MHIF FEATURED STUDY:

OPTION

Comparison 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).
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

**Title:** Health Care Disparities in Structural Heart Disease – TVINCITIES Update

**Speaker:** Mario Gössl, MD, PhD
- Director of Research & Education of the Center for Valve & Structural Heart Disease
- Minneapolis Heart Institute Foundation®
- Director of the Watchman LAAC program
- Program Director of the Interventional Cardiology & Advanced Adult Structural & Congenital Heart Disease Interventions Fellowship
- Minneapolis Heart Institute® at Abbott Northwestern Hospital

**Date:** September 9, 2019
**Time:** 7:00 – 8:00 AM
**Location:** Minneapolis Heart Institute Building, Suite 100, Learning Center

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

1. Describe typical demographics and echocardiographic findings of TVINCITIES patients
2. Describe challenges in health care delivery in patients with disparity background
3. Outline the multicenter expansion of TVINCITIES

**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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Allina Health, Learning & Development intends to provide balance, independence, objectivity and scientific rigor in all of its sponsored educational activities. All speakers and planning committee members participating in sponsored activities and their spouse/partner are required to disclose to the activity audience any real or apparent conflict(s) of interest related to the content of this conference.

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)**
Dr. Mario Gössl has disclosed the following relationships – Edwards Life Sciences: Grant/Research Support; Abbott Vascular, Caisson: Consultant; Speaker’s Bureau: Edwards Lifesciences.
Planning Committee
Dr. Alex Campbell, Jake Cohen, Jane Fox, Dr. Kevin Harris, Dr. Kasia Hryniewicz, Rebecca Lindberg, Amy McMeans, Dr. Michael Miedema, Dr. JoEllyn Moore, Pamela Morley, Dr. Scott Sharkey, Maia Hendel 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. Mario Gössl has disclosed the following relationships – Edwards Life Sciences: Grant/Research Support; Abbott Vascular, Caisson: Consultant; Speaker’s Bureau: Edwards Lifesciences. 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.

Actelion Pharmaceutical Companies
of Johnson & Johnson

Bristol-Myers Squibb

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PLEASE SAVE YOUR SERIES Flier
When you request a transcript this serves as your personal tracking of activities attended. Most professional healthcare licensing/certification boards will not accept a Learning Management System (LMS) transcript as proof of credit; there are too many LMS’s across the country and their validity/reliability are always in question.

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
“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

**Figure 1:** Distribution of U.S. Population by Race/Ethnicity, 2015 and 2045

Source: U.S. Census Bureau; ESRI forecasts for 2015 and 2020
Percentage of racial/ethnic groups among patients undergoing TAVR in the United States. The p value for trend as assessed by the Cochran-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\textsuperscript{1}
- Lack of understanding of differences AVR vs. percutaneous TAVR
- Perception of being “too old”
- Group decisions vs. individual decisions\textsuperscript{2}
- Historical distrust in the medical community (e.g. Tuskegee syphilis experiments)

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

Likelihood of Any AVR

Likelihood of TAVR

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.

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 penetrance 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).

Q9 I have referred patients with severe AS for S/ Q11 I have referred patients with severe AS to TAVR.
MHI Provider survey results

Q10 I feel that most patients with severe AS are best served with TAVR.

Answered: 66  Skipped: 3

Q12 I feel that most patients with severe AS are best served with TAVR.

Answered: 67  Skipped: 2

MHI Provider survey results

Q16 I know that low (STS score <3) and intermediate risk patients (STS score 3-8) may be eligible for TAVR.

Q15 I have the appropriate knowledge base to talk about risks and benefits of SAVR vs TAVR.

Q14 Referring patients with severe AS to either TAVR or SAVR is too difficult.

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.
MHI Provider survey results

Q17 I would like more education

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

0% 10% 20% 30% 40% 50% 60%

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

- Email/short PowerPoint
- Letter
- Lecture/grand rounds
- S-H education by x...
- Other (please specify)

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

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>
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<tbody>
<tr>
<td></td>
<td>Subtotal (n=141)</td>
<td>Subtotal (n=48)</td>
<td>Subtotal (n=21)</td>
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<tr>
<td>Death</td>
<td>6</td>
<td>2</td>
<td>2</td>
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<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>
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<tr>
<td>Pts decline AVR</td>
<td>18</td>
<td>3</td>
<td>1</td>
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<tr>
<td>Pts do not make final decision of AVR</td>
<td>4</td>
<td>4</td>
<td>0</td>
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<td>AVR is not suitable for pts</td>
<td>12</td>
<td>2</td>
<td>1</td>
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<tr>
<td>AVR is postponed &amp; Pts</td>
<td>5</td>
<td>5</td>
<td>0</td>
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<tr>
<td>Unknown reasons</td>
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<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Pts do not need AVR according to</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>AS severity requires further</td>
<td>14</td>
<td>13</td>
<td>14</td>
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<tr>
<td>Pts lost to f/u</td>
<td>28</td>
<td>17</td>
<td>16</td>
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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>
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</thead>
<tbody>
<tr>
<td>Total (before screening)</td>
<td>131</td>
<td></td>
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<tr>
<td>Screening failure</td>
<td>58</td>
<td></td>
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<tr>
<td>death</td>
<td>30</td>
<td>4</td>
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<tr>
<td>moderate AS w/ regular f/u</td>
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<td></td>
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<tr>
<td>mild AS</td>
<td>2</td>
<td></td>
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<tr>
<td>AVR done</td>
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<tr>
<td>AVR work</td>
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<tr>
<td>lack of info for enrol</td>
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<td>0</td>
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<tr>
<td>Successful enrolled</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

**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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