



## Cheng Hsin General Hospital Patient Decision Aids

### I have severe aortic stenosis, should I have a transcatheter aortic valve implantation?

#### Introduction

Your doctor has diagnosed you with "severe aortic stenosis" and you are experiencing chest tightness, shortness of breath, fainting, and other symptoms in your daily life that are affecting your quality of life and even putting you at risk for sudden death. At this time, your doctor will evaluate your overall condition and the risks of surgery and may recommend that you undergo transcatheter aortic valve implantation (TAVI) to improve the quality of life for you and your family. You may be faced with the decision to have a TAVI or to continue taking medications without surgery, or you may delay treatment because you wonder how it differs from traditional surgery. It's not an easy decision! Let us help you understand aortic stenosis and your treatment options. Follow our step-by-step process to explore your needs and concerns, which will help you think about the right options for you, and then discuss with your doctor which treatment is best for you.

#### Suitable Targets / Applicable Conditions

This decision aid is intended for patients with an aortic valve opening of less than 1.0 cm<sup>2</sup> who present with chest tightness, shortness of breath, or fainting, who have been diagnosed by a cardiologist as having severe aortic stenosis, who are not recommended for conventional open aortic valve replacement, and who are recommended for the high benefit of transcatheter aortic valve replacement (TAVI) after evaluation of the patient's overall condition and the risks of the procedure.

#### Your current condition: (to be completed with the assistance of medical personnel)

- Age:  Under 65 years old;  65 to 80 years old;  Over 80 years old.
- Aortic valve opening area: \_\_\_\_\_cm<sup>2</sup>
- Symptoms experienced -  Chest tightness;  Wheezing/difficult breathing;  
 Fainting;  Other \_\_\_\_\_;  No symptoms.



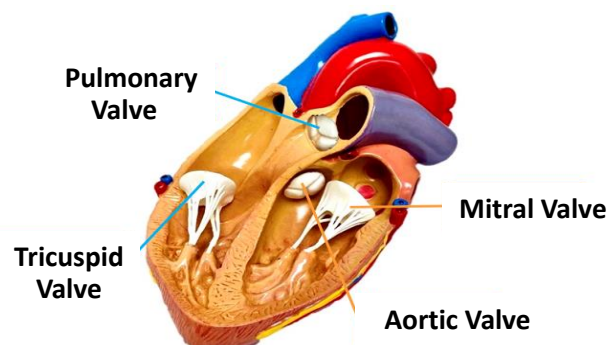
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- Traditional open-heart aortic valve replacement is not indicated in the following conditions:
- Previous cardiac surgery (coronary bypass, heart valve);
  - Severe aortic calcification (porcelain aorta); Previous radiation therapy to the mediastinal cavity;
  - Severe connective tissue disease;
  - Cirrhosis (Child Class A or B);
  - Pulmonary insufficiency (FEV <1 liter);
  - None of the above.

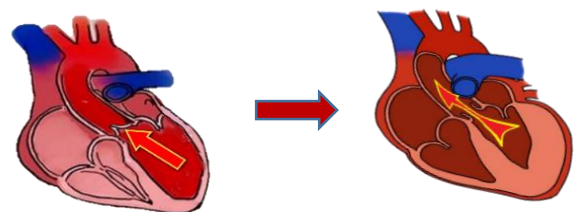
### Introduction to the Disease or Health Issues

How can aortic stenosis lead to life-threatening and disabling conditions? Let's start by understanding how the heart and aortic valve work.

The heart has four chambers: the left atrium, left ventricle, right atrium, and right ventricle. The four valves act as four doors: the mitral, aortic, tricuspid, and pulmonary valves.



- Function of the aortic valve: Located on the left side of the heart, it is the gate that controls the flow of blood throughout the body. A normal aortic valve must open and close effectively to keep blood flowing in one direction; blood can flow out and not back. However, in the elderly, calcification and aging can cause the door to deform and fail to open completely (e.g., aortic stenosis), resulting in a reduced flow. The door may also fail to close completely (e.g., aortic regurgitation), resulting in leakage.
- Effects of aortic stenosis: The door does not open completely, preventing blood from flowing out of the left ventricle, which can lead to ventricular





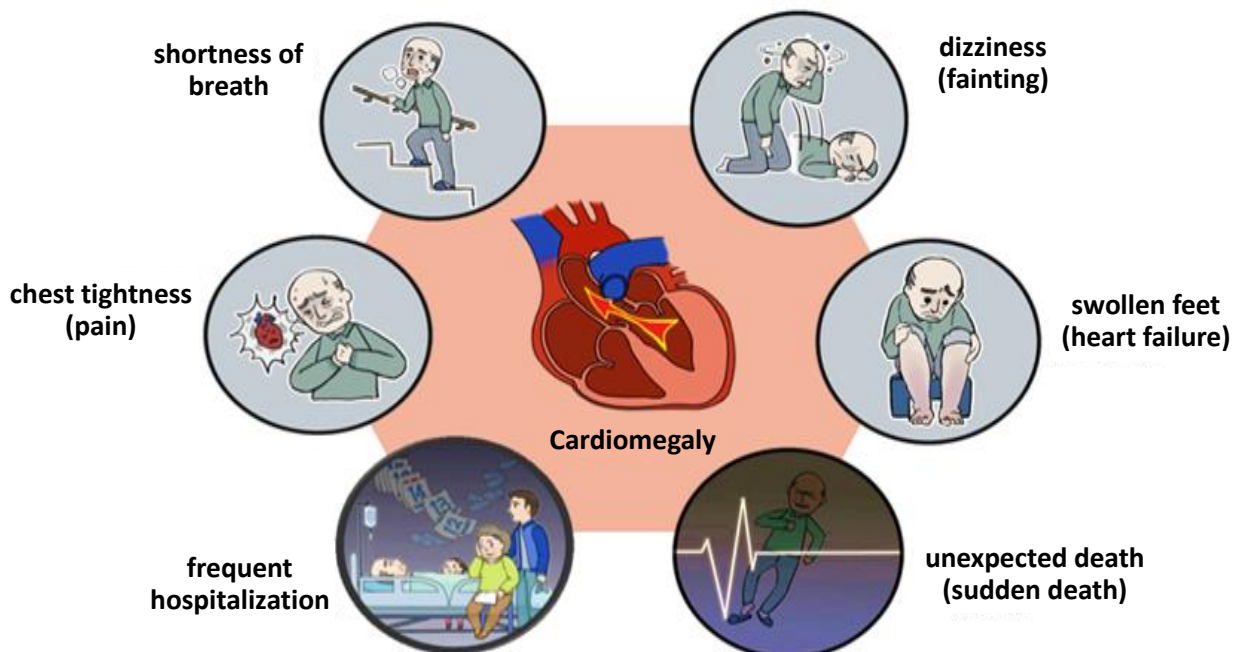
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hypertrophy. Insufficient blood flow to the body is also prone to arrhythmias and fainting.

When the size of the aortic valve opening, usually larger than a fifty-dollar coin, slowly becomes smaller than a dollar or even smaller than a shirt button, it is easy to develop uncomfortable symptoms.



- Discomfort symptoms of aortic stenosis: symptoms may include chest tightness 、 shortness of breath 、 fainting 、 swollen feet (heart failure) 、 unexpected death (sudden death).



Think about what symptoms you are currently experiencing. Are you experiencing more frequent episodes? Is it affecting your life? Are you still able to do the things you love to do?



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## Introduction to Medical Options

Replacing a valve is like replacing a broken door so that a new door (new valve) can open and close properly, eliminating discomfort and life-threatening conditions. Maintenance medication is like leaving a broken door in place but minimizing the resistance to make it easier to open and close.

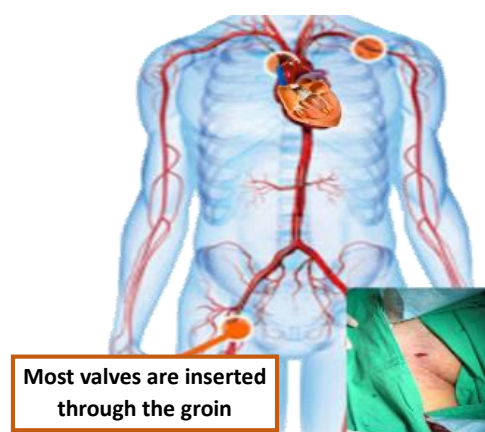
Your doctor recommends transcatheter aortic valve implantation (TAVI). This is an international standard of care for treating severe aortic stenosis in patients who are elderly, have severe chronic disease, are not candidates for traditional open-heart aortic valve replacement, or are at high surgical risk.

But what is transcatheter aortic valve implantation (TAVI)? How does it differ from traditional open-heart surgery? Why would my doctor recommend this procedure and how does TAVI compare to medical therapy?

The following is a description of each of these procedures, the target population, and a comparison of their advantages and disadvantages.

### ● **Transcatheter Aortic Valve Implantation**

1. The femoral artery in the groin is dissected and a bioprosthetic valve is delivered through a catheter into the heart to replace the existing diseased valve.



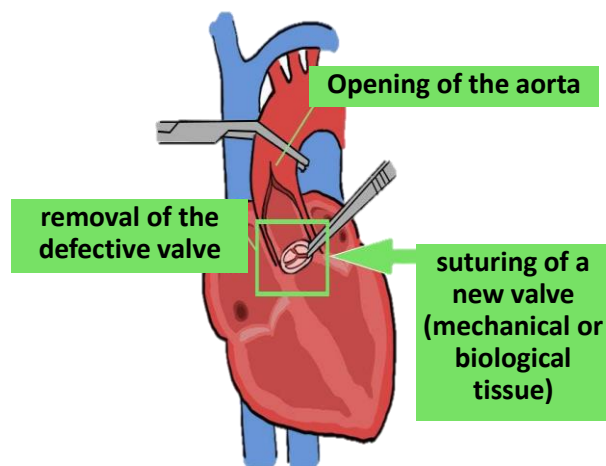
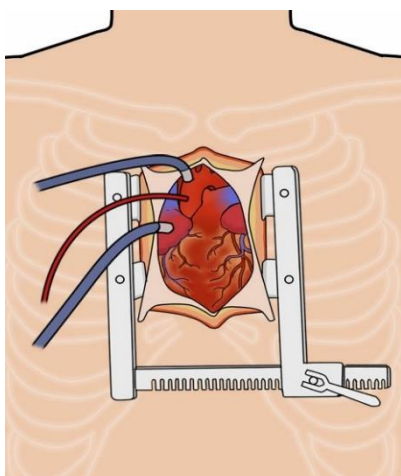
2. It is recommended for patients who are ineligible for conventional open-heart aortic valve replacement and who would be at high risk for conventional open-heart aortic valve replacement after the cardiac team has evaluated the patient's surgical situation and risk-benefit profile.



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### ● Conventional Open Heart Aortic Valve Replacement

1. After opening the chest cavity and sawing open the sternum, the patient is connected to an extracorporeal circulatory machine (which replaces the function of the heart and lungs), and the heart is temporarily stopped before the narrowed valve is removed and replaced with a new mechanical or biological tissue valve.



2. It is intended for patients with a lower surgical risk, after the cardiac team has evaluated the patient's surgical profile and risk-benefit profile and has made a recommendation.

### ● Maintenance Medication

1. It preserves the narrowed valve, which is temporarily controlled with medication. However, discomfort may increase as the valve remains narrow.
2. This is for patients who have been determined by their doctors to have little benefit from valve replacement.

The following comparative information will help you understand that transcatheter aortic valve implantation (TAVI) is a less invasive treatment recommended by doctors for people at high risk for surgery. TAVI is as effective as traditional open-heart surgery for stenotic aortic valves.



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### ● Comparison of the Two Types of Valve Replacement Procedures

The following table compares the two surgical procedures.

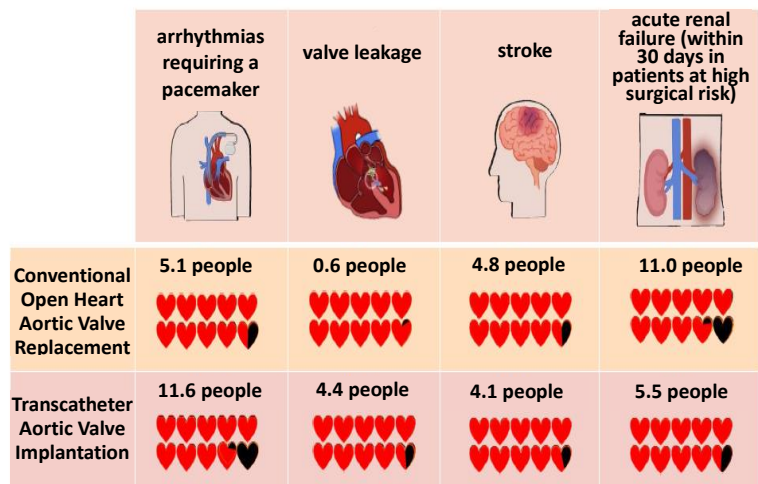
	Conventional Open Heart Aortic Valve Replacement	Transcatheter Aortic Valve Implantation
Surgery time	6 hours	2 hours
Wound size	20 cm	Less than 2 cm
Days in intensive care unit	3~4 days	One night
Inpatient recovery after surgery	10~14 days	5~7 days

※ The above table is based on the experience of 600 cases completed at our medical institution and takes into account the domestic healthcare system.

### ● A comparison of the most common complications (side effects) and survival rates for two types of heart valve replacement.

After aortic valve replacement, there is a risk of stroke, acute renal failure, valve leakage, or arrhythmias requiring a pacemaker.

The average number of possible complications (side effects) in 100 patients at moderate to high surgical risk one year after these two treatments were compared, as shown in the figure to the right, according to an international study .....







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The five-year survival rate is shown on the right.

According to international studies, for patients with severe aortic stenosis and moderate surgical risk level at an average of 81 years of age....

58 out of 100 patients survived after Conventional Open Heart Aortic Valve Replacement



54 out of 100 patients survived after Transcatheter Aortic Valve Implantation

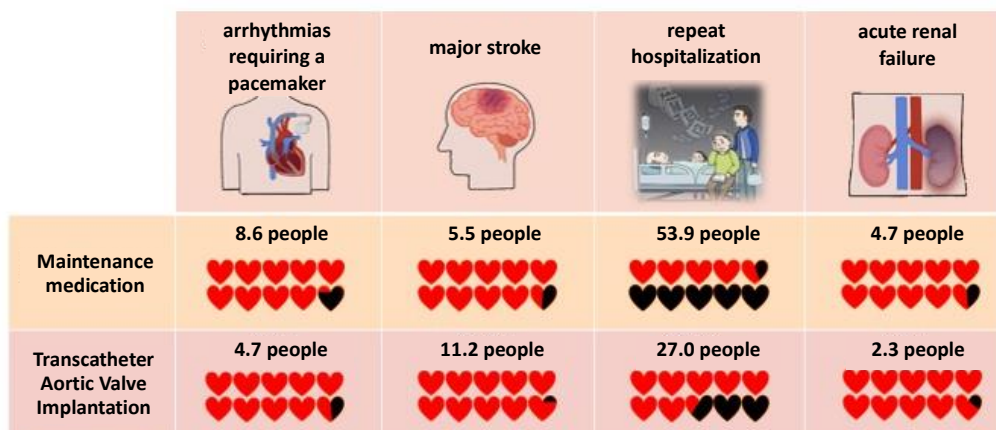


Next, let's look at the pros and cons of transcatheter aortic valve implantation versus maintenance medication without surgery.

## • Maintenance Medication vs. Transcatheter Aortic Valve Implantation

An international comparison of transcatheter aortic valve implantation and maintenance medication found that .....

According to an international study comparing maintenance medication with transcatheter aortic valve implantation, the potential complications and burdens for 100 patients at high surgical risk within one year include cardiac arrhythmia, major stroke, repeat hospitalization, and acute renal failure.





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An international study comparing the one-year survival rates of patients with severe aortic stenosis and high surgical risk, the average age of 83 years, who received maintenance medication versus transcatheter aortic valve implantation showed that .....

**50 out of 100 patients on  
maintenance medication  
survived**



**70 out of 100 patients survived  
after Transcatheter Aortic Valve  
Implantation**



Maintenance medication can temporarily control uncomfortable symptoms and eliminate the physical and family impact of valve replacement surgery. However, it does not address the possibility of persistent aortic stenosis and sudden death, and there may still be problems with stroke or kidney function. There is also a risk of frequent hospitalizations for shortness of breath, edema, and heart failure, which can affect your and your family's quality of life.

### Which Option Would You Prefer at This Time?

- Undergo transcatheter aortic valve implantation
- No surgery, I prefer maintenance medication
- Not sure yet

**To help you make your decision, please follow these four steps:**



#### **Step 1: Comparison of Options**

If a patient is not recommended by a doctor to undergo traditional open-heart aortic valve replacement, most patients and their families are concerned about the following issues when faced with the decision to undergo transcatheter aortic valve implantation. You can use the following comparison to try to understand the pros and cons of each to help you decide what to choose.





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	<b>Transcatheter Aortic Valve Implantation</b> 	<b>Maintenance Medication</b> 
<b>1. Improvement of symptoms</b>	A new valve can improve symptoms	Temporary control of symptoms
<b>2. Quality of life</b>	Assistance and companionship are needed during the 5–7-day recovery period; however, 1 in 4 people may still be hospitalized frequently after surgery.	High likelihood of needing help and care when symptoms get worse; one in two people will be admitted to the hospital repeatedly because of worsening symptoms.
<b>3. Recovery status (reoperation)</b>	The wound is small, the surgery is mildly painful, and previous activities can be resumed; the valve lasts more than 5 years, and the need for reoperation depends on the age of the valve at the time of surgery.	Repeated hospitalizations make it difficult to continue normal activities; there is no problem with the life of the new valve, but there is no way to predict how long the damaged valve will last.
<b>4. Deterioration of disease, sudden death</b>	No sudden death from valve stenosis	There is a higher rate of sudden death due to valve stenosis than in those treated with surgery.
<b>5. Drug dosage and anticoagulants</b>	Medications will be taken as determined by the physician. Anticoagulants may be used postoperatively (to be re-evaluated by the doctor).	If your symptoms worsen, your doctor may increase the type of medication you are taking to relieve your pain; however, you will not be taking anticoagulants for the procedure (to be re-evaluated by the doctor).
<b>6. Surgical expenses</b>	High medical costs	Drug costs
<b>7. Side effects of surgery</b>	Within 1 year of the procedure, approximately 3 to 11 out of 100 people will experience side effects such as pacemaker implantation, serious stroke, or acute kidney failure.	The treatment has no side effects, but about 5 to 9 out of 100 people may experience side effects such as pacemaker implantation, serious stroke, or acute kidney failure.
<b>8. Surgical pain</b>	Small wounds with limited surgical pain	No pain caused by surgical wounds



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## Step 2: Your Concerns About Treatment Options

The following items are of concern to the average patient. Think about how much you care about them to help you find the most ideal treatment plan!

※Higher numbers indicate more concern. For example, if you are very concerned about the improvement in shortness of breath, you might circle 3 or 4 to express your concern.

**Example:** I am concerned about whether my shortness of breath and edema will get better.



Not at all

0-1-2-3-4

Very much



Selecting 4 suggests that you are more suited for



- |   |  |                                |  |
|---|--|--------------------------------|--|
| 1. I am concerned about whether my shortness of breath and edema will get better. |  | Not at all 0-1-2-3-4 Very much |  |
| 2. I worry about my dependence on others.   |  | Not at all 0-1-2-3-4 Very much |  |
| 3. I care about continuing to do the things I usually like to do.                 |  | Not at all 0-1-2-3-4 Very much |  |
| 4. I am afraid that my condition will get worse, and I will die suddenly.         |  | Not at all 0-1-2-3-4 Very much |  |
| 5. I am worried that my frequent hospitalizations will affect my family.          |  | Not at all 0-1-2-3-4 Very much |  |
| 6. I don't like taking more and more medication.                                  |  | Not at all 0-1-2-3-4 Very much |  |



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- |   |   |                                |   |
|---|---|--------------------------------|---|
| 7. I cannot afford the cost of surgery.   |    | Not at all 0-1-2-3-4 Very much |    |
| 8. I am concerned about taking antiemetics.   |    | Not at all 0-1-2-3-4 Very much |    |
| 9. I am worried about the size of the wound.  |    | Not at all 0-1-2-3-4 Very much |    |
| 10. I am afraid that I will have to have surgery again when the valve reaches the end of its useful life. |    | Not at all 0-1-2-3-4 Very much |    |
| 11. I am afraid of pain.  |   | Not at all 0-1-2-3-4 Very much |   |
| 12. I am concerned about the side effects of surgery.   |  | Not at all 0-1-2-3-4 Very much |  |
| 13. Other: _____  |   |                                |   |

Once you're done circling all the questions, let's calculate the number of your



- How many items do you prefer for transcatheter aortic valve implantation?

\_\_\_\_\_ Items



- How many items do you prefer for maintenance medication?

\_\_\_\_\_ Items



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### Step 3: Did You Understand the Information Provided Above?

The following quiz can help you confirm your understanding of the information provided above. You can check the circles below to select your answer.

1. The aortic valve allows oxygenated blood to flow from the heart to the body without backflow.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Uncertain
2. Severe aortic stenosis leads to inadequate blood flow and can easily cause shortness of breath, chest tightness, swollen feet, and even fainting and death.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Uncertain
3. Transcatheter aortic valve implantation has been shown to reduce the chance of sudden death based on available clinical studies.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Uncertain
4. There remains a small risk of stroke, vascular injury, and cardiac conduction abnormalities after transcatheter aortic valve implantation.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Uncertain

### Step 4: Have you determined the type of medical treatment you want?

After completing Steps 1 through 3 above to help you understand your options, have you decided which treatment you want to receive? You can indicate your current decision in the  below.

#### I have decided on my treatment.

- I will have transcatheter aortic valve implantation.
- I will not have surgery but will take maintenance medication.



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### **I can't decide right now:**

- I would like to discuss my decision again with my attending physician.
- I would like to discuss my decision with someone else (including a spouse, family member, friend, or second opinion provider).
- I would like to learn more about the treatment options described above.

My questions are: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Once you have completed the assessment above, you can print the results and bring them to discuss with your attending physician.**