NHS
Royal Papworth Hospital
NHS Foundation Trust

Transcatheter Aortic Valve Implantation (TAVI)

Patient's guide and agreement to consent form

Valvular heart disease

The heart is a muscle which pumps blood to your lungs and around the body. There are four valves within the heart. These valves normally open to let blood flow through, or out, of the heart, and then shut to prevent blood flowing backwards.

If a valve becomes diseased or damaged this can affect the flow of blood in two ways:

1. If the valve does not open fully it will obstruct the flow. This is called valve stenosis.
2. If the valve does not close properly it will allow blood to flow backwards in the wrong direction. This is called valve regurgitation.

Aortic valve stenosis

You have been diagnosed with aortic valve stenosis. The aortic valve is on the left side of the heart. When the valve opens blood is normally pumped from the left pumping chamber of the heart (ventricle) around the body. When the aortic valve is narrowed the blood flow out of the heart is restricted. This can cause symptoms of tiredness, chest pain, breathlessness and/or dizziness when exercising, and can lead to fainting. The restriction may also put a strain onto your heart pump over time, leading to heart muscle weakness, fluid on the lungs or swollen ankles.

The traditional treatment for severe symptomatic aortic valve stenosis is conventional aortic valve replacement.

This involves open-heart surgery to replace the narrowed valve with a valve prosthesis. However, due to your overall medical condition and/or age, you may be more suitable for a transcatheter aortic valve implantation.

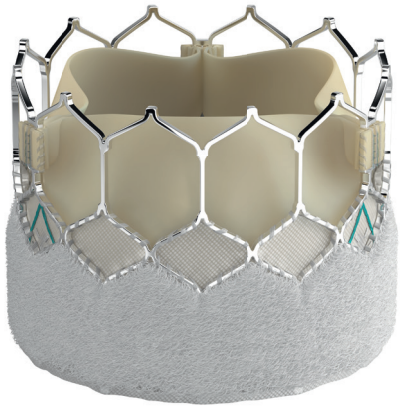
Aortic regurgitation

More rarely some patients with severe aortic regurgitation are suitable for a transcatheter aortic valve implantation. Aortic regurgitation can also put strain on the heart causing breathlessness and fluid overload.

What is transcatheter aortic valve implantation?

Transcatheter aortic valve implantation (TAVI) involves inserting a prosthetic heart valve inside your narrowed valve using a catheter. The valve is made up of a metal frame (stent) and the outer lining (pericardium) of a cow's (Edwards Sapien valve) or pig's (Medtronic Evolut valve) heart. The procedure is usually carried out under local anaesthetic and concious sedation.

There are two types of valve we use: balloon expanded and self-expandable.



Edwards SAPIEN 3TM transcatheter heart valve

Image courtesy of Edwards Lifesciences

Medtronic Evolut PRO valve

Reproduced with permission of Medtronic

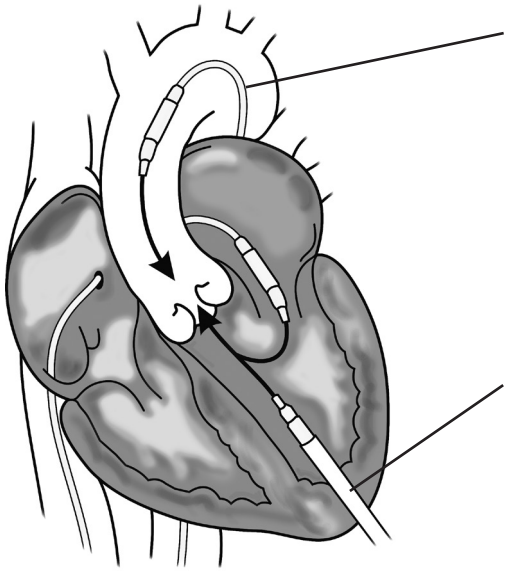
There are several access routes to deliver the TAVI valve.

1. Transfemoral - through the femoral artery, the main artery in your groin which leads back to the heart (most common route).

2. Transcarotid - through a small incision in your neck into the carotid artery leading back to the heart.
3. Transaxillary - (sometimes referred to as subclavian) through a small incision under the collar bone to the artery leading back to the heart.
4. Transaortic - through a small cut in the chest directly into the aorta (main artery).
5. Transapical - through a small cut on the left side of your chest to get to the apex (tip) of your heart.

The 'TAVI team', including your cardiologist, cardiac surgeon and anaesthetist, will review your medical condition and screening tests to decide the most appropriate treatment and access route for you.

Transcatheter aortic valve implantation techniques



Retrograde transfemoral, transcarotid, transaxillary and transaortic approaches
The delivery system is introduced through the access site artery allowing positioning of the prosthetic valve within the native stenotic aortic valve.

Transapical approach
The heart is reached by a small incision under the left breast. The valve delivery system is introduced into the heart and the new prosthetic valve positioned inside the narrowed aortic valve.

Screening tests

You may have at varying times:

- A physical examination
- An electrical heart trace (ECG)
- A chest X-ray (CXR)
- Blood tests
- An ultrasound probe and gel placed on the chest to obtain pictures of your heart (transthoracic echocardiogram).
- A transoesophageal echocardiogram (TOE) if clearer pictures are needed (this involves inserting an ultrasound probe into your gullet under sedation).
- An angiogram, which involves passing a tube (catheter) into your groin or wrist artery and taking X-ray pictures of your blood vessels supplying your heart (coronary arteries), your body's main blood vessel (aorta) and groin arteries.
- A CT scan to look at the blood vessels from the neck to the groin.

Potential benefits of a TAVI procedure

Treatment with the new valve should improve your symptoms. It will improve the aortic valve performance and your overall heart function. We would hope this will improve your quality of life and increase your life span.

Potential risks of the procedure

- Death at 30 days: 2%
- Stroke: 3-5%
- Heart attack: 1.0%
- Permanent pacemaker requirement: 6-12%
- Major bleeding: 3-5%
- Damage to blood vessels: 1-2%
- Kidney failure: 1%
- Emergency open heart surgey: 1%
- Infection (wound or valve related): 1%

Reference Papworth Outcomes - April 2021

Hospital admission

Once accepted by the medical team, you will be invited to come in for the procedure. You will receive a letter with your admission details. You may be asked to stop any blood thinning medications four days or less before your operation.

You will either attend a pre-admission clinic and come to hospital the same day as your procedure or be admitted the day before. If you don't attend a pre-admission clinic, one of the TAVI specialist nurses will call you the week before to check you are well and go through medication stoppages. Before the procedure, you will be seen by members of the operating team.

An anaesthetist will assess you before your operation and you will have an opportunity to ask questions.

You will be kept 'nil by mouth' for a few hours prior to your procedure and the nurses will assist you to shave your chest, wrists and groins and also to shower.

The procedure will be done in the X-ray laboratory (similar room to where you had the coronary angiogram) using contrast dye, X-ray screening and echocardiography to guide the valve into the correct position.

This procedure will involve either general anaesthetic or conscious sedation. By signing the consent form you are consenting to your anaesthetic.

Procedure

Following your sedation, you will have some tubes put through the blood vessels in your groin and/or wrist to deliver the contrast dye and a pacing wire to speed up the heart during the valve insertion to ensure correct positioning.

The operator will gain access making a small incision either in your groin, neck or chest wall. A catheter (narrow tube) is passed from the femoral (groin) artery to the aorta (transfemoral), neck artery (transcarotid), artery below the collar bone (transaxiallry), the aorta (transaortic) or through the heart muscle near to the aortic valve (transapical).

The prosthetic valve for implantation will be prepared and inserted. When the valve is in the correct position your heart rate will be increased using the temporary pacing wire for a few seconds. This reduces the blood pressure and the motion of the heart making the procedure safer.

The prosthetic valve is then expanded into permanent position. The tubes are removed and the valve starts to function immediately.

The operation site is repaired by the operators. A chest drain is inserted for transapical and transaortic procedures. The procedure overall takes about two hours.

Blood transfusion

When having surgery it is likely that you will lose some blood. If only a small amount is lost your body will naturally replace this over the next few weeks. If more blood is lost, it may be necessary for you to have a blood transfusion so that you do not suffer any ill effects from the blood loss. Although blood transfusion is quite safe, there are some potential risks associated with this treatment. Your doctor or nurse will explain these risks to you and will offer you an information leaflet.

In the UK the risk of contracting a viral infection, such as hepatitis or HIV from blood transfusion is extremely small. Very rarely patients receiving blood transfusion may experience an allergic reaction or develop other complications, such as haemolysis (breakdown of red cells in your blood) or a bacterial infection. The actual risk of contracting vCJD through blood is unknown but appears to be extremely small. There is also a very small risk of inadvertently receiving unsuitable blood, however there are stringent procedures in place to minimise this risk.

By signing the consent form, you are consenting to receiving a blood transfusion. If you do not wish to receive blood or blood products please make this known to your consultant.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

Consent 027
Patient agreement to Transcatheter Aortic Valve Implantation

Statement of health professional

I have explained the procedure to the patient. *In particular I have explained:*

The intended benefits: This procedure is carried out with the intention of improving symptoms which may be related to obstruction of blood flow out of the heart. These symptoms may include angina, breathlessness, exercise restriction, dizziness or collapse.

Significant, unavoidable or frequently occurring risks: Heart attack: 1.0%, stroke: 3-5%, death at 30 days: 2.0%, permanent pacemaker requirement: 6-12%, major bleeding: 3-5%, damage to blood vessels: 2%, damage to nerves: 2%, infection: 1%, kidney failure: 1%. *Reference Papworth Outcomes - April 2021*

Due to the high risk nature of your condition, in the event of your heart stopping during the procedure your doctors may have limited options available to help you.

Any extra procedures, which may become necessary during the procedure:

- ☐ Blood transfusion

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

This procedure will involve:

- ☐ General anaesthetic
- ☐ Conscious sedation
- ☐ Transfemoral
- ☐ Transcarotid
- ☐ Transaxillary
- ☐ Transaortic
- ☐ Transapical
- ☐ Other route

Consultant/Performer

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Contact details
(If patient wishes to discuss options later)

……

Statement of patient

Please read the patient information and this form carefully.

If your treatment has been planned in advance, you should already have your own copy which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now.

If you have any further questions, do ask - we are here to help you. *You have the right to change your mind at any time, including after you have signed this form.*

- **I understand** what the procedure is and I know why it is being done, including the risks and benefits.
- **I agree** to the procedure or course of treatment described on this form and have read this information leaflet on Transcatheter Aortic Valve Implantation (TAVI) (PI 43) and had the opportunity to ask questions.
- **I agree** to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.
- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

……

……

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

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- I have been told in the past by Public Health that I am at increased risk of CJD (Creutzfeldt-Jakob disease) or vCJD (variant Creutzfeldt-Jakob disease).

  ☐ Yes *(Health professional to refer to Trust CJD procedure DN92.)*

  ☐ No

Patient

Patient signature: ……

Date: ……

Name (PRINT): ……

Statement of interpreter (where appropriate). I have interpreted the information above to the patient to the best of my ability and in a way which I believe he/she can understand.

Signed: ……

Date: ……

Name (PRINT): ……

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signed: ……

Date: ……

Name (PRINT): ……

Confirmation of consent

(To be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Important notes (tick if applicable).

☐ Patient has advance decision to refuse treatment (e.g. Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ……

Date: ……

Name (PRINT): ……

Following your procedure

You will go from the X-ray department to the recovery area for up to a couple of hours where you will be closely monitored. Following this you will return either to the ward or the high dependency unit. If you have general anaesthetic you are woken up early after the operation but occasionally you may need to stay asleep so will be kept sedated and if necessary admitted to intensive care.

It is not uncommon to access both groin and/or wrist blood vessels. Whilst there are tubes in your groin you will have to be on bed rest. A few hours after these tubes are removed you can sit out and start to walk about. Patients that have a chest drain will have drips and drains removed over the next 48 hours.

Patients who have transfemoral procedure with sedation are usually quick to recover. Expected length of stay is 1-4 days.

Transaortic and transapical patients will take a few days longer. Expected length of stay is 4-7 days.

Recovery at home

The following are only general guidelines as everyone's recovery is slightly different. It is advisable that you have someone to care for you for the first week after discharge. Please speak to your nurse or doctor as soon as possible if you think this will be a problem.

Activity

You should avoid strenuous activity for a few weeks, six weeks if your procedure was via the transapical/transaortic approach. This includes heavy lifting (eg shopping, suitcases) or pushing and pulling (eg cutting grass, vacuum cleaning).

You may feel a little 'washed out' and tired and need to rest in the afternoon. However it is important for your recovery to have a short walk every day. This can be gradually increased.

You do not have to avoid climbing stairs or walking up inclines, you may have to start off at a slower pace. You may feel slightly out of breath on walking, which should improve as your fitness level increases.

There can be some fluid retention as a result of the procedure; you may notice some swelling of your ankles. If this swelling travels further than your ankles please get reviewed by your GP.

Wounds

If chest or neck incision, your wounds should be healing by the time you leave hospital, if they still require a dressing we will organise a district or practice nurse to continue this. The stitches are dissolvable so do not have to be removed, apart from one stitch if you had a chest drain. If your wound becomes red or inflamed please get your GP or practice nurse to check it.

If groin approach, you may have bruising to your groin(s) which is not uncommon and may take several weeks to resolve. You may have a hard lump under the skin due to a collection of blood (haematoma). Please consult your GP if this becomes painful or grows bigger.

Medication

As well as your normal medicines including aspirin, you will usually be discharged with an additional blood thinning medicine called clopidogrel. People on warfarin or direct oral anticoagulants may be discharged only on oral anti coagulation or a combination of oral anticoagulation and aspirin or clopidogrel. If you have had a chest incision, you will be discharged with some painkillers which we would recommend you to take regularly until you are no longer getting discomfort from your wound.

Driving

You are not allowed by DVLA to drive for four weeks after your procedure. If you have a LGV or PCV licence you will need to undergo an exercise test before getting your licence back.

Work

If you were working before your procedure there is no reason why you cannot return to this after a period of recovery up to two weeks if transfemoral, 4-6 weeks if chest incision.

Cardiac rehabilitation
You will be invited to attend cardiac rehabilitation about six weeks after your procedure. This is a programme of graduated exercise and general health discussions. If you live outside the area you may be referred to your local hospital. Patients who attend generally feel more confident about coping with everyday life. It will also help to increase your fitness level.

Follow-up care
On discharge you will be given a copy of the letter for your GP explaining what you have had done and a list of your medications. The valve/TAVI specialist nurses will phone you a week after discharge to check on your progress. If you have any concerns you can call the TAVI specialist nurses on 01223 638411 (Monday to Friday 08.30 - 18.00). We would like to hear sooner rather than later about any potential problems.

You will be invited to attend an outpatient follow-up appointment with the nurse specialist approximately six weeks after your procedure. During this visit you will have an ECG and if your procedure was transapical/ transaortic also a chest X-ray. At a further appointment after three months you will have an ultrasound scan of your heart and see a TAVI consultant. The doctor will then decide about any future appointments.

How to contact us

If you need further information please contact the TAVI specialist nurses on 01223 638411.

If you get the answerphone please leave a message and a contact number.

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Large print copies and alternative language versions of this leaflet can be made available on request.