

Balloon pulmonary angioplasty

A patient's guide and
consent form

Introduction

Chronic thromboembolic pulmonary hypertension (CTEPH) occurs in approximately 2-4% of patients who are diagnosed with blood clots on the lungs (pulmonary emboli). The conventional treatment for CTEPH is surgical removal with pulmonary endarterectomy but not all patients are suitable for this and in some patients the surgery does not fully remove the narrowings in the lung blood vessels (pulmonary arteries).

Balloon pulmonary angioplasty (BPA) is a well-established procedure that targets these narrowings and has been shown to lower the blood pressure in the lung arteries, improve breathing and increase exercise tolerance in carefully selected patients.

Observational data suggests that survival is similar after both surgery and BPA, however no direct comparison has been published. Surgery remains the preferred option for those in whom it is suitable, giving the best chance of an effective 'cure' for the condition.

How is BPA performed?

On average, BPA usually involves four catheter lab treatment sessions, each lasting approximately 90 minutes, spaced two to six weeks apart. The procedure is staged this way to minimise the risk of procedure related side effects to the kidneys (from the contrast medium used) and lung from reperfusion injury (see explanation below).

The procedure is performed under a light sedation and local anaesthetic; this means that you are given a combination of medicines to help you relax and to block the pain. You may feel very sleepy but will be able to respond to instructions.

A small tube is placed in a vein in the groin and a second hollow tube is then introduced through this and passed to the lung vessels.

The narrowed vessels are identified by injections of iodine containing contrast medium into individual vessels while performing X-ray imaging.

A very fine wire is then passed into the vessels to be treated and a balloon guided into position over the wire. The balloon is then inflated for a few seconds to push the blockage aside (see figure one) and restore blood flow to that segment of lung tissue. The balloon is then deflated and removed.

This may be repeated several times and in multiple vessel locations during a single treatment session. You might feel drowsy after the procedure and may not remember much about what happened.

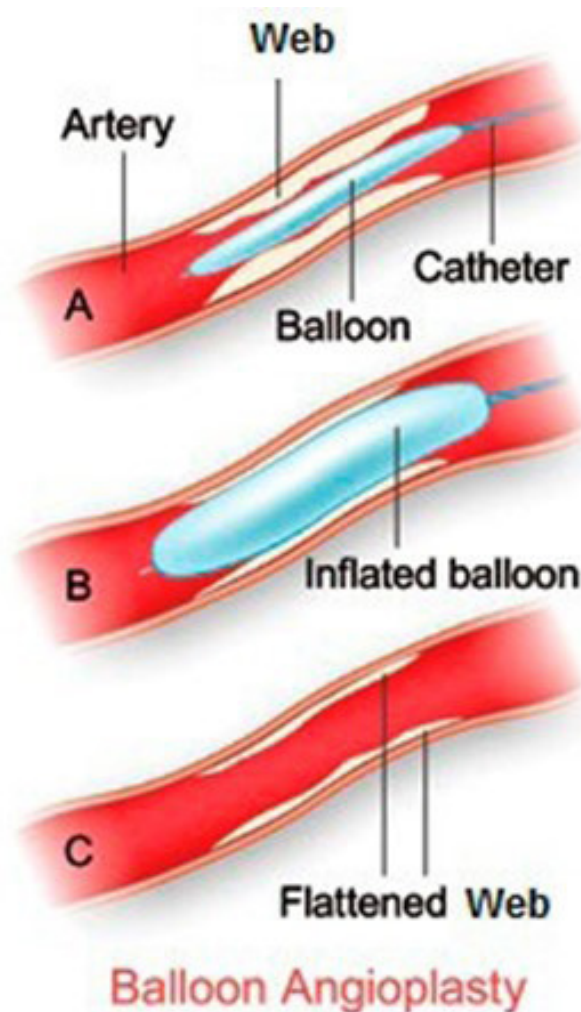


Figure 1
Balloon Angioplasty

Benefits of BPA

BPA can significantly improve breathlessness, lower lung blood vessel pressures and reduce the work your heart does. The effects are persistent at least over several years, though most patients will need to continue treatment for residual pulmonary hypertension.

Risks of BPA

BPA is associated with a risk of death, major bleeding requiring emergency surgery or the need for procedures to support the heart and lungs of less than 1% (1 person in 100).

Around 10% (1 person in 10) may experience short term deterioration in breathlessness and may cough up blood or fluid from the treated area of the lung. This is often termed reperfusion injury and occurs when lung tissue with a poor blood supply is rapidly resupplied with blood.

This is usually managed with a simple oxygen mask and medicines but occasionally requires tight-fitting mask supplying oxygen that supports your breathing. In rarer occasions it may require you to be given a general anaesthetic to allow a machine to support your breathing.

The reperfusion injury usually resolves spontaneously, within 24 - 48 hours. Your breathing will be monitored closely after your procedure for any early signs of this.

There is a 1% (1 person in 100) chance that the contrast medium given may cause damage to the kidneys. This usually responds to supportive measures but rarely (less than 0.1% or 1 person in 1,000) may require temporary kidney supportive treatment with dialysis. We may give you fluid to help the kidneys flush out the contrast medium.

There is also a 0.1% (1 person in 1,000) chance of contrast medium allergy that may require supportive treatment.

There is a 0.1% (1 person in 1,000) risk of vascular damage in the groin vein that may require surgical repair.

It is more common (10% or 1 in 10 patients) to have bruising or a collection of blood called a haematoma after the procedure. This may be painful. You will be asked to lie flat and rest after the procedure while the vessel is compressed to avoid bruising.

Procedure

Pulmonary angioplasty is performed under mild sedation in the catheter lab department and usually takes one to two hours.

The room is a little cold to prevent the apparatus from over-heating. The procedure is performed under local anaesthetic which is injected into the skin. A small tube (catheter) is passed into the vein in your groin. The X-ray table and machine move around you to obtain the best pictures.

A dye which shows up under X-ray is injected into the catheter. This can cause a warm feeling all over the body for a few seconds. The X-rays are taken at this point. The pulmonary angioplasty is not painful, but sometimes you may feel the urge to cough. Do not worry, this does not mean anything is wrong, but do tell the doctor.

During the procedure you will be asked to breathe in and hold your breath. This stretches and stabilises the vessels for the doctors to work on. While the doctors will let you know when it is okay to breathe again, if you need to breathe, it is okay to do so, as this can be seen happening on the X-ray machine, and the doctors can simply wait until you are next ready to hold your breath.

When the procedure has been completed the tube will be removed from your groin and pressure will be applied either manually or using a compressing device to stop the bleeding. You will then be returned to the ward and the groin area will continue to be monitored by the ward nurse.

It is important not to move excessively for around two hours after the procedure to reduce the chance of bleeding in your groin.

On return to the ward

You will be required to stay in bed for approximately two hours after the groin approach: one of these hours will be lying relatively flat. After this you will be assisted to sit up and then mobilised.

Your vital signs will be taken regularly after the procedure and you will have a chest x-ray. Your breathing will be monitored closely and some patients might require oxygen for the first few hours after the procedure.

You will be offered something to eat and drink after your procedure and you might be encouraged to drink plenty of water to flush the contrast dye from your body. The pulmonary hypertension (PH) team will advise you about this.

Your blood thinners will be restarted a few hours after the procedure.

Delay

Sometimes your procedure may be unavoidably delayed due to emergency cases and, on rare occasions this may lead to your procedure being cancelled.

Results

Your results and the planned treatment will be discussed with you before you go home by both the doctor and the nurse. You will be given a letter for your GP.

Discharge information

Most patients remain in hospital for one night after the procedure. You will be discharged when the pulmonary hypertension team think you are well enough.

Potential complications following BPA

Please note that complications following BPA are extremely rare. However, it is important that you know what to look for, and what to do if a problem does arise.

Increasing breathlessness

If you find that you are getting more breathless when you go home, please seek medical attention (see your GP straight away, or attend an A&E department), especially if you have any of the following symptoms:

- Fast irregular heartbeat (new)
- Feeling faint or dizzy
- New chest pain
- Worsening shortness of breath
- Coughing up blood
- Worsening ankle swelling or swelling of the tummy
- Worsening pain, and/or new bruise in the groin (femoral puncture site)

Bruising at the femoral puncture site

It is common to have bruising to your groin and leg; sometimes this can spread to your abdomen.

Care of your femoral puncture site

- Do not drive for 48 hours following the procedure.
- Apply pressure to the wound site when you climb a flight of stairs for 48 hours after your procedure.
- Apply pressure to the wound site when you cough or sneeze for 48 hours after your procedure.
- Avoid heavy lifting and strenuous exercise for 48 hours following your procedure.
- If your groin bleeds, please do not panic, lie down flat and get someone to apply pressure to your groin until the bleeding stops, this can take up to 10-15 minutes. Seek medical attention.
- You will have a small plaster over the incision site; this should be removed the day after your procedure. You may bath or shower the day after your procedure but avoid putting talcum powder on or around the wound site until the wound has healed.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

PIC 168: patient agreement to PI 168 - Balloon pulmonary angioplasty

Intended procedure/surgery

Statement of healthcare professional

(To be filled in by healthcare professional with appropriate knowledge of proposed procedure, as specified in consent policy).

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

The intended benefits:

.....

.....

Significant, unavoidable or frequently occurring risks:

- Breathlessness
- Coughing up blood
- Damaged vessel
- Bleeding and bruising
- Allergic reaction to dye
- Death

- ☐ Additional risks specific to you or your operation - please specify below:

.....

.....

.....

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

Extra-corporeal membrane oxygenation (ECMO)

Invasive ventilation

- ☐ Other procedure - please specify below:

.....

.....

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

Healthcare professional

Signed:

Date:

Name (PRINT):

Job title:

Contact details

.....

.....

Has a ReSPECT form been considered and, if relevant, appended to this form?

☐ Yes

☐ No

Statement of patient

Please read the patient information and this form carefully. If the treatment has been planned in advance, you should already have your own copy of which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

Yes No

☐

☐

I agree to the procedure or course of treatment described on this form and have read this information leaflet on balloon pulmonary angioplasty (PI 168) and had the opportunity to ask questions.

☐

☐

I agree to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.

- I understand what the procedure is and I know why it is being done, including the risks and benefits.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:



Royal Papworth Hospital

NHS Foundation Trust

- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

.....
.....
.....
.....

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

☐ Yes ☐ No

(Where patient indicates 'yes' health professional to refer to Trust CJD procedure DN092)

Statement of interpreter (where appropriate)

If an interpreter was present to support this consent, please state the name and number of the interpreter present:

Date:

Interpreter's number:.....

Name (PRINT):

If a telephone / video service has been used, please document the name of the interpreter and company below

.....
.....
.....

Top copy to be filed in medical notes, carbon copy to be retained in booklet for patient.

Patient

I consent to having unlimited procedures as described in this leaflet for a period of six months from:

Date:.....

to (and including)

Date:.....

Patient 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 they have no further questions and wish the procedure to go ahead.

Signed:

Date:

Name (PRINT):

Job title:

Important notes (tick if applicable).

☐ Patient has advance decision to refuse treatment

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

Patient signature:

Date:

Name (PRINT):

Please use and attach Consent form C for a young person who is not Gillick competent.

Recommended summary plan for emergency care and treatment (ReSPECT)

What is ReSPECT?

ReSPECT stands for 'Recommended summary plan for emergency care and treatment'. It is a process that helps people to think about what treatment is suitable in an emergency, should they be unable to make decisions at the time.

Why is it important?

We know that, when people are very unwell, they are often unable to think clearly about what treatment they may or may not want because their brain and body are overwhelmed by the illness. It is also normal for people to feel anxious about what is happening when they are sick and in hospital, and this can also make it difficult to think clearly. This is why we think it is a good idea, where possible, for decisions about medical treatment to be made in advance – before there is an emergency situation or crisis.

How does it work?

The ReSPECT process is designed to help conversations between you and your healthcare professionals: they need to make sure you understand your health problems and which treatments may or may not benefit you. You need to make sure the healthcare professionals understand what matters most to you and whether there is anything you are particularly worried about or would want to avoid.

This conversation is used to complete a ReSPECT form that records a person's health problems, their preferences and which medical treatments may or may not be suggested. The original form should stay with the patient, though it is extremely helpful to have a record of the content of the form on their electronic patient record.

A ReSPECT form is NOT a legally binding document and can be changed or withdrawn at any point.

The ReSPECT form is often used to indicate treatments that someone may not want and/or treatments that their healthcare professionals consider would no longer be of benefit to them.

If people are getting worse from progressive conditions, it may be helpful to consider in advance about things such as whether they would wish to go back into hospital and, if in hospital, what sort of treatments might or might not be helpful for them.

This often includes a decision on whether or not they should have attempted cardiopulmonary resuscitation (CPR) if their heart was to stop.

Who is it for / is this relevant for me?

This process has increasing relevance for people who have complex health needs, people who may be nearing the end of their lives and those who are at risk of sudden deterioration or cardiac arrest.

However, many people come to Royal Papworth to have major procedures or surgery with the intention of curing a progressive disease or with the intention of substantially prolonging their life and, if that is you, you may wonder how a ReSPECT discussion applies to you and others like you. One of the key things to understand about the ReSPECT process is that it can be used simply to document a person's wishes and priorities, without setting any limitations on what treatment they should have.

This is important because all the procedures and operations we do here come with the risk of complications. In the unlikely event that things do not go as planned, it is really helpful to have some idea about a person's preferences and about their fears, worries and hopes.

Once again, the document is not legally binding, but it can help those looking after you to know what you might want if you weren't able to say for yourself.

- Two to three days following the procedure, for up to about a fortnight, you may notice a small pea or marble sized lump at the incision site, this is normal healing. If the lump is bigger than this, or if you experience pain or redness around the area, please contact your GP.
- Our specialist nurses will contact you one week after discharge to check on your progress. If you have queries you can contact the specialist nurses on 01223 638826. If your query is urgent you can contact via the hospital switchboard on 01223 638000 and ask for bleep 343.
- A pulmonary hypertension consultant is available via the Royal Papworth Hospital switchboard for medical advice if the pulmonary hypertension nurse is unable to answer your query.

Medication

- Remember – your anticoagulation is lifelong.
- Your anticoagulation is usually stopped temporarily before your procedure and will be advised accordingly.
Anticoagulation is normally re started in the evening after your procedure.
- If you take warfarin and it has been interrupted prior to your procedure it is common to take higher doses for a few days to 'reload' before continuing on your usual maintenance dose. You should have your INR checked approximately five days after your procedure at your usual anticoagulant clinic. You will probably be discharged with heparin injections to self-administer until your INR is two or above two.
- If you take another type of anticoagulation, you will be advised when to restart and you will return to your usual dose and timing.
- If you take metformin; recommence this 48 hours after the procedure.

Follow-up visits

After you first BPA procedure you may be invited back to Royal Papworth for further procedures.

The cardiologist who performs your BPA procedure will normally let you know if further BPA procedures are required.

Once the cardiologist and PH team at Royal Papworth are satisfied that your BPA series is completed you will be invited back to Royal Papworth after about three months for a re-evaluation including pulmonary angiogram and right heart catheter. The purpose of this is to see what kind of a difference the BPA procedures have made to the pressures in your lungs and your symptoms and to check for any further targets for BPA.

If you have been referred to Royal Papworth from one of the other PH specialist centres in the UK, once you have completed your BPA procedures and had your follow up review you will not need to return to Royal Papworth Hospital.

Travel to Royal Papworth Hospital

You will have to make your own way to Royal Papworth Hospital NHS Foundation Trust for BPA procedures or follow up visits. If you need assistance with transport, please contact your GP or let us know in advance so we can explore way of assisting you. If you are receiving certain low income allowances, eg income support or family credit, you may be entitled to help with you travel costs. If you need someone to travel with you for medical reasons, you may also get help with their travel costs. Travel costs payable are those "necessarily incurred". This means travel by the cheapest means of transport available at the time you need to travel.

Research

Royal Papworth Hospital is a teaching hospital, and as such, you may be approached to participate in research.

**Pulmonary vascular disease unit (PVDU)
contact details**

If you have any queries or questions do not hesitate to contact the PVDU nursing team:

- Monday-Friday 09:00-17:00 on 01223 638826.
- Any other time via the Royal Papworth Hospital switchboard on 01223 638000 and ask for bleep 343 (NB: out of office hours this will be answered by a ward nurse)

Royal Papworth Hospital NHS Foundation Trust

A member of Cambridge University Health Partners



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royalpapworth.nhs.uk



01223 638000

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View a digital version of this leaflet by scanning the QR code.



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