



The AtriClip Procedure

Patient Information Booklet

INDEX

The AtriClip Procedure3

Risk of stroke with atrial fibrillation3

What is atrial fibrillation?.....4

Types of stroke4

Causes of stroke4

Reducing the risk of stroke with AF.....5

What is AtriClip?6

Determining cost and coverage.....7

Pre-procedure workup.....7

On the day of the AtriClip procedure7

After the procedure9

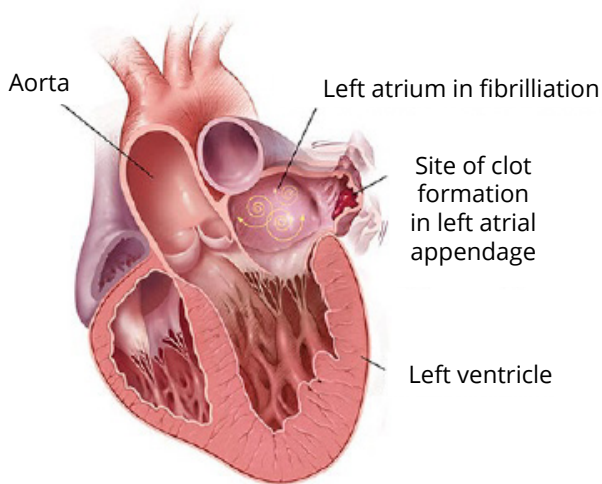
On the day of discharge.....9

Post discharge care.....9

Complications..... 10

The AtriClip Procedure

The left atrial appendage is a pouch like structure that protrudes from the upper chamber of the left side of the heart. AtriClip is a surgical device which is designed to occlude the orifice of the left atrial appendage to prevent any chance of clot formation in the appendage which could lead to stroke.



Risk of stroke with atrial fibrillation

The average person with atrial fibrillation, or AF, is 5-7 times more likely to suffer a stroke than someone with a regular heartbeat.

In AF, the upper heart chambers quiver and shake rather than contracting, or squeezing, as they should. Because blood isn't pumped out of the heart normally, it's easier for blood cells to stick together and form clots in an area of the heart called the left atrial appendage.

In people with atrial fibrillation, more than 90% of stroke-causing clots that come from the heart are formed in the left atrial appendage because it is a 'cul de sac' structure with a blind end. When a blood clot migrates out from the left atrial appendage it can potentially cut off the blood supply to the brain, causing a stroke.

What is atrial fibrillation?

The heart has an electrical system that controls the rate and rhythm of the heartbeat. In a healthy heart, the electrical signals produce a steady heartbeat as the heart contracts and pumps blood regularly.

When a patient is in AF, the electrical signals are disorganized which makes the two chambers of the heart (the atria) beat rapidly and irregularly (fibrillating). AF affects how well blood pumps through parts of your heart, which in turn affects your stroke risk. Proper treatment can help reduce the risk of stroke

Types of stroke

There are 2 types of stroke: ischemic (clot- related) stroke and haemorrhagic (bleeding-related) stroke.

An ischemic stroke is caused by a blood clot that lodges in a blood vessel and cuts off the blood supply to the brain. This is the type of stroke most associated with the irregular heartbeat of atrial fibrillation.

A haemorrhagic stroke is caused by bleeding in or around the brain. This can happen when a blood vessel in the area of the brain weakens and breaks. Blood leakage builds up and creates pressure on the brain, blocking blood flow.

Causes of stroke

Anyone can have a stroke regardless of age, race, or gender. But the chances of having a stroke are higher if you have certain stroke risk factors such as:

- Atrial fibrillation
- High blood pressure
- Diabetes
- Carotid artery disease
- High cholesterol

Atrial fibrillation and stroke facts

- *Stroke is the most common complication of AF*
- *About one-third of people with AF will have a stroke*
- *People with AF have 5-7 times the risk for stroke than people with normal heart rhythms*
- *Strokes are more often fatal and disabling in people with AF*
- *The left atrial appendage is the main source of stroke-causing clots that come from the heart*

Reducing the risk of stroke with AF

The risk of stroke can be managed and this area of medicine has advanced greatly during the past 10 years.

The most common way is with medications that prevent blood clots from forming and leading to a stroke. These medications, called anticoagulants or blood thinners, work well for many people. However blood thinning medications cannot be used in some patients for a number of reasons (usually excessive bleeding) and some new treatments have been developed to help these patients.

If a patient does not tolerate a blood thinner then a specialist may recommend left atrial appendage closure: A procedure called left atrial appendage closure provides an alternative to blood thinners in highly selected patients. The left atrial appendage is a small pouch at the top of the heart.

What is AtriClip ?

AtriClip is a clip made from titanium metal and covered by a cloth which helps the AtriClip become incorporated into the tissues of the heart. A cardiac surgeon with expertise in key-hole procedures places the AtriClip on the outside of the heart to seal off the opening of the left atrial appendage. This is a brief procedure involving three small keyhole incisions less than 1 cm long. The design allows it to be introduced via keyhole on the left side of the chest allowing for quick recovery and short hospital stay.



This permanent AtriClip heart implant effectively reduces the risk of stroke without the risk of bleeding that can come with the long-term use of blood thinners. The AtriClip implant is designed to permanently close off the left atrial appendage and keep those blood clots from escaping.

Since this device is placed on the outside of the heart, it is not in contact with blood. Unlike other devices which are placed inside the heart this device does not require any need for blood thinners. However, Prof Weerasooriya will make the final recommendation depending on your health history.

AtriClip is the only device of its kind approved by the U.S. Food and Drug Administration (FDA) and the TGA in Australia. More than 200,000 AtriClip procedures have been performed worldwide. And with over 10 years of worldwide clinical studies behind it, AtriClip has a proven safety record.

Determining cost and coverage

AtriClip is not yet covered by every private health insurer, but an increasing number of them will cover it on a case-by-case basis. It is important to determine the level of cover as there may also be some out of pocket expense for surgery. This should be discussed with your surgeon prior to the procedure.

Pre-procedure workup

You will need to stop your anticoagulation medications 2-3 days prior to surgery as guided by the surgeon. Patients will need to have an echocardiogram within 3 months of the procedure. Prof Weerasooriya or surgeon may request additional tests based on your health profile.

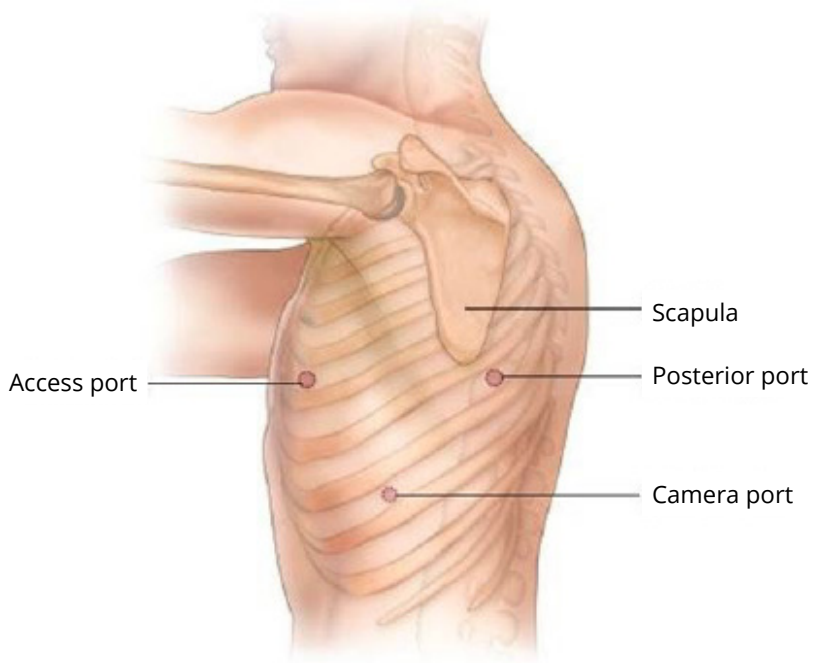
Patients also need blood tests and a chest x-ray at the pre-admission clinic at the hospital. You will meet your anaesthetist and get a chance to discuss any questions you may have. Body hair on the chest area may be clipped in preparation for surgery.

On the day of the AtriClip procedure

During the AtriClip, the patient will be under a general anaesthetic administered by a cardiac anaesthetist using an IV line. Once the patient is anaesthetised monitoring lines are inserted. A urinary catheter is generally not inserted. The cardiac anaesthetist will perform transesophageal echocardiogram (TOE) to check for blood clots in the heart. The procedure will be abandoned in the unlikely event of any clots detected in the heart.

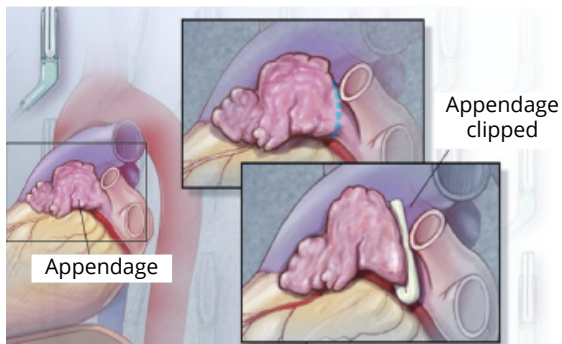
TransOesophageal Echo (TOE)

A Transoesophageal Echo is an ultrasound procedure where a probe is placed down your oesophagus (food pipe) to take high quality images of your heart. Medication is administered to make you drowsy and more comfortable. The TOE procedure is performed in a hospital as a day case and takes 3-4 hours (including recovery).



The surgeon will then make a 3 small incisions (1-1.5cm) on the left side of the chest. The AtriClip device comes with a special delivery system to deploy the device over the left atrial appendage. This usually takes less than 30 minutes. The patient will be woken after the procedure is completed.

LEFT ATRIAL APPENDAGE



After the procedure

As the procedure done as keyhole, the patient is woken up straight after the procedure and returned to the ward instead of ICU or CCU. During this time, the heart rate, heart rhythm, blood pressure, and oxygen level will be continuously monitored carefully. An IV will administer fluids and medication will be prescribed to manage the pain. The ward nurse will assess your pain on a scale of 1 to 10 and administer pain killers appropriately. Please ask for additional pain killers if you are experiencing pain.

The day following procedure your nursing team will help the patient sit in chair and also walk in the corridor to assist in recovery from surgery.

The cardiac surgeon will talk to you about the procedure on the following day and you can discuss any questions you have. Prof Weerasooriya is available to visit you in hospital after the procedure however this is usually not required.

Your hospital stay is estimated to be 2 days after surgery but can be prolonged in some situations.

On the day of discharge

The patient will have a list of medications as well as referrals for a TOE (to be done in 2 weeks at Cardio Vascular Services) and cardiac CT (to be done in 4 weeks at Perth Radiological Clinic).

The patient will have a dressing over the three incisions on the left side of the chest which can be removed after 2 weeks, the stitches will be removed by your GP after 5 days.

The patient will have an appointment to see Prof Weerasooriya 2-3 weeks after the procedure, and with the cardiac surgeon after 4 weeks.

Post discharge care

Patients will be given discharge instructions which need to be read carefully. This will include the following:

Not using ointments or creams on the wounds. If you have any unusual pain or redness, please visit your GP and also notify the cardiac surgeon.

Taking showers with care. Patients must not go swimming or use a bathtub for 2-3 weeks until the wounds are completely healed.

Staying active at home and resting between activity. It is not uncommon for patients to feel tired easily and they should see gradual improvement in stamina. Patients are not allowed to drive a motor vehicle for 2 weeks after the procedure.

Complications

Fortunately, these are uncommon given the nature of the procedure. The most relevant complications are:

1. **Cardiac perforation or injury** – any procedure on the heart has this risk. It is quite an uncommon complication, however the management of this requires sternotomy (breastbone incision) and repair of the injury. The procedure is performed by Cardiac surgeon who are trained and capable of dealing with this complications
2. **Pericarditis** – The pericardium is a sac around heart. To gain access to heart, the surgeon will incise the sac and the instruments and catheter used during procedure can rub against the sac. This and other aspects of the procedure leads to inflammation of the sac which is called “pericarditis” (inflammation of the pericardium). These complications can manifest as pain, fever, fluid build-up in the pericardial sac. Please contact Prof Weerasooriya with concerns about this/
3. **Stroke** – Although very rare it is worth a mention. It can result during or after the procedure due to pre-existing small clots. You will have an intraoperative TOE to assess and confirm the absence of any before the procedure. After surgery, you will be commenced on blood thinners to prevent clot formation in the heart.
4. **Pericardial effusion** – This is the fluid build-up around heart. This can occur secondary to inflammation of the pericardium. Depending on its size, we may observe it or aspirate it with a needle. This can occur after you are discharged. It can cause shortness of breath, fever, flu like symptoms, sweats or fast heartbeat. Please contact Prof Weerasooriya if you experience any of these symptoms.

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