Patient Information to be retained by patient

NHS
Royal Cornwall Hospitals
NHS Trust

Percutaneous coronary intervention (angioplasty) +/- rotablation

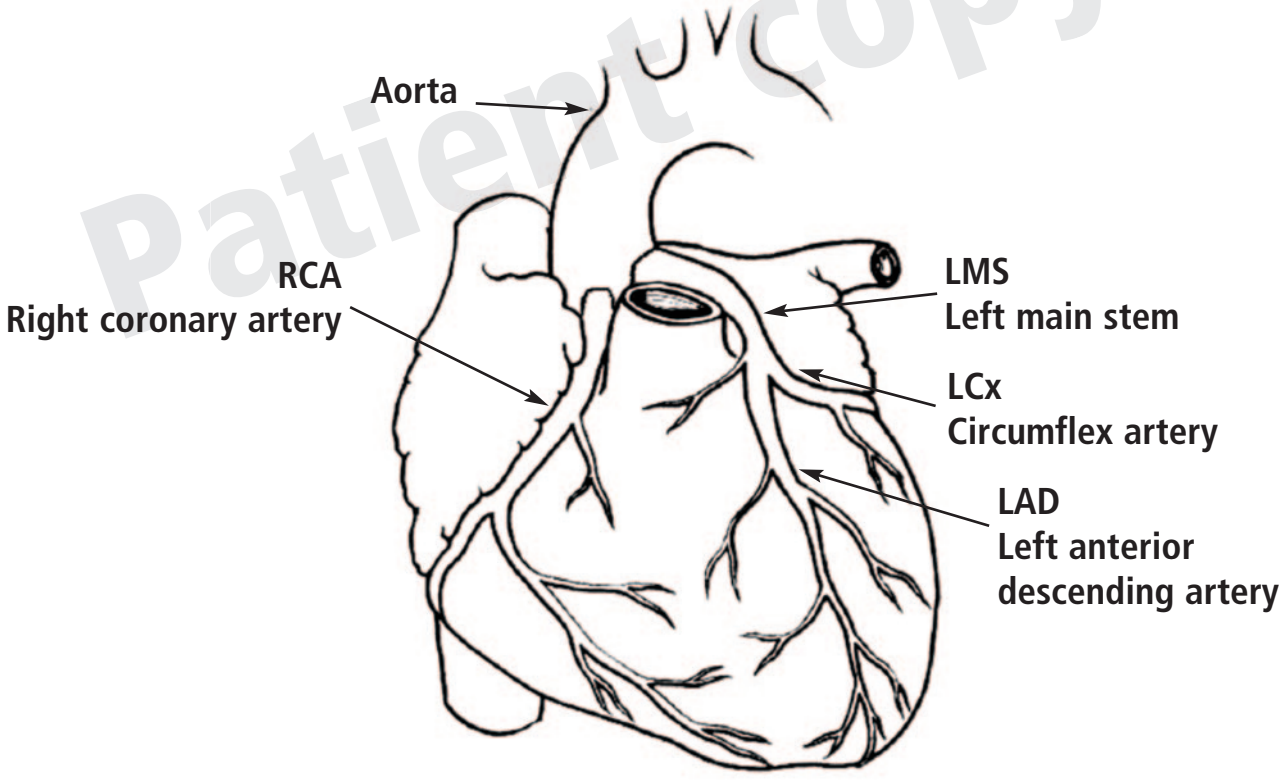
affix patient label

Why do I need this procedure?

If you are coming into hospital for a cardiac procedure this means that you may have heart disease or need to be assessed to confirm you do not have heart disease. The doctor may also gain information about your heart valves and how well your left ventricle (the main pumping chamber) is working.

The most common heart diseases are:

- **Coronary artery disease** – the coronary arteries supply blood to the heart. There are two main arteries, the left and right, which in turn divide into branches. In coronary artery disease one or more of these arteries becomes narrowed or blocked with fatty deposits called atheroma. The pain or discomfort caused when not enough blood gets to the heart muscles is called angina.
- **Heart valve disease** – your heart contains four valves which make sure that when the chambers of the heart contract, the blood flows in the right direction. If not working correctly, these valves can affect the flow of blood through the heart. Two main valve problems occur: the valve opening may be narrowed, reducing the flow of blood through the valve (called stenosis) or the valve may leak, allowing blood to flow back in the wrong direction (called regurgitation).



You may be coming to the Royal Cornwall Hospital (Treliske) for one or more of the following procedures:

- a coronary angiogram to assess your coronary arteries and/or heart valves. It is used to decide on the most appropriate treatment for you
- **a percutaneous coronary intervention (PCI) – also known as angioplasty or stenting**
- an angiogram with the potential to proceed to percutaneous coronary intervention.

What is a coronary angioplasty?

You will already have had an initial angiogram with the aim of gathering important information about the structure and function of your heart; looking at your arteries, heart valves and to see how well your heart pumps. This information was then used to decide if you need the second stage of the procedure called an angioplasty (also known as stenting or PCI).

Stage 2 Angioplasty - if a narrowed or blocked artery is identified, and you agree with your specialist doctor, they will proceed to treating the identified problem with a treatment known as a coronary angioplasty. A small inflatable balloon on the tip of a narrow tube (called a catheter) is passed through the artery in either your groin or arm until its tip reaches the narrowed section in the coronary artery. The balloon is gently inflated so that it squashes the fatty tissues responsible for narrowing the artery. A stent (a short tube made of stainless steel mesh) may also be inserted. The stent stays in the artery and often has a special drug coating to prevent the artery re-narrowing.

What will happen on the day of my procedure?

You will usually come in to hospital on the day of your procedure. A nurse will complete a pre-procedure check list and you will be given a hospital gown to change into. A specialist doctor will explain the procedure to you and ask you to sign the consent form to confirm that you understand the procedure and agree to go ahead with it. Please ask any questions you want. A porter will take you to the Cardiac Catheter Lab where you will have the procedure.

What does it involve?

On the whole, this lasts about 45-90 minutes depending on how many arteries are to be treated.

1. You will lie on a table which can be moved around, mounted above is the X-ray machine.
2. You will have an injection of local anaesthetic into the top of your leg or wrist to numb it.
3. A small plastic tube (called a sheath) is inserted into your blood vessel to keep it open.
4. A guide catheter is first passed into your artery and then a balloon catheter is guided into the narrowed or blocked coronary artery.
5. When it reaches the narrow part, the balloon is inflated to stretch and widen the artery.
6. When the balloon catheter is removed, normal blood flow can resume.
7. This may need to be done several times to successfully widen the artery.
8. In most patients, the artery needs some support to remain open wide after the angioplasty. In this case a stent may be inserted into the narrow part of the artery to hold it open.
9. The procedure may then be repeated for other narrowed heart arteries.
10. If the artery is very calcified (has a large build-up of hardened material inside) it is sometimes necessary to remove this hardened material before inserting the stent. This is called rotablation.
11. When the test is over the catheter is gently removed. If it was inserted in your wrist, a bracelet with a pressure pad is applied and inflated, which is slowly released by ward staff on return to the ward. If the catheter was inserted in your leg a special closure device called an Angioseal may be used.

Ionising radiation exposure

The proposed procedure involves the use of X-rays (ionising radiation). The amount will vary depending on the length of the procedure and is often measured as an equivalent of background radiation. Background radiation is

the very low dose of radiation that we are exposed to naturally, every day of our lives. The amount of excess radiation you receive has the potential to cause short term (reddening of the skin, burns) and long term effects. Radiation exposure carries a very small risk of developing cancers in the future. We take the upmost care to keep radiation doses as low as possible to gain the information needed for the management of your condition.

What is rotablation?

A rotablator is a miniature diamond-studded drill, which is used to treat calcified lesions prior to an angioplasty. Also known as rotational atherectomy, the plaque is ground into tiny particles, which are safe to be released into the blood stream. A rotablator machine makes a noise similar to a dentist's drill.

X-rays help guide the catheter to your heart. As previously, a dye (contrast) is injected to visualise the arteries. When the catheter and wire are in the correct position, the consultant will use the rotablator to grind down the plaque prior to inflating a balloon and stent within this area. During this time you may experience some discomfort similar to your angina. Analgesia can be given if required.

Will I have any pain or discomfort?

You will have a local anaesthetic injection to numb the area where the catheter is inserted. The cardiac catheterisation is not painful, but you may feel a slight discomfort like an angina pain. Don't worry about this (it doesn't mean anything is wrong) but do tell your doctor. If you have an angioplasty, when the balloon is blown up you may feel a brief chest pain like angina. Don't worry, but do tell the doctor.

Bleeding or bruising and soreness can occur around the site of the sheath. This can be made worse if you are on anti-clotting drugs. The bruising will disappear in two to three weeks.

What happens afterwards?

Following your procedure you will return to the ward where an ECG will be obtained. The nurse looking after you will commence regular observations of your blood pressure, pulse and wound site.

The contrast used in the procedure is excreted via your kidneys. This can often mean that you feel the need to urinate (pass water) more frequently afterwards or have visual disturbances. You will be encouraged to drink plenty of fluids to aid this process. You may eat and drink normally.

You may be able to be discharged later in the day, or it may be necessary to stay overnight. You must have someone to drive you home. The nursing team will discuss your post procedure advice with you.

How will I get my results?

The doctor will discuss your results with you before you are discharged. If the X-rays show a blockage or narrowing of your coronary arteries, medical therapy (tablets), a coronary angioplasty or bypass operation may be recommended to treat the problem. If damage to your heart valves is identified, heart valve treatment may be recommended. A letter explaining this will be sent to your GP.

What happens when I go home?

- Please ask a friend or relative to collect you and accompany you home.
- You can resume normal activities after 48 hours.
- If the wound in your wrist or leg becomes red, itchy or swollen contact your GP.
- If you have had a stent, you will be provided with a 28 day supply of the correct tablets to take home with you. It is very important to continue taking the prescribed medication for the stipulated time periods. The dual antiplatelet treatment is usually continued for between 4 weeks and 12 months and must be taken regularly to help prevent the stent from blocking due to a blood clot.

When can I drive?

You can usually resume driving one week following the procedure.

Are there any risks or complications?

Generally, coronary angioplasty is a very safe treatment, but as with all procedures there are some small risks.

- Bleeding or bruising, especially around the area where the catheter was inserted. This can be made worse if you are on anti-clotting drugs.
- Allergic reaction to the dye (risk: 1% or 1 in 100). This is usually very mild and temporary, such as a skin rash.
- Sometimes, it is not possible to stretch the artery (in 5% of cases) and, very occasionally, the treatment can make matters worse (in 1% of cases); in this event an operation may be required. It is always worth trying angioplasty first.
- Occasionally a heart pump catheter may be used. This involves putting a tube through the blood vessel in your groin, which will then sit inside your heart chamber and helps to move the blood around your body. The tube is usually removed at the end of the procedure.

For standard elective patients:

- A heart attack, stroke or death (risk: 0.5-1% or 5 in 1000 to 1 in 100).

For higher risk inpatients:

- A heart attack, stroke or death (risk: 1-3% or 1 to 3 in 100).

For rotablation inpatients:

- A heart attack, stroke or death (risk: 3-5% or 3 to 5 in 100).

For emergency inpatients:

- A heart attack, stroke or death (risk: 3-10% or 3 to 10 in 100, or even more in cardiogenic shock).

Please feel free to ask your cardiologist where you are on this risk score.

For some patients the risks may be higher; please speak to your specialist doctor before your procedure if you have any worries.

Any questions?

If you need any more information, have any queries or experience problems with your puncture site at any time following your procedure, please contact the Cardiac Investigation Unit on 01872 252226 or 01872 255952.

Further support and information is available from the:

British Heart Foundation
08450 708070
www.bhf.org

British Cardiac Society
020 7383 3887

If you would like this leaflet in large print, Braille, audio version or in another language, please contact the General Office on 01872 252690

Patient copy

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

NHS
Royal Cornwall Hospitals
NHS Trust

NHS number: .....
Name of patient: .....
Address: .....
Date of birth: .....
CR number: .....

AFFIX PATIENT LABEL

Percutaneous coronary intervention (angioplasty) +/- rotablation

Treatment of narrowing in the vessels supplying blood to the heart muscle, guided by X-rays. This procedure usually involves balloon dilation and/or stenting.

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health 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:

- To diagnose and manage heart disease (angina, breathlessness or heart attack)

Significant, unavoidable or frequently occurring risks:

- Bleeding, bruising, infection and pain

Uncommon but more serious risks:

- **For standard elective patients** – myocardial infarction (heart attack), stroke, damage to blood vessels (including those supplying the heart), dangerous heart rhythms or death (Occurs 0.5-1% or 5 in 1000 to 1 in 100).
- **For higher risk inpatients** – myocardial infarction (heart attack), stroke, damage to blood vessels (including those supplying the heart), dangerous heart rhythms or death (occurs 1-3% or 1 to 3 in 100).
- **For emergency inpatients** – myocardial infarction (heart attack), stroke, damage to blood vessels (including those supplying the heart), dangerous heart rhythms or death (occurs 3-10% or 3 to 10 in 100, or even more in cardiogenic shock).

Uncommon possible later issues:

- Sensitivity to the contrast agents, impairment of kidney function (usually reversible), major bleeding (including retro-peritoneal bleed) requiring urgent operation and compartment syndrome (bleeding into tissues causing pressure effects).

Any extra procedures which may become necessary during the procedure:

- Blood transfusion (required very infrequently)
- Other procedure (please specify): Emergency transfer to tertiary centre (Plymouth/Bristol/London) for coronary artery bypass grafting (open heart surgery)

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

I have given and discussed the Trust's approved patient information leaflet for this procedure: Percutaneous coronary intervention (angioplasty) +/- rotablation (CHA3087) which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: ☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Health Professional signature: ..... Date: .....

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

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: ..... Name (PRINT): ..... Date: .....

affix patient label

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given 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.

I agree to the procedure or course of treatment described on this form.

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

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 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 understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

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

.....

I have received a copy of the Consent Form and Patient Information leaflet: Percutaneous coronary intervention (angioplasty) +/- rotablation (CHA3087) which forms part of this document.

Patient signature: ..... Name (PRINT): ..... Date: .....

A **witness** should sign below if this patient is unable to sign but has indicated his or her consent.
Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: ..... Name (PRINT): ..... Date: .....

CONFIRMATION OF CONSENT (to be completed by 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.

Health Professional signature: ..... Date: .....

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

Important notes (tick if applicable):

☐ See advance decision to refuse treatment ☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ..... Name (PRINT): ..... Date: .....

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