**MHIF FEATURED STUDY:**
**Tendyne MAC**

<table>
<thead>
<tr>
<th>CONDITION:</th>
<th>NATIONAL PI:</th>
<th>RESEARCH CONTACT:</th>
<th>SPONSOR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral Annular Calcification w/ Severe Symptomatic Mitral Regurgitation</td>
<td>Paul Sorajja, MD</td>
<td>Karlee Gebhart, RN</td>
<td>Tendyne Holdings</td>
</tr>
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<td></td>
<td></td>
<td><a href="mailto:Karlee.Gebhart@allina.com">Karlee.Gebhart@allina.com</a></td>
<td>612-863-7821</td>
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</tbody>
</table>

**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:**

**Inclusion**
1) Symptomatic Severe MR; 2) MAC; 3) Noted to be Too High Risk for Surgery; 4) NYHA ≥ II

**Exclusion**
- Severe Stenosis not amenable to valvuloplasty
- LVEDD > 7.0
- PAS > 70 mmHg
- EF < 25%
- Prior MV Intervention
- Carotid Stenosis > 70%
- LA or LV Thrombus
- CAD
- Severe TR
- COPD w/ Home O2

**MHIF is the top enroller with 4 patients implanted! Please help us keep the momentum going!**
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
Houston, We Have a Problem...

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.

Adapted from: Avalere, “Health Services Utilization and Medical Costs Among Medicare Atrial Fibrillation Patients,” (2010)
CV Five-Year Growth Projections by Sub-Service Line

National, All-Payer, 2016-2021

- Outpatient Cardiac EP: 20%
- Outpatient Medical Vascular: 20%
- Outpatient Vascular Cath: 19%
- Outpatient Medical Cardiology: 10%

Inpatient Cardiac EP: (3%)
Inpatient Arterial Disease: (4%)
Inpatient Cardiac Surgery: (6%)
Inpatient Cardiac Cath: (8%)
Outpatient Cardiac Cath: (12%)
Inpatient Medical Cardiology: (13%)
Inpatient Other Vascular: (19%)

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?
Where do they come from?

- ER
- Aflib Patient
- PCP
- Cardiologist
- Other Specialist
- Naturopathic Physician
- EP
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+ or more. Overweight is body mass index (BMI) of 25.0 or greater but less than 30 kg/m²; obesity is BMI greater than or equal to 30; and extreme obesity is BMI greater than or equal to 40. Pregnant females were excluded from the analyses.

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

Risk of developing Afib

Hazard Ratio

Healthy < 25 Unhealthy Healthy 25-29.9 Unhealthy Healthy 30-34.9 Unhealthy Healthy ≥35 Unhealthy

0.5 1 1.5 2 2.5 3

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
LEGACY


CENT Study

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

**Central Illustration:** Habitual Alcohol Consumption: Long-Term Risk of Atrial Fibrillation and Cardiovascular Mortality

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

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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

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**

<table>
<thead>
<tr>
<th>Integrated AF management</th>
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<tbody>
<tr>
<td><strong>Patient involvement</strong></td>
</tr>
<tr>
<td>• Central role in care process</td>
</tr>
<tr>
<td>• Patient education</td>
</tr>
<tr>
<td>• Encouragement and empowerment for self-management</td>
</tr>
<tr>
<td>• Advice and education on lifestyle and risk factor management</td>
</tr>
<tr>
<td>• Shared decision making</td>
</tr>
<tr>
<td>• Informed, involved, empowered patient</td>
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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>
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</thead>
</table>
| I | B-R | 1. For overweight and obese patients with AF, weight loss, combined with risk factor modification, is recommended (S7.13-1–S7.13-3).  
**NEW:** New data demonstrate the beneficial effects of weight loss and risk factor modification on controlling AF. |
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.”

MHIF CV Grand Rounds – May 6, 2019

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
- 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  PCP  Naturopathic Physician  Other Specialist  Cardiologist  EP
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

Primary Care  Emergency Room  Hospital Medicine  General Cardiology
Atrial Fibrillation/Flutter Patient Visits (ICD-10 I48.4)
Total Patients (unique MRN): 20,654

SMG PCP

- YES: 6,735
- NO: 13,919

Seen by SHVI

- YES: 3,232
- NO: 3,503

- YES: 4,534
- NO: 9,385

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

RMC PCP

YES NO
1,220 3,335

Seen by MHI

YES NO
372 848

2009-2019 — 106,204 patients diagnosed with Afib/flutter

Count of Ablations by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
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<tbody>
<tr>
<td>Count</td>
<td>200</td>
<td>400</td>
<td>600</td>
<td>800</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Current Age</th>
<th>Patients with Stroke</th>
<th>Patients with Ablation</th>
<th>Patients with Cardioversion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male: 59.6%</td>
<td>Under 65: 25.1%</td>
<td>5.2%</td>
<td>7.4%</td>
<td>21.6%</td>
</tr>
<tr>
<td>Female: 40.4%</td>
<td>65 and Over: 79.9%</td>
<td>(1,631)</td>
<td>(1,933)</td>
<td>(3,652)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Currently on an Antiarrhythmic</th>
<th>Ever on an Antiarrhythmic</th>
<th>Currently on an Anticoagulant</th>
<th>Ever on an Anticoagulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>26.9% (7,023)</td>
<td>50.9% (13,309)</td>
<td>44.2% (11,556)</td>
<td>66.3% (17,332)</td>
</tr>
</tbody>
</table>
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
Referring Provider
- Refers all patients
- Expectation of co-management

General Cardiology
- Initiates workup
- Addresses risk factors
- Incorporates associated care team members as necessary
- Refers appropriately to EP

EP
- Assesses for higher level care
- Ablation
- Refractory cases
- Refers back to General Cardiology for additional risk factor management/workup

Leadership Structure

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

SWEDISH ? MINNEAPOLIS HEART INSTITUTE
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