MHIF FEATURED STUDY:

OPTION
Composition of Anticoagulation with
Left Atrial Appendage Closure after AF Ablation

DESCRIPTION: The primary objective of this study is to determine if left atrial appendage closure with the WATCHMAN FLX Device is a reasonable alternative to oral anticoagulation following percutaneous catheter ablation for high risk patients with non-valvular atrial fibrillation.

STUDY DESIGN: This study is a prospective, randomized, multi-center, global investigation to determine if left atrial appendage closure with the WATCHMAN FLX Device is a reasonable alternative to oral anticoagulation in patients after AF ablation. Subjects will be randomized to OAC or WATCHMAN FLX. The duration of individual subject participation is expected to last approximately 36 months. Follow-up visits to occur at 3, 12, 24, and 36 months following randomization.

PARTIAL CRITERIA LIST/QUALIFICATIONS:

Inclusion

• Underwent a prior catheter ablation procedure for non-valvular AF between 90 and 180 days prior to randomization (sequential) or is planning to have clinically indicated catheter ablation within 10 days of randomization (concomitant).

• The subject has a calculated CHA2DS2-VASc score of 2 or greater for males or 3 or greater for females.

Exclusion

The subject requires long-term anticoagulation therapy for reasons other than AF-related stroke risk reduction, for example due to an underlying hypercoagulable state (i.e., even if the device is implanted, the subjects would not be eligible to discontinue OAC due to other medical conditions requiring chronic OAC therapy).

CONDITION: Atrial Fibrillation

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RESEARCH CONTACT: Jacob Cohen, MS
Jacob.Cohen@allina.com | 612-863-4022

SPONSOR: Boston Scientific

OPEN AND ENROLLING:
Please Refer Patients!
“Healthcare disparities are differences in health care quality, access, and outcomes adversely affecting members of racial and ethnic minority groups and other socially disadvantaged populations”


Addressing underserved patient populations with structural heart disease

FOCUS – severe aortic stenosis

Mario Goessl, MD PhD
MHI/MHIF Grand Rounds kick-off Sept 9 2019
Distribution of >average racial/ethnic minority populations

Morris AA et al., J Heart Lung Transplant 2016;35:953–961

Preventable death rates

The US is projected to have a **majority non-white** population by 2050.
Percentage of racial/ethnic groups among patients undergoing TAVR in the United States. The p value for trend as assessed by the Cochrane-Armitage test. TAVR = transcatheter aortic valve replacement.

Alkhouli et al. JACC: Cardiovasc Int. 2019; 12(10) 936-48
Disease Prevalence

- Equivocal reporting on racial differences in prevalence of aortic stenosis
- AA are at increased risk for early onset aortic stenosis

1 Taylor HA et al., AJC 95(3) 2005, 401-404
Factors in Chronic Disease Control

- patient nonadherence related to costs
- health literacy
- perceived discrimination
- beliefs about medication
- untreated mental and substance use disorders
- no or poor insurance coverage


• Nearly half of Americans (47%) report that they could not cover an emergency expense costing $400 without selling something or borrowing money.

• Yet, this amount represents less than one-third of the average health insurance deductible in 2015

Cultural differences and lack of understanding

- High refusal rate of AVR\(^1\)
- Lack of understanding of differences AVR vs. percutaneous TAVR
- Perception of being “too old”
- Group decisions vs. individual decisions\(^2\)
- Historical distrust in the medical community (e.g. Tuskegee syphilis experiments)

\(^1\)Minha S, CCI 2015
\(^2\)Talcott JA, Cancer 2007
**Finding #2. The Cardiology Provider is among the most important Determinant of Treatment for ssAS in the United States**

<table>
<thead>
<tr>
<th>Likelyhood of Any AVR</th>
<th>Likelihood of TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MOR</strong></td>
<td></td>
</tr>
<tr>
<td>0.125     0.25   0.5   1 2 4</td>
<td>0.5   1 2 4</td>
</tr>
<tr>
<td>Adjusted Odds Ratios</td>
<td>Adjusted Odds Ratios</td>
</tr>
<tr>
<td>Dementia</td>
<td>8.32 (0.24, 8.40)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>8.66 (0.58, 8.74)</td>
</tr>
<tr>
<td>Dyspnea on exertion</td>
<td>1.56 (1.44, 1.70)</td>
</tr>
<tr>
<td>Pd / Qs (pa vs rd)</td>
<td>6.54 (0.49, 0.50)</td>
</tr>
<tr>
<td>IMR (s)</td>
<td>1.46 (1.30, 1.68)</td>
</tr>
</tbody>
</table>

**MOR:** the likelihood of receiving a different treatment strategy by randomly selecting a different general cardiologist. An MOR of 1 indicates no difference in outcomes between providers; an MOR of 1.5 indicates a 50% chance of a different outcome if the patient goes to another randomly selected physician.

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**TVINCITIES – aortic Valve Disease and racial disparities**

**A Multi-Center Study**

- Mario Goessl, MHI (PI)
- Mengistu Simegn, HCMC
- Alan Zajarias, Washington University
- Michele Voeltz, Henry Ford

Supported by Edwards Lifesciences
TVINCITIES – 3 step approach

• Review echo data-sets for patients with severe AS, no therapy and disparity background
  >> invite for clinical follow up

• Provider survey
• Patient survey

MHI Provider survey results

Q3 In your opinion, what are the 3 most common problems you have identified that prevent the penetration of guideline-driven care in patients with diversity background (non-white, low socio-economic status, etc.)?

Q4 Are you aware of any untreated patients with severe aortic stenosis (AS) in your patient panel?
MHI Provider survey results

Q7 I regularly see patients with diverse backgrounds (Q8 I am aware of the current AHA/ACC valvular heart disease guidelines as they relate to the appropriate use of transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR).

MHI Provider survey results

Q9 I have referred patients with severe AS for S/ Q11 I have referred patients with severe AS to TAVR.
MHIF CV Grand Rounds – Sep 9, 2019

MHI Provider survey results

Q10 I feel that most patients with severe AS are best served with TAVR.
- Strongly agree
- Agree
- Uncertain
- Disagree
- Strongly disagree

Q12 I feel that most patients with severe AS are best served with TAVR.
- Strongly agree
- Agree
- Uncertain
- Disagree
- Strongly disagree

MHI Provider survey results

Q14 Referring patients with severe AS to either TAVR or SAVR is too difficult.
- Strongly agree
- Agree
- Uncertain
- Disagree
- Strongly disagree

Q15 I have the appropriate knowledge base to talk about risks and benefits of SAVR vs TAVR.
- Strongly agree
- Agree
- Uncertain
- Disagree
- Strongly disagree

Q13 I am aware of the collaboration between my practice and a local TAVR center where I can refer patients with severe AS to SAVR and TAVR.
- Strongly agree
- Agree
- Uncertain
- Disagree
- Strongly disagree
MHIF CV Grand Rounds – Sep 9, 2019

**MHI Provider survey results**

Q17 I would like more education

- **Strongly agree**
- **Agree**
- **Uncertain**
- **Disagree**
- **Strongly disagree**

Q6 What is your preferred format of continued medical education on severe AS?

- **Email/short PowerPoint**
- **Letter**
- **Lecture/grand rounds**
- **3-1 education by...**
- **Other (please specify)**

**MHI DATA**

<table>
<thead>
<tr>
<th></th>
<th>All (N=179)</th>
<th>No prior any valve intervention</th>
<th>Prior any valve intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Subtotal</td>
<td>(n=146)</td>
<td>Severe (n=21)</td>
</tr>
<tr>
<td>Death</td>
<td>6</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>AVR has been done or scheduled</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pts need AVR according to doctor suggestion</td>
<td>41</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Pts decline AVR *</td>
<td>1</td>
<td>18</td>
<td>3</td>
</tr>
<tr>
<td>Pts do not make final decision of AVR</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>AVR is not suitable for pts $</td>
<td>14</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>AVR is postponed &amp; delayed</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Unknown reasons</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Pts do not need AVR according to HCMC guidelines</td>
<td>44</td>
<td>28</td>
<td>17</td>
</tr>
<tr>
<td>AS severity requires further evaluation</td>
<td>14</td>
<td>28</td>
<td>17</td>
</tr>
<tr>
<td>Patients lost to follow-up</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

**EDUCATION ON ALL LEVELS**

30%!
MHI DATA

<table>
<thead>
<tr>
<th></th>
<th>w/o prior valve procedure</th>
<th>w/ prior valve procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total (before screening)</strong></td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>Screening failure</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>death</td>
<td>30</td>
<td>4</td>
</tr>
<tr>
<td>moderate AS w/ regular f/u</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>mild AS</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>AVR done</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>AVR work</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>lack of interest</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td><strong>Successful enrolled</strong></td>
<td>73</td>
<td>40</td>
</tr>
<tr>
<td>unknown disparities</td>
<td>11</td>
<td>4</td>
</tr>
</tbody>
</table>

37% mental health disorder

Dr. Du, prelim. data

HCMC DATA

• 90 patients with severe AS but no therapy

• 36% with disparity background (race, language)

• High prevalence of LFLG aortic stenosis
Conclusions

• Disparity in SHD is **real and a problem** @ MHI and HCMC
• Further **education** is needed, especially in the rapidly evolving field of TAVR
  • Provider AND Patient / Community level
• Watch for LFLG aortic stenosis and mental health issues
• MULTIDISCIPLINARY TEAMS are necessary
  • Interpreter service
  • Social service
  • PCP / mental health professional
  • Cardiology / Cardio-thoracic surgery

THANK YOU!

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