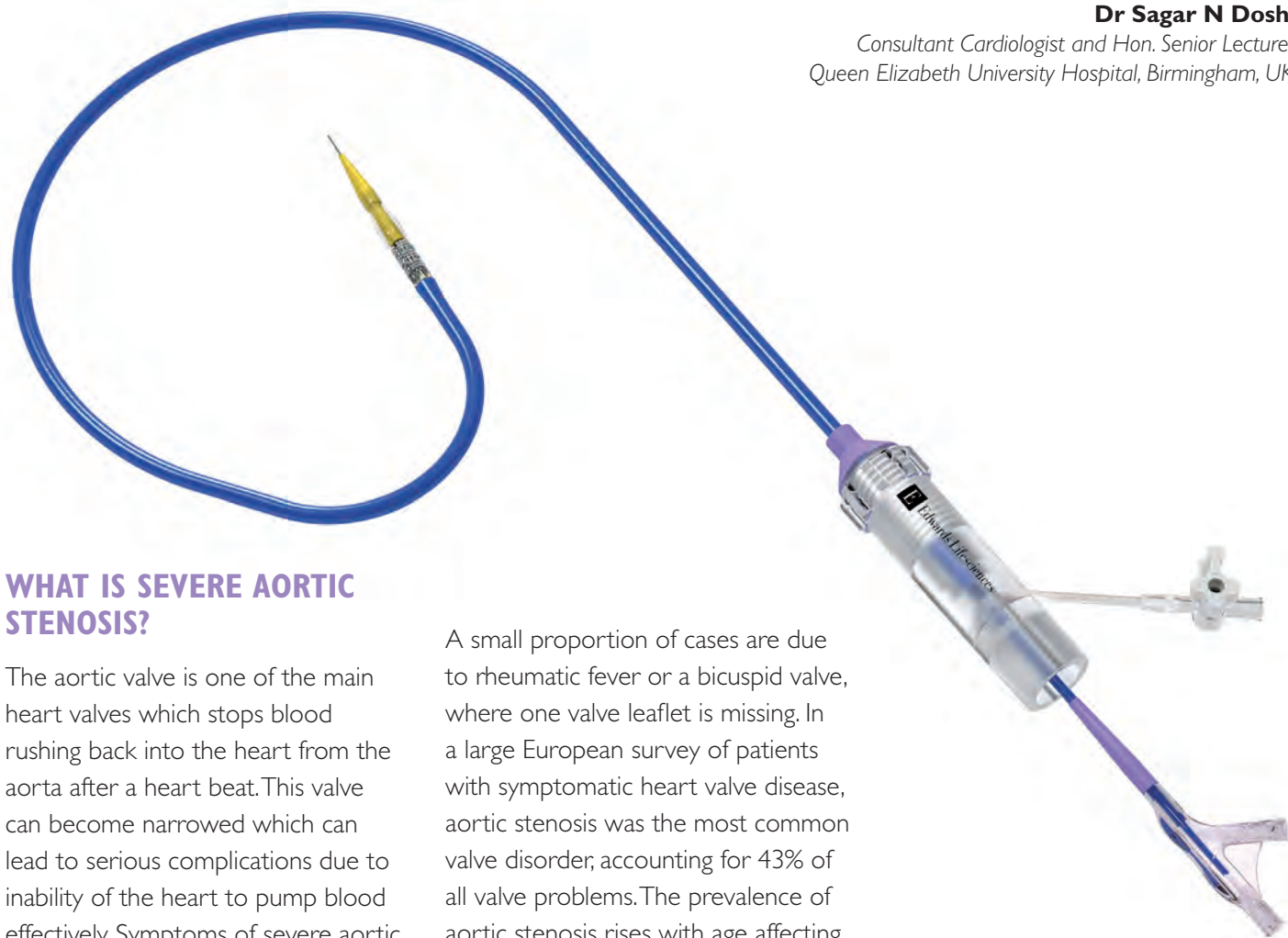


Every thing you need to know about severe aortic stenosis and transcatheter aortic valve implantation (TAVI)

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WHAT IS SEVERE AORTIC STENOSIS?

The aortic valve is one of the main heart valves which stops blood rushing back into the heart from the aorta after a heart beat. This valve can become narrowed which can lead to serious complications due to inability of the heart to pump blood effectively. Symptoms of severe aortic stenosis include angina, exertional breathlessness and blackouts. Heart failure eventually ensues and affected individuals may then develop swollen ankles and difficulty breathing at night.

WHO GETS AORTIC STENOSIS?

The most common cause of aortic stenosis, in developed countries, is calcific degeneration where the valve becomes rigid and as a result opens less well.

A small proportion of cases are due to rheumatic fever or a bicuspid valve, where one valve leaflet is missing. In a large European survey of patients with symptomatic heart valve disease, aortic stenosis was the most common valve disorder, accounting for 43% of all valve problems. The prevalence of aortic stenosis rises with age affecting less than 1% of the population below age 74 years but around 4.6% of those over 75 years. Men and women appear to be equally affected. As life expectancy in the UK and other developing countries is rising, the prevalence of aortic stenosis in the population is expected to rise.

HOW IS SEVERE AORTIC STENOSIS DIAGNOSED?

A narrowed valve causes turbulence which creates a 'murmur' which

doctors can detect with a stethoscope. Severe aortic stenosis can cause changes on the ECG, however these are non specific and may be absent. To confirm the diagnosis a painless, safe test called an echocardiogram is usually undertaken.

The echocardiogram uses sound waves to visualise the heart valves and also gives information on the strength of the left ventricle, the main pumping chamber of the heart.

WHAT TREATMENTS ARE AVAILABLE FOR SEVERE AORTIC STENOSIS?

OPEN-HEART SURGERY

American and European guidelines recommend that when patients become symptomatic of severe aortic stenosis they should be considered for open heart surgery to replace the narrowed valve. Aortic valve replacement is a very effective treatment: patients feel better; live longer and left ventricular function improves. Unfortunately not all symptomatic patients with severe aortic stenosis undergo open heart valve surgery. In the Euroheart Survey 32% of patients with symptomatic valve disease did not undergo surgery. The principle reason for this was the presence of co-existing conditions which increase the risks of open heart surgery. Factors known to increase the risk of surgery include previous open heart surgery, a history of stroke, kidney failure or vascular disease to name but a few. It is estimated that around 15-20 per million of the UK population have severe symptomatic aortic stenosis who are considered unfit for conventional valve surgery. The outlook for these patients with severe aortic stenosis is extremely bleak.

DRUG THERAPY

Unfortunately drugs have little influence in the treatment of severe aortic stenosis. Diuretics may slightly and only temporarily alleviate symptoms but do not alter the progression or outcome of the disease.

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

To combat the unmet need of patients who require aortic valve replacement but are considered at too high a risk from conventional surgery, transcatheter heart valve

technology (THV) was developed. This allows implantation of an aortic valve in a minimally invasive procedure either through the leg or through a small operation on the chest wall. At present only 2 types of THV devices are available: the Edwards valve and the CoreValve. The first human THV procedure was performed using an Edwards valve in 2002 with the first human CoreValve implant in 2004. Both valves became commercially available in 2008 and since then over 10,000 implants with each have been performed world-wide.

THE EDWARDS THV

The Edwards Sapien (Edwards LifeSciences) valve consists of a stainless steel stent in which a biological aortic valve, made from bovine pericardium (sac that contains the heart), is suspended. The valve can be implanted via the femoral artery, at the top of the leg when the leg arteries and aorta are suitable. Alternatively, the valve can be implanted via a small incision made on the left chest wall. In both procedures the valve is crimped on to a balloon which is positioned using x-rays and echocardiography. To fine-tune positioning the heart is made to beat very quickly by a temporary pacing wire. The balloon is expanded

and the stent is opened within the old valve which is forcibly pushed open. The new valve now takes over and the calcium on the redundant valve helps to hold the stent in place.

THE COREVALVE THV

The CoreValve (Medtronic) is a self expanding nitinol (type of metal) stent in which a porcine valve (made with pig tissues) is suspended. Like the Edwards valve the CoreValve can be inserted via the femoral artery at the top of the leg when the arteries are suitable. When this is not the case the valve can be implanted via an artery in the shoulder through a small incision. The valve is positioned using x-rays and deployed by retraction of a protective sheath. The self expanding stent opens within the old valve pushing the leaflets apart. This opens the porcine valve suspended within the nitinol cage which then takes over the function of the native valve.

Because procedures using the Edwards and CoreValve are performed through small incisions the hospital stay post procedure is typically much shorter than with conventional surgery and patients are mobile much earlier.

As both valves are biological there is no requirement for warfarin, a blood thinning agent, but patients are





normally given aspirin and clopidogrel (agents used after coronary stenting) to reduce the risk of clots forming on the valve. No special monitoring is required after the procedures.

WHO CAN UNDERGO TAVI?

At present TAVI is only undertaken in patients who are considered at very high risk from conventional surgery or those considered inoperable. Patients cannot elect to undergo TAVI simply by preference, although this may change in the future when further data becomes available.

IS TAVI EXPERIMENTAL?

Although still a relatively new procedure TAVI is no longer considered experimental in Europe and both valves are commercially available for use. The data for both valve technologies is comparable with respect to effectiveness and safety. The only consistent difference appears to be a higher need for a permanent pacemaker implantation following implant with the CoreValve.

Both valves are undergoing continuous refinement and development and to date there is a considerable body of evidence available on the safety of the procedure. The results of the first randomised trial which compared the Edwards Valve with medical treatment in patients at very high risk for conventional valve surgery have recently been announced. This study found the Edwards Valve to be overwhelmingly superior to medical treatment alone with marked improvements in symptoms and mortality at 1 year.

IS TAVI APPROVED BY NICE?

TAVI was reviewed in 2008 by NICE as part of their interventional procedure guidance programme. Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure

but does not make recommendations on whether or not the NHS should fund the procedure. The guidance concluded that the procedure could be undertaken in the UK in patients considered to be at very high risk from conventional cardiac surgery but left funding to be decided at local level by primary care and hospital trusts. To date NICE has not conducted a cost-effectiveness review due to the limited data available. A review of the current procedure guidance is anticipated in summer 2011.

IS TAVI AVAILABLE IN THE UK?

Although there is no central funding for TAVI in the UK, Primary Care Trusts and Hospital Trusts can develop TAVI programmes according to local need. However as no additional money has been made available by the Department of Health to fund delivery of TAVI programmes this has led to wide variation in access to TAVI with treatment freely available in some areas and severely restricted or unavailable in others.

WHERE IS TAVI UNDERTAKEN?

At present TAVI is only performed in large surgical centres where conventional aortic valve surgery is undertaken by multidisciplinary teams consisting of surgeons, cardiologists, anaesthetists, vascular surgeons and nurses.

CONCLUSION

TAVI is an effective treatment for patients with severe symptomatic aortic stenosis who are considered at high risk from conventional aortic valve surgery. Benefits for patients typically include a shorter hospital stay and an earlier return to normal activities due to the less invasive nature of the procedure. The supporting clinical evidence for TAVI continues to grow.