Understanding Tissue and Mechanical Aortic Valves:
A Patient Engagement Resource

How to use this interactive counseling tool

• Press Get Started to go to the Patients section
• For matching discussion guidelines for healthcare professionals, select the HCPs tab
• For a printable take-home resource for patients, select Summary for Patients
• Important Safety Information and References may be found at the end of the guide or by clicking on their respective tabs on the pages that follow

Get Started
Overview of Aortic Valve Disease

What is the aorta?
Your heart is a strong muscle that sits in your chest between your lungs. It works to keep blood moving through your body. The aorta is a large blood vessel that carries the blood to the rest of the body.

What is the aortic valve?
The aortic valve serves as the “door” between your heart and the rest of your body. It has three leaflets (or flaps) to make sure blood moves correctly from the lower left chamber of the heart to the aorta.

What is aortic valve disease?
There are two types of problems that can occur with aortic valves:

Aortic stenosis: The valve is narrowed and does not completely open, blocking the normal flow of blood.

Aortic regurgitation: The valve does not fully close and blood leaks backward (in the wrong direction) in the heart.

What are the symptoms of severe AVD?
The symptoms of aortic disease are commonly misunderstood by patients as normal signs of aging.

Physical signs of heart valve disease include:

shortness of breath

tiredness

lightheadedness or fainting

chest pain

Pay attention to new or worsening symptoms.
After your aortic valve disease has been diagnosed and you have jointly decided with your healthcare professional to receive treatment with surgical aortic valve replacement, you still have treatment decisions to make.

**Aortic valve replacement**

Valve replacement is the only treatment shown to improve survival and provide durable improvements in related symptoms.

**Surgical aortic valve replacement (SAVR)**

The most common treatment for severe aortic valve disease is to replace the valve through open heart surgery.

**Tissue valve**

The choice between a tissue valve and a mechanical valve should be based on a **shared decision-making process**.

**Mechanical valve**

- Mechanical valves are made from man-made materials
- Mechanical valves include leaflets that are made of a special type of carbon

**Tissue Valve**

- Tissue valves are made with
  - bovine (cow) heart tissue (the tough sac around the heart)
  - porcine (pig) tissue
  - human valves from cadavers

**What is shared decision making?**

Shared decision making is a process in which healthcare providers and the patient **jointly decide on his or her best treatment path** after considering the clinical evidence and the patient's preferences.

Use this time with your healthcare professional to discuss which valve choice is best for you.

**What are my valve options?**
Options for Surgical Aortic Valve Replacement

What surgical approach options are available?

**Standard surgical approach**
- The surgeon makes an opening in the middle of the chest and breastbone to access the heart
- To keep the heart still enough for the surgeon to operate, a heart-lung machine takes over the job of pumping blood through the body
- The surgeon removes the diseased valve and puts a new heart valve in its place

**Small-incision surgical approach**
- The surgeon makes a small incision between the ribs or in the upper part of the chest
- Many of the steps that a surgeon follows for standard open-heart surgery are the same in small-incision surgery. However, because the incision is smaller, this surgery may be associated with faster healing times, less blood loss and tissue trauma, and a smaller scar on your chest
- Although patients often desire a simpler approach to surgery, you and your surgeon should discuss these options now, making sure that there is never a compromise of safety and results
Making a Decision: Tissue or Mechanical Valve?

Which valve you choose should be based on a shared decision-making process between you and your surgeon that takes into account your values and preferences.

Key Tradeoffs Between Tissue and Mechanical Valves

<table>
<thead>
<tr>
<th>Blood-thinning medicine requirement</th>
<th>Mechanical Valve</th>
<th>Tissue Valve</th>
</tr>
</thead>
</table>
| **Lifetime requirement** for a blood thinner | • Taking a blood thinner requires consistent daily management, including
  - routine **blood tests**
  - more frequent **physician visits**
  - **dietary** restrictions
  - **lifestyle** and **activity limitations**
  • Blood-thinning medicine that isn’t managed correctly is associated with a higher risk of major bleeding or stroke | **No lifetime requirement** for a blood thinner
  • Short-term treatment with a blood-thinning medicine is sometimes recommended for some patients |

| Likelihood of needing replacement | Less likely than a tissue valve to require replacement in the future | More likely than a mechanical valve to require replacement in the future
  • Replacement requires open heart surgery | • Replacement requires another procedure. This could be open heart surgery, or some patients may be eligible for a less invasive option called valve-in-valve transcatheter aortic valve replacement |
Summary of Decision Points

This choice between a mechanical valve and a tissue valve should be made jointly between you and your healthcare professional.

<table>
<thead>
<tr>
<th>Recommendation Based on Age Only</th>
<th>Blood Thinning Considerations</th>
<th>Medical Concerns</th>
<th>Other Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>A mechanical valve may be a better choice if you...</td>
<td>are already taking a blood thinner for another reason</td>
<td>have certain features of your heart that may limit your eligibility to have a future valve-in-valve procedure if your new valve ever needs to be replaced</td>
<td>prefer to decrease the risk of needing another procedure</td>
</tr>
<tr>
<td>• are younger than 50 years</td>
<td>• do not want to take blood thinners, regardless of your age</td>
<td>• are a woman who wants to become pregnant</td>
<td>• think that a clicking sound a mechanical valve makes will bother you</td>
</tr>
<tr>
<td>If you are between the ages of 50 and 70 years, either valve may be appropriate for you.</td>
<td>• are unwilling or unable to take blood thinners as prescribed</td>
<td>• have other health conditions as discussed with your doctor</td>
<td>• have an active lifestyle with a high risk of injury</td>
</tr>
<tr>
<td>A tissue valve may be a better choice if you...</td>
<td>• have a high risk of complications from taking blood thinners</td>
<td></td>
<td>• have limited access to routine medical care to help manage blood thinners</td>
</tr>
<tr>
<td>• are older than 70 years</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Consider these decision points listed in the 2017 clinical guidelines from the American Heart Association and American College of Cardiology.
Considerations for Surgery

Before you decide to have surgery, it's important to fully understand the potential risks and benefits. There are also many things to keep in mind and instructions that you will need to follow before and after surgery.

**Benefits and Risks of Surgery**

**Benefits**
- Greater ability to do the things you want and need to do
- Ease your symptoms
- Greater chance of longer life

**Risks**
- Bleeding during or after surgery
- Stroke
- Infection
- Low red blood cell count, resulting in weakness

**Considerations Before and After Surgery**

**Before Surgery**
- You will undergo medical tests and exams to check your heart and overall health
- Make sure you are prepared for surgery by following all of your surgeon’s instructions
- Get all of your questions answered by your surgeon
- Talk to your surgeon about all of your concerns

**After Surgery (Recovery)**
- Standard recovery time is 8 to 12 weeks
- Follow all discharge instructions for medications, exercise, diet, and self-care
- Attend all follow-up appointments and checkups
- Discuss with your doctor any problems you are having with appetite, mood, sleep, constipation, and site healing

An estimated **80,000 to 85,000** aortic valve replacement procedures are performed every year in the United States.
Overview of Aortic Valve Disease

Define for your patients

- Heart valve disease
- Aortic valve disease (AVD)
- Aortic stenosis (AS)
- Aortic regurgitation
- Asymptomatic
- Heart failure
- Bicuspid aortic valve versus tricuspid aortic valve (if applicable)

Review with your patients

- **Symptoms** your patients may not have previously noticed or told you about
- **Tests** your patients may undergo to assess the **severity of their AVD**
- **Risk of disease progression** associated with your patient’s current diagnosis

Key statistics

- Aortic stenosis affects 2% to 3% of the adult population in the United States
- As many as 32% of patients who initially present as asymptomatic actually show symptoms after further examination
- At least 40% of patients who need valve replacement do not get treatment
Treatment of Aortic Valve Disease With Surgical Aortic Valve Replacement

Define for your patients
- Mechanical valves
- Tissue valves
  - Porcine valves
  - Bovine valves
- Surgical aortic valve replacement (SAVR)
- Shared decision making

Review with your patients
- Factors that may determine the timing of treatment
  - Rate of disease progression
  - Disease severity and staging
  - Surgical risk
  - Concomitant heart disease
- Differences between tissue valves and mechanical valves in terms of their
  - performance
  - outcomes
  - quality
  - reliability
  - innovation

Lead the discussion by
- defining medical terms
- reviewing health information for informed decision making
- reinforcing key takeaway points

Engage your patients by
- asking them for their thoughts, concerns, and questions
- confirming they understand throughout the discussion

Explain that there is a shared decision-making opportunity regarding tissue versus mechanical valves for SAVR procedures.
Options for Surgical Aortic Valve Replacement

Define for your patients
- Standard surgical approach
- Small-incision surgical approach

Review with your patient
- Risks and benefits of surgical approach options
  - Safety
  - Outcomes
  - Recovery

Ask your patients about their preferences or concerns regarding surgical approach options.

Lead the discussion by
- defining medical terms
- reviewing health information for informed decision making
- reinforcing key takeaway points

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This tab contains information from references 7-11.
Making a Decision: Tissue or Mechanical Valve?

Define for your patients
- Durability
- Warfarin/blood thinners
- INR (international normalized ratio)
- Transcatheter valve-in-valve
- Bleed risk
- Stroke risk

Review with your patients
- Durability
  1. Patient-specific risk of reoperation
  2. Potential for a future valve-in-valve procedure
- Anticoagulation
  1. Patient-specific risk of bleeding and thromboembolic events
  2. Monitoring requirements
  3. Modifications to diet
  4. Lifestyle considerations

Important discussion points that may influence a patient’s decision:

<table>
<thead>
<tr>
<th>Physical factors</th>
<th>Psychosocial factors</th>
<th>Lifestyle factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mental health</td>
<td>Quality of life</td>
</tr>
<tr>
<td>Surgical risk</td>
<td>Family dynamics</td>
<td>Hobbies</td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td>Career demands</td>
<td>Day-to-day activities</td>
</tr>
<tr>
<td></td>
<td>Access to healthcare</td>
<td></td>
</tr>
</tbody>
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This tab contains information from references 18 and 21.
Summary of Decision Points

Define for your patients

- Valve size (if applicable)
- Complications
- Comorbid conditions

Review with your patients

- Reassure your patients that you want them to ask you as many questions as they want so that they feel comfortable with their decision
- Show your patients the decision summary found on the Download Summary for Patients tab above to help them express their preferences and feelings concerning the key decision points, including durability and anticoagulation
- Remind your patients to talk to their family about their decision and to seek additional support from patient organizations and other online resources (included on the attached decision summary)

Lead the discussion by

- defining medical terms
- reviewing health information for informed decision making
- reinforcing key takeaway points

Engage your patients by

- asking them for their thoughts, concerns, and questions
- confirming they understand throughout the discussion
Considerations for Surgery

Define for your patients
- Stroke
- Infection
- Anemia

Review with your patients
- **Expectations** associated with presurgery and postsurgery
  - **Tests** that may be part of the presurgery assessment
  - **Standard recovery time**
  - **Potential concerns or problems** (eg, appetite, swelling, sleeping, constipation, mood swings, site healing) associated with recovery and explain how these problems may go away over time or be addressed
- **Postsurgery instructions** relating to diet, exercise, and rehabilitation
- **Answers to common questions about surgery**
  - How often do you perform the procedure that you’ve recommended, and what is your success rate?
  - Can you walk me through the entire process of surgery?
  - What are the potential side effects of this treatment?
  - Is minimally invasive surgery an option for me?
  - How long will I be in the hospital?
  - How long will I be out of work?
  - Will I have to take any long-term medications?
  - What will my follow-up care be like?

It is very important to make sure that your patients have asked all of their **questions** by this time in the discussion.

This tab contains information from references 18, 22-23.
Important Safety Information

Brief Summary: Aortic Bioprostheses

**Indications:** For use in patients whose aortic valvular disease warrants replacement of their natural or previously placed prosthetic valve. **Contraindications:** Do not use if surgeon believes it would be contrary to the patient’s best interests. **Complications and Side Effects:** Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults, and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis. **CAUTION:** Federal (USA) law restricts these devices to sale by or on the order of a physician.
References