Royal Brompton and Harefield hospitals

NHS

Your Tendyne transcatheter mitral valve implantation (TMVI)

Contents

This patient information leaflet is for patients with mitral regurgitation who may be suitable for a Tendyne TMVI procedure. It does not replace the need for personal advice from a qualified healthcare professional. Please ask your doctor or nurse if you if you have any questions.

What is Tendyne transcatheter mitral valve implantation (Tendyne TMVI)?

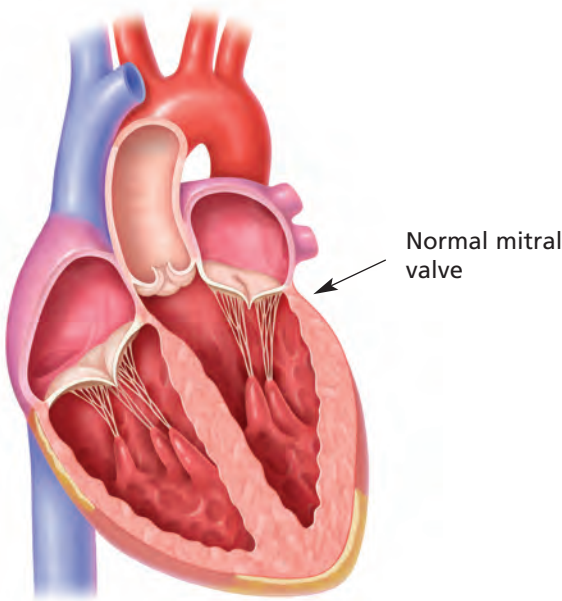
A Tendyne TMVI involves inserting a new heart valve device inside your existing mitral heart valve to relieve the symptoms of mitral regurgitation.

The mitral valve

The mitral valve is one of the four heart valves that control the flow of blood in and out of your heart. The mitral valve separates the upper left heart chamber (left atrium) from the lower left heart chamber (left ventricle).

The mitral valve (Figure 1) has two flaps called leaflets. The leaflets open to let blood flow into the left ventricle, and close to stop blood flowing backwards to the left atrium.

Figure 1: Heart without mitral regurgitation

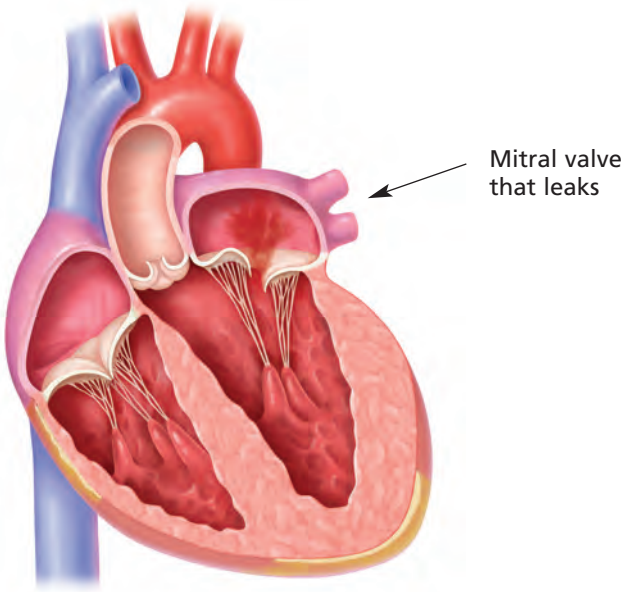


Mitral regurgitation

Mitral regurgitation happens when your mitral valve leaks (Figure 2). The leaflets do not meet in the middle so your heart pump (left ventricle) must work harder in an attempt to cope with the leak.

At this stage, you may experience symptoms of breathlessness or heart palpitations. If the leak is not fixed, eventually the heart's pump function may not be effective and the chambers of the heart may enlarge. If this happens you will have heart failure (worse breathlessness, fatigue, palpitations).

Figure 2: Heart with mitral regurgitation

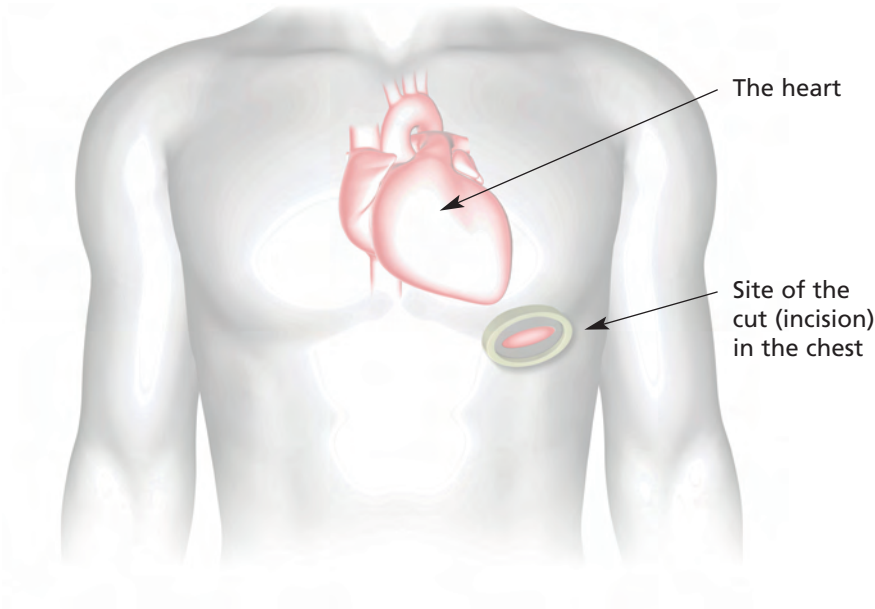


A Tendyne TMVI procedure

A Tendyne TMVI procedure involves implanting a new mitral valve device inside your leaking mitral valve.

The procedure is carried out under general anaesthetic. The surgeon makes a small 4cm to 6cm length cut (incision) in the left side of the chest (Figure 3) just underneath the left nipple to access the mitral valve through the base (apex) of the heart and the left ventricle.

Figure 3: A cut (incision) is made in the left side of the chest



Once the cut in the chest is made, a tube (called the delivery sheath) is inserted directly into the heart. The Tendyne valve is placed through this delivery sheath to sit within the leaking mitral valve (Figure 4). The old mitral valve stays in place and the new Tendyne valve is expanded into it.

Figure 4: The Tendyne valve is inserted and an apical pad attached to the base of the heart

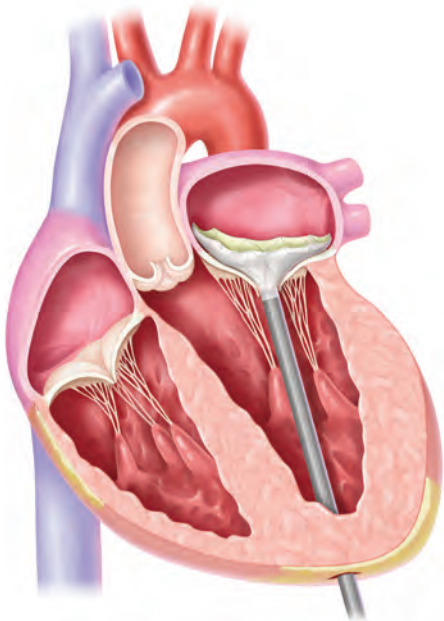
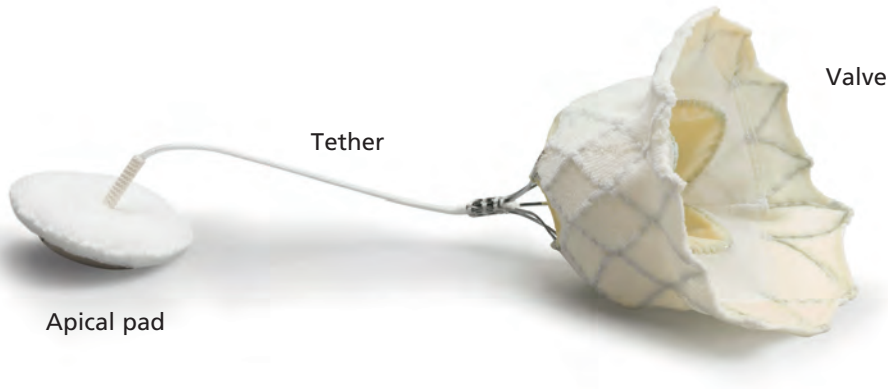
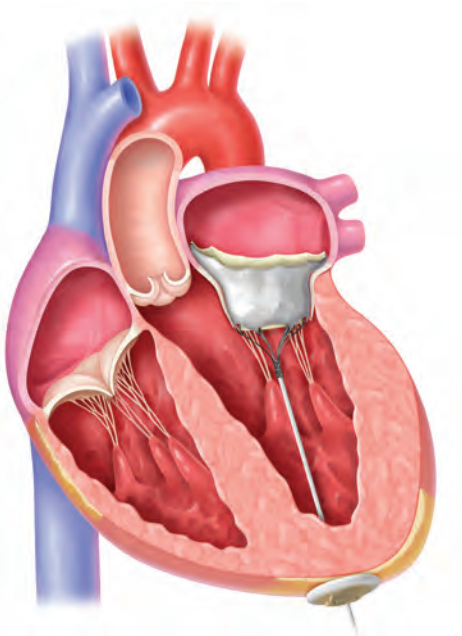


Figure 5: The complete Tendyne device (valve, tether, apical pad)



The tether stabilises the Tendyne valve by attaching the new mitral valve to an apical pad at the apex of the heart. Apical just refers to the point of the heart where the pad is placed. The apical pad acts as an anchor to hold the Tendyne device in place and helps to close the apical puncture site in the heart once the delivery sheath is removed (Figure 6).

Figure 6: The implanted Tendyne device



Benefits of a Tendyne TMVI procedure

Even with the best medical treatment, mitral regurgitation usually gets worse over time, leading to signs and symptoms of heart failure such as breathlessness, fatigue and swollen ankles or legs (fluid overload).

A Tendyne TMVI procedure is less invasive than other forms of mitral valve surgery, including open heart and keyhole surgery (see alternatives to a Tendyne TMVI procedure on page 9).

Since the procedure is performed on a beating heart, there is no need for the patient to be placed on a heart-lung machine during the procedure, and so the recovery period is usually shorter than if you were to undergo conventional open heart or keyhole surgery.

Another major advantage of the Tendyne TMVI procedure is that most patients have complete elimination of mitral regurgitation. In a recent study of 100 patients, 98 patients had no or only a trace of mitral regurgitation a year after their procedure. As a result, almost 90 out of 100 patients find their symptoms get better after the procedure, and 70 out of 100 report a significant improvement in their quality of life.

Risks of a Tendyne TMVI procedure

Your doctors believe you are at high risk of complications from conventional open heart surgery to repair or replace your mitral valve, and that a Tendyne TMVI procedure may be a safer alternative for you.

However, every procedure carries some risk and the risks are different for each person. Your doctor will discuss the risks with you before you decide to go ahead with a Tendyne TMVI procedure.

The risks of having a Tendyne TMVI procedure include:

Recurring heart failure symptoms

12 in 100 of people who had the Tendyne TMVI procedure needed to re-visit hospital due to their heart failure symptoms.

Bleeding

1-5 out of 100 people may have problems with bleeding to the heart incision site. This is managed with manual pressure and/or a pressure device. Bleeding usually resolves within a few hours.

Death

1-2 out of every 100 people may die while having a Tendyne TMVI procedure.

Complications from the device

1-2 out of 100 of patients may have complications such as a blood clot, which is usually resolved with blood thinners, or an infection which is treated with antibiotics.

Stroke

1 out of 100 people may have a stroke while having a Tendyne TMVI procedure. This is usually treated with 'clot-busting' medicines.

Collection of blood around the heart requiring drainage

Less than 1 in 100 people have a collection of blood around the heart. The blood may need draining using a small tube inserted below the breastbone, or with an operation.

Arrythmia (irregular heartbeat):

Less than 1 in 100 people develop an irregular heartbeat. This can be treated with medicine or by using electric shocks to the heart.

Kidney injury

Less than one in 100 people have a reduced kidney function. This may get better by itself or need to be treated with fluids.

Alternatives to a Tendyne TMVI procedure

The alternative treatments available for mitral regurgitation are:

Two other surgery procedures:

- open heart mitral valve surgery which involves cutting through the breastbone to reach the heart.
- or keyhole surgery where a small cut (incision) is made in right side of the chest.

During both these procedures a patient's heart is stopped and a heart-lung bypass machine is used to temporarily take over the

function of both the heart and lungs. Whereas when a Tendyne TMVI procedure is carried out a patient's heart continues to beat (beating heart surgery) as usual without the use of a heart-lung bypass machine.

Continuing medicine to control symptoms

Medicine can help to relieve symptoms, but will not stop the mitral valve from leaking. If the mitral valve is not repaired, patients continue to have symptoms such as breathlessness, fatigue and fluid overload.

Alternative transcatheter mitral valve repair

With a MitraClip device if your mitral valve is suitable.

It is important to talk to your doctor about the effects of not having the procedure.

The risks of having a Tendyne TMVI need to be balanced against the risk of not having the procedure at all.

Before your Tendyne TMVI

To find out if a Tendyne TMVI procedure is the right procedure for you, we need to do some tests. We may be able to use some of the tests you have already had done or invite you to the hospital for one to two days to complete them.

Tests may include:

Blood tests

We will need some up-to-date blood test results. We will carry out the blood tests in the outpatient department, or we may be able to get the results from your GP if you have had a blood test recently.

Electrocardiogram (ECG)

This enables us to look at your heart rate and rhythm.

Echocardiogram (Echo)

An echocardiogram uses sound waves (ultrasound) to build up a moving picture of your heart. It shows the structure and function of your heart valves and heart chambers. An echocardiogram takes around 20 minutes.

Transoesophageal echo (TOE)

A TOE is another way of carrying out an echo and allows your doctor to look more closely at your heart. A flexible tube (probe) is passed down your throat, to send sound waves to your heart, and collect echoes that bounce back. A TOE takes approximately 20 to 30 minutes.

Coronary angiogram

A coronary angiogram uses a series of X-rays to allow doctors to look at the main arteries that supply your heart muscle – the coronary arteries. A thin plastic tube (catheter) is guided through an artery in your wrist or groin, to your heart. Then a special dye is injected through the catheter so your arteries clearly show. A coronary angiogram takes about 30 minutes.

Cardiac catheterisation

Cardiac catheterisation (also known as right-heart catheterisation) provides information about the structure and function of the heart. A catheter is inserted into a vein in your neck, arm or groin. The catheter is guided to your heart using X-rays shown on a screen. Once in place, doctors can look at the blood flow through your heart and blood pressures in your heart and lungs.

Cardiac catheterisation takes about 30 minutes and can be done at the same time as a coronary angiogram.

Computed tomography (CT) scans

A CT scan is an X-ray that produces three-dimensional images of your body. A radiographer will give you an injection containing a special dye so that your blood vessels and heart show clearly on the scan. A CT scan takes about an hour and is used to look

at the blood vessels in your chest, neck and legs. This is an important test as it helps to plan the size of the Tendyne device needed for your heart.

What happens after the tests?

After your tests, your healthcare team will decide if a Tendyne TMVI procedure is the best treatment for you. A member of the team will call you to explain the procedure recommended for you and discuss the next steps.

If a Tendyne TMVI procedure is right for you, a letter will be sent to you telling you when your procedure will be, and which ward you will stay on.

About 1 to 2 weeks before the date of your hospital admission, you will have a pre-admission appointment. This is carried out by telephone or video. A nurse will call you to discuss your medical history and to find out what medication you are taking. You will be advised which medicines you need to stop taking before your procedure and when. You will be able to ask any questions about the procedure during this appointment.

You will come into the hospital either on the day of your procedure, or the day before. Before you leave home, please contact the ward to make sure that a bed is available. Ward telephone numbers are listed in the 'Useful contacts' section on page 16.

What to bring to hospital

Please bring:

- all your current medicine
- your completed hospital forms
- a dressing gown

- comfortable clothes – such as shirts that button up, loose blouses or tops, tracksuit bottoms, trousers or skirts, and sturdy, non-slip trainers or shoes
- a book to read or a device with headphones or your mobile phone and charger

Improving your health before the procedure

Improving your health before any mitral valve intervention can reduce the risks of the procedure and ensure a Tendyne TMVI is successful.

Exercise

Try to keep as fit as possible. Do light daily exercise, such as slow walking or light housework, such as dusting and washing dishes. Practise getting in and out of bed, and on and off of chairs and toilets (as long as it does not make you breathless, light-headed or cause chest pain).

Food

Eat as healthily as possible. Include plenty of fresh fruit and vegetables in your diet, and moderate amounts of carbohydrate (such as bread, potatoes and pasta) and protein (such as meat, fish, beans and eggs).

Visit your dentist

Visit your dentist and ensure you have any cleaning, filling or other dental work completed before your Tendyne TMVI procedure.

Good dental hygiene is important before you have a procedure on your heart as germs (bacteria) can enter the bloodstream from your teeth and gums, causing an infection called endocarditis.

Endocarditis can damage the heart valves and cause other serious complications.

As you have a heart condition, you are at risk of endocarditis and will need to take antibiotics if you have any filling, root canal work, or tooth removal before your Tendyne TMVI. We can give you a letter to give to your dentist about this. Please ask the secretary to Mr Cesare Quarto (see Useful contacts on page 16).

Medicine

Continue to take your medicines as usual, unless your doctor or transcatheter mitral valve nurse has asked you not to.

After your Tendyne TMVI

After a Tendyne TMVI procedure, you will be cared for on the high dependency unit for 1 to 2 days where you can be closely monitored.

Once your condition is stable, you will return to the ward. You will continue to have your heart rate and rhythm monitored, and you may need some intravenous fluids (directly into a vein) to keep you hydrated or intravenous medicine to support your heart for a short time.

You are likely to have a chest drain (tube) after having a Tendyne TMVI. The chest drain will be removed within 2 to 3 days, together with any drips and catheters (tubes) you may have.

We expect you to get up, dressed and moving as soon as possible after your procedure. Being active will help you to recover more quickly.

Going home

You will probably stay in hospital for 5 to 7 days after your procedure. You will need to take blood-thinning (anticoagulation) medicine after your procedure. This is usually warfarin, but in some cases may be one of the newer anticoagulation medicines. We recommend blood-thinning medicine is taken for life after having a Tendyne TMVI.

We will give you a 14-day supply of blood-thinning medicine to take home with you. After that, you will need to see your GP to get a repeat prescription. We will send a discharge letter to your GP explaining your condition, what you have had done in hospital, and the reason for starting you on anticoagulation medicine. You will receive a copy of this discharge letter.

Warfarin

If you have been started on warfarin, you will be booked into your nearest anticoagulation clinic to monitor your blood-thinning 1 to 2 weeks after discharge. The aim of treatment with warfarin is to thin your blood but not stop it clotting completely. Getting this balance right means your dose of warfarin must be carefully monitored.

You will have a regular blood test called the international normalised ratio (INR). It measures how long it takes your blood to clot. The longer your blood takes to clot, the higher the INR.

We would like your target INR to be 2.5. This means the blood takes 2.5 times longer to clot than usual. We will include this information in your discharge letter.

The dose of warfarin you need depends on your blood test result. If the blood test result has gone up or down, your warfarin dose will be increased or decreased.

Follow-up care

Before you go home, you will have blood tests, an echocardiogram, and the specialist healthcare team will review how the procedure went and how you are recovering. A member of the team will discuss the results with you before you go home.

You will also have a follow-up appointment 6 to 8 weeks after your procedure. At the follow-up appointment, you will have

a clinical reassessment and an echocardiogram to check how well your new mitral valve is working.

At home

Once home, you can gradually return to normal activities. You can do gentle exercise, but you need to avoid strenuous exercise or heavy lifting for 3 to 4 weeks.

If you have symptoms of breathlessness, or the area in your chest where the Tendyne device was inserted becomes red, or starts to itch, ooze or swell, please contact your transcatheter mitral valve clinical nurse specialist, your GP, or go to your local accident and emergency department.

Please note that Royal Brompton and Harefield hospitals do not have accident and emergency (A&E) departments.

Useful contacts

If you have any questions, please contact either:

Transcatheter mitral valve clinical nurse specialists (available Monday to Friday, 8am-4pm)	**0330 12 88121** and ask the operator to contact him/her
Secretary to Mr Cesare Quarto consultant in cardiac surgery (available Monday to Friday, 8am-4pm)	**0330 12 88121 ext 88157**
York/Paul Wood wards (Royal Brompton Hospital)	**0330 12 88121 ext 88592**

Your notes

If you have any concerns about any aspect of the service you have received in hospital and feel unable to talk to those people responsible for your care, call Patient Advice and Liaison Service (PALS):

- Royal Brompton Hospital – 020 7349 7715
- Harefield Hospital – 01895 826 572

Or email gstt.rbhh-pals@nhs.net. This is a confidential service.

Royal Brompton Hospital
Sydney Street
London
SW3 6NP
Phone: 0330 12 88121

Harefield Hospital
Hill End Road
Harefield
Middlesex
UB9 6JH
Phone: 0330 12 88121

Website: www.rbht.nhs.uk

Royal Brompton and Harefield hospitals are part of Guy's and St Thomas' NHS Foundation Trust

إذا كنت ترغب في الحصول على ترجمة فورية لمضمون هذه الوثيقة إلى اللغة العربية، يرجى منك الاتصال بأحد مستخدمينا بجناح المصلحة التي يتم فيها استشفائك. أحد موظفينا سيسعى لترتيب إجراءات الترجمة وإتمامها في الوقت المناسب لك.

Brosurteki bilginin Turkçe tercumesi için tedavi goruyor oldugunuz bolume bas vurunuz. Bolum personeli tercumenin gerçeklesmesini en kisa zamanda ayarlacaktir.

July 2022