Transcatheter Aortic Valve Implantation (TAVI)

Information for patients
You have been diagnosed with a condition called aortic stenosis – narrowing of the aortic valve. Your Cardiologist has decided that you may benefit from having your valve replaced. However, due to your overall medical condition, you are a high-risk candidate for conventional (standard) open-heart surgery to replace the diseased heart valve. The Cardiologist and a Cardiothoracic Surgeon have decided that you have at least a 20% (1 in 5) risk of death if you were to have your valve replaced through a conventional open-heart procedure.

Conventional surgery is not suitable for you because of this level of risk. However, there is a new method of treatment which may benefit you in which a catheter is used to insert a new aortic value. The medical name for the procedure is Transcatheter Aortic Valve Implantation (TAVI).

The aim of this procedure is to avoid the risks of open-heart surgery, prolonged deep anaesthesia, and the resulting long recovery period.

**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 around the body.

Aortic stenosis is the term used when the aortic valve is narrowed, so blood can’t flow so easily out of the heart. The main causes of aortic stenosis are:

- Being born with this abnormality (congenital)
- Rheumatic valve disease
- ‘Wear and tear’.
Aortic stenosis puts extra strain on the heart and may affect the circulation of blood. This can result in breathlessness and fluid retention – which can cause swollen ankles and legs. You may also suffer from chest pain, dizziness or blackouts.

What is a Transcatheter Aortic Valve Implantation (TAVI)?

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 material taken from cows. The procedure is carried out under general anaesthetic.

How will the valve be put into my heart?

There are two ways to implant the Transcatheter Aortic Valve:

1. **Transfemoral access** – through the femoral artery, the main blood vessel in your groin which leads directly to your heart.

2. **Transapical surgical access** – through a 5 - 10 cm cut on the left side of your chest, to get to the apex (tip) of the heart and the aortic valve inside.

Either or both of these may be suitable for you. Your Cardiologist and Cardiac Surgeon will review your specific physical condition and all your screening tests and then decide which procedure is best for you.
What happens before the TAVI procedure?

**Screening procedures**
Before we can decide whether this treatment is suitable for you we will have to carry out a number of screening tests.

You will have:

- A routine physical examination
- An ECG (a recording of your heart rhythm)
- A chest X-ray
- Routine blood tests to look at:
  - The function of your kidneys and liver
  - To make sure there is no acute heart muscle damage
  - To make sure you have no infection in your blood
  - To check that your blood can clot properly
  - To make sure your blood has enough haemoglobin (which carries oxygen around the body)
- A transthoracic echocardiogram. This is where some gel and a probe are placed on your chest to record images of your heart using ultrasound.

If the pictures we get are of poor quality, we may need to do a procedure called a transoesophageal echo. This is when you swallow a small probe and pictures are taken from the inside of your oesophagus (the tube that leads from your mouth to your stomach).

The echocardiogram usually takes between 10-30 minutes.
• An angiogram. This is when a small tube is inserted into your femoral artery (a blood vessel in your groin) and a dye which shows up on X-ray is injected through the tube and travels up into the heart. An angiogram gives us information about:
  - The left and right sides of the heart
  - How severe the narrowing of your aortic valve is
  - The coronary arteries (the blood vessels supplying the heart muscle)
  - The aorta (the main blood vessel of the body)
  - The femoral arteries

The angiogram usually takes between 30 - 45 minutes.

• Lung function tests – which involve blowing into a tube to measure your lung capacity. This usually takes 10 - 30 minutes.

• An ultrasound of the arteries of your neck. This usually takes 5 - 15 minutes.

Possible extra screening

You may also have:

• An X-ray of your teeth to see if there is any infection in your mouth.

• Computerised tomography (CT scan) of your chest and abdomen. This usually takes about one hour.

• Magnetic Resonance Imaging (MRI) scans of your chest and/or legs. This usually takes one hour.

You will have the lung function tests at the Churchill Hospital in Headington. All the other tests and the procedure itself will take place at the John Radcliffe Hospital.

If you are taking Warfarin, Aspirin or Clopidogrel you may need to stop taking them before the TAVI procedure to lower your
risk of bleeding. We will send you a letter telling you when you should stop taking them, which is usually one week before your admission date.

What happens during the procedure?

Immediately before the procedure we will put some local anaesthetic in your wrist and then insert a cannula (a small tube) into an artery to allow us to closely monitor your blood pressure. After you are anaesthetised you will have a drip 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. These are usually removed the next day, or sooner, depending on your progress.

The TAVI procedure will be performed in a cardiac catheterisation laboratory under general anaesthesia. Special X-rays using a contrast dye and echocardiography (ultrasound of the heart) are used to guide the new valve into the correct position. The X-ray exposure should last no more than 20 minutes.

• **If you are having a transfemoral access**
  The Cardiogist, assisted by the Cardiac Surgeon, will perform the procedure. A vascular surgeon, who specialises in problems with blood vessels, will also be present.

  The doctor will make a puncture (small hole) in the femoral artery at the top of your leg and insert a catheter (narrow tube) into the artery. The catheter has a special balloon on the end which is then inflated to stretch open your narrowed aortic valv. This is called balloon aortic valvuloplasty. The new valve is then carefully compressed and inserted through the femoral artery into your narrowed aortic valve using a balloon delivery catheter and a special device. A balloon is then used to expand the new valve. The balloon is then deflated and
removed and the cardiac surgeon repairs the puncture site in your groin.

- **If you are having the transapical (surgical) approach:**
The Cardiologist, assisted by the Cardiac Surgeon, will perform the procedure. A small cut (called a thoracotomy) is made on the left side of your chest so that the surgeon can access the apex (tip) of your heart. A catheter (narrow tube) which has a special balloon on the end is then introduced through the heart muscle wall into the aortic valve. The balloon is then inflated to stretch open your narrowed valve. This is called balloon aortic valvuloplasty.

The replacement valve will be carefully compressed and mounted onto a balloon delivery catheter, using a specially designed device. The replacement valve is then carefully compressed and inserted directly through the chest wall and placed in the correct position. A balloon is then used to expand the replacement valve and hold it open permanently. The balloon is then deflated and removed and the cardiac surgeon repairs the puncture site in your groin. The puncture site in the heart is then repaired by the cardiac surgeon and a pleural (chest) drain put in.

During both types of procedure we will speed your heart rate up to 200 beats a minute using a temporary pacing wire. This wire is put in through a vein in your groin on the other leg 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 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 the next day, depending on the decision of the surgeon. The whole procedure takes 1 - 2 hours.
What happens after the procedure?

You will go to the Cardiothoracic Critical Care Unit (CTCC) 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 possible. This will happen within 24 hours so that you can get up and move around.

If you had the transapical approach you will be given antibiotics.

You will stay in the CTCC area for a day and then we will move you to the Cardiothoracic Ward (CTU). You will be in hospital for 2-8 days, depending on how quickly you get better. If you live alone please think about whether it is possible to arrange for a friend or relative to stay with you, or for you stay with them, for the first few days after discharge.

After the procedure your doctor may ask you to take aspirin and/or clopidogrel (a blood thinning tablet). Your Cardiologist or 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 hospital:

- A chest x-ray
- A urine analysis
- Routine blood tests to measure the function of your kidneys and liver. This will make sure you that you do not have a blood infection. They will also make sure that your blood can clot properly and that it has enough haemoglobin (haemoglobin carries oxygen around the body).
- An Electrocardiogram (ECG)
- An Echocardiogram, this is a simple heart ultrasound scan that you will have had already in the outpatients’ clinic before your procedure.
How will I be followed up?

We will ask you to come back to the outpatient clinic 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 valve implantation?

Treatment with the new valve should give you both short and long term relief of your symptoms. It will 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 procedure?

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

These are the risks associated with transcatheter aortic valve implantation:

**Major risks**

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

- An allergic reaction to the contrast dye used (less than 2%)
- A reaction to the anaesthesia (less than 1%)
- An infection (less than 2%), including
  - Endocarditis (an inflammation of the heart)
  - Septicaemia (an infection in the blood)
- A pericardial effusion – bleeding into the sack around the heart (less than 5%)

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

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

In extreme cases it may be necessary to carry out immediate emergency open-heart surgery to replace the aortic valve. The surgical team and all the emergency equipment are always 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 a cardiopulmonary bypass include a stroke and getting an infection in the groin incision. We will make every effort to reduce the risks.

Radiation exposure

Some of the procedures you have will expose you to extra radiation. For each X-ray you have you will get the same amount of radiation as the average person gets from the atmosphere over 10 days.
If you need to have a CT scan it would be the same as getting 3 years of background radiation.

It is anticipated that the amount of radiation used will be the same as during a coronary angioplasty (this is when the narrowing in the heart arteries are stretched open using an inflated balloon).

What are the alternatives to valve implantation?

The usual treatment options for patients with aortic stenosis are:

- A balloon aortic valvuloplasty which will stretch the aortic valve opening
- A surgical aortic valve replacement (conventional open-chest surgery to replace your aortic valve with a new one)
- Treatment with medication

The preferred treatment for severe aortic stenosis is conventional aortic valve replacement, but at the moment you are considered too high risk for this type of surgery.
Further information

You can find more information from:

- The Oxford Cardiac Surgery booklet, which will be given to you to read before your procedure. This will tell you about the ward and your stay in hospital.
- Your Cardiologist or Cardiac Surgeon
- Your TAVI Nurse Specialist, Helen Jackson. You can telephone her on 01865 221330.

How to contact us

If you have any questions please contact:

Helen Jackson, TAVI and Heart Failure Nurse Specialist
Telephone: 01865 221330

If you need an interpreter or need a document in another language, large print, Braille or audio version, please call 01865 221473 or email PALSJR@orh.nhs.uk