



Minimally Invasive Surgery for Mitral Valve Disease in Dogs

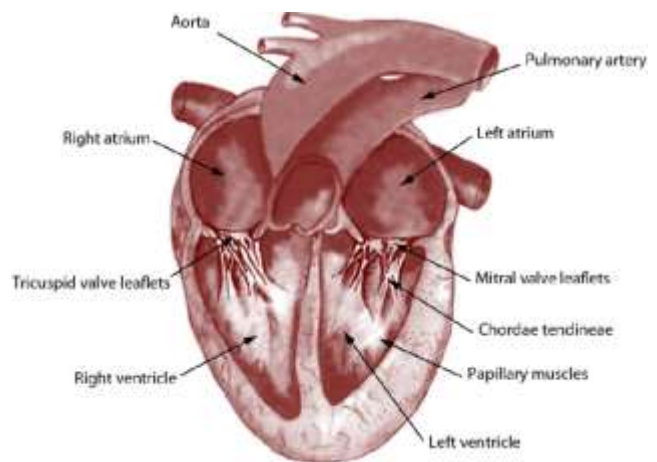
V-Clamp - Transcatheter Edge-to-Edge Repair

Mitral valve disease is the most common cardiac disease in the dog. Historically, treatment has focussed on medical management before the onset of heart failure (when there has been heart chamber enlargement detected) or when symptoms of congestive heart failure occur. Medical management may slow the progression of the disease but it does not reverse it. Ultimately mitral valve disease can be fatal.

In people with mitral valve disease, the recommendation is to repair or replace the valve. This reduces damage to the heart and improves outcome and longevity. In people, the procedure is either carried out as an open-heart cardiopulmonary bypass procedure or minimally-invasive keyhole procedure if the patient is deemed too high risk for open-heart bypass procedure.

Two methods of mitral valve repair can now be offered to dogs. Open heart cardiopulmonary bypass procedure and minimally invasive transcatheter edge-to-edge repair (TEER) procedure using a **V-clamp device**.

Open-heart bypass surgery to perform mitral valve repair has been performed by a team of doctors in Japan who travel to Australia to perform the procedure in particular hospitals. The procedure costs in the range of \$60,000-75,000. The published results of these procedures demonstrate that 45 of 48 dogs survived to time of discharge from hospital and 25% were alive 3 years following the surgery (Uechi, M et al., JAVMA 2012). The disadvantage of this



procedure is that it involves major surgery and the surgery requires the patient to be placed on a heart-lung bypass machine for the procedure.

Recently, a minimally invasive repair option has become available for dogs with mitral valve disease using a device called a **V-Clamp**. This procedure has been successfully performed in dogs around the world. The first procedure was performed by Colorado State University in 2020 in a Schnauzer.

How do I know if my dog is a candidate for the procedure?

We recommend a consultation and echocardiogram with our internal medicine specialists to confirm and stage the mitral valve disease according to the ACVIM staging classification. Dogs that have mitral valve disease and are in stage B2 or C are considered ideal candidates for the procedure. Patients that fulfill these requirements will also need to have the mitral valve and heart measured to see if they meet the appropriate criteria for V-clamp placement. After the detailed echocardiographic assessment of your pet's heart, we can advise whether your pet is a suitable candidate for the procedure.



We would recommend that if your pet has a known heart murmur to have an echocardiogram as early intervention is key for a good outcome for your pet's heart condition.

What if I decide not to proceed with the procedure?

If you do not wish to proceed with the procedure, we recommend ongoing medical management of your pet.

What is the TEER (transcatheter edge-to-edge repair) procedure?

The transcatheter edge-to-edge mitral valve repair procedure is a minimally invasive procedure that is performed in the beating heart, without the requirement for open-heart bypass surgery. It is a form of mitral valve repair.

The technique is also used in people with mitral valve regurgitation with an implant called a *MitraClip*. In humans, the procedure has been developed since 2002 as an alternative option to open-heart bypass surgery and is considered a very successful procedure.

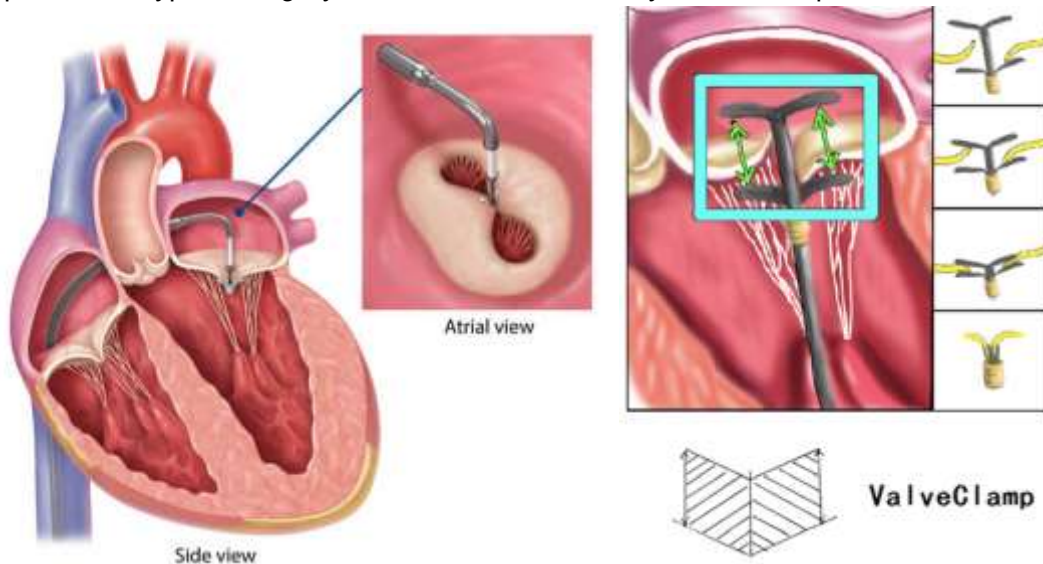


Image comparing the human *MitraClip* device (left) and the **Canine Valve Clamp (V-clamp device)** (right). Image cited from Pan et al. 2018 and Abbott Medical.

In the dog, a device called the V-clamp has been designed to mimic the action of the human device to clamp the two edges of the mitral valve leaflets to reduce the mitral valve regurgitation leakage. The procedure has been developed and used since 2020 in many institutions around the world.

This procedure has been performed in more than 100 dogs over the past 3-4 years. Analysis of the outcomes of these patients has revealed that TEER of the mitral valve is a highly successful, low-risk procedure with a rapid recovery time.

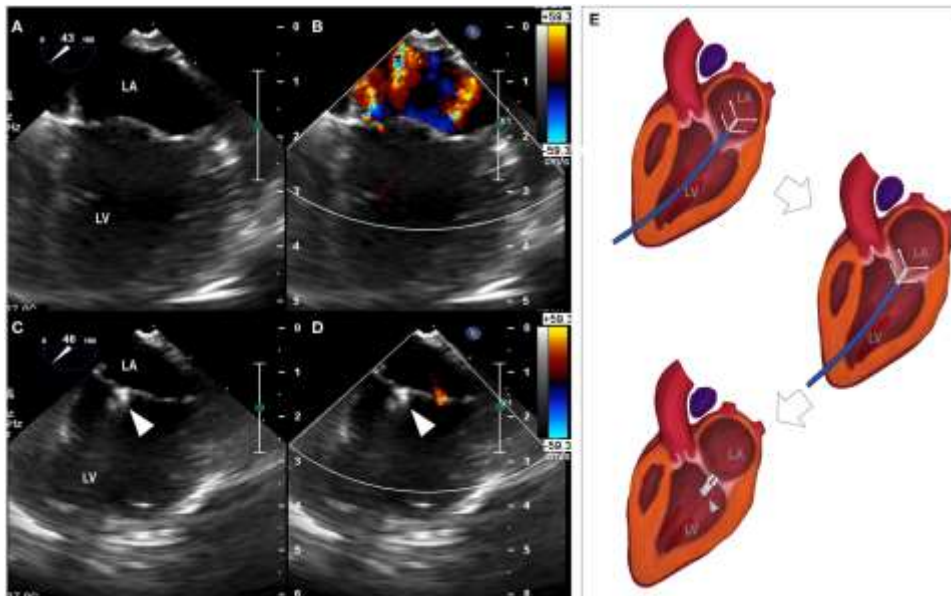
- Typically a 50 to 90% reduction in the severity of the mitral valve leak has been documented.
- The procedural survival rate of the procedure is 95%.
- Patients will be up and walking as soon as they recover from the anaesthetic.
- Hospitalisation time is expected to be 1-3 days.

The V-clamp device is a small implant that is approximately 8mm in size and is made of Nitinol alloy, and encased in a polymer. It is designed to be delivered through a small catheter device

into the left ventricle of the heart and then across the mitral valve to clamp the two leaflets together in the central position of the valve (see image). This action closes down the mitral valve leak. Blood can still flow normally either side of the clamp, but the centre of the valve is sealed to reduce the leak. The clamp is left in place and it becomes a permanent fixture within the heart.

How is the procedure performed?

The procedure is performed under general anesthesia. The surgeon will make a small surgical incision into the chest to gain access to the heart. A transesophageal ultrasound is performed to guide the minimally invasive placement of the V-clamp through a series of small catheters that are placed into the left ventricle of the heart. Once the correct positioning of the V-clamp is confirmed via ultrasound, the clamp is applied to reduce the mitral valve leak. The procedural time, on average, is 60-80 minutes.



Schematic image showing the V clamp device (on the right) being delivered through the left ventricle across the mitral valve to perform the edge-to-edge repair of the mitral valve (TEER). The image on the left, shows the mitral valve and the associated leak (red jets) through the valve on ultrasound before (images A and B) and after (C and D) the V-clamp device is positioned. The white arrow points to the V-clamp device attached to the mitral valve. Liu B et al, 2020

What are the risks or complications?

Risks are considered low in suitable candidates. 95% of patients survive to hospital discharge. Despite the positive procedural success rates, it is important to acknowledge that this procedure is *not without risk*.

The most serious complication is detachment of the clamp (~ 7% risk) which can

be potentially fatal if this occurs. The risk for leaflet detachment is highest within the 72 hours after the procedure and diminishes after several weeks due to healing around the clamp.

Other low risks include infection, bleeding, pneumothorax (air in the chest post surgery).

How long will my dog need to stay in the hospital after the procedure?

As the procedure is performed as a minimally invasive procedure, we would expect your pet to be discharged home 1-3 days post procedure.

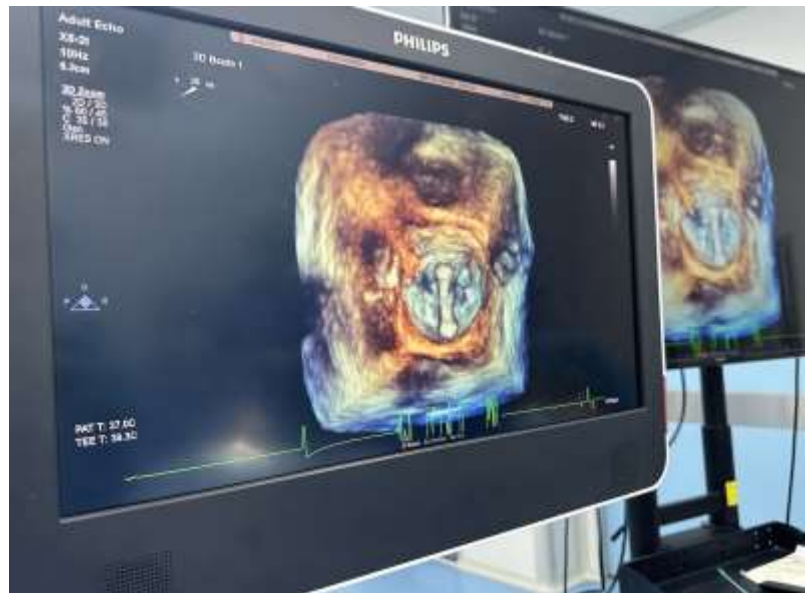


Image above is a 3D ultrasonographic view of the mitral valve with V-clamp in position.

What would be the cost of the procedure?

The cost of the implant and procedure, including anaesthesia and hospitalisation is estimated to be \$25,000.

What outcomes can we expect?



We do not have long-term data at this stage, however, we know from humans that mitral valve repair is superior to medical treatment alone. We would expect that over time we will find the same outcomes in dogs with mitral valve disease. The other main advantage of this procedure is that it is less invasive than other mitral valve repair options that involve open heart bypass surgery. The V-clamp procedure has shown good potential to improve longevity and quality of life.

Is there a need for ongoing heart medications?

If your pet is in clinical heart failure (stage B2 or C), we would expect to be able to reduce the requirement for cardiac medications as the heart size reduces with control of mitral valve leakage. The tapering of medications would be tailored to the individual, based on follow-up clinical assessments and ultrasounds with our team, in the months following the procedure.



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