Catheter Ablation for Atrial Fibrillation:
AF Think Tank April 27, 2009

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Boston Scientific / EPT: Research Funding***
ESI-St. Jude: Research Funding*** / Patent Royalties*
Biosense-Webster: Research Funding*** / Scientific Advisory Board*/Consulting**
Cardiofocus: Research Funding*** / Past Scientific Advisory Board**
Prorhythm: Research Funding***
Symphony Medical: Research Funding*** / Scientific Advisory Board*
Interventional Research Management: Scientific Advisory Board*
Medtronic: Symposium Speaker / Consulting**
NIH: Research Funding for CABANA***

* None / ** Modest / *** Significant
Concept, Challenges, Uptake and Adoption of Atrial Fibrillation Ablation: An Academic View

Concept
Mechanisms of Atrial Fibrillation

AF Ablation Consensus Statement Calkins et al Heart Rhythm June 2007
Underlying Pathogenesis of Atrial Fibrillation

Paroxysmal

Persistent

Permanent

Relative importance

AF/disease progression

Substrate

Initiation substrate

Trigger
Ablation of AF

Which One?
Ablation Success
How Do You Get There?

Paroxysmal

Persist/chronic

PV isolation

PV isolation

%
Outcome of the AF CHF Trial

Rate control (n = 694)
Rhythm control (n = 682)

CV Mort
Total Mortality
CVA
CHF
Composite

P=0.59
P=0.73
P=0.32
P=0.17
P=0.20

Roy D et al, AHA 2007
## Outcomes of the ATHENA Trial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Placebo (n=2,327)</th>
<th>Dronedarone (n=2,301)</th>
<th>HR (CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>139 (6.0%)</td>
<td>116 (5.1%)</td>
<td>0.66 (0.62, 0.70)</td>
<td>0.08</td>
</tr>
<tr>
<td>CV mortality</td>
<td>90 (3.9%)</td>
<td>63 (2.7%)</td>
<td>0.51 (0.45, 0.58)</td>
<td>0.03</td>
</tr>
<tr>
<td>Arrhythmic</td>
<td>48 (2.1%)</td>
<td>26 (1.1%)</td>
<td>0.34 (0.22, 0.54)</td>
<td>0.01</td>
</tr>
<tr>
<td>Non-arrhythmic</td>
<td>49 (2.1%)</td>
<td>53 (2.3%)</td>
<td>0.74 (0.67, 0.81)</td>
<td>0.65</td>
</tr>
<tr>
<td>Cardiac (other)</td>
<td>18 (0.8%)</td>
<td>17 (0.7%)</td>
<td>0.49 (0.36, 0.69)</td>
<td>0.89</td>
</tr>
<tr>
<td>Non-CV mortality</td>
<td>49 (2.1%)</td>
<td>53 (2.3%)</td>
<td>0.74 (0.67, 0.81)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

Hahnloser et al: HRS, 2008
Maintenance of Sinus Rhythm

- No (or minimal) Heart Disease
  - Flecainide
  - Propafenone
  - Sotalol
  - Amiodarone
  - Dofetilide

- Hypertension
  - Substantial LVH
    - No
      - Amiodarone
      - Dofetilide
    - Yes
      - Flecainide
      - Propafenone
      - Sotalol
      - Amiodarone
      - Catheter ablation

- Coronary Artery Disease
  - Dofetilide
  - Sotalol

- Heart Failure
  - Amiodarone
  - Dofetilide

Concept, Challenges, Uptake and Adoption of Atrial Fibrillation Ablation: An Academic View

Challenges
Where Do We Go From Here?

Does ablation reduce AF mortality?
Is AF ablation superior to drug Rx for reducing mortality?
Is there a CV mortality benefit to AF ablation?
Does AF ablation reduce stroke risk?
Does AF ablation reduce heart failure complications?
Does AF type and chronicity impact outcome?
Does underlying disease or LV dysfunction alter outcome of ablation?
Will ablation improve LV function?
Is there a survival advantage to maintaining sinus rhythm?
Will ablation achieve that better than drug therapy?
Does symptom state matter?
Can AC therapy can be discontinued following successful ablation?
Which AF ablation / mapping / guidance / end-point approach best?
Does the ablation line set matter?
Does the physiology of AF matter?
Will atrial size and function improve with AF elimination?
Can complications of ablation be prevented?
Is this technique-specific?
Is there a Cost of Living / Quality of life Benefit to ablation?
AF Ablation: Clinical Trial Considerations

- What are the long-term efficacy outcomes for ablation?
- What are the comparative success rates of various drug and ablative techniques?
- What are the outcomes of AF ablation in patients with persistent and longstanding AF?
- Does symptom state at enrollment contribute to trial outcomes?
- What is the impact of ablation on atrial size, morphology, and function?
- What is the benefit of AF ablation in patients with varying types of underlying cardiac and noncardiac disease?
- Do these interventions have an impact on long-term occurrence of stroke / peripheral thrombo-embolic events?
<table>
<thead>
<tr>
<th>Pt</th>
<th>Veins</th>
<th>AF type</th>
<th>Success off drug</th>
<th>Controlled on drug</th>
<th>F-U (mo)</th>
<th>Redo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Chen</td>
<td>79</td>
<td>103</td>
<td>Parox</td>
<td>68</td>
<td>86</td>
<td>10</td>
</tr>
<tr>
<td>Haissaguerre</td>
<td>90</td>
<td>197</td>
<td>Parox</td>
<td>64</td>
<td>71</td>
<td>12</td>
</tr>
<tr>
<td>Haissaguerre</td>
<td>15</td>
<td>32</td>
<td>Perm</td>
<td>9</td>
<td>60</td>
<td>–</td>
</tr>
<tr>
<td>Pappone</td>
<td>251</td>
<td>956</td>
<td>Parox</td>
<td>152</td>
<td>85</td>
<td>–</td>
</tr>
<tr>
<td>Gerstenfeld</td>
<td>41</td>
<td>95</td>
<td>Parox</td>
<td>29</td>
<td>90</td>
<td>6</td>
</tr>
<tr>
<td>Macle/Haiss irrigitip</td>
<td>136</td>
<td>544</td>
<td>Parox</td>
<td>90</td>
<td>66</td>
<td>7</td>
</tr>
<tr>
<td>Oral/Morady Marrouche</td>
<td>40</td>
<td>125</td>
<td>Parox</td>
<td>26</td>
<td>81</td>
<td>–</td>
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<tr>
<td>Marrouche</td>
<td>190</td>
<td></td>
<td></td>
<td>162</td>
<td>85</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>102</td>
<td>330</td>
<td>Parox</td>
<td>87</td>
<td>85</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>29</td>
<td></td>
<td>Persist</td>
<td>24</td>
<td>83</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>59</td>
<td></td>
<td>Perm</td>
<td>51</td>
<td>86</td>
<td>–</td>
</tr>
<tr>
<td>Oral</td>
<td>70</td>
<td>230</td>
<td>Parox</td>
<td>58</td>
<td>70</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Persist 12</td>
<td>3</td>
<td>22</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Haines</td>
<td>64</td>
<td>82</td>
<td>Parox</td>
<td>42</td>
<td>66</td>
<td>–</td>
</tr>
<tr>
<td>Deisenhofer</td>
<td>75</td>
<td>226</td>
<td>Parox</td>
<td>38</td>
<td>51</td>
<td>–</td>
</tr>
<tr>
<td>Packer</td>
<td>203</td>
<td>Parox</td>
<td>104</td>
<td>70</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Persist</td>
<td>25</td>
<td>56</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Outcome of Ablation for Atrial Fibrillation

Pt Veins AF type Success off drug Controlled on drug F-U (mo) Redo

Controlled on drug

FF--U U Redo

AF type

Time in mo
Recommendations for Reporting Outcomes of Clinical Studies

Limitations of Current Literature

1. Highly variable definitions and endpoints
2. Substantial differences in treatment modalities,
3. Definitions of acute and long-term success
4. Variability of post-ablation blanking periods, follow-up, redo and cross-over treatments
5. Variability in accounting for asymptomatic AF
6. Incomplete accounting of adverse events occurring beyond the first week of therapy
AF Ablation Guidelines: Recommendations and Level of Evidence

Where’s the Beef?
<table>
<thead>
<tr>
<th>Author</th>
<th>Pt</th>
<th>Veins</th>
<th>AF Type</th>
<th>Success Off Drug</th>
<th>Controlled on Drug*</th>
<th>F-U (mo)</th>
<th>Redo</th>
<th>No AF*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Takahashi</td>
<td>49</td>
<td>112</td>
<td>Parox</td>
<td>39 80</td>
<td>na na 7±4</td>
<td>13 27</td>
<td>39(80%)</td>
<td></td>
</tr>
<tr>
<td>Mansour</td>
<td>80</td>
<td>na</td>
<td>Par/Pers</td>
<td>47 59</td>
<td>7 9 ≥11±3</td>
<td>10 13</td>
<td>54(68%)</td>
<td></td>
</tr>
<tr>
<td>Pappone</td>
<td>297</td>
<td>na</td>
<td>Parox</td>
<td>267 90*</td>
<td>na na 12</td>
<td>na na</td>
<td>267(90%)</td>
<td></td>
</tr>
<tr>
<td>Oral PVI/WACA</td>
<td>80</td>
<td>na</td>
<td>Parox</td>
<td>62 78*</td>
<td>na na 6</td>
<td>7 9</td>
<td>62(78%)</td>
<td></td>
</tr>
<tr>
<td>Pappone</td>
<td>589</td>
<td>na</td>
<td>Parox (69%)</td>
<td>469 80*</td>
<td>na na 30</td>
<td>na na</td>
<td>469(80%)</td>
<td></td>
</tr>
<tr>
<td>Chen/Lin</td>
<td>240</td>
<td>na</td>
<td>NonPV</td>
<td>53 73</td>
<td>na na 22±11</td>
<td>na na</td>
<td>53(73%)</td>
<td></td>
</tr>
<tr>
<td>Marchlinski</td>
<td>107</td>
<td>293</td>
<td>Parox Persist</td>
<td>65 61</td>
<td>9 8 12</td>
<td>na na</td>
<td>74(69%)</td>
<td></td>
</tr>
<tr>
<td>Marrouche</td>
<td>315</td>
<td>1202</td>
<td>Parox (51%)</td>
<td>271 86*</td>
<td>na na 14</td>
<td>na na</td>
<td>271(86)</td>
<td></td>
</tr>
<tr>
<td>Nademanee</td>
<td>121</td>
<td>-</td>
<td>Parox (47%)</td>
<td>100 83</td>
<td>10 8 12</td>
<td>18 15</td>
<td>110(91%)</td>
<td></td>
</tr>
<tr>
<td>Cappato</td>
<td>8745</td>
<td>na</td>
<td>na</td>
<td>4550 52</td>
<td>2094 24 12±8</td>
<td>2389</td>
<td>27 6644(75%)</td>
<td></td>
</tr>
<tr>
<td>Haissaguerre</td>
<td>70</td>
<td>na</td>
<td>Prolonged</td>
<td>55 79</td>
<td>na na 7±3</td>
<td>9 13</td>
<td>55(79%)</td>
<td></td>
</tr>
</tbody>
</table>

Pt = patient; AF=atrial fibrillation; F-U=follow up; PVI=pulmonary veins; Parox/Par=paroxysmal; Pers/Persist=persistent; Perm=permanent; na=not applicable; Circ=Circulation; JCE=Journal of Cardiovascular Electrophysiology; JACC=Journal of the American College of Cardiology
Evidence Trajectory in Clinical AF Ablation Trials

Scientific Merit Reliability Value Quality

Pt (no.) 20 100 100 1000 10,000 1000 3,000

Early single center Single center observ Single center RCT Meta-Analysis Multi-center registries Multi-center RCT Multiple mortality RCT

Meta--
Outcomes of Ablation and Drug Therapy in Randomized Trials

Freedom From Recurrent AF

- RAAFT: n=13, P<0.001
- CACAF: n=38
- APAF: n=21, P<0.001
- AAAA: n=40
- ORAL: n=57

## Success in AF Ablation: 2nd International Ablation Registry

<table>
<thead>
<tr>
<th>Type of AF</th>
<th>No. of Centers</th>
<th>No. of Pts</th>
<th>Success without AADs</th>
<th>Success with AADs</th>
<th>Overall Success</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>No. of Pts</td>
<td>Rate</td>
<td>No. of Pts</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Median</td>
<td>Range</td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>85</td>
<td>9,590</td>
<td>6,580</td>
<td>74.9</td>
<td>[64.9-82.6]</td>
</tr>
<tr>
<td>Persistent</td>
<td>73</td>
<td>4,712</td>
<td>2,800</td>
<td>64.8</td>
<td>[52.4-72.0]</td>
</tr>
<tr>
<td>Permanent</td>
<td>40</td>
<td>1,853</td>
<td>1,108</td>
<td>63.1</td>
<td>[53.3-71.4]</td>
</tr>
</tbody>
</table>

Capatto et al 2009
Efficacy of Anti-arrhythmic Drugs and Catheter Ablation in Patients with Atrial Fibrillation

Calkins et al 2009
Multi-Centered Outcomes Trials

1. Smaller, more agile

2. Quickly provide answers to more specific questions

3. Further evaluate the safety and efficacy of RF catheter ablation as first line therapy

4. Relevant to patients with various types of AF or underlying disease

5. Could provide outcomes data more applicable to a wider range of patients

6. Without limitations of single center studies or requisite randomization against drug therapy.
End-Point Pyramid of AF Treatment

Approach to Patients After Ablation Therapy

The Clinician

The Theorist / Purist
The Pragmatist
The Happy Nihilist
The Reformist
The Grateful

The Issue

The Warfarin Worries
Monitoring Mandater
The Time-Bider
Self Deception
No Change

- No AF
- No drug
- No Sx AF
- No intervention
- Occ AF w/Sx
- No intervention required
- 75%↓ freq/duration of AF
- No AF on previously ineffective AAD
- ↓DFT/↑ATP success
- PPM prevention
- <75%↓ in frequency/duration on drugs
Establishing AF Ablation End-points

- When do you look?
- How do you look?
- How hard do you look?
- What intensity of monitoring?
- How will you look at other recurrences?
- Who should look?
- Who will pay for it?
Time Course of All Recurrences

<table>
<thead>
<tr>
<th>Months after ablation</th>
<th>Recurrence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>30%</td>
</tr>
<tr>
<td>4</td>
<td>40%</td>
</tr>
<tr>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
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<tr>
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<td>29</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

PAF (n=428)
Perm/Pers AF (n=346)

Wokhlu et al, HRS 2007
Outcome of Catheter Ablation for AF in CHF

Change in LVEF (n=74)
Parox AF=8%; SHD=44%

LVEF (%)

36±7%

57±12%

Baseline Final (12±7 months)

Major Complications with Pulmonary Vein Ablation in 1,049 Patients (7 Series)

- Air emboli: n=5
- Brady-cardia: n=3
- Tamponade: n=13
- TIA: n=8
- CVA: n=3
- PV stenosis: n=29
- Phrenic nerve: n=4
- PV dissect: n=1
Evidence Trajectory in Clinical AF Ablation Trials

Scientific Merit Reliability Value Quality

Pt (no.) 20 100 100 1000 10,000 1000 3,000

Early single center Single center observ Single center RCT Meta-Analysis Multicenter registries Multicenter RCT Multiple mortality RCT

Meta-Analysis
## Risks of AF Ablation: The Second International AF Ablation Registry

<table>
<thead>
<tr>
<th>Type of Complication</th>
<th>No of Pts</th>
<th>Rate,%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>25</td>
<td>0.15</td>
</tr>
<tr>
<td>Tamponade</td>
<td>213</td>
<td>1.31</td>
</tr>
<tr>
<td>Pneumo/ Hemo thorax</td>
<td>19</td>
<td>0.11</td>
</tr>
<tr>
<td>Sepsis, abscesses or endocarditis</td>
<td>2</td>
<td>0.01</td>
</tr>
<tr>
<td>Permanent diaphragmatic paralysis</td>
<td>28</td>
<td>0.17</td>
</tr>
<tr>
<td>Femoral pseudoaneurysm / A-V Fisula</td>
<td>152/88</td>
<td>.93/0.54</td>
</tr>
<tr>
<td>Valve damage/requiring surgery</td>
<td>11/7</td>
<td>0.07</td>
</tr>
<tr>
<td>Atrium-esophageal fistulae</td>
<td>3</td>
<td>0.02</td>
</tr>
<tr>
<td>Stroke / TIA</td>
<td>37 /115</td>
<td>0.23 / 0.71</td>
</tr>
<tr>
<td>Pulmonary veins stenoses requiring intervention</td>
<td>48</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>741</strong></td>
<td><strong>4.54</strong></td>
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</table>
Mortality Estimates: Drug vs Ablation

Drug Therapy

<table>
<thead>
<tr>
<th>Study</th>
<th>% Mortality per Year</th>
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</thead>
<tbody>
<tr>
<td>AFFIRM</td>
<td>4.5%</td>
</tr>
<tr>
<td>RACE</td>
<td>3%</td>
</tr>
<tr>
<td>STAF</td>
<td>3.5%</td>
</tr>
<tr>
<td>CTAF</td>
<td>3.2%</td>
</tr>
<tr>
<td>Pappone</td>
<td>5.6%</td>
</tr>
</tbody>
</table>

Ablation

<table>
<thead>
<tr>
<th>Study</th>
<th>% Mortality per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pappone</td>
<td>2.6%</td>
</tr>
<tr>
<td>Packer</td>
<td>0.9%</td>
</tr>
<tr>
<td>Cappato</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

X 3 (%)

- AFFIRM: 13.5
- RACE: 9
- STAF: 10.5
- CTAF: 9.6
- Pappone: 16.8
- Pappone (control): 7.8
- Packer: 2.7
- Cappato: 1.5
CABANA Trial Design

Atrial Fibrillation Eligible for ablation and drug Rx

≥65 yrs of age
<65 yrs w/ ≥1 CVA risk factor

Drug Rx & AC
- Rate Control
- Rhythm Rx

1° ablation & AC
- PV Isolation
- WACA
- CAFE
- G Plexus

Descriptive analysis
1) NSR vs AF impact
2) ± Heart disease
3) AF type (parox, pers, perm)
4) D/C anticoagulation
5) CT/MR and ECG cores

≥65 yrs of age
<65 yrs w/ ≥1 CVA risk factor
CABANA Trial
Secondary Endpoints

1. A composite endpoint consisting of total mortality, disabling stroke, serious bleeding, or cardiac arrest
2. CV hospitalization and total mortality
3. Cardiovascular death
4. Cardiovascular death and disabling stroke
5. Arrhythmic death and cardiac arrest
6. Heart failure death
7. Freedom from recurrent AF
8. Medical costs and resource utilization and cost effectiveness
9. Quality of life
10. Composite adverse events
Evidence Trajectory in Clinical AF Ablation Trials

Scientific Merit
Reliability Value Quality

Early single center Single center observ Single center RCT Meta-Analysis Multi-center registries Multi-center RCT Multiple mortality RCT

Pt (no.) 20 100 100 1000 10,000 1000 3,000
# Comparison of Catheter and Surgical Ablation for AF

<table>
<thead>
<tr>
<th></th>
<th>Ablation</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elimination of AF</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Freedom From Complications</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Cost effectiveness</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Preserved LA Function</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>LA Appendage Removal</td>
<td>--</td>
<td>++++</td>
</tr>
<tr>
<td>Stroke Risk Reduction</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Visualization</td>
<td>++→++++</td>
<td>++++→++</td>
</tr>
<tr>
<td>Patient Wear and Tear</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Standardized Procedure</td>
<td>++→++++</td>
<td>+++→+</td>
</tr>
</tbody>
</table>
Concept, Challenges, Uptake and Adoption of Atrial Fibrillation Ablation: An Academic View

Uptake and Adoption
Whole Scale Adoption of AF Ablation: Issues

1. Efficacy in various AF types / Underlying disease
2. Safety in wide spectrum of practice centers
3. Consistency in academic and non-academic practices
4. Cost vs benefit
5. Outcomes in comparison with other therapies (drug / surgical)
6. Mortality benefit
7. Impact on Quality of life
8. Decreased procedure times and increased simplicity
9. Work force availability and training
10. Operator competencies / credentialing
11. Health care costs and barriers to access of care
12. Reimbursement
13. Regulatory pathways and time
14. Funding discovery of science, techniques, and technology
15. Impact of AF prevention
Consensus recommendations For Monitoring After AF Ablation

1) Trans-telephonic monitoring for four weeks around the follow-up interval for symptom-triggered recording with a minimum of weekly transmissions to detect asymptomatic events;

2) 24 to 72 hours of Holter monitoring or

3) Thirty-day auto/ triggered event monitoring or mobile cardiac outpatient telemetry.
1. When do you look?
2. How do you look?
3. How hard do you look?
4. What intensity of monitoring?
5. How will you look at 2nd, 3rd and other recurrences?
6. Who will pay for it?
Cost of Technology in EP

- Ablation catheter: $2,000
- ICE catheter: $2,500
- Cardiac mapping system: $350,000
- Sheath robotics: $800,000
- Stereotaxis system: $2,500,000
- Particle therapy: $200,000,000
Data on Cost of AF
Ablation:
0
Estimated joint Density of Incremental Costs vs Incremental Effects of Rhythm vs Rate Control* in AFFIRM

Rhythm more costly and less effective than rate

Rhythm more costly and more effective than rate

Incremental (rhythm-rate) costs, U.S.

Incremental (rhythm-rate) life-years

Base-case point estimate
Change in cost $5,077
Change in effect -0.08 life-yr

*Boot strap resampling
Ann Med Int 141:653, 2004
### Cost Effectiveness of Radiofrequency Catheter Ablation for Atrial Fibrillation

#### ICER in Base-Case Estimates, Stratified by Ischemic Stroke risk

<table>
<thead>
<tr>
<th>Stroke risk</th>
<th>Strategy</th>
<th>Cost</th>
<th>Life-years</th>
<th>QALYs</th>
<th>ICER ($/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate (age=65 yr)</td>
<td>Rate control + warfarin</td>
<td>$39,391</td>
<td>11.47</td>
<td>10.81</td>
<td>Reference</td>
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<tr>
<td></td>
<td>Amiodarone + warfarin</td>
<td>$43,358</td>
<td>11.45</td>
<td>10.75</td>
<td>Dominated</td>
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<tr>
<td></td>
<td>LACA + warfarin</td>
<td>$52,369</td>
<td>11.55</td>
<td>11.06</td>
<td>$51,800/QALY</td>
</tr>
<tr>
<td>Moderate (age=55 yr)</td>
<td>Rate control + warfarin</td>
<td>$50,509</td>
<td>14.80</td>
<td>13.95</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>Amiodarone + warfarin</td>
<td>$55,795</td>
<td>14.75</td>
<td>13.81</td>
<td>Dominated</td>
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<tr>
<td></td>
<td>LACA + warfarin</td>
<td>$59,380</td>
<td>14.88</td>
<td>14.26</td>
<td>$28,700/QALY</td>
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<tr>
<td>Low</td>
<td>Rate control + ASA</td>
<td>$24,540</td>
<td>11.65</td>
<td>11.21</td>
<td>Reference</td>
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<tr>
<td></td>
<td>Amiodarone + ASA</td>
<td>$38,425</td>
<td>11.60</td>
<td>11.02</td>
<td>Dominated</td>
</tr>
<tr>
<td></td>
<td>LACA + ASA</td>
<td>$43,036</td>
<td>11.70</td>
<td>11.40</td>
<td>$98,900/QALY</td>
</tr>
</tbody>
</table>

#### Variables with Influence on ICER for Moderate Stroke-Risk Cohorts

- Rate of stroke in AF (warfarin) (1.0%-2.05/y)
- Discount rate (0%-5%)
- LACA reversion rate to AF (0%-4%/y)
- LACA ablation cost ($13,500-19,500)
- Utility of warfarin therapy (0.92-1.00)
- Rate of hemorrhage (warfarin) (1.2%-2.5%/y)
- Efficacy of rate control (30%-50%)

**Chan et al: JACC 47:2513, 2006**

*ICER = incremental cost-effectiveness ratios*
Renewed emphasis on patient education of personal health

Increased focus on disease prevention

More reliance on allied health staff

Greater emphasis on research

Give efficiency a higher priority

Greater emphasis on quality

Increase appropriate health care incentives
Expanding Technology in Medicine
What is Needed?

- Less expensive devices/technology
- Better risk stratification
- Targeting highest-risk patients
- Targeting most symptomatic patients
- Outcomes-based decision making
- More cost data from large randomized clinical trials, registries and observational studies
- Quality of life data
- Health care rationing?
- Data, data, data