



## Hartford Hospital Informed Consent for Transcatheter Aortic Valve Replacement (TAVR)

You have been diagnosed with a condition called aortic stenosis – narrowing of the aortic valve in your heart. There are several different treatment options that may be available to a patient with this condition depending upon the circumstances involved with that patient. These options include:

1. Treatment with medication
2. Open-heart surgery to replace the aortic valve with a new one
3. A procedure called balloon aortic valvuloplasty which is intended to temporarily stretch the aortic valve open with a balloon
4. A procedure called Transcatheter Aortic Valve Replacement (TAVR) which is intended to implant a new artificial valve in your heart without using open heart surgery

Each of these options has risks and benefits which will be explained.

What is aortic stenosis?

Your heart contains four valves. These valves make sure that the blood flows in the right direction out of the heart. The aortic (outlet) valve is on the left side of the heart and opens when blood is pumped from the heart to the rest of the body.

Aortic stenosis is the term used when the aortic valve is narrowed, interfering with flow of blood out of the heart. Once you develop aortic stenosis with time it usually worsens. The main causes of aortic stenosis include:

- Being born with this abnormality (congenital)
- Rheumatic valve disease
- “Wear and tear “of the valve.

Aortic stenosis places an extra strain on the heart and may affect the circulation of the blood. This can result in breathlessness and fluid retention – which can cause swollen ankles and legs. You may also suffer from chest pain, dizziness and fainting.

### **Treatment of your aortic stenosis with medications:**

No medications can reverse aortic valve stenosis. However, once you develop symptoms from aortic stenosis, your doctor may prescribe certain medications to help your heart. These medications include, among others, diuretics (water pills), medications to lower your blood pressure, medications to lower your cholesterol and medications to control heart rhythm disturbances associated with aortic valve stenosis.

No medication has been proven to prolong your life once you develop symptoms from aortic stenosis. **In general, after a patient has developed symptoms from aortic stenosis, average survival is two to three years if the aortic valve remains narrowed.**



### **Treatment of your aortic stenosis with open heart surgery:**

In patients with symptomatic aortic stenosis, open heart surgery to repair or replace your narrowed aortic valve is considered conventional (standard) treatment. In most patients, open heart surgery for aortic stenosis has been shown to relieve symptoms and to prolong the patient's life.

Due to your overall medical condition, however, your cardiologist and cardiac surgeon have determined that you are a high-risk candidate for standard open-heart surgery. Specifically, your cardiologist and cardiac surgeon believe that you have **at least a 50% (1 in 2)** risk of death or serious complications if you were to have your valve replaced through a conventional open-heart procedure. Accordingly, conventional surgery is not suitable for you because of this level of risk.

### **Treatment of your aortic stenosis with balloon aortic valvuloplasty:**

In patients with severe aortic stenosis who are not considered candidates for standard open heart surgery, a procedure called balloon aortic valvuloplasty may be performed to improve your symptoms. This procedure involves stretching the narrowed valve with a balloon inserted into the heart using a catheter (thin tube). **This procedure is associated with a 3-5% risk of death, has not been shown to prolong your life, and results in only a temporary improvement in symptoms for a period of three to six months.**

### **Treatment of your aortic stenosis with Transcatheter Aortic Valve Replacement (TAVR)?**

In November 2011, the United States Food and Drug Administration approved the use of new procedure called Transcatheter Aortic Valve Replacement (TAVR) for treating patients with aortic stenosis who are not considered candidates for standard open heart surgery. In this procedure, a new valve is inserted via a catheter (a thin tube) into the heart. The new valve is made up of a stent (a stainless steel tube) and biological tissue taken from cows.

The TAVR valve is inserted into your heart from your femoral artery, the main blood vessel in your groin. Your cardiac surgeon will expose the femoral artery by making a small incision in your groin.

The TAVR procedure is carried out under general anesthesia.

After a thorough review of your medical condition, your cardiologist and cardiac surgery have determined that you are a potential candidate for the TAVR procedure. The possible risks and benefits of the TAVR procedure are discussed below.

### **How will it be determined if I am a candidate for the TAVR procedure?**

All patients must undergo a series of screening tests to determine if they are eligible for the TAVR procedure.

These tests include:

- A routine physical examination
- An ECG (a recording of your heart rhythm)
- Routine blood tests
- A transthoracic echocardiogram- an ultrasound of your heart.

If the pictures obtained by transthoracic echocardiogram are of poor quality, it may be necessary to perform another procedure called a transesophageal echocardiogram. This procedure involves temporarily inserting a small ultrasound probe which obtains pictures of your heart from the inside of your esophagus (the tube that leads from your mouth to your stomach).



- A cardiac catheterization. This procedure involves inserting catheters into your femoral artery and femoral vein to directly measure the narrowing of your aortic valve and to inject X-ray dye into your heart arteries to see if you have any coronary blockages. This procedure involves staying in the hospital usually overnight.
- Computerized tomography (CT scan) of your chest and abdomen. This involves an injection of X-ray dye into an intravenous placed in your arm.

Some patients may require additional screening tests which include:

- Lung function tests – which involve breathing into a tube to measure your lung capacity.
- An ultrasound of the arteries of your neck.
- An X-ray of your teeth to see if there is any infection in your mouth.
- Magnetic Resonance Imaging (MRI) scans of your chest and/or legs.

#### **What happens during the TAVR procedure?**

Immediately before the procedure, a cannula (a small tube) will be inserted into an artery in your wrist to allow us to closely monitor your blood pressure. After you are anesthetized, you will have a second cannula inserted into a vein in your neck to allow us to monitor you and to give you medication and/or fluids easily. You will also have a urinary catheter inserted into your bladder so that you can pass urine freely into a bag.

The TAVR procedure will be performed in the operating room under general anesthesia by a team of physicians including cardiac surgeons, cardiologists and anesthesiologist. Special X-rays using a contrast dye and transesophageal echocardiography (a small ultrasound probe which obtains pictures of your heart from the inside of your esophagus) are used to guide the new valve into the correct position.

A surgeon will operate on the top of your leg to expose your femoral artery and insert a catheter into the exposed artery. The catheter has a special balloon on the end which is then inflated to stretch open your narrowed aortic valve. Next, the new TAVR valve will be carefully compressed and mounted onto a second balloon delivery catheter, using a specially designed device. The mounted valve will be inserted through the femoral artery into your narrowed aortic valve where the balloon is used to expand and implant the new valve after it is properly positioned. The balloon is then deflated and removed and the surgeon repairs the puncture site in your groin.

We will speed your heart rate up to 200 beats per minute using a temporary pacing wire. This wire is put in through a vein in your groin and passed through the vein to your heart. An electrical impulse is then passed through the wire in order to speed up your heart rate for only a few seconds. This reduces the blood pressure and motion of the heart, which makes the TAVR valve positioning procedure easier. When the new valve is in place, the pacing is stopped and your heart rate will return to normal. The pacing wire is then removed immediately or a later time, depending on the decision of the surgeon.

The whole procedure takes 1-3 hours.



### **What happens after the TAVR procedure?**

You will go to the Surgical Intensive Care Unit so that you can be closely monitored. You will have your breathing tube removed first and then the tubes in your neck, wrist and chest as soon as you are medically stable. You will stay in the intensive care unit area until you are ready to be moved to regular hospital bed.

After the procedure, your doctor will ask you to take Aspirin and Clopidogrel (a blood thinning tablet). Your cardiologist or cardiac surgeon will tell you for how long you will need to take the tablets; it may be for the rest of your life.

You will have the following tests after the procedure while you are still in the hospital:

- A chest X-ray
- A urine analysis
- Routine blood tests
- An electrocardiogram (ECG)
- A transthoracic echocardiogram.

### **How will I be followed up?**

We will ask you to come back to the hospital six weeks later for a physical examination. You may need further tests; for example, another echocardiogram, ECG or chest X-ray.

Assuming you are doing well, we will then see you only once every 6-12 months to keep an eye on your condition.

### **What are the potential benefits of the TAVR procedure?**

Treatment with the new TAVR valve may give you both short and long term relief of your symptoms. It may give you normal aortic valve function and improve your overall heart function. This could potentially increase your life expectancy and your quality of life.

### **What are the potential risks of the TAVR procedure?**

It is important to remember that aortic stenosis is a serious condition. Without treatment, there is a high risk of progressive symptoms and death. Your cardiologist and cardiac surgeon will carefully consider the risks and benefits and then talk about them with you.

The risks associated with transcatheter aortic valve implantation include:

#### **Major risks**

- Death (7-10%)
- Stroke (2-5%)
- Bleeding or damage to the groin artery, needing blood transfusion or surgery (5%)
- Heart attack (less than 2%)
- Kidney failure (2-5%)

If you already have kidney failure, the dye that is used during the X-rays may cause additional kidney damage and require dialysis. To prevent this from happening, your doctor will continually monitor the amount of dye you are given.

- Emergent cardiac surgery (5%)

In extreme cases where placement of the TAVR valve is suboptimal or where the procedure results in worsening of your heart function, it may be necessary to carry out immediate emergent open-heart surgery to replace the aortic valve. The surgical team and all the emergency equipment will be immediately available. The cardiopulmonary (heart and lung) bypass machine will be used to take over the circulation of your blood during the operation. The risks of cardiopulmonary bypass include a stroke and getting an infection in the groin incision.



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**Serious risks**

- An allergic reaction to the X-ray dye (less than 2%)
- A reaction to the anesthesia (less than 1%)
- An infection (less than 2%) including:
  1. Endocarditis (an inflammation of the heart)
  2. Septicemia (an infection in the blood)
- A pericardial effusion – bleeding into the sack around the heart (less than 5%).
- Esophageal perforation, bleeding or infection. (less than 1%)

**Less serious risks**

- An arrhythmia – abnormal heart beat
- Bruising around the wound site
- A non-emergency repeat operation
- A paravalvular leak – a leakage of blood around the device

**What are the alternatives to TAVR valve implantation?**

As discussed above, the alternative treatment options for patients with aortic stenosis are:

- Surgical aortic valve replacement (conventional open-chest surgery to replace your aortic valve with a new one)
- Balloon aortic valvuloplasty
- Treatment with medication

The preferred treatment for severe aortic stenosis is conventional aortic valve replacement, but at the present time, you are considered too high risk for this type of surgery. Balloon aortic valvuloplasty is associated with 3-5% risk of death, may result in a three to six month improvement in symptoms, and has not been shown to prolong your life. Medical therapy is associated with a two to three year lifespan once a patient has developed symptoms from aortic stenosis.

**Questions about the TAVR procedure may be answered by calling:**

- The TAVR Coordinator: 860-214-2628
- The TAVR Cardiologists (Francis Kiernan MD, Raymond McKay MD, Immad Sadiq MD): 860-545-1518
- The TAVR Cardiac Surgeons (Paul Preissler MD, David Underhill MD): 860-545-3672

**Before having the TAVR, you will be asked to sign a copy of this Consent Form. By signing this form you are acknowledging that you have been advised of the above information, have had an opportunity to have of your questions answered and have agreed to having TAVR procedure done, recognizing that it may be necessary to convert the procedure to an open-heart surgery to replace the aortic valve. By signing this form you are also consenting to that procedure if deemed necessary.**

\_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_  
Patient

\_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_  
Witness