



A Chance to Enjoy Life Again

WHAT YOU SHOULD KNOW ABOUT MITRAL REGURGITATION
AND PERCUTANEOUS MITRAL VALVE REPAIR

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ABOUT MITRAL REGURGITATION

Mitral regurgitation – or short MR – is a disorder affecting one of your heart valves, the mitral valve. The valves in your heart control the blood flow through the four chambers of your heart. Each valve consists of fine but solid tissue leaflets. While blood is flowing through the four chambers of the heart, the valves open and shut so that the blood may flow in the right direction.

The mitral valve is located between the two left heart chambers and ensures that during a normal heart beat blood will flow through your heart in a forward direction. It serves as a valve. If the mitral valve does not close completely, blood will flow back in the opposite direction. This backflow is called mitral regurgitation.



ILLUSTRATION OF THE FOUR HEART CHAMBERS AFFECTED BY MITRAL REGURGITATION. THE YELLOW ARROWS INDICATE BLOOD FLOWING BACK.

SIGNS AND SYMPTOMS OF MITRAL REGURGITATION

Signs and symptoms of mitral regurgitation depend on how far and how fast the disorder has developed. Sometimes, there are few or no symptoms at all. If there are symptoms – especially in case of severe MR – they may include the following:

- 1 Shortness of breath, especially on exertion or when lying down
- 2 Weakness and exhaustion, especially with increased activity (e.g. climbing stairs)
- 3 Dry cough, often worsening when lying down
- 4 Palpitations or fast, fluttering heart beat
- 5 Excessive water retention (edema)
- 6 Excessive urination at night



DIAGNOSIS OF MITRAL REGURGITATION

If mitral regurgitation is suspected, the physician will start as a first diagnostic measure to auscultate the heart using a stethoscope. Blood flowing back from the left heart chamber through the diseased mitral valve into the left atrium can be heard easily through a stethoscope. Other measures include:

An electrocardiogram (ECG) records the electrical activity of the heart and enables to identify abnormal heartbeats or damages to the heart muscle. A chest x-ray may detect an enlarged left atrium and water retentions in the lung (edema). Cardiac catheterization may help determine the quantity of blood flowing back from the left heart chamber through the diseased mitral valve into the left atrium.

One of the most important and most conclusive investigations to determine mitral regurgitation is a **cardiac ultrasound**, the so-called echocardiography. The physician will be able to detect blood flowing back from the left heart chamber into the left atrium and an enlarged left atrium.



Echocardiography may be performed from the outside (transthoracic echocardiography) or from the inside (transesophageal echocardiography). During the so-called stress echocardiography, the patient is exposed to slight exertion while on a bike ergometer. This will increase the patient's heartbeat and make it easier to determine the severity of the disease compared to the condition at rest. Should the patient's physical condition not allow such examination, repeatedly squeezing a soft ball with the hand might help to slightly increase the heartbeat and better visualize mitral regurgitation.

SEVERITY CLASSIFICATION OF MITRAL REGURGITATION

If there is a weakness of the heart such as mitral regurgitation, the severity may be classified based on a variety of criteria. The New York Heart Association (NYHA) has established a classification based on the physical capacity:



NYHA- Stage I

» Heart disease is known, without limitation of physical capacity



NYHA- Stage II

» The physical capacity is slightly reduced, without complaints at rest, complaints during everyday physical activity



NYHA- Stage III

» The physical capacity is severely limited, complaints during slight physical activity, no symptoms at rest



NYHA- Stage IV

» Symptoms during any physical activity and at rest, bedridden

CAUSES OF MITRAL REGURGITATION

There are a variety of causes for mitral regurgitation which include:

- » Deterioration of valve tissue
- » Congenital valve anomaly (inborn anomaly)
- » Heart diseases such as myocardial infarction or other factors resulting in a weakening of the heart muscle

In general, medicine distinguishes between organic mitral regurgitation (also referred to as primary or degenerative MR) and functional mitral regurgitation (also referred to as secondary MR). Mitral regurgitation is referred to as organic if changes of the heart valve itself are identified as the root cause of the disorder. Functional MR, on the other hand, is the result of changes in the surrounding structures, especially the left ventricle (heart chamber).

EFFECTS OF MITRAL REGURGITATION

Mitral regurgitation is an additional burden for the heart and lungs. Depending on the severity, a smaller or larger quantity of oxygen-enriched blood – destined to supply organs such as brain, kidneys, intestines,

etc. – flows back into the atrium instead of reaching the circulation.

This will result in certain health implications: To make up for the lacking

blood volume in the organs, the heart may enlarge in some patients because it has to work harder to pump blood through the body. However, this enlargement will weaken the heart over time.

This weakness of the heart will result in limited capacity, shortness of breath on exertion and backflow of blood in the pulmonary circulation involving the risk of pulmonary edema which may be life-threatening if untreated.

The blood flowing back into the atrium also results in enlarging the atrium. This may lead

to cardiac arrhythmia (such as atrial fibrillation) or even stroke.

A leaking heart valve will long be tolerated by the body without the patient necessarily noticing the problem. However, when symptoms occur, the heart valve disease may often have reached an advanced stage.

Severe mitral regurgitation is a serious disease that needs to be diagnosed and treated in a timely manner in order to avoid the above mentioned health implications.



TREATMENT OF MITRAL REGURGITATION

Mitral regurgitation therapy depends on how advanced the disease is, whether it is worsening and what the symptoms are. In mild cases, no treatment might be required. However, you should be checked by your physician on a regular basis.

If symptoms are few and minor, medication might be sufficient. In serious cases, surgical or less invasive mitral valve repair methods will often be used.

MEDICATION

Your physician may prescribe you drugs that can help alleviate the symptoms of mitral regurgitation. However, this medication will only treat MR symptoms and cannot eliminate the root causes.

Diuretics

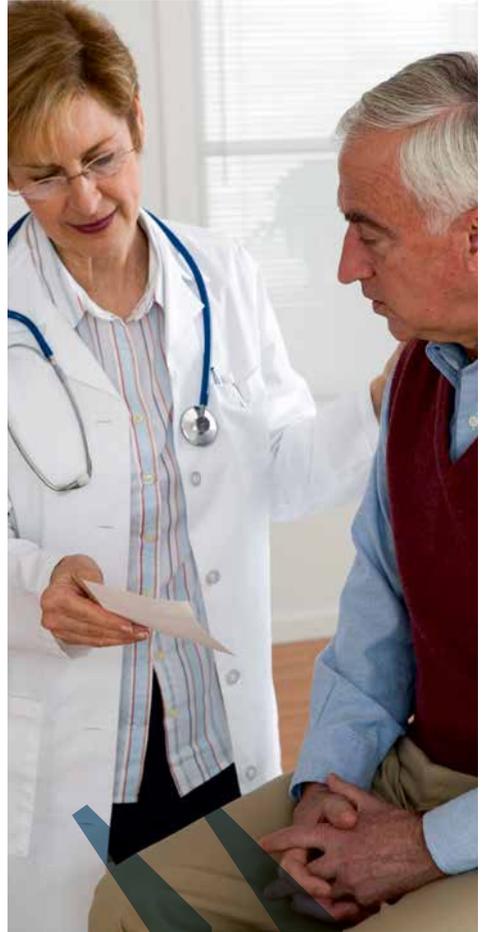
Diuretics are drugs that promote the production of urine in your kidneys in order to remove excessive fluid from your body. This will help your heart to pump less fluid through your body and should result in alleviating water retention (edema), e.g. in your lungs or legs.

Antihypertensive Drugs

Antihypertensive drugs (e.g. ACE inhibitors or AT1 blockers) are used to reduce the pressure at which your heart will have to pump blood through your body, i.e. lower the resistance. This will result in lowering your heart's burden and in less blood flowing „backwards“.

Blood-thinners

Blood thinners (anticoagulants) are supposed to reduce the risk of blood clot formation. In that function, they may provide protection against strokes which are often the result of cardiac arrhythmias which are, in turn, caused by mitral regurgitation.



OPEN-HEART SURGERY

Depending on MR root cause, severity and symptoms, your physician may recommend do undergo surgery in order to have the mitral valve repaired (reconstructed) or replaced. For patients eligible for surgery due to their disease patterns and general physical conditions this method is the number one choice – with good long-term outcomes and good prospects for MR improvement.

Mitral Valve Repair

Surgery to repair the mitral valve is often used when the defect can be eliminated while preserving the patient's heart valve. A variety of techniques may be used for mitral valve repair. The valve annulus, for example, may be tightened using a plastic ring in order to improve coaptation of the valve leaflets. In exceptional cases, some of the less complex repair techniques may be performed minimally invasive via a small incision below the right nipple.

Mitral Valve Replacement

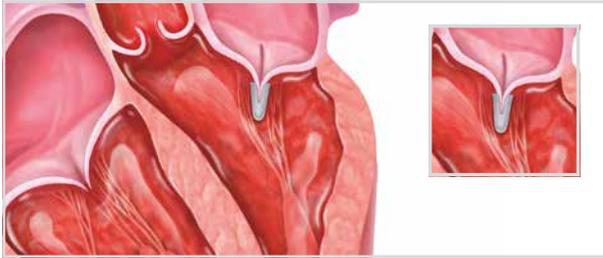
Depending on the severity of the damage the mitral valve may have to be replaced surgically. For replacement, either a mechanical valve of metal or plastic or a biological valve may be used. If a mechanical valve is used, patients will have to take anticoagulants (blood thinning drugs) for the rest of their life. Mitral valve replacement is performed with the chest cut open and using a heart-lung machine since the heart will stand still during surgery.



PERCUTANEOUS MITRAL VALVE REPAIR

If you meet certain criteria, your physician may recommend to undergo a procedure which is less invasive compared to open-heart surgery: the so-called percutaneous mitral valve repair. This technique is a minimally invasive method not requiring open-heart surgery.

Cardiologists and cardiac surgeons using this technique are able to repair your mitral valve by “clipping“ the two valve leaflets. The mitral valve clip provides that the valve closes completely so that normal blood flow through your heart is restored.



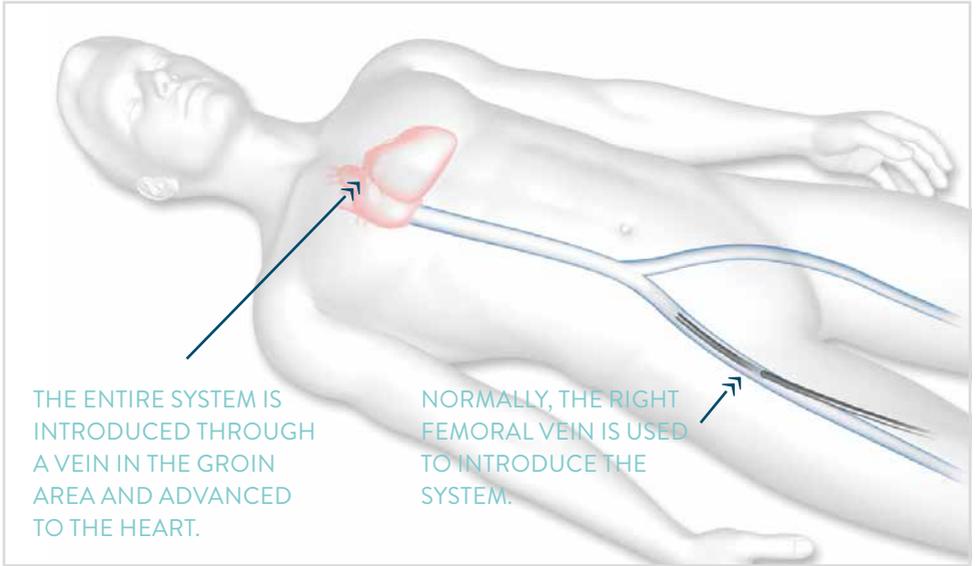
PICTURE OF THE CLOSED MITRAL CLIP FIXED TO THE MITRAL VALVE. CLOSE-UP OF THE MITRAL VALVE CLIP (DETAIL).

PERCUTANEOUS MITRAL VALVE REPAIR – HOW DOES IT WORK?

The mitral valve clip is sort of a clamp fastened directly to the mitral valve without having to open the chest or use a heart-lung machine. To get access to the mitral valve, a long and flexible guiding catheter is introduced via vein in the groin area and advanced to the heart.

This catheter then helps to fasten the mitral valve clip to the mitral valve so that it can close more tightly. During the procedure, physicians may check the clip’s position with the heart beating and, if required, correct the position until the desired best possible MR reduction has been achieved because MR reduction is monitored in real time via 3D ultrasound. The procedure is performed under general anesthesia and the patient will have to stay in hospital for a few days after the procedure.





THE ENTIRE SYSTEM IS INTRODUCED THROUGH A VEIN IN THE GROIN AREA AND ADVANCED TO THE HEART.

NORMALLY, THE RIGHT FEMORAL VEIN IS USED TO INTRODUCE THE SYSTEM.

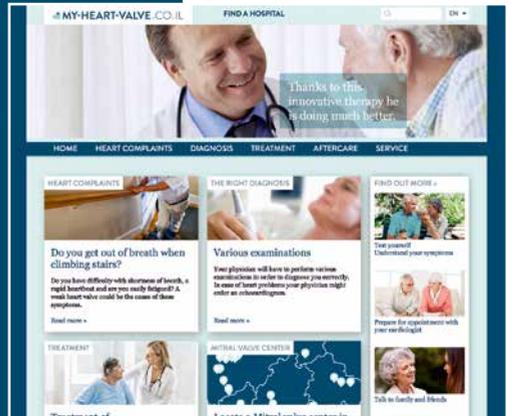
HOW TO FIND HELP NEAR YOU

If you should be looking for a clinic or cardiologist in private practice near you to contact and discuss the appropriate type of therapy for you, we recommend to use the clinic search at www.my-heart-valve.co.il

Just enter your ZIP code and/or your city and you will receive information on those in your proximity experienced in mitral valve clip therapy. You may also check for rehab offers in your vicinity.



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AFTER THE PROCEDURE

FIRST DAY AFTER

You should avoid strenuous activities (such as lifting or carrying) for at least 30 days after the procedure. Your physician will let you know which drugs to take for a limited time after the procedure (e.g. blood thinners). It is very important that you follow your physician's orders and turn to him or her directly if you should have any questions or problems.

After percutaneous mitral valve repair, most patients do not require special assistance at home exceeding the care they get for their other diseases.



GOOD TO KNOW

For medical care, especially in cases of emergency, it is important to know that a mitral valve clip has been implanted. Therefore, your physician will hand to you after the procedure a mitral valve clip patient ID which you should always have with you.



By the way, even after mitral valve clip implant you will be able to use diagnostic imaging techniques such as magnetic resonance imaging if certain conditions are met. Please always remind your physician that you have a mitral valve clip implanted.

OTHER HEART VALVE DISEASES

Apart from mitral regurgitation, there are other heart valve diseases which may require treatment depending on their severity:

MITRAL VALVE

Mitral Valve Stenosis

- » Mitral valve stenosis means that the mitral valve has a narrowing, i.e. the valve does not open up wide enough to allow blood to flow from the left atrium to the left ventricle.

AORTIC VALVE

The aortic valve, which is also located in the heart's left side, controls the blood flow from the left ventricle back into the aorta and, thus, in the systemic circulation.

Aortic stenosis

- » Aortic stenosis is the most common heart valve defect. It means that the heart valve is hardened and narrowed at the left ventricle's exit. This results in the heart having to apply more energy to pump the oxygen-rich blood into the aorta and the body. Depending on the severity of the disease, the volume of oxygen-rich blood reaching the systemic circulation might not be enough, thus causing symptoms like dizziness or circulatory failure. The most common causes for aortic stenosis at an advanced age are deterioration and calcification of the heart valve.

Aortic insufficiency

- » Aortic insufficiency means that the aortic valve is not able to close properly so that part of the blood pumped from the left ventricle into the aorta will flow back. Since the left ventricle also has to accommodate the new blood entering from the left ventricle, it is severely stretched – which may result in general heart failure (weakness of the heart). Among the root causes for aortic insufficiency may be rheumatic fever which may also affect the heart valves or a bacteria-triggered inflammation of the aortic valve (endocarditis).

Glossary

- » **Blood thinner:** These drugs reduce the blood's ability to clot in order to avoid the formation of blood clots.
- » **Catheter:** Medical tube used to provide access to the inside body. When performing percutaneous mitral valve repair, a catheter will be entered in the patient's groin area and advanced to the mitral valve in the heart.
- » **Congenital valve anomaly:** Anomaly of the heart valve existing since birth. It may affect size or shape of the valve but also how the valve is attached to the heart.
- » **Mitral regurgitation:** Heart disease in which the mitral valve does not close properly when the heart pumps blood so that blood flows back in the opposite direction.
- » **Mitral valve:** The valve in the heart that is located between the left atrium and the left ventricle. The mitral valve allows oxygen-rich blood to enter the left ventricle, then closes tightly to keep blood from flowing back (valve function).
- » **Stroke:** Rapid loss of brain functions due to disturbed blood supply in the brain. This may be the result of lacking blood due to blockage or bleeding.

The information contained herein shall not replace medical advice by a licensed physician. If you should have any further questions regarding this therapy, please turn to your physician.

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