

Transcatheter Aortic Valve Implantation (TAVI)

A patient's guide

Acknowledgment

You have been found to have a condition known as aortic valve disease, in which there is either a severe narrowing or leaking of the aortic valve, the main valve through which blood is pumped out of the heart to be supplied to the body. This is a serious condition which causes symptoms of breathlessness, chest pain, dizziness, and blackouts, and which can be, if left untreated, fatal. This condition can be treated by a procedure known as transcatheter aortic valve implantation (TAVI). Your doctors are considering this procedure for you, and this information sheet aims to provide details of the procedure, in order to help you to decide, along with your doctors, whether to go ahead.

Background

For many years doctors have treated aortic stenosis by replacing the aortic valve using open-heart surgery. This is a well-established and very effective operation. However, in some patients, such as older patients, those with other medical problems, or those who have had previous cardiac surgery, the risks of surgical aortic valve replacement are very high, and the surgeon and patient may decide that the risks are unacceptable. Transcatheter aortic valve implantation allows the aortic valve to be replaced without the need for open-heart surgery, and is therefore a good option for patients in whom the risks of open-heart surgery are unacceptably high.

Leeds is one of the largest TAVI centres in the United Kingdom. We, the cardiologists who carry out the TAVI procedures, are all committed to improving the service that we provide to our patients. This means that we are involved in a number of different national and international research studies. Some of these studies involve using the very latest types of valve or devices to potentially help reduce the chances of complications, while others involve the comparison of different treatments. Some studies do not involve using anything new, but simply involve an extra investigation so that we can better assess the benefit of the TAVI treatment.

You may be invited to participate in one of these studies when you are admitted for your TAVI. If you are, then the purpose of the study, and the tests involved, will be explained to you in detail. You are, of course, entirely free to decline to take part in any study and your treatment will not be affected in any way.

What does the procedure involve?

TAVI is usually performed under local anaesthetic with sedation, though can be performed under a general anaesthetic. There are two common routes of valve insertion transfemoral (through the femoral artery, the main artery in your groin) and subclavian (through the artery under your collarbone). Your doctors will tell you which approach they plan to use for you. Tubes are then passed into the arteries and veins. Through one of these tubes the doctors pass a large balloon into the aortic valve and inflate the balloon to stretch open the narrowed valve. A long tube or 'delivery sheath' is then passed through the artery either in the groin or under your collarbone to the heart. The new aortic valve is contained within this tube. The valve is a 'tissue valve' made out of the lining of a pig's heart and then sewn into a metal tubular frame. The delivery sheath is passed across the aortic valve, and then pulled back to deliver the new valve. The metal tubular frame containing the valve expands, pushing your old valve out of the way, and allowing the new valve to start working immediately.

After the procedure you will spend the first 24 hours on the coronary care unit, after which you will be transferred to the ward. You will be discharged home about 2-4 days after the procedure.

What are the benefits of the procedure?

The chance of a successful procedure, in other words the valve is successfully replaced and the new valve functions well, is very high, around 95%. After a successful procedure your symptoms will be considerably improved. In most patients previously severe symptoms (of breathlessness and/or chest pain, and/or dizziness and blackouts) are either abolished completely or are only mild after the procedure. This results in a considerable improvement in exercise capacity and quality of life.

What are the risks of the procedure?

Although transcatheter aortic valve implantation does not involve open-heart surgery, it is still a high-risk procedure. This is partly because of the procedure itself, and also because patients undergoing the procedure are often older people and/or have other medical problems. There is a 2% risk of not surviving the procedure to leave the hospital. There is a 5% risk of a major / minor stroke. There is a 10-20% risk of needing a permanent pacemaker.

How long has TAVI been used as a treatment for aortic valve disease?

TAVI was first performed in 2002. The first procedure in the United Kingdom was undertaken in 2007. The first procedures in the Yorkshire Heart Centre in Leeds were undertaken in May 2008. The evidence that this is an effective and safe procedure is therefore limited to a relatively small number of patients, and no information about long-term outcome after this procedure is available yet. However, the procedure is being performed increasingly frequently. Several hundred thousand patients have now been treated worldwide.

What are the alternatives?

The alternative options are to undergo aortic valve replacement by open heart surgery, or to continue with drug treatment alone.

- Surgical aortic valve replacement is a well-established and very effective procedure, but which carries a high risk in some patients.
- Drug treatment can sometimes help the symptoms caused by the narrowed aortic valve. However, the effectiveness of drug treatment alone is limited. Without a procedure to replace the narrowed valve your symptoms are likely to remain very troublesome, and indeed to deteriorate over the months to come. Without definitive treatment the condition is usually fatal.

Will I need any further tests?

In order for us to assess your suitability for this procedure we will provisionally arrange a number of investigations once we have received your referral, these may include some of the following:

Outpatient appointment with Dr Blackman / Dr Malkin or Dr Cunningham (in some cases you may be asked to see a Cardiac surgeon as well). You may also meet the TAVI Nurse at this appointment. The consultation will provide us

with information about your symptoms, lifestyle, physical and mental health as well as frailty. Please note that age is not an excluding factor.

TAVI Angiogram: A detailed X-Ray of the heart which gives us information about the heart arteries, the femoral arteries, the heart pump and the severity of the aortic valve narrowing.

Transthoracic echocardiogram: This provides information about the heart and valve using ultrasound.

Transoesophageal echo: Pictures are taken from the inside of your oesophagus providing a more detailed measurement of the aortic valve.

Stress echocardiogram: Ultrasound pictures are taken while the heart is under stress either with exercise or drugs - to increase the heart rate.

CT scan: Sophisticated X-ray providing more detailed pictures and measurements of the aortic valve and access vessels.

Lung function tests: Which measure lung capacity

You may have already had some tests carried out, we will review these. However please note you may need some test repeating.

You will receive these appointments through the post. Where possible we do try to limit the number of visits to hospital.

How is a decision made about the procedure and which treatment is right for me?

After your screening tests have been completed and you have been seen in the clinic by your consultant your case will then be discussed in a multidisciplinary (MDT) meeting made up of Consultant Cardiologists, Imaging specialist, nurse specialists, Vascular consultants and a Consultant Cardiac Surgeon who specialises in open-heart surgery. We will analyse all of the data and information to make an informed decision about the best management and treatment option for your condition.

This meeting takes place every Wednesdays and alternate Mondays, once your case has been discussed we will try and contact you via telephone to inform you of the decision, however you will also receive written confirmation.

What are the possible outcomes from the MDT?

- Accepted for TAVI - Your name will be added to the waiting list for the procedure which can be around 12 weeks long.
- Recommended for open heart surgery - you and your GP will be informed of the decision and the process that follows.
- Recommended for treatment of Balloon Aortic Valvuloplasty (BAV) - This is a treatment in which we stretch open the aortic valve using a balloon. The benefits are only temporary, and this is only usually done in certain situations.
- We may recommend no intervention - This is when we feel that the valve disease is not severe or the risk of TAVI outweighs any benefit.

It is important to contact the TAVI nurse should your symptoms increase or your health starts to deteriorate. We will also need to be informed of any unplanned admissions to hospital. Contact the TAVI Nurse on **0113 392 5298**.

Once you have been allocated a date for your procedure you will be invited to attend a pre-assessment clinic so we can review your health and discuss your admission.

Summary

Transcatheter aortic valve implantation is a new and high-risk procedure, but has a very high success rate and is effective at treating the problem of the narrowed aortic valve, resulting in a substantial improvement in patients' quality of life.

Useful links:

www.heartvalvevoice.com

British Heart Foundation

Advice for post-procedure rehabilitation

Recovery

Time taken to completely recover will vary from patient to patient. On average it will be at least 1-2 weeks for recovery from the procedure. Some patients will take longer and some less.

Subclavian TAVI - Wound Care

Your dressing should be removed before you go home. If the wound is clean and dry, you need not have the wound redressed.

You will have some stitches which are dissolvable and therefore do not need removing.

Please look at your wound daily in a mirror. Please report any extra swelling, redness, oozing of wound, hotness to touch and/or excessive pain to the TAVI nurse using the contact number below.

Transfemoral TAVI - Groin care

During your procedure tubes will have been inserted into both groins. These will be removed after the procedure. There will be bruising, therefore it is important to check for swelling or bleeding. If this occurs contact the ward you were discharged from immediately. Inform your GP if you notice any of the following:

- A hard tender lump under the skin around the area of incision (a small, lump is normal)
- Any increased pain, swelling, redness and/or discharge at the groin site
- A cold hand or foot on the same side as the procedure
- Raised temperature or fever
- In the unlikely event that your groin starts to bleed you should lie down. Apply pressure to the area keeping your or leg (or arm, if the incision was made here) as straight as possible. If bleeding does not stop after 10 minutes you must seek immediate medical attention
- **It is important to remember you will have stitches in your groin and these should be removed after 5-7 days. If you have any concerns please speak to your practice nurse.**

Medication

Your medication is very likely to change and the ward staff will take you through all of your medicines before your discharge.

Nearly all patients will take Aspirin life long and Clopidogrel for 3 months only, unless you are already Warfarin.

Driving

Your Consultant recommends not to drive for 4 week post procedure (please note there is no official guidance on this). If you drive you do not need to inform the DVLA about your procedure. We do advise you to tell your insurance

company to avoid problems with any claims you make in the future. If you have problems with your insurance the British Heart Foundation (BHF) will be able to give you details of insurance companies on 0845 070 8070. If you hold a commercial licence you will need to inform the DVLA who will advise you further.

Flying

Your consultant advises not to fly for 2 weeks post-procedure, please note this is only guidance.

Emotion

If you experience any problems either physically or emotionally post-procedure it is important to mention these to your GP so that he/she can monitor them.

Exercise

Gradual re-introduction of exercise after discharge from hospital. For the first week walking around the house only or perhaps short walks out of the house. After the first week out of hospital aim to gradually increase exercise by walking only. More vigorous exercise than walking should be left for at least 4 weeks post-procedure.

Follow-up

- You will be followed up in the outpatient clinic by the TAVI Nurse Specialist Helen Reed / Kerry Pena 6-8 weeks post procedure.
- We will arrange for you to have a transthoracic echocardiogram on the same day as your outpatient appointment.
- If you do not have a pacemaker you **may** need to have a 24hour ECG monitor fitted once you are back at home. For non-Leeds patients this can be done at your local hospital.

Donations

Donations are welcome and there are two main sources to which you can donate:

- The TAVI Trust Fund 3585 - Provides direct resources to the TAVI team
- Take Heart - provides support and resources to the cardiology department

Contact: Kerry Pena / Helen Reed TAVI Nurse Specialist 0113 392 5298