

Coronary Angiogram &/or Angioplasty and Stenting

Facility:

Family Name:

URN:

Given Names:

Address:

Date of Birth:

Sex: M F

A. INTERPRETER / CULTURAL NEEDS

An Interpreter Service is required? Yes No

B. CONDITION AND TREATMENT

The doctor has explained that you have the following condition:

.....
This condition requires the following procedure.

The following will be performed:

After an injection of local anaesthetic, a fine tube (catheter) is put into the artery in the groin. The tube is carefully passed into the coronary arteries. A series of pictures are taken using x-rays and x-ray dye. If any narrowing or blockages are found, then a tube with a tiny wire is passed down the affected 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.

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 which 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 some drugs, which reduce your risk of blood clotting and the stent blocking.

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.

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits

C. RISKS OF A CORONARY ANGIOGRAM &/OR ANGIOPLASTY AND STENTING

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.

The risks/complications of this procedure are;

Common risks (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.
- Major bruising or swelling at the puncture site.

Uncommon risks (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 puncture site or blood vessel.

Rare risks (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 medications 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 as 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.

D. SIGNIFICANT RISKS AND TREATMENT OPTIONS

Coronary Angiogram &/or Angioplasty and Stenting

Facility:

Family Name:

URN:

Given Names:

Address:

Date of Birth:

Sex: M F

E. RISKS OF NOT HAVING AN CORONARY ANGIOGRAM &/OR ANGIOPLASTY AND STENTING

- I understand I have the right to change my mind at any time before the procedure, including after I have signed this form but, preferably following a discussion with my doctor.

On the basis of the above statements,

I REQUEST TO HAVE THE CORONARY ANGIOGRAM &/OR ANGIOPLASTY AND STENTING

Name of Patient/
Substitute decision
maker and relationship :

Signature :

Date:

Substitute Decision-Maker: Under the Powers of Attorney Act 1998 and/or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision-maker must give consent on the patient's behalf.

F. ANAESTHETIC

This procedure may require an anaesthetic.

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 accordingly.
- If I am a public patient a doctor other than my Cardiologist may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheets;

Local Anaesthetic and Sedation for your procedure

Coronary Angiogram &/or 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.

H. DOCTOR'S STATEMENT

I acknowledge that 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:

Designation : Cardiologist

Signature :

Date :

J. INTERPRETER'S STATEMENT

I have given a sight translation in

.....
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 :

Consent Information - Patient Copy

Coronary Angiogram &/or Angioplasty and Stenting

1. WHAT IS AN CORONARY ANGIOGRAM?

An Angiogram is used to show any narrowing or blockage of your coronary arteries.

2. WHAT IS AN ANGIOPLASTY AND STENTING?

Angioplasty and stenting is often used instead of surgery to treat narrowed or blocked coronary arteries.

You may have one or both of the following procedures.

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. The tube is carefully passed into the coronary arteries. A series of pictures are taken using x-rays and x-ray dye. If any narrowing or blockages are found then a tube with a tiny wire is passed down the affected 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.

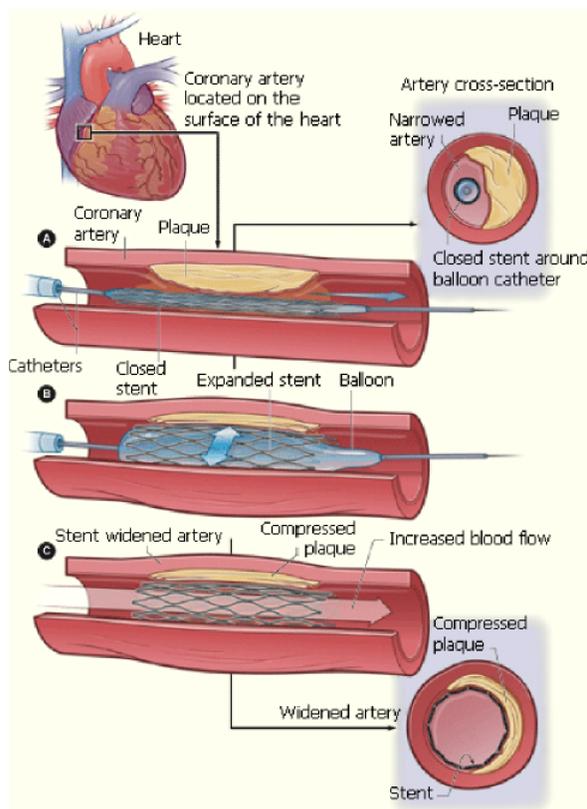


Fig 1. National Heart, Lung and Blood Institute

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 (Plavix or Iscover) 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.

3. 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, talk these over with your doctor.

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

4. 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.

The risks/complications of this procedure are;

Common risks (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.
- Major bruising or swelling at the puncture site.

Uncommon risks (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 puncture site or blood vessel.

Consent Information - Patient Copy

Coronary Angiogram &/or Angioplasty and Stenting

Rare risks (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 medications 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.

NOTES TO TALK TO MY DOCTOR ABOUT

A coronary angioplasty and possible stenting may be offered as a treatment option for patients presenting with heart attacks at some centres. An alternative treatment is for patients to be given a clot busting medication.

Outcomes after angioplasty and stenting depend upon the following:

- age of the patient
- number of arteries supplying blood to the heart that are diseased
- location of the heart attack
- time taken to present to the hospital following the heart attack
- degree of blood flow in the blocked artery
- clinical status of the patient.

The less the number of these risk factors the better the clinical outcomes. If more than one artery is diseased the patient may need further procedures after some time.

If you are having angioplasty and stenting as 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.