

Informed Consent for Percutaneous Aortic Balloon Valvuloplasty

Name:	Age (in years):	Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other
UHID No./Registration No.:		
Interpreter Service: <input type="checkbox"/> Yes <input type="checkbox"/> No	Consultant's Name:	

Medical Condition

The doctor has explained that I/my child/myhave the following medical condition:

 and I/my child/my.....have been explained and advised to undergo the following treatment/procedure:

 I authorise Dr. and his/her associates to perform the above treatment/ procedure.
 The doctor should document the site and/or side where relevant to the procedure:.....

Introduction

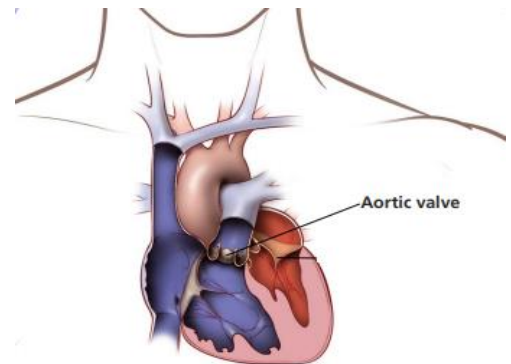
Aortic stenosis is the narrowing of the aortic valve opening. In severe cases, it will cause acute pulmonary edema, malignant arrhythmias or even sudden death.

A balloon aortic valvuloplasty (BAV) is a procedure where the aortic valve is widened using a balloon. This will allow the blood to flow more easily. It is performed under the guidance of X-ray, through percutaneous method.

The procedure may also involve:

- Angiogram to show any narrowing or blockage in your coronary arteries. After an injection of local anaesthetic, a fine tube (catheter) will be put in the artery into the groin/arm. The tube will be passed into each coronary artery. A contrast medium (X-ray dye) may be injected into the main pumping chamber of the heart (left ventricle). And a series of images will be taken using the X-ray machine. This will help in measuring the size of the heart and how well it is functioning.
- Right heart catheter or a soft balloon 'pressure catheter': It will be inserted into the vein in your groin. It will be passed up until it reaches the heart and then goes into the blood vessels of the lungs. This will be used to record the pressure in the lungs and heart.
- Echocardiogram: It is an ultrasound which uses soundwaves to form a picture of the heart. This will be taken either through the oesophagus (food pipe) or through the catheter which is already in the artery.
- Aortic valvuloplasty: A wire will be passed through the blood vessel, up to the heart, until it reaches the aortic valve. The doctor will use an X-ray imaging to check the placement of the wire. Once the wire is in place, a balloon will be passed through the wire and into the damaged valve. The balloon will be inflated to widen the valve, as far as possible. The doctor may inflate the balloon several times.

At the end of the procedure, the doctor will remove the wire and balloon.



Valvuloplasty treats a narrow or stiff aortic valve.

Consent for Blood Transfusion

Please see Blood Transfusion Consent Form. This will give you information about the type of the blood products, benefits and risks of blood transfusion. If you have any concern(s), please discuss with your doctor.

Consent for Anaesthesia

Please see Anaesthesia Consent Form. This will give you information about the type of the anaesthesia, its benefits and general risks. If you have any concern(s), please discuss with your anaesthetist(s).

Informed Consent for Percutaneous Aortic Balloon Valvuloplasty

Potential Benefits (To be documented by doctor)	Alternatives (To be documented by doctor)	Possible Results of Non-Treatment (To be documented by doctor)
<ul style="list-style-type: none"> ▪ A valve that works more efficiently, which may relieve symptoms that were caused by a stiff or narrow heart valve. ▪ Avoiding or postponing open heart surgery. ▪ Others, if any specify: 	<ul style="list-style-type: none"> ▪ Heart valve repair surgery ▪ Heart valve replacement surgery ▪ Others, if any specify: 	
Risks and Potential Complications (To be documented by doctor)		
<ul style="list-style-type: none"> ▪ Bruising at the puncture site ▪ Abnormal heart rhythm ▪ The valve may leak or can get damaged ▪ Infection ▪ Cardiac arrest ▪ Surgical repair of the groin/arm puncture site or blood vessel ▪ An allergic reaction to the contrast medium ▪ Alteration in kidney function due to the side effects of the contrast medium ▪ Damage to the nerve in the leg ▪ Blockage due to air or blood clot ▪ Accidental puncture of the heart. This may need surgery to repair. 	<ul style="list-style-type: none"> • Emergency heart surgery due to complications • Skin injury from radiation, causing reddening of the skin • Stroke which may cause disability • A higher lifetime risk from X-ray exposure • Death • Others, if any specify: 	Patient Specific Risks (To be documented by doctor) 1) 2) 3) 4) 5)
Specific Notes Related to Procedure (Strike out if not required)	Precise Action Points Understood by the Patient/Substitute Decision Maker (To be documented by patient/substitute decision maker in his/her language)	

Informed Consent for Percutaneous Aortic Balloon Valvuloplasty

Patient's Authorisation

- The doctor has explained my/patient's medical condition and proposed treatment/procedure. I have been explained and have understood the intended benefits/risks known to be attached with the planned treatment/procedure including the risks that are specific to me/my patient and their likely outcomes.
- The doctor has explained other relevant/alternate treatment options and their associated benefits/risks. The doctor has also explained the risks of not having the procedure. I have been given the choice to take a second opinion.
- I was able to ask questions and raise concerns with the doctor about the procedure and its benefits/risks and my/patient's treatment options. My queries and concerns have been discussed and answered to my full satisfaction.
- I understand that the treatment/procedure may include blood/blood product transfusion (for which a separate consent shall be obtained).
- The doctor has explained the requirement for anaesthesia for this procedure and I understand the risks associated with anaesthesia, including the risks specific to me (for which a separate consent shall be taken).
- I understand that if organs or tissues are removed during the surgery that these may be retained for prescribed tests and shall be disposed of sensitively by the hospital as per the regulatory provisions.
- The doctor has explained to me, that during the course of or subsequent to the operation/procedure, unforeseen conditions may be revealed or encountered which may necessitate urgent surgical or other procedures in addition to or different from those contemplated. In such exigency, I further request and authorise the above-named physician/surgeon or his designee to perform such additional surgical or other procedures as he or they consider necessary or desirable in my interest. I understand and agree that in such condition there will be no requirement of any additional consent from me or my family members/attendants.
- I declare that no guarantee of whatsoever nature has been given by anyone as to the results that may be obtained.
- I understand that I have the right to refuse treatment before the surgery/procedure. I agree that any such refusal shall be in writing and acknowledged by the hospital and I shall be solely responsible for the outcome of such refusal.

- I consent to if any photographing or television of operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes. However, suitable precautions shall be taken by the hospital that my identity is not revealed anywhere. Yes No
- For purposes of advancing medical education, I consent to the admittance of observers to the operating room. Yes No

Patient /Substitute Decision Maker Name:	Relationship:	Signature:	Date and Time:
Witness 1 Name:	Relationship:	Reason (patient is unable to give consent because):	Signature:
Witness 2 Name:	Relationship:	Signature:	Date and Time:
Interpreter Name:	Translation given in:	Signature:	Date and Time:

Declaration by the Doctor

I have explained to the patient / authorised representatives the medical condition, need for the procedure, its alternatives and benefits/risks, likely consequences if those risks occur and the significant risks and problems specific to this patient including the risks of not undergoing the procedure. I have given the patient/ authorised representatives an opportunity to ask questions about any of the above matters and raise any other concerns. I have answered all their queries to the best of my knowledge.

Name and Signature of the Doctor with Reg No:

Date and Time: