



Coronary Angioplasty and Stenting

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A. Interpreter / cultural needs

- An Interpreter Service is required? Yes No
- If Yes, is a qualified Interpreter present? Yes No
- A Cultural Support Person is required? Yes No
- If Yes, is a Cultural Support Person present? Yes No

B. Condition and treatment

The doctor has explained that you have the following condition: *(Doctor to document in patient's own words)*

.....

This condition requires the following procedure. *(Doctor to document - include site and/or side where relevant to the procedure)*

.....

The following will be performed:

After an injection of local anaesthetic, a fine tube (catheter) is put into the artery in the groin or arm. The tube is carefully passed into the affected part of the artery using x-rays. A tiny wire is passed down the artery so a sausage shaped balloon can be passed over it and into the part that is narrowed or blocked.

To open up the artery, the balloon is blown up with fluid, which then presses against the plaque, pushing it out of the way.

Most of the time, one or more stents may be placed in the artery to help keep the artery open. A stent is a metal tube or spring coil. This is passed into the diseased part of the artery using a balloon. The balloon is removed once the stent is in place.

The stent stays in for life. After the procedure, you will be given drugs, which reduce your risk of blood clotting and blocking the stents.

At the end of the procedure the artery may be closed with a special plug to stop the bleeding.

C. Risks of coronary angioplasty & stenting

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment. The risks are higher if you are having the procedure for a heart attack.

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (more than 5%) include:

- Minor bruising at the puncture site.
- The coronary artery can become narrowed or blocked again. Many factors can influence this and your doctor will discuss these with you.
- Loss of pulse in the arm after a radial artery (arm) procedure.
- Major bruising or swelling at the puncture site.

Uncommon risks and complications (1- 5%) include:

- Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
- A heart attack.
- Surgical repair of the groin/arm puncture site or blood vessel.

Rare risks and complications (less than 1%) include:

- The stent may suddenly close within the first month. This can cause angina or heart attack. It may be treated with another angioplasty or with surgery.
- Emergency heart surgery due to complications with the procedure.
- A reaction to the drugs given to prevent blood clotting.
- Minor reaction to the x-ray dye such as hives.
- Loss of kidney function due to the side effects of the x-ray dye.
- A stroke. This can cause long term disability.
- An allergic reaction to the x-ray dye.
- A higher lifetime risk from x-ray exposure.
- Rupture of a blood vessel requiring surgical repair and blood transfusion.
- Skin injury from radiation causing reddening of the skin.
- Death as a result of this procedure is rare.

If you are having angioplasty and stenting treatment for a heart attack, the risk of poor outcomes may be higher than the risks above and depend on the severity of the heart attack.

PROCEDURAL CONSENT FORM



Coronary Angioplasty and Stenting

Facility:.....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

G. Patient consent

I acknowledge that the doctor has explained;

- my medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- other relevant procedure options and their associated risks.
- my prognosis and the risks of not having the procedure.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- the procedure may include a blood transfusion.
- tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- a doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheet/s:

Local Anaesthetic and Sedation for Your Procedure

Angioplasty and Stenting

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

On the basis of the above statements,

I request to have the procedure

Name of Patient:.....

Signature:.....

Date:.....

Patients who lack capacity to provide consent

Consent must be obtained from a substitute decision maker/s in the order below.

Does the patient have an Advance Health Directive (AHD)?

Yes ▶ Location of the original or certified copy of the AHD:

No ▶ Name of Substitute Decision Maker/s:

Signature:

Relationship to patient:

Date:..... PH No:

Source of decision making authority (tick one):

- Tribunal-appointed Guardian
- Attorney/s for health matters under Enduring Power of Attorney or AHD
- Statutory Health Attorney
- If none of these, the Adult Guardian has provided consent.

H. Doctor/delegate statement

I have explained to the patient all the above points under the Patient Consent section (G) and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of Doctor/delegate:

Designation:

Signature:

Date:.....

I. Interpreter's statement

I have given a sight translation in

.....
(state the patient's language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of Interpreter:

Signature:

Date:.....

1. What is a coronary angioplasty and stenting?

Angioplasty and stenting is often used instead of surgery to deal with narrowed or blocked coronary arteries. The procedure is performed in much the same way as a coronary angiogram.

You will have the following procedure:

A needle with a tube connected to it will be put in your arm. This is called an intravenous line or IV.

After an injection of local anaesthetic, a fine tube (catheter) is put into the artery in your groin or arm. The tube is carefully passed into the affected part of the artery using X-rays. A tiny wire is passed down the artery so that a sausage shaped balloon can be passed over it and into the part that is narrowed or blocked.

To open up the artery, the balloon is blown up with fluid, which then presses against the plaque, pushing it out of the way.

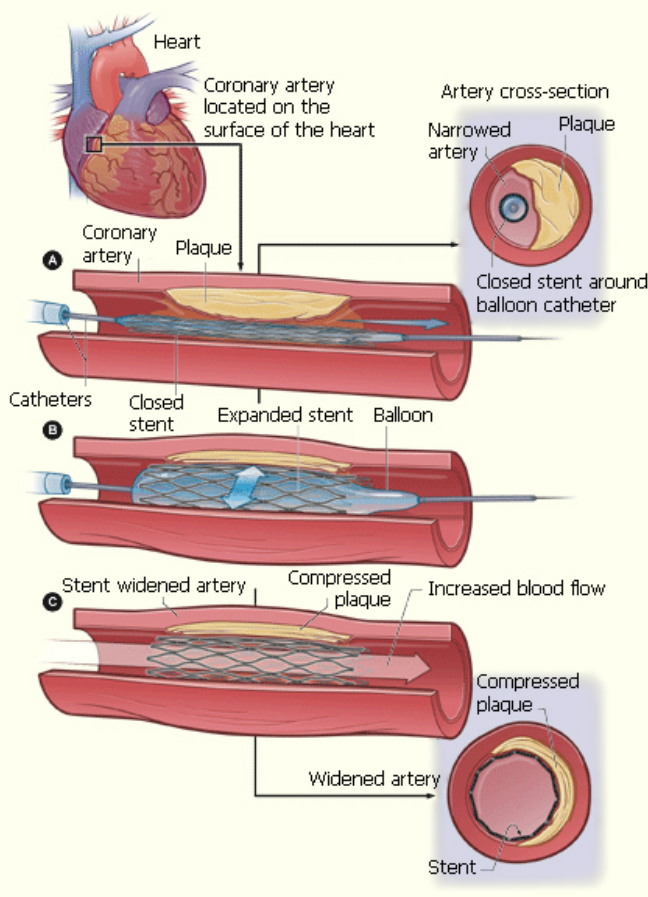


Fig 1. National Heart, Lung and Blood Institute

The balloon

In some people,

- the coronary artery may be split or damaged; OR
- the artery may become narrowed again as the balloon goes down; OR
- the artery may become blocked again.

Most of the time, one or more stents may be placed in the artery to help keep the artery open. A stent is a metal tube or spring coil. This is passed into the diseased part of your artery using a balloon. The balloon is removed once the stent is in place.

The stent stays in for life. After the procedure, you will be given drugs which reduce your risk of blood clotting and the stent blocking.

While the catheter is in the artery, a number of additional mechanical devices may be used to complete the procedure. These include pressure wires and an Intravascular Ultrasound (IVUS).

If the heart becomes unstable during the procedure, an additional balloon device to stabilise the heart may be required. This is called an intracardiac balloon pump.

At the end of the procedure the artery may be closed with a special plug to stop the bleeding. Your Cardiologist will discuss this with you.

Medication such as Clopidogrel, Prasugrel or Ticagrelor is used for up to four weeks and sometimes longer. A small daily dose of Aspirin may need to be taken for the rest of your life.

2. My anaesthetic

This procedure will require an anaesthetic.

See **Local Anaesthetic and Sedation for Your Procedure information sheet** for information about the anaesthetic and the risks involved. If you have any concerns, discuss these with your doctor.

If you have not been given an information sheet, please ask for one.

3. What are the risks of this specific procedure?

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment. The risks are higher if you are having the procedure for a heart attack.

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (more than 5%) include:

- Minor bruising at the puncture site.
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