THE IMPORTANCE OF CLINICAL TRIALS: WHY THEY MATTER

JUNE 17TH
3:00 PM ET

Advancing Innovation Through Clinical Trial Education

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Mended Hearts ® mission is to inspire hope and improve the quality of life for heart patients and their families through ongoing peer-to-peer support, education and advocacy.

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All attendees are in listen only mode

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Please type your questions into the Q&A box at any time during the presentation. The moderator will read your questions during the question-and-answer period.

Note: The presenter will not be able to answer specific questions about you or your loved one, as they are not the treating physician.

The PDF version of the slides, as well as the recording of this presentation, will be available on the Mended Hearts® website following the event.
Dr. Megan Coylewright

- Director of the Structural Heart Program at The Erlanger Heart and Lung Institute
- Dr. Coylewright serves as the PI for multiple trials
- Serves on the planning committees and faculty for the Scientific Sessions of ACC and TCT
- 2022 Structural Heart Program Lead for SCAI’s Annual Meeting
- Dr. Coylewright completed her medical school, residency, and Master of Public Health training at John Hopkins
A Shared Decision Making Primer for Heart Disease

Megan Coylewright, MD MPH FSCAI FACC
Director, Structural Heart Program
Vice Chief, Cardiology
The Erlanger Heart and Lung Institute
Conflicts of Interest

• Grant funding: Edwards LifeSciences, Boston Scientific
• Global steering committee: CHAMPION AF
Preference-sensitive decisions

• More than one reasonable option exists
• Uncertainty exists in evidence
• Patients vary in their values (i.e. geographically or by race, class and gender)
• Patient preferences may be distinct from healthcare professional preferences
<table>
<thead>
<tr>
<th>Decision</th>
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<tbody>
<tr>
<td>A formal shared decision making interaction (on anticoagulation choices)</td>
</tr>
<tr>
<td>with an independent, non-interventional physician</td>
</tr>
<tr>
<td>using an evidence-based decision tool</td>
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* Continues to perform ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum, of which at least 12 are LAAC, over a two year period.
Decision: Choose treatment to lower Stroke or Clot risk?

- **no medicine**
- Aspirin
- Warfarin
- Apixaban
- Dabigatran
- Rivaroxaban
- Edoxaban
- Watchman

**Treatment Frequency:**
- No pills
- Blood tests needed: None
- Interactions with medications: None

For 100 men age 82 taking no medicine for 1 year:

- 19 Have a Stroke or Clot
- 79 Have no Stroke, Clot or Major Bleed.
- 2 Major Bleeds based on HAS-BLED Score of 2.
- 2 Bleeds with no treatments

Population: 100, 1000
Years: 1, 5, 10

Continue
Decision: Choose treatment to lower Stroke or Clot risk?

- no medicine
- aspirin
- warfarin
- apixaban
- dabigatran
- rivaroxaban
- edoxaban
- Watchman

- Treatment frequency: 1 pill/day
- Blood tests needed: Yearly
- Interactions with medications: Uncommon
- Interactions with food: Uncommon

For 103 men age 82 taking rivaroxaban for 1 year:

- 6 have a Stroke/Clot
- 13 (of 19) save a Stroke/Clot
- 91 have no Stroke, Clot or Major Bleed.
- 3 Major Bleeds based on HAS-BLED Score of 2
- 2 Bleeds with no treatments
- 1 More bleed from rivaroxaban

Continue
A decision aid for Implantable Cardioverter-Defibrillators (ICD)
For patients with heart failure considering an ICD who are at risk for sudden cardiac death (primary prevention).

What is an ICD?
An ICD is a small device that is placed under the skin of the chest. Wires (called “leads”) connect the ICD to the heart. An ICD is designed to prevent an at-risk person from dying suddenly from a dangerous heart rhythm. When it senses a dangerous heart rhythm, an ICD gives the heart an electrical shock. It does this in order to get the heart to beat normally. An ICD is different than a pacemaker. A pacemaker helps the heart beat but does not give a shock like an ICD.

Is an ICD right for me?
Your doctor has suggested that you might benefit from having an ICD. This is a big decision. Understanding what to expect after getting an ICD might help you to feel better about your decision. The ICD may not be right for some people. Although this may be hard to think about, other patients like you have wanted to know this information.
A DECISION AID FOR
TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS
FOR PATIENTS DECIDING BETWEEN TAVR AND SURGERY

For Clinicians: For Patients with INTERMEDIATE OR HIGH SURGICAL RISK
Process of shared decision making for preference sensitive conditions

1. Name the choices
Process of shared decision making
for preference sensitive conditions

1. Name the choices
2. Explain shared decision making
Process of shared decision making for preference sensitive conditions

1. Name the choices
2. Explain shared decision making
3. Describe the choices using the decision aid
Severe Aortic Stenosis Decision Aid

SYMPTOM MANAGEMENT / TAVR

Shared decision making: Your Heart Team shares information on choices, you share information on your values and preferences, and together a decision is made.

What are my choices?

SYMPTOM MANAGEMENT
(Palliative Care)

- Valve is not changed
- Not invasive
- Decision can be revisited over time

TAVR
Transcatheter Aortic Valve Replacement

- Valve is changed
- More invasive
- Approved in 2011

Will I feel better?

What matters most to you?

1 person will live with disability after stroke
3 people will die
2 people will live with disability after stroke

4 people will live with disability after stroke

TRANSCATHETER

- Leaky valve
- Pacemaker
- Blood vessel damage
- Irregular heart rhythm
- Repeat valve procedure

Based on our conversation, our shared decision is:
A DECISION AID FOR TREATMENT OPTIONS FOR SEVERE AORTICstenosis FOR PATIENTS DECIDING BETWEEN TAVR AND SURGERY

ADVICE
Navigating Aortic Valve Treatment Choices

Making a Decision About Aortic Valve Treatment Based on What is Important to You

Common Aortic Valve Problems
Calcification
Evaluated
Process of shared decision making for preference sensitive conditions

1. **Name** the choices
2. **Explain** shared decision making
3. **Describe** the choices using the decision aid
4. **Listen** to what matters most to the patient
Process of shared decision making for preference sensitive conditions

1. **Name** the choices
2. **Explain** shared decision making
3. **Describe** the choices using the decision aid
4. **Listen** to what matters most to the patient
5. **Make a decision together** using patient preferences
Decision aids vs. usual care

Systematic review of 105 RCTs (31,043 patients)

- Patient involvement and knowledge
  - Visit time by 2.5 min
- Decisional conflict
  - Proportion of patients undecided
- Inconsistent effect on choice, adherence, costs

Stacey et al. 2017 Cochrane Database Syst Rev
Barriers to implementation

- Physician attitudes and skillsets (“minimally present in clinical practice”)
- Biases of which patients want to be involved (“patients want more engagement than they get”)
- Effective, tested (and acceptable) decision aids
- Perceived impact of time
- Policy

Legare and Witteeman Health Affairs, 2013.
Knowledge is not power for patients: A systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making

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ABSTRACT

Knowledge - disease - outcomes - preferences

Capacity to participate in SDM

Power - perceived influence - permission

55 year old farmer

- History of hypertension, on losartan
- CCS Class III
- Exercise echo stress test: preserved EF, mild anterior and apical regional wall motion abnormalities following 8 METs
- Referred for cardiac catheterization
Which options do you offer?

• Optimal medical therapy
• Optimal medical therapy and PCI
PCI Choice: Class I/II Stable Angina

This is a tool for you and your clinician to discuss treatment choices for stable angina. In stable angina, stents are useful for symptom relief but do not reduce the risk of heart attack or death. However, stents can reduce the risk of death in other heart diseases, such as unstable angina or heart attack.

**Medicines alone**

![Medicines icon]

or

**Medicines + stents**

![Medicines and stent icon]
Benefits

Prevention of heart attack or death in stable coronary artery disease with medicines + stents compared to medicines alone:

**NO DIFFERENCE** in heart attack or death.

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How symptoms improve in 100 people with medicines + stents compared to medicines alone:

<table>
<thead>
<tr>
<th>Time</th>
<th>One month</th>
<th>Six months</th>
<th>One year</th>
</tr>
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<tbody>
<tr>
<td>No improvement</td>
<td>43</td>
<td>27</td>
<td>47</td>
</tr>
<tr>
<td>Added symptom improvement from medicines + stents</td>
<td>64</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Symptoms improved with medicines alone</td>
<td>71</td>
<td>28</td>
<td>1</td>
</tr>
</tbody>
</table>

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Risks

During the stent procedure:
Bleeding, heart attack, stroke or death

- In 100 people:
  - TWO will have bleeding or damage to a blood vessel; 98 will not.
  - ONE will have a complication such as heart attack, stroke or death; 99 will not.

During the first year after stent:
Bleeding and heart attack

- In 100 people:
  - THREE will have a bleeding event from the additional blood thinner needed with a stent; 97 will not.
  - TWO will develop a clot that forms in the stent leading to a heart attack; 98 will not.

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Based upon the benefits, which choice do you prefer?
Common myths

• The decision is shared between the two subspecialists and a recommendation is made
• Impossible - patients always ask me what I would do
• We already do it perfectly (or, at least, our patients are happy)
• It’s easy! Just give the patient a pamphlet to review

Shared decision making is not patient education or informed consent.

1. Knowledge transfer
2. Patient preferences
3. Deliberation/consensus

Initial Preferences

Choice Talk

Option Talk

Deliberation

Decision Support – brief or extended

Decision Talk

Decision

Informed Preferences

Adapted from Joseph-Williams et al. BMJ 2017;357:bmj.j1744
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Medicines alone

or

Medicines + stents
Overall knowledge

Correct answers (%)

Knowledge

Decision aid
Usual care

p=0.0004

Use of decision aids in cardiology is “rare”: of the nearly 10,000 decision aids distributed at Mass General in 2016, only 24 were for cardiology topics.
Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis

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Abstract

Background Patients with severe aortic stenosis (AS) at high risk for aortic valve replacement are a unique population with multiple treatment options, including medical therapy, surgical aortic valve replacement and transcatheter aortic valve replacement (TAVR). Traditionally, in elderly populations, goals of treatment may favour quality of life over survival. Professional guidelines recommend that clinicians engage patients in shared decision making, a process that may lead to decisions more aligned with patient-defined goals of care. Goals of care for high-risk patients with AS are not well defined in the literature, and patient-reported barriers to shared decision making highlight the need for explicit encouragement from clinicians to engage patients in shared decision making.

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Keywords: aortic stenosis, aortic valve replacement, elderly, patient-centered care
thank you!

The Clinical Trial Journey: A Device Clinical Trial Patient Panel

Register at www.mendedhearts.org

June 24, 2021
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