Media Backgrounder: Aortic valve disease

Dysfunction of the aortic valve with life-threatening consequences

- The aortic valve is a one-way valve, which ensures that oxygenated blood out of the left ventricle is carried into the aorta. **Aortic valve disease is defined as an inadequate closing or opening of this valve, resulting in its dysfunction.**
- Aortic valve stenosis is the process of **thickening and stiffening in the valve**, which can result in an abnormal narrowing of the aortic valve opening and reduction in blood flow. As a consequence, the heart needs to work harder to pump the sufficient amount of blood past the narrowed valve and throughout the body.

Principal symptoms associated with aortic stenosis include shortness of breath upon exertion (dyspnea), chest pain or tightness (angina), and dizziness/fainting episodes (syncope).

Left untreated, **severe aortic stenosis can eventually lead to heart failure, severe infection and even sudden death.** From the onset of aortic stenosis symptoms, the average survival rate is 63 percent at two years and 20 percent at five years. In people with **very severe aortic stenosis**, the rate decreases to 36 percent at two years and 12 percent at four years.

Aortic valve stenosis is a progressive, fatal, and expensive condition affecting approximately three percent of the population over age 65 and five percent of people older than 75.

In Europe and North America, aortic stenosis is considered the **most common valvular lesion**. It can be caused by a congenital abnormality or by infections such as rheumatic fever or endocarditis. The most common cause of aortic stenosis in Europe, however, is **calcific degenerative disease**, a build-up of calcium on the valve cups that occurs with increasing age. There are approximately 1.2 million patients with severe, symptomatic aortic stenosis in Europe.

Replacement of the diseased valve in patients with severe aortic stenosis

- Treatment of aortic valve disease remains a significant and **growing unmet clinical need**, among others, due to its increasing occurrence with age and an ageing population.

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*Based on extrapolated figures from Bordoni et al. 2013 and Lung et al. 2007. See reference section.*
• Today, the mainstay of treatment for severe symptomatic aortic stenosis is replacement of the native diseased valve with an artificial valve, normally during open-heart surgery using cardiopulmonary bypass.

• Nevertheless, not all patients are eligible for this treatment, and some are assessed to be a high risk patient for cardiac surgery. Approximately up to one third of patients with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction or multiple medical comorbidities.\(^\text{12}\)

• **For patients who are considered inoperable or at high risk for cardiac surgery, minimally invasive aortic valve replacement technologies such as Transcatheter Aortic Valve Implantation (TAVI)\(^b\) may be the only viable treatment option.**\(^{12,13}\) A 2013 meta-analysis of aortic stenosis in elderly patients in North America and Europe showed that under the current indications, approximately 290,000 elderly patients with severe aortic stenosis are TAVI candidates. This population stands to grow as approximately 27,000 new patients become eligible for the procedure each year.\(^{14}\)

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**TAVI – an alternative treatment for patients who are considered inoperable or assessed to be high risk patients for cardiac surgery**

• TAVI (Transcatheter Aortic Valve Implantation) is designed to reduce the risks and morbidity associated with open surgical valve replacement and allows for reduced recovery times and fewer postoperative complications.

• During TAVI, which is performed on the beating heart without the need for cardiopulmonary bypass, a replacement valve is introduced.

• Multiple avenues for the delivery of the TAVI device are possible.\(^{15}\) In most cases, the valve is implanted through the femoral artery (trans-femoral approach) via a small incision in the thigh.\(^{16}\)

• The prosthetic valve is pre-mounted on a catheter that is gently inserted and threaded across the native aortic valve. The prosthetic valve is then deployed and displaces the native aortic valve leaflets out of the way.

• **Several studies demonstrated potential benefits** of the TAVI procedure. For example, data from the PARTNER (Placement of Aortic Transcatheter Valves) trial population of 358 people with severe aortic stenosis who were not eligible for surgery show that all-cause death rates at one year (measured by Kaplan-Meier analysis) were 30.7 percent with TAVI as compared with 50.7 percent with standard therapy.\(^{17}\) Nevertheless, **limitations** associated with the first generation of TAVI devices included stroke, bleeding and vascular complications, challenges with the precise positioning of the device as well as paravalvular leak, which has proven to be a strong predictor of post-procedural mortality.\(^{18,19,20,21}\)

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\(^b\) Also referred to as TAVR = Transcatheter Aortic Valve Replacement.
References

5 Lindross M et al. Epidemiological studies estimate the prevalence of AS at 5% in subjects over the age of 75 years. J Am Coll Cardiol 1993; 21-1220-5.
6 Lester SJ, Heilbron B, Gin K et al. The natural history and rate progression of Aortic Stenosis. Chest 1998; 113:1109-14
21 Data from the FRANCE 2 registry presented by Prof Eric Van Belle at the ESC Congress 2013 in Amsterdam, Netherlands.