**MHIF FEATURED STUDY:**

**Tendyne MAC**

**DESCRIPTION:**
Early feasibility study of the Tendyne Mitral Valve System in Mitral Annular Calcification. This is a multi-center study with 10 sites participating to enroll 30 patients total.

**CRITERIA LIST/ QUALIFICATIONS:**

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Symptomatic Severe MR; 2) MAC; 3) Noted to be Too High Risk for Surgery; 4) NYHA ≥ II</td>
<td>Carotid Stenosis &gt; 70%</td>
</tr>
<tr>
<td>Severe Stenosis not amenable to valvuloplasty</td>
<td>LA or LV Thrombus</td>
</tr>
<tr>
<td>LVEDD &gt;7.0</td>
<td>CAD</td>
</tr>
<tr>
<td>PAS &gt; 70 mmHg</td>
<td>Severe TR</td>
</tr>
<tr>
<td>EF &lt; 25%</td>
<td>COPD w/ Home O2</td>
</tr>
<tr>
<td>Prior MV Intervention</td>
<td></td>
</tr>
</tbody>
</table>

**NATIONAL PI:**
Paul Sorajja, MD

**RESEARCH CONTACT:**
Karlee Gebhart, RN
[Karlee.Gebhart@allina.com](mailto:Karlee.Gebhart@allina.com) | 612-863-7821

**SPONSOR:**
Tendyne Holdings

**OPEN AND ENROLLING:**
Please Refer Patients!

MHIF is the top enroller with 4 patients implanted! Please help us keep the momentum going!
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

Title: Atrial Fibrillation - Shifting the Paradigm
Speaker(s): Joshua M. Buckler, MD, FACC, FAHA
Consulting Cardiologist
Minneapolis Heart Institute® at Abbott Northwestern Hospital

Date: May 6, 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. Recall the importance of risk factor screening for atrial fibrillation.
2. Restate the need for development of integrated practice units in addressing atrial fibrillation.
3. Discuss alternative therapies that patients will ask about.

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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Moderator(s)/Speaker(s)
Dr. Joshua Buckler has disclosed that he DOES NOT have any real or apparent conflicts with any commercial interest as it relates to presenting their content in this activity/course.

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.

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We would like to thank the following company for their generous support of our activity.

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Please save a copy of this flier as your certificate of attendance.

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
Atrial Fibrillation:
Shifting the Paradigm

Joshua Buckler, MD, FACC, FAHA
Consulting Cardiologist
Minneapolis Heart Institute

Disclosure Statement

• I have no financial interests/arrangements or affiliations with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.
CME Objectives

• At the completion of this activity, the participants should be able to:

  • Recall the importance of risk factor screening for atrial fibrillation.
  
  • Discuss alternative therapies that patients may ask about.
  
  • Restate the need for development of integrated practice units in addressing atrial fibrillation.

Overall Goals

• Recognize how Afib patients enter the healthcare system

• Understand why atrial fibrillation is like diabetes and what that can teach us

• Gain insight into emerging data on risk factors for atrial fibrillation

• Be receptive to patients with alternative therapy ideas

• Walk away today understanding the need to build a multidisciplinary team around Afib
Projected number of persons with AF in the United States between 2000 and 2050, assuming no further increase in age-adjusted AF incidence (solid curve) and assuming a continued increase in incidence rate as evident in 1980 to 2000 (dotted curve)

http://www.silverbook.org

Data adapted from Coyne et al 2006; 9(5):348-356.
**Annual Incremental Cost of AF in the US**

- **Patient without AF**:
  - $11,965
  - $3,714
  - $5,629
  - $2,622

- **Patient with AF**:
  - $20,671
  - $3,605
  - $9,225
  - $7,841

- **Total Incremental Cost of AF per patient**: $8,705

---

**Utilization Patterns of Patients with AF**

- **Average number of outpatient hospital visits**: 12
- **ED visits among patients who visited the ED at least once**: 61%
- **Average number of provider encounters**: 67
- **Average number of ED visits among patients who visited the ED at least once**: 3

---

*Adapted from: Avalere, “Health Services Utilization and Medical Costs Among Medicare Atrial Fibrillation Patients,” (2010)*

*The Advisory Group, 2018*
Who are we talking about?

Afib MadLibs….

Age
Gender
New or Existing?
Paroxysmal or Persistent
Symptoms?
Rate controlled?
Risk factors?
Tolerant of medications?
Associated issues?
Aging Population

- The number of Minnesotans turning 65 in this decade (about 285,000) will be greater than the past four decades combined.

- Around 2020, Minnesota's 65+ population is expected to eclipse the 5-17 K-12 population, for the first time in history.

- The total number of older adults (65+) is anticipated to double between 2010 and 2030, according to our projections. By then, more than 1 in 5 Minnesotans will be an older adult, including all the Baby Boomers.

https://mn.gov/admin/demography/data-by-topic/aging/
State of Affairs

• Common disease with increasing incidence

• Costing the system significantly

• Presents not only in a myriad of ways but every individual is unique

• This is a problem that is not going away….
Afib is like diabetes…
- It affects everything
- It is affected by everything
- And nobody wants to deal with it…..
Afib is like diabetes…

- Common disease with increasing incidence
- Costing the system significantly
- Presents not only in a myriad of ways but every individual is unique
- Complex diagnosis that would benefit from integrated team approach
- Little to no coordination of care
- Underappreciation by primary care and others of the significance

Emerging Risk Factors
Obesity


NOTES: Age-adjusted by the direct method to the year 2000 U.S. Census Bureau estimates using age groups 20–39, 40–59, and 60+ years. Overweight is body mass index (BMI) of 25.0 or greater but less than 30.0 kg/m²; obesity is BMI greater than or equal to 30.0; and extreme obesity is BMI greater than or equal to 40.0. Pregnant women were excluded from the analyses.

SOURCES: CDC, National Health Examination Survey and National Health and Nutrition Examination Surveys.
Obesity and Afib

Adapted from Feng et al. Obesity (2019) 27, 332-338.
ARREST-AF

- Risk Factor Management in patients undergoing ablation
  - BP control
    - Goal <130/80
    - Dietary Salt Restriction and ACE/ARB (+/− additional agents as needed)
  - Weight Management
    - Goal >10% loss
    - Utilized face to face counseling
    - High-protein, low glycemic index, calorie controlled
    - If <3% loss at 3 months then very low calorie replacement meals given
  - Lipid management
    - Goal LDL<100mg/dL.
  - Sleep Apnea
  - Alcohol and Smoking counseling

Pathak RK, et al. JACC 2014;64:2222−31

ARREST-AF

Pathak RK, et al. JACC 2014;64:2222−31
**LEGACY**


---

**CENT Study**


---

**TABLE 1 Health Care Use**

<table>
<thead>
<tr>
<th></th>
<th>Control Group (N=147)</th>
<th>RFM Group (N=208)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiarrhythmic use</td>
<td>0.91 ± 0.6</td>
<td>0.26 ± 0.5</td>
<td>0.003</td>
</tr>
<tr>
<td>Antihypertensive</td>
<td>0.78 ± 0.6</td>
<td>0.53 ± 0.7</td>
<td>0.043</td>
</tr>
<tr>
<td>Lipid therapy</td>
<td>81 (64)</td>
<td>73 (40)</td>
<td>0.032</td>
</tr>
<tr>
<td>CVAP use</td>
<td>62 (43)</td>
<td>70 (34)</td>
<td>0.058</td>
</tr>
<tr>
<td>Interventional requirement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardioversion</td>
<td>1.51 ± 2.3</td>
<td>0.89 ± 1.5</td>
<td>0.002</td>
</tr>
<tr>
<td>Single AF ablation</td>
<td>43 (29)</td>
<td>86 (41)</td>
<td>0.009</td>
</tr>
<tr>
<td>Second procedure</td>
<td>24 (16)</td>
<td>15 (7)</td>
<td></td>
</tr>
<tr>
<td>Third procedure</td>
<td>5 (3)</td>
<td>3 (1)</td>
<td></td>
</tr>
<tr>
<td>In-patient visits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED presentation</td>
<td>0.76 ± 1.2</td>
<td>0.18 ± 0.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospitalization for AF</td>
<td>1.15 ± 1.6</td>
<td>0.74 ± 1.3</td>
<td>0.034</td>
</tr>
<tr>
<td>Out-patient visits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialist, planned</td>
<td>14 ± 3</td>
<td>10 ± 2</td>
<td>0.01</td>
</tr>
<tr>
<td>Specialist visit, RFM clinic</td>
<td>0.16 ± 0.4</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Specialist visit, unplanned</td>
<td>1.94 ± 2.0</td>
<td>0.19 ± 0.4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Sleep Apnea

Sleep Apnea and Atrial Fibrillation

• >60% of the Afib population has sleep apnea
• Independent risk factor
Sleep Apnea and Atrial Fibrillation

Untreated sleep apnea reduces success of catheter ablation

Naruse et al. Heart Rhythm 2013; 10(3): 331-7

Alcohol
Alcohol and Atrial Fibrillation

Yan et al. JACC 2018; 71(13): 1459-70

Alcohol and Atrial Fibrillation

Yan et al. JACC 2018; 71(13): 1459-70
Diabetes

Diabetes and Atrial Fibrillation

Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958-2015

- Percentage with Diabetes
- Number with Diabetes

CDC’s Division of Diabetes Translation, United States Diabetes Surveillance System available at http://www.cdc.gov/diabetes/data
Diabetes and Atrial Fibrillation


PREFER in AF Registry

Endurance Athletics

Endurance Athletics and Afib

Emerging Risk Factors

- Obesity
- Sleep Apnea
- Diabetes
- Alcohol
- Exercise

Risk Factors

- Growing body of evidence that obesity and the management of can have huge effects on afib
- Sleep apnea isn’t going away and needs to be addressed
- Alcohol related risk now has a molecular cause and possible therapeutic target
- Diabetes, like obesity and sleep apnea, is a clear independent risk factor which shares common treatment strategies
- Endurance athletics place a “healthy” group in a higher risk category
Updated Guidelines

**ESC Guidelines 2016**

**Integrated AF management**

<table>
<thead>
<tr>
<th>Patient involvement</th>
<th>Multidisciplinary teams</th>
<th>Technology tools</th>
<th>Access to all treatment options for AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Central role in care process</td>
<td>• Physicians (general physicians, cardiologists, and stroke specialists) and allied health professionals work in a collaborative practice model</td>
<td>• Information on AF</td>
<td>• Structured support for lifestyle changes</td>
</tr>
<tr>
<td>• Patient education</td>
<td>• Efficient mix of communication skills, education, and experience</td>
<td>• Clinical decision support</td>
<td>• Anticoagulation</td>
</tr>
<tr>
<td>• Encouragement and empowerment for self-management</td>
<td>• Physicians (general physicians, cardiologists, and stroke specialists) and allied health professionals work in a collaborative practice model</td>
<td>• Checklist and communication tools</td>
<td>• Rate control</td>
</tr>
<tr>
<td>• Advice and education on lifestyle and risk factor management</td>
<td>• Physicians (general physicians, cardiologists, and stroke specialists) and allied health professionals work in a collaborative practice model</td>
<td>• Used by healthcare professionals and patients</td>
<td>• Antiarrhythmic drugs</td>
</tr>
<tr>
<td>• Shared decision making</td>
<td>• Physicians (general physicians, cardiologists, and stroke specialists) and allied health professionals work in a collaborative practice model</td>
<td>• Monitoring of therapy adherence and effectiveness</td>
<td>• Catheter and surgical interventions (ablation, LAA occluder, AF surgery, etc.)</td>
</tr>
<tr>
<td>• Informed, involved, empowered patient</td>
<td>• Working together in a multidisciplinary chronic AF care team</td>
<td>• Navigation system to support decision making in treatment team</td>
<td>• Complex management decisions underpinned by an AF Heart Team</td>
</tr>
</tbody>
</table>

Updated Guidelines

**ACC/AHA Guideline 2019**

**Recommendation for Weight Loss in Patients with AF**

Referenced studies that support the new recommendation are summarized in Online Data Supplement 10.

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>B-R</td>
<td>1. For overweight and obese patients with AF, weight loss, combined with risk factor modification, is recommended (S7.13-1–S7.13-3). <strong>NEW:</strong> New data demonstrate the beneficial effects of weight loss and risk factor modification on controlling AF.</td>
</tr>
</tbody>
</table>
Overall Goals

• Recognize how Afib patients enter the healthcare system

• Understand why atrial fibrillation is like diabetes and what that can teach us

• Gain insight into emerging data on risk factors for atrial fibrillation

• Be receptive to patients with alternative therapy ideas

• Walk away today understanding the need to build a multidisciplinary team around Afib
Alternative and Complementary Therapies
Your Patients Might Ask About.....
... And You Should Listen

Acupuncture

Recurrence of Afib after Cardioversion
Yoga

“The rhythm of the body, the melody of the mind & the harmony of the soul create the symphony of life.”

Yoga

Herbal medicine

- **Barberry** – shrub - alkaloid causing vasodilation and positive inotropic and negative chronotropic actions through outward potassium channel inhibition
- **Shensongyangxin** – Chinese medication used to treat tachyarrhythmias, sodium and calcium channel inhibition
- **Cichona** – bark - alkaloids including quinine
- **Hawthorn** – flowers, leaves, berries - pharmacologic active flavonoids and procyanides which prolong action potential and lead to negative chronotropic effects
- **Motherwort** – plant – inward calcium and potassium channel inhibition
- **Khella** – plant – amiodarone derived from extracts
- **Wenxin Keli** – Chinese herb – prolong refractory period of atrial cardiomyocytes

Other complimentary therapies

- Biofeedback
- Breathing techniques
- Meditation
Change perspective
M87

- 55 million light years away
- 24 microarcseconds across
- Event Horizon Telescope
- Observations over 10 days
- Petabytes (1M GB) of data manually transferred

Current State
&
Why and How We Need to Shift
Afib Programs Traditionally

Cardioversion
Catheter Ablation
Surgical Ablation
Watchman

Where do they come from?

ER → Afib Patient
Afib Patient → PCP
PCP → EP
EP → Cardiologist
Cardiologist → Other Specialist
Other Specialist → Naturopathic Physician
Naturopathic Physician → Google
Shifting the Paradigm

- Patients entering the system from many directions
- Emerging risk factor data
- Rapidly growing treatment options
- Non-traditional therapeutic treatments
- But...
  - No cohesion
  - No collaboration
  - Unknown numbers of unrecognized patients
  - Opportunity to have a large impact
Atrial Fibrillation/Flutter Patient Visits (ICD-10 I48.*)
Total Patients (unique MRN): 20,654

**SMG PCP**
- Yes: 6,735
- No: 13,919

**Seen by SHVI**
- Yes: 3,232
- No: 3,503

Allina PCP
- Yes: 26,618
- No: 40,755

**Seen by MHI, UHVC, MHVC**
- Yes: 20,936
- No: 5,682

2009-2019
Total: 106,204
Alive: 67,373
2016-2019
Total: 4555

2009-2019 – 106,204 patients diagnosed with Afib/flutter
Drivers of increased focus on AF care delivery
- Patient volumes are increasing
- Patients are chronic and comorbid
- AF is costly to treat
- Value and episodic cost is increasingly important
- AF is difficult to identify
- Variety of treatment options available
- Emerging risk factors

Reimagine Atrial Fibrillation
- Afib is like diabetes...
  - Change the way Atrial Fibrillation care is delivered
    - Optimizing, standardizing and integrating comprehensive care algorithms based on current evidence for patients across our institution at all points of entry for patients (ED, Hospital medicine, Primary care, Cardiology, etc.)
    - Address risk factor modification and build a comprehensive care model for new and established patients to optimize patient outcomes and improve access to truly comprehensive care beyond cardiology and across specialties such as sleep medicine, behavioral health, neurology, pulmonary, endocrinology, naturopathy, etc.
      - Bidirectional communication between groups
    - Build a world class Center of Excellence focused on care, research, and education
Program Vision

• Develop a program which shifts the paradigm away from the current piecemeal state largely focused on reactionary treatments to one which incorporates the values of the Integrated Practice Unit and focuses on coordinated interdisciplinary care to optimize screening, risk factor management, and guideline based care.

• Develop and deliver new care models to advance access to state-of-the-art clinical care, while simultaneously improving health outcomes, reducing costs, and enhancing the quality of life for patients with atrial fibrillation.

• Be recognized as the regional, national, and international thought leader in how atrial fibrillation care is delivered.

Integrated Practice Units (IPU)

• Organized around a medical condition or set of closely related conditions
• Multidisciplinary team
• Treat the disease, related conditions, complications
• Responsible for full cycle of care (outpatient, inpatient, support services)
• Patient education and engagement are integrated
• Ideally co-located in dedicated facilities
• Provider “team captain” oversees each patient’s care process
• Team measures outcomes, costs, and processes
• Regular meetings to discuss patients, processes, and results
Core Beliefs

Customer Service
- Access
- Education
- Recognition as leader

Completeness
- Evaluation
- Treatment

Communication and Connections
- Patients
- Providers
- Industry

Global Goals

Increase access
- Address Risk Factors
- Standardize care
- Reduce ER visits/LOS

Increase use of definitive therapies
- Catheter ablation
- LAA closure
- Increase anticoagulation utilization, particularly NOACs
- Reduce Costs
- Improve Outcomes/QoL
Tools to Reach Goals

Multidisciplinary team

Standardization of Care

Communication

Multidisciplinary team

- General Cardiology
- Electrophysiology
- Cardiac Surgery
- Primary Care
- Hospital Medicine
- Emergency Department
- Neurology
- Informatics
- Business Development
- Interventional/Structural Cardiology
- Heart Failure
- Cardiac Rehab
- Sleep Medicine
- Pharmacy
- Pulmonary
- Endocrinology
- Weight Management/Bariatric Surgery
- Nutrition
- Naturopathy
- Psychology/Behavioral Health
Standardization of Care

Care Pathways
- Primary Care
- ER
- Hospitalist
- Cardiology

Communication

Primary Care
ER
Hospitalists
Sleep Medicine
Neurology
Cardiology
MHIF CV Grand Rounds – May 6, 2019

Leadership Structure

<table>
<thead>
<tr>
<th>Program Director</th>
<th>Steering Committee</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triad&lt;br&gt;- Physician (General cardiologist)&lt;br&gt;- APP&lt;br&gt;- Administration</td>
<td>Electrophysiology&lt;br&gt;Primary Care&lt;br&gt;ER&lt;br&gt;Hospitalist&lt;br/Cardiac Surgery&lt;br&gt;Neurology&lt;br&gt;Informatics&lt;br&gt;Business Development</td>
<td>Develop program&lt;br&gt;Meet monthly to review data&lt;br&gt;Oversee program modules</td>
</tr>
</tbody>
</table>
Program Modules

Access
- Clinic
- Inpatient consult
- Curbside

Referral Communication and Coordination

Risk Factor Management

Patient Education

Research

Program Innovation & Technology Integration

Short Term Goals

• All patients be offered appointment within 48 hours

• Be a resource for the ER and Primary Care to help reduce ER visits and admissions

• Keep as many patients and procedures internally as possible

• Ensure new access points into the system

• Build risk factor management program and referral pathways
Long Term Goals

• Capture majority if not all atrial fibrillation patients

• Increase anticoagulant utilization

• Increase use of definitive therapies
  • Catheter ablation
  • LAA closure

• Demonstrate success of key goals:
  • Decrease costs
  • Improved outcomes
  • Increased quality of life for patients

Initial Work

Ensure Access

• General Cardiology clinic appointments within 48 hours (or sooner?)
• “Hotline” for Primary Care and ER
  • Pager/Phone number
• ER and Primary Care “advertising”
• Single point of access for patients – One Number – (206)215-AFIB

Closely monitor accessibility

• Track referrals, 3rd next available, “secret shopper”
Initial Work

Design Care Pathways
- Guideline based
- Practical and easy to institute
- Visible

Leverage power of Epic
- Templated notes
- SmartSets
- SmartPhrases

Initial Work

Build referral pathways
- In conjunction with partners
- Each link has unique requirements
- Both internal and external connections

Risk Factor Management
- Initially APP clinic to address weight loss
- Future plans for diet, alcohol, stress management, etc.
Initial Work

Develop patient facing elements
- Group visits
- Screening/community events
- Website/Google

Educational materials
- Branded
- Paper and electronic
- App

On the horizon....

- Benefactor named program
- Designated multidisciplinary clinic space
- Robust data infrastructure
- Model for integrated atrial fibrillation care
Shifting the Paradigm

Current
• Piecemeal
• Reactionary
• Disjointed

Future
• Comprehensive
• Cohesive
What did we learn?

- Afib patients enter the system in many ways, many of which do not involve cardiology
- Afib is like diabetes...
- Body of evidence for risk factor modification is growing rapidly
- Patients will come to you discussing alternative therapy options and we need to be informed
- The future of atrial fibrillation care is in comprehensive programs