MHIF FEATURED STUDY: VISITAG SURPOINT

DESCRIPTION:
Primary objective of study is to demonstrate safety and 12-month effectiveness of Tag Index-guided ablation using VISITAG SURPOINT Module with External Processing Unit when used with THERMOCOOL SMARTTOUCH® SF (STSF) and THERMOCOOL SMARTTOUCH® (ST) catheters for pulmonary vein isolation (PVI) in the treatment of subjects with drug refractory symptomatic paroxysmal AF.

CRITERIA LIST/QUALIFICATIONS:
Inclusion
1. Symptomatic paroxysmal AF; had at least 1 AF episode electrocardiographically documented within 1 year prior to enrollment. Documentation may include ECG, TTM, Holter monitor or telemetry strip.
2. Failed at least 1 antiarrhythmic drug (AAD Class I or III) as evidenced by recurrent symptomatic AF, or intolerable to the AAD.

Exclusion
1. Previous surgical or catheter ablation for AF.
2. Previous cardiac surgery (including CABG) within past 6 months (180 days).
3. Valvular cardiac surgical/percutaneous procedure (i.e., ventriculotomy, atriotomy, and valve repair or replacement and presence of a prosthetic valve).

AF is the most common sustained arrhythmia. It affects 0.4% to 1% of the general population, and increases in prevalence with age.

CONDITION: Atrial Fibrillation (AF)
PI: Daniel Melby, MD
RESEARCH CONTACT: Jacob Cohen
Jacob.Cohen@allina.com | 612-863-4022
SPONSOR: Biosense Webster

OPEN AND ENROLLING: Please Refer Patients!

AF is the most common sustained arrhythmia. It affects 0.4% to 1% of the general population, and increases in prevalence with age.
Title: Current concepts in atrial fibrillation

Speaker: Daniel Melby, MD
Cardiac Electrophysiologist
Medical Director, Electrophysiology Lab
Minneapolis Heart Institute® at Abbott Northwestern Hospital

Date: January 14, 2019
Time: 7:00 – 8:00 AM
Location: ANW Education Building, Watson Room

OBJECTIVES
At the completion of this activity, the participants should be able to:
1. Review pathophysiology of atrial fibrillation.
2. Understand patient selection for atrial fibrillation.
3. Explain the management of ablation patients pre and post procedure.

ACCREDITATION

Physician - Allina Health is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. Allina Health designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nurse - This activity has been designed to meet the Minnesota Board of Nursing continuing education requirements for 1.0 hours of credit. However, the nurse is responsible for determining whether this activity meets the requirements for acceptable continuing education.

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The ACCME defines a commercial interest as “any entity” producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

Moderator(s)/Speaker(s)
Daniel Melby, MD has disclosed the following relationship – Biosense Webster: honoraria for educational activities.

Planning Committee
Dr. Alex Campbell, Jake Cohen, Jane Fox, Dr. Mario Gössl, Dr. Kevin Harris, Dr. Kasia Hryniewicz, Rebecca Lindberg, Amy McMeans, Dr. Michael Miedema, Dr. JoEllyn Moore, Pamela Morley, Dr. Scott Sharkey, and Jolene Bell Makowesky have disclosed that they DO NOT have any real or apparent conflicts with any commercial interest as it relates to the planning of this activity/course. Dr. David Hurrell has disclosed the following relationship - Boston Scientific: Chair, Clinical Events Committee.

**NON-ENDORSEMENT OF COMMERCIAL PRODUCTS AND/OR SERVICES**

We would like to thank the following company for exhibiting at our activity.

**Bristol-Myers Squibb**

**Janssen Pharmaceutical Companies of Johnson & Johnson**

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If audited by a licensing board or submitting for license renewal or certification renewal, boards will ask you not the entity providing the education for specific information on each activity you are using for credit. You will need to demonstrate that you attended the activity with a copy of your **certificate/evidence of attendance, a brochure/flier and/or the conference handout**.

Each attendee at an activity is responsible for determining whether an activity meets their requirements for acceptable continuing education and should only claim those credits that he/she actually spent in the activity.

**Maintaining these details are the responsibility of the individual.**

**PLEASE SAVE A COPY OF THIS FLIER AS YOUR CERTIFICATE OF ATTENDANCE.**

| Signature: __________________________________________ |
| My signature verifies that I have attended the above stated number of hours of the CME activity. |

Allina Health - Learning & Development - 2925 Chicago Ave - MR 10701 - Minneapolis MN 55407
An estimated 2.7–6.1 million people in the United States have AFib. With the aging of the U.S. population, this number is expected to increase.

Approximately 2% of people younger than age 65 have AFib, while about 9% of people aged 65 years or older have AFib.

Afib: Demographics by Age


Afib: Hospitalization common
Afib: Risk factors

- High blood pressure accounts for 14% to 22% of AFib cases.\(^2\)
- Other risk factors for AFib include:\(^2\):
  - Obesity
  - European ancestry
  - Diabetes
  - Heart failure
  - Ischemic heart disease
  - Hyperthyroidism
  - Chronic kidney disease
  - Heavy alcohol use
  - Left atrial or left ventricular chamber enlargement
  - Obstructive Sleep Apnea

Afib: Costs and Consequences

- More than 750,000 hospitalizations occur each year because of AFib.
- The condition contributes to an estimated 130,000 deaths each year.
- The death rate from AFib as the primary or a contributing cause of death has been rising for more than two decades.\(^3,4\)
- AFib costs the United States about $6 billion each year.
- Medical costs for people who have AFib are about $8,705 higher per year than for people who do not have AFib.\(^1,2\)

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Afib: Costs and consequences

- 2007 Report on 154,070 patients in France
- Mean Follow-up 15.2 years
- In patients with atrial fibrillation
  - HR for all cause mortality
    - Men 1.5 / Women 1.8
  - HR for cardiovascular mortality
    - Men 2.2 / Women 3.4
- ALLHAT Trial Analysis (42,000pts)
  - Baseline AF
    - Mortality HR 2.8, CHF HR 3.16

J Am Coll Cardiol. 2009 Nov 24;54(22):2023-31

Afib: Treatment goals

- Adverse Event Prevention
  - Anticoagulation
  - ? Other tx

- Symptom Control
  - Heart rate control
  - Rhythm control
Afib: Adverse event prevention

- Anticoagulation for thromboembolic prophylaxis
- CHA²DS²-Vasc Risk score based
  - CHF
  - Hypertension
  - Age ≥ 75 = 2
  - Diabetes
  - Stroke/TIA/Thromboembolism = 2
  - Vascular disease
  - Age 65-74
  - Female

Annualized stroke rate

Afib: Anticoagulation, warfarin versus apixaban

NNT 300 to prevent one CVA, 240 to prevent one death

NNT 100 to prevent one major bleed, 50 to prevent minor bleed

N Eng J Med 2011; 365:981-992
Afib: Adverse event prevention

- Aside from anticoagulation
- No other definitive treatment to reduce other adverse events
- *Except those with reduced LVEF – ablation significantly reduces mortality and CHF progression

Afib Treatment: Progression over time

- Rate control drugs
- Anti-arrhythmic drugs
- Ablation

Time:
1940 - 2019
Atrial Fibrillation: Sinus Rhythm or Rate Control
AFFIRM Trial

All-cause mortality
Cumulative mortality (%)

Years after randomization
0 1 2 3 4 5

0 5 10 15 20 25 30

Rhythm control
Rate control

*No difference in quality of life


AFFIRM TRIAL RESULTS

Death (NS) Stroke (NS) Hospitalization (p<0.001)

Rate-Control Rhythm-Control

25.9 26.7 5.5 7.1 73 80.1

4060 pts, CHADS 1

P=0.08
Cabana Trial: AA drugs v. Ablation

Estimates of All-Cause Mortality Risk (ITT)

Ablation vs. Drug
Hazard ratio: 0.85 (95% CI, 0.60–1.21)
P=0.377

Number at risk

<table>
<thead>
<tr>
<th>Drug</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
<th>36</th>
<th>48</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>1095</td>
<td>1086</td>
<td>1077</td>
<td>1068</td>
<td>1059</td>
<td>1049</td>
<td>1040</td>
<td>1030</td>
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<tr>
<td>Ablation</td>
<td>1096</td>
<td>1087</td>
<td>1078</td>
<td>1069</td>
<td>1060</td>
<td>1051</td>
<td>1042</td>
<td>1032</td>
</tr>
</tbody>
</table>

Primary Endpoint (Death, Disabling Stroke, Serious Bleeding, or Cardiac Arrest) (ITT)

Ablation vs. Drug
Hazard ratio: 0.86 (95% CI, 0.65–1.15)
P=0.303
Cabana Trial: Caveats

- 27.5% of the drug therapy arm underwent ablation
- 9.2% of the ablation arm did not undergo ablation
- By Treatment received analysis, ablation arm showed:
  - All cause mortality reduced 40% (7.5% versus 4.4%, p=.005)
  - Death or CV hospitalization reduced 33% (74.9% to 41.2%, p=0.002)
  - 47% reduction in AF
- Only ~50% of patients post ablation were free of AF
- Only ~25% of patient on AAD were free of AF

Afib: Symptom control

- Rate Control
  - Resting HR <80 no better than <110bpm *if no symptoms
Afib: symptom control

- Maintenance of NSR
  - Antiarrhythmic drugs
  - Ablation

AA drug efficacy over time


Afib: Symptom control

- Ablation superior to medications

ThermoCool: Trial of Ablation vs. Alternative Antiarrhythmic Medication

N = 167 with paroxysmal AF
  - Randomized to catheter ablation (n = 166) or AAD (n = 61)
  - Single procedure
  - Mean age 55.7 yrs
  - 33.5% women

Protocol-Oriented Treatment Failure

- Catheter ablation
- Antiarrhythmic drug therapy
MHIF CV Grand Rounds – Jan. 14, 2019

MHI Research: Local contributions to national outcomes

2014-

Paroxysmal AF Catheter Ablation With a Contact Force Sensing Catheter

Results of the Prospective, Multicenter SMART-AF Trial

Andrea Natale, MD1, (Yveline A. Rouby, MD, George Marcus, MD1, Javid B. Safavi, MD2, Grace E. Lindsay, MD2, B. Thomas McLaurin, MD1, Celine Karimzadeh, MD1, Monika C. Maniscalco, MD1, Michael S. Molitch, MD1, Douglas L. Packer, MD2, Hiroshi Nakagawa, MD1, Ben S. Chung, MD1, ROBOTH, Robert B. Kragg, PA1, Y Li, MD, PhD, (Paul R. Selman, MD1, Zhicheng Guo, MD, PhD, 2, 1Paciencia B. Martinez, MD1, 1)

ABSTRACT

Background: Catheter ablation is important for the treatment of paroxysmal atrial fibrillation (PAF). Limited animal and human studies suggest a correlation between electronic tissue contact and radiofrequency lesion generation.

Objectives: The study sought to assess the safety and effectiveness of an irrigated, contact force (CF)-sensing catheter in the treatment of drug refractory symptomatic PAF.

Methods: A prospective, multicenter, nonrandomized study was conducted. Enrollment criteria included 33.

Results: The primary endpoints of this study included failed ablation, and the success rate of the ablation procedure was 88%. The procedure was well tolerated, with no reported complications. The long-term follow-up revealed no recurrence of atrial fibrillation, and the success rate remained stable over the 12-month period.

Conclusion: This study demonstrates the safety and effectiveness of the CF-sensing catheter in the treatment of drug refractory PAF, with a success rate of 88% at 12 months.

2016-7

Success rates improved to 88%
Background –
Atrial fibrillation mechanism

- Multiple wavelet hypothesis of Atrial fibrillation
  - Moe proposed in 1959
  - AF is a self-sustaining arrhythmia independent of focal discharges
  - Multiple independent reentrant wavelets are necessary to maintain fibrillation. These wavelets are always changing in position, shape, size and number with each successive excitation
  - Experimentally demonstrated by Allessie in 1985
  - Factors allowing for development of multiple wavelets
    - Atrial size – Sufficient surface area necessary for critical number of multiple wavelets to develop
    - Heterogeneous conduction velocity and tissue refractory periods allow for functional reentry
  - Led to the MAZE surgical procedure
Background – Atrial fibrillation mechanism

- 1997 - Haissaguerre et al described focal discharges that initiate AF
  - 94% of AF triggers observed from within the pulmonary veins
  - Shifted focus of ablation efforts to triggers

Background Trigger ablation for AF

- PV antral isolation
  - In paroxysmal AF
    - PV isolation can achieve approximately 80% 12-month freedom from AF with optimal contact-force radiofrequency ablation or second generation cryoballoon ablation
  - In persistent AF
    - PV isolation can achieve approximately 60% 12-month freedom from AF
    - Less successful likely due to the presence of non-PV drivers.
  - Insufficient success rates have led to further investigation into methods to identify AF drivers
Leading Circle Model of Atrial fibrillation

Functional Reentry

- Differs from simple reentry around a fixed barrier
- No excitable gap
- Central core of constant activation becomes refractory and unexcitable
- Small size, highest rotation frequency


Functional reentry

- Allessie, et al. Rabbit model
- Membrane potential recordings
- D3 and D4 indicate refractory central core activated twice as often
- Low amplitude potential cannot propagate out of the center. Functionally unexcitable due to continual membrane depolarization


Rotors as form of functional reentry

- Rotors are specific form of functional reentry
- Described in 1992 with optical mapping
- Curved or spiral form
- Wavefront and wavetail meet at a focal point
  - Phase singularity
- Wavefront velocity is not constant
- Standard functional reentry has fixed unexcitable core
- Rotor core
  - At the phase singularity wavefront curvature is extreme and conduction velocity very slow
  - Unable to penetrate refractory core
  - Phase singularity rotates around core
  - Rotor is able to move through space as no fixed barrier and no center of completely unexcitable tissue

Rotor initiation with PAC

- In certain instances
  Rotors may anchor in place
  - Often to areas around the pulmonary veins and in areas of heterogeneous atrial tissue

https://doi.org/10.1371/journal.pone.0149695
Complex Rotors

- Spatial and propagation instability is observed
- As the rotating wavefronts spread away from the PS and core, they interact with other in areas of anatomic or functional inhomogeneity fragment.
- They can then induce multiple disorganised ‘fibrillatory’ waves which then induce the chaotic atrial activation associated with AF

AF Driver Mapping

- 2012 Narayan - Focal Impulse and Rotor Modulation
  - CONFIRM trial
    - 92 Patients
    - 72% Persistent AF
    - 86% Acute AF termination
    - 82.4% single procedure freedom from AF
- 2017 Seitz – Spatiotemporal Electrogram Dispersion
  - 96 patients
  - 77.2% persistent AF
  - 95% Acute AF termination
  - 89% single procedure freedom from AF
  - 55% single procedure freedom from AF/AT
AF Driver Mapping
Spatiotemporal Dispersion

- 2017 Seitz, et al
  - Spatiotemporal dispersion mapping
  - During optical mapping of isolated LA tissue
  - Pseudo-multipolar electrograms demonstrated dispersion in regions of AF drivers

AF Driver Mapping
Ripple Map

- Ripple display corresponds directly to the recorded electrogram
  - No interpolation between points or other processing
- An acquired point is not assigned just a single activation time value
- Allows display of all electrical events per acquired point

Fractionated electrogram as displayed by Ripple map
Ripple Map: Macrotearrant AT example

- There is no interpolation between points, as all data presented is "real".

Courtesy of Drs. Kanagaratnam, Luther & Linton from Imperial College Healthcare, London, UK

AF Driver Mapping Ripple Map

- Potential benefits
  - Allows complete chamber evaluation
  - High density, long duration, time continuous point display
    - Depolarization frequency, EGM fractionation, and voltage
  - Voltage/substrate display in combination with depolarization characteristics
  - Easily and rapidly performed using currently available catheters and software
    - Pentaray
    - Confidense
    - Ripple map
  - It is possible these attributes may demonstrate AF driver sites which have proven challenging to otherwise display
AF Driver Mapping
Ripple Map

Definition: High Frequency Ripple Activation (HFRA)
- Atrial sites with near continuous, and high frequency atrial depolarization as displayed by Ripple map

Hypothesis:
- 1) regions on Ripple with HFRA would correspond to bipolar electrograms demonstrating CFAE and / or spatiotemporal dispersion
- 2) ablation of HFRA sites would terminate AF and lead to improved freedom from AF.

AF Ripple Mapping
AF Example, Trigger and AF driver map

- Patient with prior PVI, now with recurrent AF
- AF Trigger observed
  - Isoproterenol
  - 15mcg/min
  - Spontaneous left atrial
- Sustained AF initiated with left atrial PACs
- Left PV reconnected
  - Pulmonary vein-initiated AF

Figure: Sustained AF initiated with PACs
AF Ripple Mapping
AF Example, Trigger and AF driver map

- PV initiated AF
- PVI performed, AF did not terminate
- AF driver map performed using Ripple

Figure: Sustained AF initiated with PACs

AF Driver Map with Ripple

2 AF Drivers located
Inferior posterior LA
Adjacent Right Inferior Pulmonary Vein
AF Driver Map with Ripple

- AF terminates with HFRA sites
- AF Trigger eliminated with PV isolation
  - Isoproterenol 15mcg no spontaneous PACs or AF
- AF Drivers modified
  - Noninducible atrial pacing 200ms

AF Driver Map with Ripple - Persistent AF Driver – Left PV antrum

- AF present for prior 4 months
- Trigger not revealed while in sustained AF
- AF Ripple map performed for AF drivers
Ripple Map Study

- A total of 161 consecutive patients underwent a first-time ablation for persistent AF
  - Ripple map guided (n=56)
  - standard stepwise (n=105) approach

Ripple map approach
- PV antral isolation Ablation of HFRA locations
- Up to 3 Remaps performed if needed
- Ablation proceeded until AF termination or loss of all HFRA sites within LA and RA

Stepwise approach
- Haïssaguerre technique
- PV antral isolation Posterior LA LA roof CFAE Mitral isthmus

Ripple Map Study: Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Ripple map (n=56)</th>
<th>Standard stepwise (n=105)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean in yr ±SD)</td>
<td>65.1 ± 10.3</td>
<td>64.8 ± 9.2</td>
<td>0.90</td>
</tr>
<tr>
<td>Male - no. (%)</td>
<td>67.8</td>
<td>85.7</td>
<td>0.008</td>
</tr>
<tr>
<td>Structural Heart Disease* (%)</td>
<td>14.3</td>
<td>17.1</td>
<td>0.64</td>
</tr>
<tr>
<td>Diabetes - no. (%)</td>
<td>16.1</td>
<td>21.0</td>
<td>0.45</td>
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<tr>
<td>Hypertension - no. (%)</td>
<td>46.4</td>
<td>62.3</td>
<td>0.045</td>
</tr>
<tr>
<td>Baseline LA dimension (cm ±SD)</td>
<td>4.3 ± 0.5</td>
<td>4.5 ± 0.6</td>
<td>0.068</td>
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<tr>
<td>Baseline LVEF (%±SD)</td>
<td>53.4 ± 11.3</td>
<td>55.2 ± 10.7</td>
<td>0.32</td>
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<tr>
<td>Prior BB or CCB use (%)</td>
<td>91.1</td>
<td>90.5</td>
<td>0.90</td>
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<tr>
<td>Failed AAD (class Ic or III) (%)</td>
<td>89.3</td>
<td>78.1</td>
<td>0.078</td>
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<tr>
<td>Duration since 1st AF diagnosis (months)</td>
<td>30.9 ± 41.6</td>
<td>41.2 ± 49.4</td>
<td>0.19</td>
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<tr>
<td>Duration continuous AF prior to RFA (months)</td>
<td>5.00 ± 5.7</td>
<td>7.3 ± 10.8</td>
<td>0.14</td>
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<tr>
<td>CHA2DS2-Vasc score</td>
<td>2.3 ± 1.5</td>
<td>2.4 ± 1.6</td>
<td>0.74</td>
</tr>
</tbody>
</table>

Table 1: Characteristics of patients who underwent Ripple map guided AF ablation. *SHD=Congestive heart failure, Constrictive pericarditis, Amyloid cardiomyopathy, Cardiac surgery.
Ripple Map Study

Results – Acute Termination All AF Types

- Paroxysmal
  - N=75
  - Acute AF Termination: 95.8%

- Persistent
  - N=56
  - Acute AF Termination: 91.4%

Ripple Map Study

Results - HFRA characteristics

- Persistent AF
  - 4.2 Mean HFRA Regions
- Paroxysmal AF
  - 1.9 Mean HFRA Regions

Most Common HFRA Regions in Persistent AF

- PV Antrum
- LA Roof
- LA Septum
- Inferior LA
- Posterior LA
After a single procedure, at 18 months significantly more patients in the Ripple map guided strategy were free of AF, compared to the standard stepwise strategy (98.2% versus 81.9, p=0.009).

This difference remained after adjusting for gender and presence of HTN.

Best Randomized Study for Persistent AF – Single Procedure Freedom from AF
Ripple Map Study
Results – 18 Month Single Procedure

- There was no difference in freedom from AT (53.6% versus 52.4%, p=0.89) or freedom from any atrial arrhythmia (51.8 versus 40.0, p=0.12).

Ripple Map Study
Multiple procedure outcome

- After an average of 1.4 ablation procedures
  - Freedom from any AF was significantly higher in the Ripple group compared to the standard group (100% versus 88.6%, p=0.015)
  - There was no difference in freedom from AT (86.9% Ripple versus 76.2% standard, p=0.11) or any atrial arrhythmia (83.4% versus 70.5, p=0.09).
- 19 patients with AF or AT Recurrence in Ripple map group underwent second ablation
  - After 2 ablations, 17 of 19 (89.5%) were free of AF/AT
MHI Research: Improving outcomes national ablation outcomes -

- 2000-14 65% success
- 2014 81% success
- 2016-17 88% success
- 2018 93-95+% success

MHI Research: 2019 and beyond

- Improved accuracy of afib ablation targets using Ripple map technique developed at MHI
- Manuscript of 18 month follow up nearly complete for submission
- Research Version of Biosense Carto Mapping system under development with engineers in Israel
- Multicenter national trial proposed for 2019
MHI Research: 2019 and beyond

- Biosense VisiTag SurePoint Study
  - Enrolling Now
  - National Multicenter Study
  - Paroxysmal Afib, Failed AAD
  - New Method for accurately estimating lesion size
    - First Ever Available
  - May demonstrate consistently high success rates due to improved lesion consistency

- Biosense QDOT Study
  - Expected March 2019 Initial enrollment
  - National Multicenter Study
  - New Catheter for Afib ablation
    - Allows for surrogate lesion temperature assessment
    - QMODE: Automatic adjustment of power and tip cooling flow to keep temperature under char and steam pop zone
    - First Ever Available
    - QMODE +: Allows for safe high power, short duration ablation (90Watts, 4 Seconds versus current 30-35watts, 25-35 seconds)
    - In Europe, PAfib left atrial procedure times were reduced to from 120 to 45 minutes
  - Paroxysmal Afib, Failed AAD
Conclusions

- Afib is common, and associated with increased risk of stroke, mortality, and CHF
- Anticoagulation reduces stroke rate
- No treatment definitively reduces mortality
- For symptom control, ablation more effective than AA drugs
- With current research avenues, improved treatment options are emerging