Patient information and consent to endovascular repair of thoracic aortic aneurysm– 'key hole' repair of a ballooned artery in your chest

Key messages for patients

- **Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation**.
- **You must not have anything to eat six hours before and no clear fluids two hours before your operation**.
- Please bring with you any medications you use (including patches, creams and herbal remedies) and any information that you have been given relevant to your care in hospital, such as x rays or test results.
- Take your medications as normal on the day of the procedure **unless** you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. **Do not** take any medications used to treat diabetes.
- Please call the vascular surgery nurse practitioner **01223 245151** ext **6382** if you have any questions or concerns about this procedure.

Please read this information carefully, you and your health professional will sign it to document your consent.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the responsible health professional, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.

About endovascular repair of thoracic aortic aneurysm

A thoracic aortic aneurysm (TAA) is an abnormal dilatation (ballooning) of the aorta, which is the main artery in the body and carries blood away from the heart. The other arteries in the body are supplied by the aorta, for example those that supply blood to the head, limbs and body organs.

An arterial aneurysm is an abnormal dilatation (ballooning) of an artery caused by a weakness in the wall of the artery. Generally an artery is called aneurysmal when it increases to twice its normal size. Any artery in the body can develop an aneurysm but some are more commonly affected than others. In particular, the aorta, which is the main artery in the chest and abdomen is commonly affected. The main risks of aneurysms are either that they burst (leading to life-threatening bleeding) or they block, therefore, cutting off the blood supply to the areas supported by them.

Aneurysms are more common in people aged over 60 years. They are also more common in people who have high blood pressure and/or those who smoke.

Aneurysms can also run in families, particularly between brothers, because, in general, men are more commonly affected than women.

Diagnosis of TAA

The majority of TAAs cause no symptoms and are discovered by chance. A routine chest X-ray, or a CT/MR scan performed for some other reason, may pick up the presence of an aneurysm.

Investigation of TAA

Accurate diagnosis and sizing of the TAA is done by a CT scan with dye to show up the aorta. The risk of rupture (bursting) of TAA is related to the size: TAAs bigger than 6.0cms in diameter are at risk of rupture and require surgical repair to avoid this. Smaller aneurysms are monitored with CT scans every six to twelve months, and surgery is only considered if they increase in size, or start to cause pain or other symptoms. The CT is particularly important when considering and planning endovascular repair of a TAA. Only about half of patients with TAA will be suitable for this. Other investigations to measure the function of the heart, lungs and kidneys might also be arranged, because this surgery tends to put an extra strain on these organs.

Before your procedure

Most patients attend a nurse led pre-admission clinic. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring any packaging with you.

This procedure involves the use of anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

Depending on the arrangements made for you, you will be admitted to the ward either the day before surgery or on the day of surgery. The ward nursing staff will show you your bed and help you settle in. They will explain the preparations for the operating theatre, and show you where everything is.

You must not have anything to eat six hours before and no clear fluids two hours before your operation.

Most people who have this type of procedure will need to stay in hospital for two to three days.

Your surgeon will visit you before your operation to explain the procedure again and to answer any questions.

Hair removal before an operation

For most operations, you do not need to have the hair around the site of the operation removed. However, sometimes the healthcare team need to see or reach your skin and if this is necessary they will use an electric hair clipper with a single-use disposable head, on the day of the surgery. Please do not shave the hair yourself or use a razor to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

It may be necessary during the procedure to shave other areas of your body if appropriate to allow equipment/machines, for example diathermy machines (used to seal blood vessels), to stick to your skin to achieve the best and safest performance.

During the procedure

At the start of the surgery, we make an incision in the groin to expose and control the artery. In the other groin a needle and catheter are placed in the artery without a full incision.

The aortic aneurysm will be fixed by passing the endovascular graft (a polyester or Gore-tex graft supported by metal struts) through the artery in your groin under x-ray control up to the thoracic aorta. The wound will be closed with dissolvable sutures.

Commonly patients recover from aneurysm surgery in the theatre recovery area for the first night, but you may return to the ward.

After the procedure

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too.

You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your ward.

At this time, you might find there is a urinary catheter inserted into your bladder, which allows your urine to drain into a bag. This is a temporary measure to prevent urine becoming retained which can cause your blood pressure to become unstable.

[After certain major operations you may be transferred to the intensive care unit (ICU/ITU), high dependency unit (HDU), intermediate dependency area (IDA) or fast track/overnight intensive recovery (OIR). These are areas where you will be monitored much more closely because of the nature of your operation or because of certain pre-existing health problems that you may have. If your surgeon or anaesthetist believes you should go to one of these areas after your operation, they will tell you and explain to you what you should expect.

If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.

Eating and drinking. You will be able to eat and drink as soon as you feel ready.

Getting about after the procedure. Most of the catheters and drips will be removed the day after surgery and you should then be able to get up and walk around.

Leaving hospital. While you are staying with us, the surgical team will visit you every day and can answer any questions you might have about your surgery. On each visit, we will assess your progress and work out the best time for you to be discharged from hospital. **Most people go home between two and five days after the operation.**

Resuming normal activities including work. It will probably take one to three weeks before you feel as well as you did before this surgery.

Check-ups and results. Following discharge from the ward we will make arrangements to review you in the outpatient clinic in six to eight weeks time. You will then be followed up regularly for the rest of your life and will undergo yearly scans to check the endovascular graft.

Intended benefits

To surgically repair your aneurysm, to prevent it either bursting or blocking.

Who will perform my procedure?

This procedure will be performed by the consultant and the specialist registrar and a consultant radiologist.

Alternative procedures that are available

Monitoring only: if the AAA is larger than 6.0cms, the risk of rupture without surgery is usually higher than the risk of surgery. Therefore not operating and continuing to monitor the thoracic aortic aneurysm is not the safest option.

Open aneurysm repair is an alternative technique. This is a more complex operation where the aneurysm is repaired with a graft sewn in to the aorta through a larger incision in the chest.

Significant, unavoidable or frequently occurring risks of this procedure

As with any major operation there is a very small risk that you may have a medical complication such as a heart attack, chest infection or kidney failure. There is a 5% (5 in a 100) risk of a stroke. The doctors and nurses will try to prevent these complications and to deal with them rapidly if they occur.

Sometimes after this surgery the blood supply to the legs can become compromised and further operations to restore the circulation are required. There is a 5% risk that the blood supply to the nerves in the spine can also be affected leading to weakness or paralysis of the legs. A drain can be placed in the spine to help the nerves recover.

Overall, the incidence of major complications (including death) is in the region of 3-5% but the risks may be increased in those patients who have pre-existing disease. The risk of death is lower than for open aneurysm repair.

Other complications include graft infection and wound infection.

There is an extremely small chance that it may not be possible to manoeuvre the endovascular graft into the aorta and the surgeon may have to revert to open aneurysm repair.

Endovascular TAA repair is still a relatively new procedure and we will keep a close eye on your endovascular graft for life after surgery with regular scans. Occasionally blood may leak around the endovascular graft ‘endoleak’ and up to one in six patients may require a further procedure at a later date. However this is likely to be a small procedure under a local anaesthetic. There is a very small chance that the endovascular graft may need to be removed at a later date and the aneurysm repaired by a conventional technique.

Anaesthesia

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. **The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness**. Sometimes different types of anaesthesia are used together.

Before your operation

Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery.
To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and may review your test results.

Pre-medication

You may be prescribed a 'premed' prior to your operation. This a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.

Moving to the operating room or theatre

You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted and you may be asked to breathe oxygen through a face mask.

It is common practice nowadays to allow a parent into the anaesthetic room with children; as the child goes unconscious, the parent will be asked to leave.
Before starting your anaesthesia the medical team will perform a check of your name, personal details and confirm the operation you are expecting.

General anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery.

Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

Regional anaesthesia

Regional anaesthesia includes epidurals, spinals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you.

Local anaesthesia

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted and some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

Sedation

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as an anaesthetic. The anaesthesia prevents you from feeling pain, the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. This is known as ‘conscious sedation’, and may be used by other professionals as well as anaesthetists.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects after local or regional anaesthesia. When the effects of the anaesthesia wear off you may need pain relieving medicines.

What are the risks of anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

Very common (1 in 10 people) and common side effects (1 in 100 people)

Feeling sick and vomiting after surgery
Sore throat
Dizziness, blurred vision
Headache
Bladder problems
Damage to lips or tongue (usually minor)
Itching
Aches, pains and backache
Pain during injection of drugs
Bruising and soreness
Confusion or memory loss

Uncommon side effects and complications (1 in 1000 people)

Chest infection
Muscle pains
Slow breathing (depressed respiration)
Damage to teeth
An existing medical condition getting worse
Awareness (becoming conscious during your operation)

Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications

Damage to the eyes
Heart attack or stroke
Serious allergy to drugs
Nerve damage
Death
Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

Information about important questions on the consent form

1 Creutzfeldt Jakob Disease ('CJD')

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4 Use of Tissue

As a leading bio-medical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet '*Donating tissue or cells for research'* gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on **01223 216756.**

Information and support

The Circulation Foundation: http://www.circulationfoundation.org.uk/

Privacy & Dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet

If you would like this information in large print, another language or in audio format, please ask the department to contact Patient Information on 01223 216032 or patient.information@addenbrookes.nhs.uk

Document history

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Consent Form

Endovascular repair of thoracic aortic aneurysm

For staff use only:
Hospital number:
Surname:
First names:
Date of birth:
NHS no: _ _ _ / _ _ _ / _ _ _ _
Use hospital identification label

A **Patient's side** left / right or N/A

Consultant or other responsible health professional

Name and job title: .....

☐ Any special needs of the patient (e.g. help with communication)? .....

Please use 'Procedure completed' stamp here on completion:

B **Statement of health professional** (details of treatment, risks and benefits)

1 I confirm I am a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the hospital's consent policy. I have explained the procedure to the patient. In particular, I have explained:

a) the intended benefits of the procedure (please state)

To surgically repair your aneurysm.

b) the possible risks involved. Addenbrooke's always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient

- sometimes after this surgery the blood supply to the legs can become compromised
- graft infection
- wound infection
- an extremely small chance that it may not be possible to manoeuvre the endovascular graft into the aorta
- occasionally blood may leak around the endovascular graft.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:

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d) any extra procedures that might become necessary during the procedure such as:
☐ Blood transfusion ☐ Other procedure (please state)

.....

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The following information leaflet has been provided:

Endovascular repair of thoracic aortic aneurysm

Version, reference and date: V3, CF246, April 2012

or ☐ I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:
☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation ☐ None

Signed (Health professional): ..... Date: D D / M M / Y Y Y Y

Name (PRINT): ..... Time (24hr): H H : M M

Designation: ..... Contact/bleep no: .....

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional. ☐ Yes ☐ No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment. ☐ Yes ☐ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting. ☐ Yes ☐ No

3 Students in training
I agree to the involvement of medical and other students as part of their formal training. ☐ Yes ☐ No

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Surname:
First names:
Date of birth:
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Use hospital identification label

4 Use of Tissue

a) **I agree** that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research. ☐ Yes ☐ No

b) *Where additional clinical information is needed for the purposes of ethically approved research*, **I agree** that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records. ☐ Yes ☐ No

I have listed below any procedures that **I do not wish to be carried out without further discussion**.

.....

.....

I have read and understood the Patient Information about this procedure and the above additional information. **I agree** to the procedure or treatment.

Signed (Patient): ..... Date: D.D./M.M./Y.Y.Y.Y.

Name of patient (PRINT): .....

If signing for a child or young person; delete if not applicable.
I confirm I am a person with **parental responsibility** for the patient named on this form.

Signed: ..... Date: D.D./M.M./Y.Y.Y.Y.

Relationship to patient: .....

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): ..... Date: D.D./M.M./Y.Y.Y.Y.

Name of witness (PRINT): .....

Address: .....

.....

.....

Consent Form

Endovascular repair of thoracic aortic aneurysm

For staff use only:
Hospital number:
Surname:
First names:
Date of birth:
NHS no: _ _ _ / _ _ _ / _ _ _ _
Use hospital identification label

D Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): ..... Date: ..D D / M M / Y Y Y Y..

Name (PRINT): ..... Job title: .....

Please initial to confirm all sections have been completed: .....

E Interpreter's statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed (Interpreter): ..... Date: ..D D / M M / Y Y Y Y..

Name (PRINT): .....

Or, please note the language line reference ID number: .....

F Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): ..... Date: ..D D / M M / Y Y Y Y..

Signed (Health professional): ..... Date: ..D D / M M / Y Y Y Y..

Name (PRINT): ..... Job title: .....