

Patient agreement to investigation or treatment

Endovascular repair of abdominal aortic aneurysm (EVAR) – ‘key hole’ repair of a ballooned artery in your abdomen

Authors: Department of Vascular Surgery

Brief description:

- 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 for some reason some arteries are more commonly affected than others. In particular, the aorta, which is the main artery in the abdomen is commonly affected; as are the iliac arteries (in the pelvis), and the femoral arteries (in the thigh), and the popliteal arteries (behind the knee). 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.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure (operation/treatment). We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website:
<http://www.addenbrookes.org.uk/consent>
- Remember, you can change your mind about having the procedure at any time.

For staff use:

Does the patient have any special requirements? (eg requires an interpreter or other additional communication method)

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About: Endovascular repair of abdominal aortic aneurysm (EVAR)

An abdominal aortic aneurysm (AAA) 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. The part of the aorta that lies below the kidney arteries and above the iliac (pelvic arteries) is particularly prone to this problem.

Diagnosis of AAA

- The majority of AAA cause no symptoms and are discovered by chance. A routine examination by a doctor or an ultrasound scan performed for some other reason may pick up the presence of an aneurysm. Alternatively, some patients notice an abnormal pulsation in their abdomen (tummy). In some parts of the country, routine screening for aneurysms has been established.

Investigation of AAA

- The majority of AAA can be diagnosed by a simple ultrasound scan, which also provides an accurate measurement of their size. The risk of rupture (bursting) of AAA is related to their size: AAA bigger than 5.5 cm in diameter are at risk of rupture and require surgical repair to avoid this. Smaller aneurysms are monitored with ultrasound scans every three to six months, and surgery is only considered if they increase in size, or start to cause pain or other symptoms.
- When an aneurysm requires surgical repair, other investigations are arranged including a CT body scan. This provides accurate anatomical information regarding the aneurysm so the operation can be planned in more detail. The CT is particularly important when considering and planning EVAR. Only about half of patients with AAA will be suitable for EVAR. 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 pre-admission clinic, when you will meet when you will meet the house officer, nurse practitioner and/or the Consultant.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring with you details of anything you are taking (for example: bring the packaging with you).

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- This procedure involves the use of general anaesthesia. See below for further details about the types of anaesthesia/sedation we shall use. Please turn to page five for further details about the types of anaesthesia/sedation we shall use.
 - Depending on the arrangements made for you, you will be admitted to the ward the day before 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 or drink for at least six 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.

During the procedure (operation/treatment) itself

- Before your procedure, you will be given the necessary anaesthetic; see below for details of this.
- At the start of the surgery, we make two incisions (cut) in the groin.
- 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.
- The wounds will be closed with dissolvable sutures.
- Commonly, patients recover from aneurysm surgery in the theatre recovery area for the first night.

After the procedure (operation/treatment)

- If you have had a general anaesthetic you will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- After this procedure, most people will have a small, plastic tube in one of the veins of their arm. This might be attached to a bag of fluid (called a drip), which feeds your body with fluid until you are well enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to a ward.
- Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.
- 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.
- **Eating and drinking:** You will be able to eat and drink as soon as you feel ready.
- **Getting around and about:** You may have most of the catheters and drips removed the day after surgery and will be able to get up and walk around.

- **When you can leave 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.** The actual time that you stay in hospital will depend on your general health, how quickly you recover from the procedure and your doctor's opinion.
- **Once at Home:** It will probably take one to two weeks before you feel as well as you did the night 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 of the procedure

- 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 5.5 cms, the risk of rupture without surgery is usually higher than the risk of surgery. Therefore not operating and continuing to monitor the abdominal aortic aneurysm is not the safest option.
- **Open aneurysm repair** is an alternative technique. This is a larger operation where the aneurysm is repaired with a graft sewn in to the aorta through a larger incision in the abdomen.

Serious or frequently occurring risks

- 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, kidney failure or stroke, but 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.
- Overall, the incidence of major complications (including death) is in the region of one in every 70 patients but the risks may be increased in those patients who have pre-existing disease. The risk of death is three times lower than for open aneurysm repair.
- Other complications include graft infection and wound infection.

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- There is an extremely small chance that it may not be possible to maneuver the endovascular graft into the aorta and the surgeon may have to revert to open aneurysm repair.
 - Endovascular AAA repair (EVAR) 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 6 patients may require a further procedure at a later date. However if required 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.

Information and support

Additional information will be given to you in the form of patient information leaflets. Do feel free to contact the vascular surgery, Nurse Practitioner, Tel: 01223 245151 ext 6382 if you have any questions or anxieties.

Further information

- The Vascular Society's website: <http://www.vascularsociety.org.uk>

Your anaesthesia

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.

Before your operation

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. If you are a day case patient it may not be until just before your operation. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.

Pre-medication is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets, injections or liquids (to children). They relax you and may send you to sleep. They are not always given.

Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may have, so that you can forget your fears and worries.

Before your operation you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe. It is common practice nowadays to allow a parent into the anaesthetic room with children: as the child goes unconscious, the parent will usually be asked to leave.

During your operation

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 in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. 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. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you. Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel, and systems, such as Patient Controlled Anaesthesia (PCA) may be set up to continue pain control on the ward.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this

time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel completely normal immediately!

What are the risks of general 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 done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, 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, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.

Please ask if you require this information in other languages, large print or audio format: 01223 216032 or patient.information@addenbrookes.nhs.uk

Potete chiedere di ottenere queste informazioni in altre lingue, in stampato grande o in audiocassetta.

Italian

若你需要本信息的繁體中文、大字體或音訊格式的版本，請要求索取。

Cantonese

તમને આ માહિતી બીજી ભાષાઓમાં, મોટા અક્ષરોમાં અથવા સાંભળી શકાય એવા માધ્યમ (ઓડીઓ ફોર્મેટ)માં જોઈતી હોય તો કૃપા કરીને પૂછો.

Gujarati

Kurdish

تکایه پرسپیار بکه نه گهر نهو زانیاریهت دهوی به زمانیکی تر ، به پیتی گهوره یانیش به شیوهی دهنگ

Urdu

اگر آپ کو یہ معلومات دوسری زبانوں میں، بڑے الفاظ کی اشاعت میں یا آڈیو ٹیپ پروگراموں تو براۓ مہربانی اس کیلئے درخواست کریں۔



Addenbrooke's is smoke-free. Please do not smoke anywhere on the site.

For advice on quitting, contact your GP or the NHS smoking helpline free, 0800 169 0 169.

Document History

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Consent form 1

Patient agreement to investigation or treatment

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Responsible health professional/job title

.....

Special requirements
(For example, other language/other communication method)

Name of proposed procedure or course of treatment

Endovascular repair of abdominal aortic aneurysm

Side (left/right).....

Statement of health professional

(To be filled in by 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:

- The intended benefits of the procedure
 - Any serious or frequently occurring risks from the procedures including those specific to the patient
 - Any extra procedures that might become necessary during the procedure
- Blood transfusion Other procedure (please specify)

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

- The following information leaflet has been provided:
- Version/Date/Ref:

This procedure will involve:

- General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature: Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

- I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

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

Interpreter's signature..... Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will (eg Jehovah's Witness form)

Copy accepted by patient: yes / no (please circle)

<p>For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)</p>
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Statement of patient

Please read 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. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you.

You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** **If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	<input type="checkbox"/>		<input type="checkbox"/>

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: **Date:**

Name (PRINT):

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

Witness' signature: **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 s/he has no further questions and wishes the procedure to go ahead.

Signature Date:

Name (PRINT): Job Title: