Patient information and consent to Balloon dilation of the eustachian tube (BET)

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.

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

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x-rays or test results.

- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.

- 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. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Please call the hearing implant nurse practitioner on telephone number 01223 217589 if you have any questions or concerns about this procedure or your appointment.

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 health professional responsible for your care, 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.

Balloon dilation of the eustachian tube (BET), Document ID 100476, September 2017
What is BET?
BET is a short and simple procedure that uses a small balloon to stretch the blocked eustachian tube open again. The balloon is only left in place for a few minutes and at the end of the procedure everything is removed.

Why is BET done?
You have been offered BET because an assessment has suggested that your eustachian tube is not working properly and it is causing problems with your ear. The eustachian tube is a small structure that connects your ear to your nose, and it helps to control the pressure in the ear. When this tube becomes blocked, the pressure in your ear can cause unpleasant symptoms, hearing loss or glue ear. The most common symptoms are: a feeling of full or blocked ears, popping, clicking, or discomfort. This may be particularly problematic with changes of pressure such as flying, driving through tunnels or diving. In some cases the blockage may damage the ear drum. BET is a way of unblocking the eustachian tube to return the pressure in the ear to normal.

What to expect from BET
BET is a procedure that has been completed over 25,000 times internationally, but we are still learning more about how well it works. We believe that around 8 out of 10 people will notice a significant improvement in their symptoms. Frequently this will happen immediately after surgery, though in some individuals it takes a little longer before they notice the change.

Intended benefits
To stretch the blocked eustachian tube open again.

Does it hurt?
Many patients have no discomfort at all after BET, though mild discomfort may require you to take painkillers.

Who will perform your procedure?
This procedure will be performed by a member of the ear, nose and throat surgical team with suitable experience, working with a member of the anaesthetic team.

Before your procedure
During your consultation in clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigation.

You may change your mind about the operation at any time, and signing a consent form does not mean that you have to go ahead with the operation.

Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.
If you would like to have a second opinion about the treatment, you can ask your specialist or GP for referral to another specialist.

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 all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

This procedure involves the use of general anaesthesia. There are different types of anaesthesia or sedation that may be used. This is explained below. You will see an anaesthetist before your procedure and attend a pre-admission clinic.

You should be able to go home on the day of surgery, although it may occasionally be necessary to stay in hospital for one night.

**During the BET**

The procedure is performed using a camera and telescope to guide the BET balloon device through the nose and into the end of the eustachian tube. No cuts are required and there will be no external sign that you have had surgery. The balloon is inflated to a high pressure with a special syringe, and left in place for two minutes. The device is then removed completely and so nothing is left within the tube. BET may be performed on its own, or at the time of other ear or nose surgery. It can be performed on both left and right eustachian tubes in the same operation.

**After the BET**

Once your surgery is completed, you will usually be transferred to the recovery ward where specially trained nurses will monitor you closely. Most patients who have BET alone will go home the same day, although you should come prepared for an overnight stay.

**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**

After this procedure, you will be able to drink sips of water when you return to the ward. After a couple of hours, you will be able to have a light meal.

**Getting about after the procedure**

We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. If you have any mobility problems, we can arrange nursing or physiotherapy to help.
Leaving hospital
Most people who have had this operation will be able to leave hospital on the day of surgery or the following morning. The head bandage may be removed before you leave hospital, or you may be advised to remove it yourself at home the day after surgery. There is sometimes some dizziness but this usually settles quickly. You should be able to drive the next day.

Resuming normal activities including work
Usually you can resume light activities after 24 hours, and normal activity after a few days.

Special measures after the procedure
- We recommend that you avoid straining and blowing to pop your ears for two weeks.
- We may provide you with a nasal spray to use after the surgery.

Check-ups and results
We will arrange to see you again in clinic to find out how you are doing and assess your hearing and ear pressure.

Significant, unavoidable or frequently occurring risks of this procedure
There are some risks that you must be aware of before giving consent to this treatment. These potential complications are rare. You should consult your surgeon about the likelihood of problems in your case. Although the procedure is becoming widely used, the rate at which some complications occur is not fully known.

Anaesthesia
There are risks associated with general anaesthesia which have been detailed in the previous sections, but can be discussed with the anaesthetist on the day of the surgery.

Bleeding
Opening the eustachian tube with BET can cause small amounts of bleeding. As this occurs at the back of your nose and usually stops quickly you may not be aware that it has happened (1 in 10 risk). Occasionally the blood can collect in the middle part of the ear and cause hearing loss until the blood drains away, either naturally or with a small operation (1 in 1000 risk).

Infection
Sometimes an ear infection can occur after BET. The infection can usually be easily treated with antibiotic tablets or ear drops. (Less than 1 in 100 risk)

Tinnitus (ringing in the ear)
If you have tinnitus (ringing or other sounds in the ear) it is possible that this will be worse after BET. Where this has occurred it has been temporary. (Less than 1 in 100 risk)
Facial swelling
Small tears may occur in the eustachian tube after BET. This is normal, but it can allow small amounts of air to escape into the tissues below the skin, causing some swelling. The risk of this complication can be reduced by not trying to pop your ears in the period after surgery. (1 in 1000 risk)

Possible risks not yet seen
So far there have been no reports of scarring causing problems inside the eustachian tube, but in theory this could occur. This could make the blockage return, possibly worse than before the surgery. In theory, there is also the risk of injury to one of the major blood vessels supplying the brain: the internal carotid artery. Injury to this blood vessel could result in major bleeding or stroke. However, the equipment and procedure are designed in a way to avoid this, and for this reason it has never occurred. As with any surgery in the ear, there is an extremely small chance of permanent hearing loss. To date, no hearing loss has been reported from BET.

Alternative procedures that are available
Alternatives to this surgery are no intervention or insertion of a ventilation tube (grommet) into your ear drum. Ventilation tube insertion can help some patients, but often makes symptoms worse and then requires removal. You will not come to harm if you opt for no treatment at all.

Information and support
Please contact the hearing implant nurse practitioner on telephone number 01223 217589 if you have any further queries.

Anaesthesia
Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. BET is performed under a general anaesthetic so you will be fully asleep for the duration of the operation.

Before your operation
Before your operation you will meet an anaesthetist who will discuss with you the type of anaesthetic they will use, and the pain relief after your surgery.

The anaesthetist will need to know about:

- Your general health, including previous and current health problems, and 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 will review your test results and may need to listen to your heart and lungs, ask you to open your mouth or move your neck.

**Pre-medication**

You may be prescribed a ‘pre-med’ prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief or reduce the risk of you being sick. Not all patients will be given a pre-med 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 and **before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.**

Once that is complete, 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 oxymeter). An intravenous line (drip) may be inserted. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.

**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.

**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.
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.

For more information about anaesthesia, please visit the Royal College of Anaesthetists website: [www.rcoa.ac.uk](http://www.rcoa.ac.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.
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 now a smoke-free site: smoking will not be allowed anywhere on the hospital site.
For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.info@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history

Authors: James Tysome, ENT Consultant
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Balloon Dilation of the Eustachian tube

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)

   Improved eustachian tube opening to improve ear symptoms / glue ear / ear drum abnormalities*

   *delete as appropriate

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

   • Bleeding
   • Infection
   • Tinnitus
   • Facial swelling
   • Scarring
   • Carotid injury
   • Hearing loss

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:
Balloon Dilation of the Eustachian tube

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

2 The following information leaflet has been provided:

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Version, reference and date: Version 1, 100476, September 2017
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.
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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File: in the procedures and consents section of the casenotes

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Balloon Dilation of the Eustachian tube, v1, September 2017
Consent Form

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.

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: ..............................................................

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

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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: .................................
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: .................................
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: .................................
Signed (Health professional): .......................................................... Date: .................................
Name (PRINT): .............................................................. Job title: ..............................................................