Canberra heart clinic

Percutaneous Mitral Balloon Valvuloplasty

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 procedure may involve any of the following *(Please tick):*

☐ ***Angiogram*** - After an injection of local anaesthetic, a fine tube (catheter) is put into the artery in the groin/arm. The tube is passed into each coronary artery. A series of video pictures are taken using x-rays and a contrast medium (x-ray dye). The contrast medium may be injected into the main pumping chamber of the heart (left ventricle). This is to measure the size of the heart and how well it is pumping.

☐ ***Right Heart Catheter*** – a soft balloon 'pressure catheter' is put into the vein in your groin. It is passed along until it reaches the heart and then goes up into the blood vessels of the lungs. Pressures in the lungs and heart are recorded.

☐ ***Trans Septal Puncture*** – a procedure to create a small hole to allow passage of the balloon catheter from the right to the left side of the heart.

☐ ***Echocardiogram*** – this can be either via the oesophagus (food pipe) or via the catheter in the artery.

The procedure will involve a:

- ***Mitral Valvuloplasty*** - A wire is passed along the blood vessel, up to the heart, until it gets to the mitral valve. The doctor uses x-ray imaging to see the wire. Once the wire is in place, a balloon is passed along the wire and into the damaged valve. The balloon is pumped up where the valve is narrowed. This widens the valve, as far as possible. The balloon may be pumped up several times. At the end of the procedure the wire and balloon are removed.

C. Risks of a percutaneous mitral balloon valvuloplasty

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.

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.
- Abnormal heartbeat lasting several seconds, which settles by itself.
- Major bruising or swelling at the groin/arm puncture site.
- Loss of pulse in the arm after a radial artery (arm) procedure.
- A severe leak in the mitral valve can happen. This will need surgery to repair.

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

- A stroke. This can cause long term disability.
- Embolism. A blood clot may form and break off from the catheter. This is treated with blood thinning medication.
- Accidental puncture of the heart. This may need surgery to repair.
- Death is possible due to the procedure.

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

- Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
- Surgical repair of the groin puncture site and blood vessel.
- Loss of kidney function due to the side effects of the x-ray dye.
- Unable to get the catheter into the leg vein. The procedure may be changed to the opposite leg or to a different approach eg neck or arm.
- The femoral artery (in the groin) is accidentally punctured. This usually requires pressure on the artery. Rarely, this may require surgery to repair.
- Infection. This will need antibiotics.
- Heart attack.
- An allergic reaction to the x-ray dye.
- A higher lifetime risk from x-ray exposure.
- Air embolism. Oxygen may be given.
- Damage to the nerve in the leg.

PROCEDURAL CONSENT FORM

Continues over page ►►►

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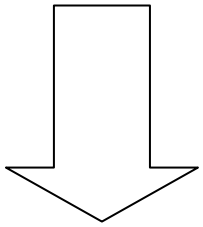
- Emergency heart surgery due to complications with this procedure.
- Skin injury from radiation, causing reddening of the skin.

D. Significant risks and procedure options

(Doctor to document in space provided. Continue in Medical Record if necessary.)

- This consent document continues on page 3 -



E. Risks of not having this procedure

(Doctor to document in space provided. Continue in Medical Record if necessary.)

F. Anaesthetic

This procedure may require an anaesthetic. *(Doctor to document type of anaesthetic discussed)*

Continues over page ►►►

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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/treatment. 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**

☐ **Percutaneous Mitral Balloon Valvuloplasty**

- 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: .....

Consent Information - Patient Copy
Percutaneous Mitral Balloon Valvuloplasty

1. What is mitral stenosis?

Mitral stenosis is a blockage of the mitral valve in the heart. The two flaps of the valve (leaflets) have become stuck together. This reduces the blood flow from one heart chamber to another, causing a back-up of fluid into the lungs. This makes you feel short of breath (puffed).

2. What is percutaneous mitral balloon valvuloplasty?

A valvuloplasty is a procedure where the valve is widened using a balloon. This will allow the blood to flow more easily. The procedure may also involve the following:

- Angiogram to show any narrowing or blockage in your coronary arteries.
- Right Heart Catheter to measure pressures in the heart
- Echocardiogram is an ultrasound of the heart. This can be either intracardiac or oesophageal.

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

Angiogram - After an injection of local anaesthetic, a fine tube (catheter) is put into the artery in the groin/arm. The tube is passed into each coronary artery. A series of video pictures are taken using x-rays and a contrast medium (x-ray dye). Contrast medium may be injected into the main pumping chamber of the heart (left ventricle). This is to measure the size of the heart and how well it is pumping.

Right Heart Catheter – a soft balloon 'pressure catheter' is put into the vein in your groin. It is passed up until it reaches the heart and then goes into the blood vessels of the lungs. Pressure in the lungs and heart are recorded.

Trans Septal Puncture – a procedure to create a small hole to allow passage of the balloon catheter from the right to the left side of the heart.

Echocardiogram – an ultrasound which uses soundwaves to form a picture of the heart. This can be either via the oesophagus (food pipe) or via the catheter already in the artery.

Mitral Valvuloplasty - A wire is passed along the blood vessel, up to the heart, until it gets to the mitral valve. The doctor uses x-ray imaging to see the wire. Once the wire is in place, a balloon is passed along the wire and into the damaged valve. The balloon is pumped up where the valve is narrowed. This widens the valve, as far as possible. The balloon may be pumped up several times. At the end of the procedure the wire and balloon are removed.

A mitral valvuloplasty can give you complete relief of symptoms in over 90% of patients. This improvement can last for up to 20 years. Most patients have relief for at least 5 to 10 years.

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, discuss these 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.

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

Common risks and complications (> 5%) include:

- Minor bruising at the puncture site.
- Abnormal heartbeat lasting several seconds, which settles by itself.
- Major bruising or swelling at the groin/arm puncture site.
- Loss of pulse in the arm after a radial artery (arm) procedure.
- A severe leak in the mitral valve can happen. This will need surgery to repair.

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

- A stroke. This can cause long term disability.
- Embolism. A blood clot may form and break off from the catheter. This is treated with blood thinning medication.
- Accidental puncture of the heart. This may need surgery to repair.
- Death is possible due to the procedure.

Rare risks and complications (< 1%) include:

- Abnormal heart rhythm that continues for a long time. This may need an electric shock to correct.
- Surgical repair of the groin puncture site and blood vessel.
- Loss of kidney function due to the side effects of the x-ray dye.
- Unable to get the catheter into the leg vein. The procedure may be changed to the opposite leg or to a different approach eg neck or arm.
- The femoral artery (in the groin) is accidentally punctured. This usually requires pressure on the artery. Rarely, this may require surgery to repair.
- Infection. This will need antibiotics.
- Heart attack.
- An allergic reaction to the x-ray dye.
- A higher lifetime risk from x-ray exposure.
- Air embolism. Oxygen may be given.
- Damage to the nerve in the leg.
- Emergency heart surgery due to complications with this procedure.
- Skin injury from radiation, causing reddening of the skin.