A DECISION AID FOR

TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS FOR PATIENTS DECIDING BETWEEN TAVI AND SURGERY



For Clinicians: For Patients with LOW OR INTERMEDIATE SURGICAL RISK



This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. You, your family, and your clinicians can begin to discuss which treatment option is best for you.

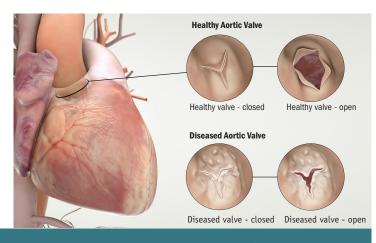
? ALONG THE WAY, WE WANT YOU TO THINK ABOUT:

- What your goals are for treating your AS?
- What concerns you have about your treatment options?
- What additional questions you have for your clinician?



UNDERSTANDING AS

Some patients are born with a valve that has two leaflets rather than three. This might make a difference in treatment options for replacing your valve. Talk to your doctor about treatment options.



SYMPTOMS OF SEVERE AS INCLUDE:

- feeling dizzy like you might pass out
- feeling tired
- trouble breathing
- chest pain
- swelling of the legs

You may be experiencing some of these symptoms. They may make it harder to do the things you want to do. If left untreated, these symptoms usually get worse over time and can lead to death. Prior to the decision, you may need to have additional testing to help your clinician understand what your options are.

What options do I have to fix my valve? THIS IS THE BIG QUESTION!

FIXING YOUR VALVE: Most people decide between two different procedures: **TAVI and SAVR.** The rest of this brochure will help you understand these options.

Most people with severe AS symptoms choose to have their valve fixed. Other people may not be sure if their symptoms are caused by AS. These people should talk with their clinician about their options.



Sometimes people do not fix their valve right away, often because:

- 1. They aren't sure their symptoms are from AS. Other common problems share a lot of symptoms with AS, including:
 - Being out of shape
 - Cancer
 - Depression
 - Arthritis

- Kidney disease
- Lung disease
- Other heart disease
- Alzheimer's
- 2. They have more urgent health care needs, such as:
 - Serious infections
- Cancer





TREATMENT OPTIONS

TAVI

<u>Transcatheter Aortic Valve Implantation</u> transcatheter procedure

WHAT:

TAVI is a procedure where a new valve is placed in the heart through a small tube (called a "catheter") typically in the leg.

HOW:

This procedure usually involves a small incision in the groin where a catheter inserted to access the heart to replace the valve.

WHO:

This method is an option for both patients who are and those that are not candidates for open-heart surgery.

HOSPITAL STAY:

On average, 2-3 days

RECOVERY TIME:

On average, 1-2 weeks

VALVE TYPE:

A bioprosthetic valve is used



SAVR

Surgical Aortic Valve Replacement open-heart surgery

WHAT:

SAVR is open-heart surgery where a new valve is placed in the heart directly, replacing the old valve.

HOW:

This surgery usually involves an incision through the breastbone to access the heart to replace the valve.

WHO:

Those without other severe health problems are good candidates for open-heart surgery.

HOSPITAL STAY

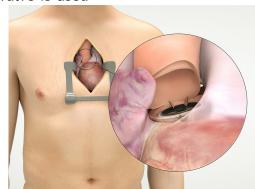
On average, 1 week

RECOVERY TIME:

On average, 6-8 weeks

VALVE TYPE:

A bioprosthetic valve or mechanical valve is used



Every patient is different, and there may be certain features about your heart which affect what your doctor thinks about your treatment. We cannot see into the future to know how long your new valve will last. At this time, we know more about how long surgically replaced valves last than we

do about TAVI valves. While valve replacements are durable, eventually your new valve may need to be replaced. The timing of this is different for every patient. Also, TAVI valves have not been as well studied for certain valve problems. Talk to your clinician about any concerns you have about your specific case, how long your valve might last, and what your options might be.

THE RISKS & BENEFITS OF YOUR OPTIONS

TAVI vs. SAVR: Which is the best decision for me?

*Mack et al. (2019). New England Journal of Medicine; Mack et al. (2020). ACC20.

For patients with low surgical risk.

TAVI

BENEFITS:

- Helps you live longer
- Helps you feel better
- Less invasive procedure
- Shorter recovery time

Almost 98 out of 100 patients are still living within two years and more than 2 in 100 patients will die.



98% live 2% die

RISKS:

More than 2 in 100 patients suffer from a **stroke** in two years.

\(\frac{1}{2} \) \(\fra

Nearly 8 in 100 patients suffer from major bleeding



Almost 8 in 100 need a pacemaker within 30 days



Almost 8 in 100 patients develop new atrial fibrillation within two years



SAVR

BENEFITS:

- Helps you live longer
- Helps you feel better
- Over 50 years of experience with procedure
- Can address other heart problems like blocked heart arteries or problems with other valves

Almost 97 in 100 patients are still living within two years and just over 3 in 100 patients will die.



RISKS:

More than **3 in 100** patients suffer from a **stroke** in two years.



Nearly 26 in 100 patients suffer from major bleeding



4 in 100 need a pacemaker within 30 days



Almost 42 in 100 patients suffer from atrial fibrillation





THE RISKS & BENEFITS OF YOUR OPTIONS

TAVI vs. SAVR: Which is the best decision for me?

*Mack et al. (2019). New England Journal of Medicine; Mack et al. (2020). ACC20.

For patients with intermediate surgical risk.

TAVI

⊕BENEFITS:

- Helps you live longer
- Helps you feel better
- Less invasive procedure
- Shorter recovery time

Nearly 9 in 10 patients are still living within two years and just over 1 in 10 patients will die.



Risk:

Nearly 1 in 10 patients suffer from a stroke within 2 years.



Nearly 1 in 10 patients suffer from serious injury to blood vessels.



2 in 10 need a pacemaker within 2 years.



SAVR

BENEFITS:

- Helps you live longer
- Helps you feel better
- Over 50 years of experience with procedure

Nearly 9 in 10 patients are still living within two years and just over 1 in 10 patients will die.



Risk:

Nearly 1 in 10 patients suffer from a stroke within 2 years.



Less than 1 in 10 patients suffer from serious injury to blood vessels.



1 in 10 need a pacemaker within 2 years.



IN SUMMARY:

- TAVI and SAVR are each effective options for helping your aortic valve
- TAVI is a less invasive procedure
- The risk for needing a pacemaker implanted is higher after TAVI
- More is known about how long mechanical valves last (used in SAVR)



TREATMENT SCENARIO 1



Option 1: Choose TAVI

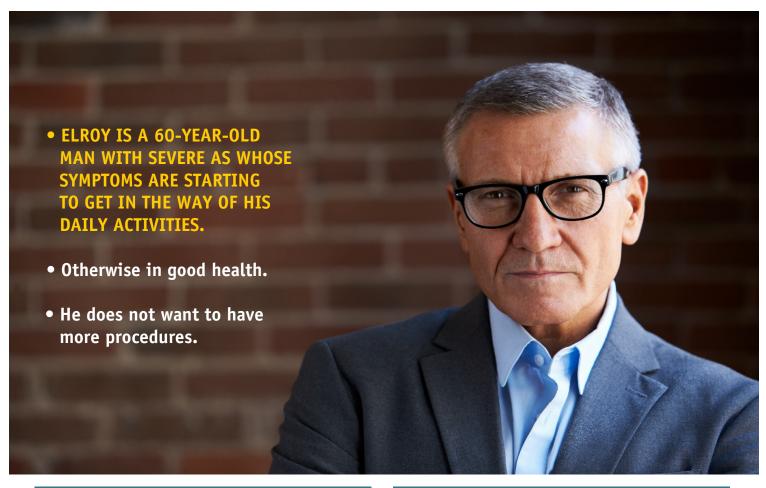
- TAVI is less invasive.
- ▶ The recovery time is shorter.
- Jane can expect similar results.

After talking to her clinician, Jane decided the TAVI procedure was the best option for her. She is concerned her other illnesses will make recovering from open-heart surgery more difficult.

Option 2: Choose SAVR

- TAVI is a newer procedure, while SAVR has been around for a long time.
- Jane knows people who have had open-heart surgery.

TREATMENT SCENARIO 2



Option 1: Choose TAVI

- TAVI is less invasive.
- The recovery time is shorter.
- Elroy can expect similar results.

Option 2: Choose SAVR

- TAVI is a newer procedure, while SAVR has been around for a long time.
- Elroy knows people who have had open-heart surgery.

Elroy decided the SAVR procedure was the best choice for him. He wanted a valve that is known to last and he wasn't concerned about the longer recovery time.



TAVI and SAVR are each effective options for helping your aortic valve; the choice is ultimately a very personal one based on your overall health, values and individual preference.

There is a lot to think about when trying to decide which path is right for you. Take some time to consider what you have learned about treatments for AS. If you're still not sure what the best choice is for you, ask yourself these questions.

What do you hope for with TAVI or SAVR?
What concerns do you have with TAVI or SAVR?
What questions do you have for your clinician?
What questions do you have for your family and loved ones?

DISCLOSURES: Updated: July 2020 (This decision aid will be reviewed annually) | Funded by: American College of Cardiology | Authors: Christopher Knoepke, PhD, LCSW; Kenneth Pierce, BA; M. Pilar Ingle, MSW; Larry A. Allen, MD, MHS, FACC; Amy Jenkins, MS; Javier Valle, MD, MS; Kristy Gama MSN, APRN, NP-BC; John Carroll, MD, FACC, Daniel D. Matlock, MD, MPH | Conflicts of Interest: Christopher Knoepke: none; Kenneth Pierce: none; M. Pilar Ingle: none; Larry A Allen: Novartis, Janssen, PCORI, AHA, NIH, (employer CU); Javier Valle: None; Kristy Gama: None; John Carroll: Local investigator for the Medtronic clinical trial of TAVI versus SAVR for low risk aortic stenosis patients; local investigator for the Edwards LifeSciences PARTNER II clinical trial; Dan Matlock: None

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