigators, NEJM, 2002;347

Rate or Rhythm for CHF Patients

- 1376 patients with h/o afib, EF<35%, sx of CHF
- RCT rate vs. rhythm
- Outcome: time to death from CV causes, followed 37 months
- Results
  - 27% in rhythm-control group died from CV causes
  - 25% in rate-control group died from CV causes
  - HR 1.06
  - Other outcomes similar (CVA, worse CHF, all-cause mortality)

Rate Control

- Previous goal HR: 60-80 bpm at rest; 90-115 bpm during exercise
- No evidence getting HR <80 vs. <110 any better for mortality
- Guidelines: <110 BPM
  Ok if no symptoms

Van Gelder IC et al. NEJM 2010;362
Groenveld HF; et al. J Am Coll Cardiol 2013

Rate Control

- What do I use?
  - First choice: beta-blockers or calcium-channel blockers
    - Don’t give if Wolf-Parkinson-White or other accessory pathways
  - OK to combine nodal-blocking agents
  - Digoxin is second-line as it does not control HR during exercise

Rhythm vs. Rate…Bottom Line

- Highly symptomatic or unstable: rhythm control
- If minimal symptoms: rate control is safe and appropriate (maintain goal HR <110)
- Anticoagulation therapy should be continued regardless of the strategy (rhythm vs. rate)

What About Cardioversion?

- Electrical cardioversion preferred
  - Best if within 7 days of AF onset
  - Requires conscious sedation or anesthesia
- Most thrombi in atrial fibrillation arise from the LA appendage
- Cardioversion can reduce LA appendage function
- Peri-cardioversion period is particularly pro-thrombotic
  - Regardless of mode of cardioversion
Electrical Cardioversion

- If AF < 48 hrs, AND low stroke risk, can safely undergo cardioversion without anticoagulant therapy
  - Must be documented!
- If AF > 48 hrs (or unknown duration) OR high-risk for stroke (h/o stroke/TIA, mechanical heart valve), then 2 choices:
  - Anti-coagulate X 3 weeks (therapeutic INR) before cardioversion
  - TEE to r/o clot
- Anti-coagulate for at least 4 weeks afterward
  - Anti-coagulate also for those who would not normally require coumadin


Cardioversion – Thrombus Risk

- Other factors besides LA clot may affect stroke risk
  - Age
  - DM
  - LA flow velocity
  - HTN
- One study showed intra-atrial thrombus has been detected by TEE in 15% of patients with AF < 72 hours duration
- No difference in thrombus risk between electrical and pharmacologic cardioversion

Pharmacologic Cardioversion –
Stable Patients

- Pharmacologic cardioversion in AF
  - Type 1C
    - Flecainide
    - Propafenone
  - Type III
    - Dofetilide (do not give out of the hospital)
    - Ibutilide
  - Alternative to above: amiodarone


The Next Step…

55 yo woman being seen for a new patient visit. Asymptomatic.
PMH: HTN (untreated)
PE: 150/80, HR 125 Irregularly irregular

Does she need anti-coagulation?
1) Yes, with coumadin
2) Yes, with ASA
3) Yes, with coumadin and ASA
4) Yes, with dabigatran (pradaxa)
5) No
Key Point…

- A rhythm control strategy does not negate the need for anticoagulation therapy
  - Assuming anticoagulation is indicated

Risk/Benefits of Coumadin

- Pooled analysis from five primary prevention trials in non-valvular AF
  - Annual rate of stroke 4.3% in control group
  - 1.4% risk of stroke in the warfarin group (NNT=32)
  - Only 20% of subjects >75 yrs; excluded pts at risk for bleed
  - Need to consider warfarin risks
    - Symptomatic intracranial hemorrhage 0.4% with warfarin; 0.2% in control
    - Major bleeding: 2.2% with warfarin; 0.9% in control

What About Aspirin?

- Two randomized trials evaluated the use of ASA (75mg, 325mg) in primary stroke prevention
  - Pooled data: Risk of stroke with ASA 4.2%; risk of stroke in controls 6.4%
  - ASA may be better in preventing non-cardioembolic strokes and non-disabling strokes


Secondary Prevention of Stroke

- Risk of stroke with warfarin 3.1%; placebo 10%
- Risk of stroke with ASA (300mg) 7.7%

EAFT Study Group, Lancet, 1993
Anti-Platelets vs. Coumadin?

- ACTIVE-W trial
  - 3335 patients with AF + 1 other stroke risk factor
  - ASA + clopidogrel vs. coumadin
  - Outcomes: stroke, non-CNS systemic embolus, MI or vascular death
  - Stopped early because of superiority of warfarin in preventing vascular events (165 events vs. 234 events). Warfarin even better for those who entered the study already taking it.

Active Writing Group. Lancet, 2006;367(9526)

Anti-Coagulation

- Bottom line…anticoagulation with warfarin superior to ASA and superior to ASA + clopidogrel. Effective in the prevention of primary and secondary stroke.

Active Writing Group. Lancet, 2006;367(9526)
Who Needs Anti-Coagulation in AF?

- CHADS\(_2\) previously used as an accurate predictor of stroke
- 0 pts: no treatment
- 1 pt: ASA vs. anticoagulation*
- 2 pts: anticoagulation
  - Problem: doesn’t account for other stroke RF

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>CHF (or reduced systolic function)</td>
<td>1</td>
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<tr>
<td>Htn</td>
<td>1</td>
</tr>
<tr>
<td>Age &gt;75 yrs</td>
<td>1</td>
</tr>
<tr>
<td>DM</td>
<td>1</td>
</tr>
<tr>
<td>h/o Stroke/TIA</td>
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Who Needs Anti-Coagulation in AF?

- For low-risk patients CHA\(_2\)DS\(_2\)-VASc outperformed CHADS\(_2\). Now recommended

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Score</th>
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<tr>
<td>CHF/LV dysfunction</td>
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<tr>
<td>Htn</td>
<td>1</td>
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<tr>
<td>Age ≥75 yrs</td>
<td>2</td>
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<tr>
<td>DM</td>
<td>1</td>
</tr>
<tr>
<td>Stroke/TIA/Thromboembolism</td>
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<tr>
<td>Vascular Dz (h/o MI, PVD)</td>
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<td>Age 65-74 yrs</td>
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<tr>
<td>Sex category (female)</td>
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Olesen JB et al. BMJ, 2011;342
Anticoagulation...Who Needs It?

<table>
<thead>
<tr>
<th>CHA₂DS₂-VASc score</th>
<th>Adjusted stroke rate based on cohort data (percent/year)</th>
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<tbody>
<tr>
<td>0</td>
<td>0%</td>
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<tr>
<td>1</td>
<td>1.3%</td>
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<tr>
<td>2</td>
<td>2.2%</td>
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<tr>
<td>3</td>
<td>3.2%</td>
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<tr>
<td>4</td>
<td>4.0%</td>
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<tr>
<td>5</td>
<td>6.7%</td>
</tr>
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<td>6</td>
<td>9.8%</td>
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<td>7</td>
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<tr>
<td>8</td>
<td>6.7%</td>
</tr>
<tr>
<td>9</td>
<td>15.2%</td>
</tr>
</tbody>
</table>

Lip GY et al. Stroke, 2010;41(12).

- CHA₂DS₂-VASc
  - No benefit of oral anticoagulation if patients low-risk (score=0)
    - No treatment vs. ASA 81-325mg daily
  - Neutral or positive benefit of anticoagulation for score ≥1
    - Score of 1: ASA or anticoagulation (anticoagulation preferred)
    - Score ≥2: anticoagulation

Prediction for Major Bleeding Risk – HAS-BLED

- HAS-BLED risk scheme for AF
  - Hypertension
  - Abnormal renal/liver function*
  - h/o Stroke/TIA

- Bleeding predisposition
  - Labile INR
  - Elderly (age>65 yrs)
  - Drugs*(NSAID or steroids) or alcohol concomitantly

* = 2 different components


HAS-BLED Risk Classification

- Validated using trial data; appears to be best prediction model
- Max=9pts
- Risk of major bleeding=intracranial, transfusion, hospitalization

<table>
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<tr>
<th>HAS-BLED score</th>
<th>Bleeds/100 patients</th>
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<tr>
<td>0</td>
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<td>8.70</td>
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<tr>
<td>5</td>
<td>12.50</td>
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Back to Our Case…

- 55 yo woman being seen for a new patient visit. Asymptomatic.
- PMH: HTN (untreated)
- PE: 150/80, HR 125 Irregularly irregular
- CHADS<sub>2</sub> score=1
- CHA<sub>2</sub>DS<sub>2</sub>-VASc score = 2 points
- Offer anticoagulation

Anti-Coagulation Special Considerations

- What about my 85 yo patient who falls?
  - Predisposition to falling not considered a contraindication for warfarin
- What about my patient with a remote h/o GIB?
  - Risk of recurrent bleeding 1.2%
  -Resolved peptic ulcer disease bleeding (with H. Pylori testing/treatment) not a contraindication for warfarin

Anti-Coagulation Special Considerations

- What are absolute contraindications to warfarin?
  - Bleeding diathesis
  - Thrombocytopenia (<50K)
  - Untreated or poorly-controlled htn (> 160/90)
  - Non-compliance with INR monitoring
- Relative contraindications
  - Significant ETOH use, NSAID use without PPI, activities predisposing to trauma


Anti-Coagulation Special Considerations

- What about stopping anti-coagulation for a procedure?
  - Mechanical heart valve → heparin (UFH vs LMWH)…most of the time…
  - Non-valvular AF
    - High-risk (CHADS 5 or 6) → heparin
    - Medium-risk (CHADS 3 or 4) → heparin full or low-dose
    - Low-risk (CHADS 1 or 2) → ok to stop coumadin for <1 week
  - Novel agent: hold 1 day prior to procedure. If complete hemostasis needed, hold for 48 hours

Non-Vitamin K Antagonist Oral Anticoagulants (NOACs)

- Oral Xa Inhibitors
  - Rivaroxaban
  - Apixaban
  (Edoxaban)

Direct Thrombin Inhibitor
- Dabigatran

NOACs – A Few Take Home Points Up Front

- All NOACs have a black box warning with 2 key points:
  - Premature discontinuation (in afib trials) increases risk of thrombotic events
    - Parental bridging if NOAC to warfarin
    - Spinal/Epidural hematoma risk
  - Decline in renal function leads to increased bleeding risk
  - Do not use with mechanical heart valves
## NOACs

<table>
<thead>
<tr>
<th></th>
<th>Dabigatran (Pradaxa) 2010</th>
<th>Rivaroxaban (Xarelto) 2012</th>
<th>Apixaban (Eliquis) 2012</th>
<th>Edoxaban</th>
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<tr>
<td>Approval Status</td>
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<td>-Nonvalvular Afib</td>
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<tr>
<td></td>
<td>-DVT/PE Treatment*</td>
<td>-DVT Prevention</td>
<td>-DVT and PE treatment</td>
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<tr>
<td>Mechanism</td>
<td>DTI</td>
<td>Anti-Xa</td>
<td>Anti-Xa</td>
<td>Anti-Xa</td>
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<tr>
<td>Renal Metabolism</td>
<td>80%</td>
<td>30-60%</td>
<td>25%</td>
<td>35-39%</td>
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</table>

**Mechanism**: DTI Anti-Xa Anti-Xa Anti-Xa

**Renal Metabolism**: 80% 30-60% 25% 35-39%

**T ½ Hours**: 12-17 5-9 8-15 9-10

**CYP3A4**: --- Yes Yes Yes

**Substrate of p-glycoprotein**: Yes Yes --- Yes

**Antidote**: None None None None

**Monitoring**: PTT Anti Xa Anti Xa Anti-XA

**Plasma Protein Binding**: 35% 92.95% 87% 40-59%
Dabigatran

- **AF Guidelines:** “with prior stroke, TIA or CHA₂DS₂-VASc ≥ 2, oral anticoagulants recommended. Options include: warfarin, dabigatran, rivaroxaban, apixaban.”


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Dabigatran

- Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY) Study
  - 18,113 patients with non-valvular afib and stroke risk (CHADS2 score mean 2.1)
  - RCT Dabigatran vs. warfarin
    - Dabigatran 110mg or 150mg BID (blinded) vs. unblinded adjusted warfarin

Dabigatran – RE-LY

- Primary outcome: stroke or embolism, F/U 2 years
  - 1.69% warfarin
  - 1.53% for 110mg dabigatran (non-inferior)
  - 1.11% for 150mg dabigatran (superior)
- Rate of major bleeding
  - 3.36% warfarin
  - 2.71% dabigatran 110mg
  - 3.11% dabigatran 150mg (p-value NS)


Dabigatran

- Caveats…
  - Dyspepsia/gastritis
  - GI bleeding increased with dabigatran
  - Increased MI’s in dabigatran groups (RR 1.38; CI 1.0-1.91 for high-dose).
  - Valvular AF excluded
  - Warfarin 64% in therapeutic range
- As effective as coumadin post-cardioversion
Dabigatran

- Pros: No INR monitoring, fewer dietary/drug interactions
- Cons: BID, expensive, no antidote (somewhat dialyzable), renally cleared
- Dosing: 150mg BID if CrCl >30 (75mg BID if CrCl 15-30). Not for CrCl<15
- Substrate of transporter p-glycoprotein
  - P-gp inducers (St. John’s wart, rifampin) decrease levels
  - P-gp inhibitors (ketoconazole) increase levels

Starting Dabigatran

- Baseline labs: CBC, Cr, PTT (LFTs)
- Patient Education med guide
- Monitoring
  - Adherence
  - Adverse effects (GI)
  - Bleeding/Stroke

Follow-Up
- 2 weeks
- 1 month
- 3 months
- Continue monthly check-in

2014 Guidelines: “Re-evaluate renal function when clinically indicated and at least annually”
Rising Concerns with Dabigatran…

- 12/7/11: FDA investigation into bleeding reports with pradaxa→260 fatal bleeding events
  - 11/2/12: “bleeding rates associated with new use of Pradaxa do not appear to be higher than bleeding rates associated with new use of warfarin”

- Meta-analysis: more coronary events
  - 30,514 patients
  - OR 1.33 (CI 1.03-1.71) for MI or ACS
  - May be class effect with direct thrombin inhibitors

Uchino K and Hernandez AV. Arch of Intern Med, 2012

Factor Xa Inhibitors

- Rivaroxaban, epixaban (edoxaban)
- 4/13 Cochrane Review on Xa Inhibitors vs. Warfarin:
  - Decreased strokes (OR 0.78, CI 0.69-0.89)
  - Decreased embolic events (OR 0.53, CI 0.32-0.87)
  - Decreased intra-cranial hemorrhages (OR 0.56; CI 0.45-0.70)
  - Decreased all-cause mortality (OR 0.88, CI 0.81-0.97)

Bruins Slot KMH and Berge E. Cochrane Review, 2013 (8).
Rivaroxaban (Xarelto)

- Direct Xa inhibitor
- Once daily dosing
  - 20mg qhs if CrCl >50
  - 15mg if CrCl 15-50
- Beware CYP3a4 inhibitors: diltiazem, amiodarone, verapamil will increase effect

Rivaroxaban - ROCKET AF Trial

- 14,264 non-valvular afib (mean CHADS$_2$=3.5)
  - Rivaroxaban 20mg/d vs. 15mg/d vs. warfarin
  - Endpoint: stroke or systemic embolism
  - Non-inferior to warfarin in AF patients
    - 1.7% rivaroxaban vs. 2.2% warfarin
    - Bleeding rates overall equal but statistically fewer intracranial and fatal bleeding with rivaroxaban (more GIB)
    - Low rate of therapeutic INR (58%)

Apixaban

- Factor Xa inhibitor
- ARISTOTLE Trial
  - 18,201 afib patients with 1 additional risk factor for stroke (mean CHADS₂=2.1)
  - Apixaban 5mg BID (2.5mg BID in select pts) vs. warfarin
  - Outcomes: stroke, systemic embolism
  - Apixaban superior to warfarin in primary outcome (1.27% vs. 1.6%)
    - Lower mortality and less bleeding
  - Approved Dec 2012


Apixaban

- Dose 5mg vs. 2.5mg BID
  - Use 2.5mg BID if 2 of the following:
    - Cr ≥1.5 mg/dL, ≥ 80 yrs, body weight ≤60 kg
  - Not recommended if severe hepatic impairment
New Medicines – Edoxaban
ENGAGE Study

- **Design:** Double-dummy RCT trial of 21,105 mod-high risk afib patients. Studied 2 edoxaban regimens (30mg and 60mg daily)
- **End-pt:** stroke or systemic embolism


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New Medicines – Edoxaban
ENGAGE Study

- **Results:** Edoxaban non-inferior to warfarin
- Primary end-point (stroke/systemic embolism)
  - 1.5% warfarin
  - 1.18% high-dose edoxaban (HR 0.79, CI 0.63-0.99)
  - 1.61% low-dose edoxaban (HR 1.07, CI 0.87-1.31)
- Lower rates of major bleeding and mortality

The Next Step…

55 yo woman being seen for a new patient visit. Asymptomatic.
PMH: HTN (untreated)
PE: 150/80, HR 125 Irregularly irregular

CHADS\textsubscript{2} score=1; CHA\textsubscript{2}DS\textsubscript{2}-VASc score = 2 points; HAS-BLED score = 1

Does she need anti-coagulation?
1) Yes, with coumadin
2) Yes, with ASA
3) Yes, with coumadin and ASA
4) Yes, with dabigatran (or rivaroxaban or apixaban)
5) No

What’s “In” and What’s “Out”?

- What’s “Out”---Dronedarone
  - Approved July 2009 for low-to intermed-risk pts with AF
  - Similar to amiodarone but non-iodinated, thus no thyroid/pulm toxicity
Dronedarone in CHF

- ANDROMEDA trial
- Patients with symptomatic CHF RCT
  - dronedarone vs. placebo
    - Stopped early due to increased mortality in dronedarone group
    - Mostly worsened CHF


Dronedarone in High-Risk Permanent Afib

- 3236 patients >65 yrs with at least 6 mo h/o permanent afib and risk factors for major vascular events
- Dronedarone vs. placebo
- Outcome: stroke, MI, systemic embolism, death from CV causes
- Study stopped early for safety reasons (more stroke, CV deaths, CHF)
  - Post marketing reports of hepatocellular injury
- Bottom line…would avoid dronedarone in CAD/vascular/CHF pts or pts with permanent afib

Connolly SJ et al.  NEJM, 2011:365;24
What’s “In”--Ablation

- Paroxysmal AF primarily emanates from the pulmonary veins
  - Less effective than ablation for SVT, a-flutter
- Guidelines: ablation recommended (in experienced center) for pts with symptomatic, paroxysmal AF who have failed drug treatment


Future Directions

- Obliteration of left atrial appendage
  - Where 90% of thrombi form
- PROTECT AF Study
  - 707 non-valvular AF patients + 1 stroke RF
  - Watchman device vs. warfarin
    - Percutaneous LA appendage closure filter device
  - End-points: stroke, systemic embolism, CV death
  - Mean follow-up 2.3 years
  - Non-inferior to warfarin but more safety events

Circulation, 2013;127
Recap…Current Guidelines

- **Paroxysmal**
  - Anticoagulate; treat if symptoms

- **Persistant**
  - Anticoagulate, rate control
  - Can then decide whether to accept permanent AF vs. antiarrhythmic drug therapy +/- cardioversion

- **Recurrent paroxysmal**
  - Anticoagulate, rate control
  - If disabling symptoms, antiarrhythmic meds and ablation if this fails

Current Guidelines…To Maintain Sinus Rhythm

- No heart disease→flecainide, propafenone, dofetilide or sotolol (dronedarone)
  - If no response→amiodarone or ablation

- If heart disease→dofetilide or sotolol (dronedarone)
  - If no response→amiodarone or ablation

- If CHF→amiodarone or dofetilide
  - If no response→ablation

Fuster et al. ACC/AHA/ESC Practice Guidelines. JACC, 2006;48(4).

Current Guidelines…To Maintain Sinus Rhythm

- Hypertension with LVH → amiodarone
  - If no response → ablation
- Hypertension and NO LVH → flecainide, propafenone, sotalol (dronedarone)
  - If no response → amiodarone or dofetilide or ablation


Thank You!!