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Dear reader



Have you ever heard of aortic stenosis?

If not, you are not alone: Surveys have shown that nearly 98 percent of people in the UK over the age of 60 are unaware of the condition.¹

These findings are quite alarming as aortic stenosis is common and can be life-threatening if left untreated.² The condition affects one out of eight people over the age of 75.³ At least 400,000 people

in the UK are estimated to live with aortic stenosis and this number continues to rise.⁴ The long-term health for untreated patients with severe aortic stenosis is poor,⁵ but despite this being a severe condition, it is important to remember that aortic stenosis can be effectively treated.⁶ Being aware of the condition and knowing the symptoms and how to identify them is therefore vital.

In the early stages, many people might be unaware that they have aortic stenosis as they do not experience any symptoms, or simply put symptoms down to 'feeling their age'.^{7,8} The easiest way to detect aortic stenosis is to ask your GP for a stethoscope check of your heart. Getting regular stethoscope checks of your heart together with identifying the symptoms is critical, so that the disease can be detected and treated early.⁹

This brochure aims to help you better understand aortic stenosis, its signs and symptoms, how the disease progresses, and available treatment options. You will also hear from Colin, who was treated for severe aortic stenosis during the COVID-19 pandemic. Even though aortic stenosis is serious, I want you to feel reassured as the condition can be effectively treated with minimal stress, so that you may return to a good quality of life. I hope you find this information useful.

Best wishes,

Dr Hazim Rahbi Consultant Interventional Cardiologist Great Western Hospital



Your heart: A miracle machine

Our heart is located in the center of the rib cage, under the sternum, and is well protected by this structure.

The heart's job is to pump the blood through the body – around 70 times a minute – via two different blood circuits (a circuit with blood that is oxygen rich and a circuit with blood that has little oxygen in it).

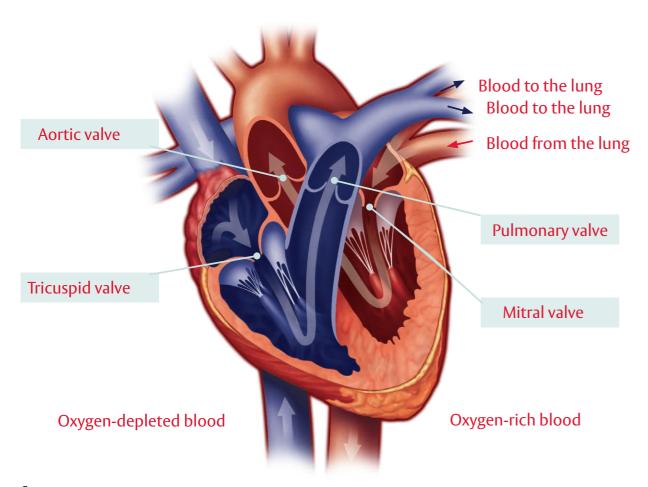
The heart is divided into two halves, each of which has an upper chamber (atrium) and a lower chamber (ventricle).

While the chambers on the right take the blood with little oxygen and transport

it to the lungs, the two left chambers pump blood rich with oxygen from the lungs into the circulatory system and thus to the organs.

The four heart valves (mitral valve, aortic valve, tricuspid valve and pulmonary valve) act like doors between the heart chambers and the great blood vessels.

They open in only one direction to ensure blood flows in the right direction. The perfect interaction between the heart chambers and heart valves enables our organs to be supplied with oxygen through the blood with every heart beat.



When your heart valve calcifies

Our heart is a truly miraculous machine. It pumps blood through our body, supplying oxygen and nutrients to our organs – up to 10,000 liters a day. Most of the time, this ultra-high performance goes completely unnoticed. We don't pay any attention until our heart stops working properly. Even then, we often don't notice anything until very late in the disease. This is because we dismiss the symptoms and physical complaints as harmless signs of aging and fail to link them to a heart problem.

Feeling short of breath? Tired? Dizzy?
These are all symptoms that you need to pay closer attention to

You might be familiar with one or more of the following scenarios:

- Physical activity is becoming harder
- You run out of breath more quickly than usual, for instance, when climbing stairs
- You feel dizzy or faint when you have been active
- You occasionally or regularly have pain in the chest and heart area

Many people interpret these and similar problems as normal age-related symptoms or a sign of waning physical fitness. But they can also be a warning of aortic valve stenosis (or aortic stenosis for short), which refers to a build up of calcium deposits or narrowing of one of

our heart valves, a condition that requires medical attention. If left untreated, it can lead to death.

Our heart valves

The four heart valves keep the blood in our body from flowing in the wrong direction.

The aortic valve regulates the blood flow from the heart into the aorta (the blood vessel that goes from the heart to the rest of the body).

It is particularly susceptible to a build-up of calcium.

As a result of a build up of calcium deposits, the valve can no longer fully open, which restricts

blood flow.

Blood supplies oxygen and nutrients to the body and when something stops this happening properly you can experience

symptoms such as shortness of breath, dizziness or increased stress upon physical exertion.

"It started on the golf course, sometimes I would have to stop to put my head between my knees after a steep incline. At this point I knew it was time to visit my GP"

Colin

Aortic Stenosis

ortic stenosis is a common condition:
Up to one out of eight people over
the age of 75 develop aortic stenosis³ but
it can also affect much younger people.
Studies have shown that if left untreated,
half of the patients die within two years
of the start of symptoms.¹0

That's why it is even more important to pay attention to the body's warning signals and to seek immediate medical attention.

"The clock is ticking for severe aortic stenosis patients, every week counts, and we can't afford to have them hanging on the system for too long."

Dr Rahbi

The first point of contact should be your general practitioner (GP).

If you are increasingly having symptoms such as shortness of breath or dizziness, you should also ask your doctor to listen to your heart.

The doctor can use a stethoscope to work out immediately if a heart murmur can be heard that indicates aortic stenosis.

If it meets the criteria, your GP will refer you to a heart specialist (cardiologist) to confirm the diagnosis using special tests such as ultrasonography or electrocardiography (ECG), and discuss treatment.

Aortic stenosis: These are all symptoms that you need to pay attention to

- Shortness of breath / respiratory distress
- Dizziness
- Fainting
- Chest / heart pain
- Rapid fatigue / feeling of weakness
- Increasing difficulties during physical exertion

While these signs are very typical in older people, it is also possible for aortic stenosis to occur with few or no symptoms, especially in the early stages, or for your symptoms to be caused by something else. In order to prevent an existing stenosis from worsening without noticing it, you should attend regular check-ups and have regular heart stethoscope checks with your general practitioner.

Good to know: A calcified valve is treatable!
(Read more about this starting on page 10)

The main risk factor for developing aortic stenosis is age:

- Up to 7 % of people over the age of 65 are affected¹⁰
- In people aged 75 and over, this share is even higher at 12%³

While in principle, anyone can develop aortic stenosis, there are some factors and pre-existing conditions that increase this risk. These include:

- Smoking
- Diabetes
- Disorders of lipid metabolism
- High blood pressure

Heart valve disorders can also be something someone is born with (called 'congenital') and can occur independent of age and lifestyle.

"Aortic stenosis has a latent period, meaning it can remain hidden, which can go on for a long time. Patients can also underplay their symptoms or put them down 'to feeling their age'. Not actively seeking it out impacts mortality and morbidity in a disease such as severe aortic stenosis, it is therefore important to probe patients on symptoms otherwise they won't tell you. Questions like "are you breathless?" are not enough, a better question would be "when going up a hill or climbing stairs do you get breathless?"

Dr Rahbi

For this reason, younger people experiencing typical symptoms should also see their general practitioner and have the symptoms checked.



Diagnosed with aortic stenosis: What you need to know now

oday, if your doctor determines that you have a ortic stenosis, it does not automatically mean that you will need a big operation.

The following pages will provide an overview of the treatment methods currently available. Your doctor – possibly also in consultation with other doctors and specialists – will first thoroughly examine you and will then advise you about which option is best suited for you. In most cases of diagnosed aortic stenosis, the calcified valve must be replaced. Replacing a damaged heart valve is the standard treatment for aortic stenosis. Different replacement methods exist: Surgical aortic valve replacement (sAVR) and transcatheter aortic valve implantation (TAVI).9

"To some patients it comes as a surprise because they think they are 'fine' and then they are being told they have a serious condition, which many have never heard of, and it needs to be treated."

Dr Rahbi

Surgical aortic valve replacement (sAVR)

This procedure was the only effective method for replacing a calcified valve for decades.^{6,11,12}

For the procedure, you are often placed under general anesthesia, the chest cavity is opened and the heart temporarily "stopped" to allow doctors to implant the artificial valve directly into the heart.

During the surgery, you are connected to a heart-lung machine, which performs the tasks of the heart and lung and supplies the organs with oxygen. Once the new aortic valve is attached in the heart, the heart-lung machine is switched off, the natural circulation is restored and the heart usually resumes beating completely automatically. The chest cavity is then closed.

After one or two days in the intensive care unit, you can generally be transferred to the normal ward and are then discharged for rehabilitation for several weeks.

The surgery is tried and tested and the prognosis is very good.¹³ Most patients feel much better after the rehabilitation program and have much more stamina than before the surgery. Activities that were previously possible only with a maximum of effort are then much easier to do.

However, the method also has some disadvantages.

For example, open-heart surgery is relatively stressful for the body.

This applies not only to the procedure itself, but also to the general anesthesia,¹⁴ if this is required, which must sometimes be administered for several hours and is always associated with some risk.¹⁵

Complications during or after the surgery can never be completely ruled out.

These include irregular heart rhythm (arrhythmia), infections of the surgical wound, abnormal blood flow in the brain (resulting even in stroke) or kidney problems.¹⁶

In particular for people who are sick, elderly or weak, surgery is therefore not always suitable.

For this reason, especially for these patients, the second method for heart valve replacement should be considered: transcatheter aortic valve implantation (TAVI).

Access options during surgical aortic valve replacement

1 Full sternotomy
2 Mini sternotomy
3 Mini thoractomy



No major surgery: TAVI

n addition to surgical valve replacement, transcatheter aortic valve implantation (TAVI) is an option for replacing calcified aortic valves.

Particularly for patients with an elevated risk of surgery-related complications, this alternative is often the better choice.

TAVI is a less invasive procedure^{11,17} than surgery meaning that the chest cavity does not need to be opened in order to implant the artificial heart valve. Instead, the valve is implanted through a catheter (a very thin tube) that is introduced into the body through a small incision. Since TAVI is performed with the heart still beating, a heart-lung machine is also not needed. And general anesthesia is not always required, because in some cases TAVI can be performed under local anesthesia.¹⁸

How TAVI works

If TAVI has been decided on as the right treatment for you, the first step involves preparing the artificial valve.

Owing to their flexibility and consistency from soft tissue, only biological valves are suitable for this procedure.

The artificial valve is first folded up to the thickness of a pencil inside a catheter.

The catheter is then introduced into the body, usually through the femoral artery in the leg, and from there is moved through the bloodstream to the heart and positioned with millimeter precision.

Other points of access are in the chest near the heart.

When the valve reaches the implant site, it unfolds, pushing aside the calcified aortic valve and starts to work immediately.

Dr Rahbi on why TAVI was chosen for Colin

"Two reasons really. First, the European Society of Cardiology guidelines, which clearly state an age of 75 or over would favour TAVI. Secondly, it was Colin's preference, he said to me: "TAVI is the way forward".

After that, the catheter can be removed.

Recovery from the procedure usually takes just a few days, ^{19,20} depending on what other conditions or diseases you may have.

The possible risks associated with TAVI include arrhythmia (e.g. atrial fibrillation), blood vessel complications caused by the catheter, kidney damage and a slight risk of stroke. Your doctor will inform you about any possible complications before the procedure. 19,21

In general, TAVI has a very good prognosis.²² Your quality of life is generally already significantly better soon after the procedure.¹¹

Advantages of TAVI at a glance

- Less invasive^{11,17}
- Shorter recovery period^{19,20,22}
- In most cases, quick discharge from the hospital^{19,20}
- In some cases, can be performed under local anesthesia¹⁸

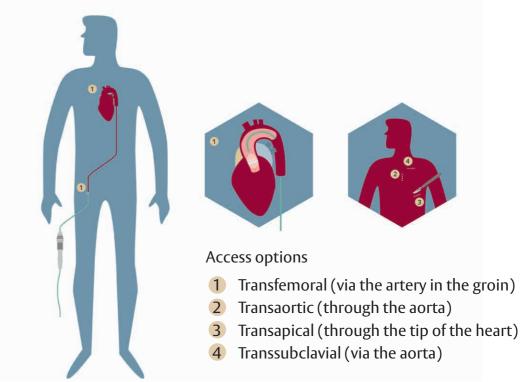
TAVI is especially well-suited for patients who might be at risk of, or unable to have surgery, such as elderly people or those with pre-existing conditions or diseases, such as elderly people or patients with pre-existing conditions or diseases.

In most cases, a special Heart Team consisting of a cardiologist, a heart surgeon and an anesthetist make the treatment decision.

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Colin's experience of the TAVI treatment process

"Everything went smoothly, it was reassuring to have the familiar face of Dr Rahbi there throughout the process from diagnosis to treatment and follow-up consultation, as he was the cardiologist my GP referred me to."



Mechanical or biological heart valve?

When it comes to heart valve replacement, two different valve types are available that each offer specific advantages and disadvantages. Your doctor will discuss which valve is best suited for you.

Mechanical heart valve^{23,24}

A mechanical heart valve is made from strong materials such as metal.

The advantage of this is that it is able to withstand damage

and can last a life time.

The disadvantage is that if you have a mechanical heart valve implanted, you have to take blood thinners for the rest of your life. Because

of its long lifespan, this valve type is often implanted in younger patients.

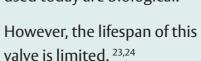
Biological heart valve

A biological heart valve consists of animal tissue from pigs or cows that is cleaned and prepared for use in the human heart.^{23,24}

Its huge advantage is that blood thinners can already be discontinued after just a few weeks.^{23,24}

In addition, the valve can be folded during implantation and can thus be used for TAVI as well (p. 12).

Owing to these qualities, an increasing number (and around 90% of those in people aged >70 years) of the artificial heart valves used today are biological.²⁵



The period during which a biological valve can remain in a person's body varies from 10 to 20 years, depending on the patient.^{23,24}

"I would urge aortic stenosis patients to reach out and ask for help. It is important as there are lots of misconceptions and we are here to support."

Dr Rahbi

Patient Colin Bulley:



'I never really experience any pain or general discomfort. The only thing was a general feeling of being unable to keep up the same pace as before.'

What happened after your

diagnosis and how did you feel?

My feelings were mixed, I didn't really know much about aortic stenosis so wanted to learn more about it and the various treatment options.

None of my friends knew of it either so I did a lot of reading online.

Was your diagnosis and treatment impacted by COVID-19 in anyway?

Due to lockdown, I had a longer wait to see my GP about my symptoms. The government advice was to stay at home and protect the NHS, so I did exactly that.

I went to see my GP as soon as I was able.

Once I was in the system things went quickly and seemed to work well so I do not believe things were impacted very much at all.

Cardiologist Dr Hazim Rahbi:



'Once a patient develops symptoms, survival is significantly reduced without active treatment.'

The clock is ticking for severe aortic

stenosis patients, every week counts, and we can't afford to have them hanging on the system for too long.

I would urge aortic stenosis patients to reach out and ask for help. It is important as there are lots of misconceptions and we are here to support. There are treatment options which are safe, effective, and depending on the individual case a keyhole procedure may be considered.

What would you say to patients who fear coming in due to COVID-19?

Regardless of any restrictions, we are here to treat our patients and do our best.

There are systems in place to reduce the transmission at the hospital.

Things might therefore take a bit longer, but that should not mean that patients should avoid seeking medical advice.

Doctor Discussion Guide

Aortic stenosis is not a harmless condition. Do not wait too long. Go to your doctor and discuss your symptoms. Having this condition diagnosed early on and exploring your treatment options are important steps for protecting your health.

Don't allow yourself to be controlled by your disease. Take control of yourself by bringing this guide along with you to your next doctor's appointment. It's important for you to tell your doctor if you have noticed any of these symptoms or if symptoms have become worse.

☐ I have been diagnosed with aortic stenosis

I have noticed the following symptoms

heart beat

6 months ago

(Please check all that apply)

Pain or tightness in the chest
Shortness of breath
Dizziness
Fainting
Heart palpitations
Swollen ankles or feet

☐ Difficulty walking short distances Sensations of an irregular or rapid

☐ I no longer engage in physical

activities that I still enjoyed doing

What activities could you still do		
6 months ago that you cannot do today?		
What medications are you currently		
taking, and what are you taking them for?		
Important questions to ask your doctor		
When you visit your doctor, it's important		
to mention even minor symptoms or		
changes to your daily routine, as this may		
be a sign of aortic stenosis or your aortic		
stenosis getting worse.		
Relow you will find additional questions		

find the best-suited treatment option for you.

- I have experienced one or more symptoms of aortic stenosis. What should I do?
- How is a ortic stenosis diagnosed?
- What types of tests will I need to go through for diagnosis?
- If I am diagnosed with aortic stenosis, how frequently will I need follow-up tests?
- If my aortic stenosis is severe, what are my treatment options?
- What types of tests will I need to go through for determining the best treatment option for me?
- Am I a candidate for transcatheter aortic valve implantation (TAVI)?

Write down any other questions you
may have for your doctor here:

to ask your doctor.

Talking through your answers with your doctor can help you to recognize potential aortic stenosis early on and help

Keep in mind:

- Heart valve diseases are common and can cause heart murmurs
- Your general practitioner can use a stethoscope to determine whether you have a heart murmur
- Different treatment options are available
- Talk to your doctor to find out which treatment option is best-suited for you



For further information and to utilise our step-by-step guide, go to

www.newheartvalve.co.uk

References:

- 1. Gaede L, et al. Clin Cardiol. 2020;43(12):1539-1546.
- 2. Carabello BA. Circ Res. 2013;113(2):179-185.
- 3. Osnabrugge RLJ, et al. J Am Coll Cardiol. 2013;62(11):1002–1012.
- 4. British Heart Foundation. New trial from Leicester to identify best treatment for aortic stenosis. Available at: https://www.bhf.org.uk/what-wedo/news-from-the-bhf/news-archive/2019/october/aortic-stenosis-clinical-trial-in-leice (accessed June 2021)
- 5. Ross | Jr & Braunwald E. Circulation 1968;38(1 Suppl):61–67.
- 6. Brown ML, et al. J Thorac Cardiovasc Surg. 2008;135(2):308–315.
- 7. Amato MCM, et al. Heart 2001;86(4):381–386.
- 8. Redfors B, et al. Circulation. 2017;135(20):1956–1976.
- 9. Baumgartner H, et al. Eur Heart J. 2017 Sep 21;38(36):2739–2791.
- 10. Otto C. Timing of aortic valve surgery. Heart 2000;84(2):211–218.
- 11. Reynolds MR, et al. J Am Coll Cardiol. 2012;60(6):548-558.
- 12. Rogers T, et al. J Am Heart Assoc. 2018. 7(10):e007147.
- 13. Lindman BR, et al. Nat Rev Dis Primers. 2016;2:16006.
- 14. Chacko M & Weinberg L. BJA Education. 2012;12(6):295–301.
- 15. NHS. General anaesthesia. Available at: https://www.nhs.uk/conditions/general-anaesthesia/ (accessed June 2021).
- 16. NHS. Risks: Aortic valve replacement. Available at: https://www.nhs.uk/conditions/aortic-valve-replacement/risks/ (accessed June 2021).
- 17. Kleczyński P, et al. Kardiol Pol. 2014;72(7):612–616.
- 18. Edwards LifeSciences. Edwards SAPIEN 3 System, Edwards SAPIEN 3 Transcatheter Heart Valve, Edwards Commander Delivery System Transfemoral. Available at: https://eifu.edwards.com/eifu/pages/viewers/pdf?projectKey=5970f1a946e0fb00015e5f4c&item-Key=5f7794e0812dff00011f6b76 (accessed May 2021).
- 19. Mack MJ, et al. N Engl J Med. 2019;380(18):1695–1705 and supplementary material.
- 20. Thourani VH, et al. Lancet. 2016;387(10034):2218-2225.
- 21. VARC-3 WRITING COMMITTEE, et al. Eur Heart J. 2021;42(19):1825–1857.
- 22. Leon MB, et al. N Eng | Med 2016;374(17):1609–1620.
- 23. Harris C, et al. Ann Cardiothorac Surg. 2015;4(4):399.
- 24. British Heart Foundation. How do replacement heart valves work? Available at: https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/replacement-heart-valves (accessed June 2021).
- 25. Head SJ, et al. European Heart Journal 2017;38(28):2183–2191.

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