History of percutaneous aortic valve replacement

Open heart surgery with mechanical or porcine bioprosthetic valve replacement is the current gold-standard therapeutic approach for the vast majority of patients with severe aortic valve disease, offering symptomatic relief and improving long-term survival. However, the etiology of aortic stenosis in the Western population is primarily degenerative, and patients are typically elderly with multiple co-morbid conditions which increase surgical risk [1–3]. In high-risk patients with baseline features such as left ventricular failure, concomitant coronary artery disease, prior bypass graft surgery, chronic obstructive pulmonary disease and/or advanced age, expected operative mortality ranges from 10% to even 50% in high-risk patients subgroups [1]. Moreover, surgery is often not performed in high-risk patients. In the Euro Heart Survey, up to 33% of patients in NYHA functional class III/IV with a single diseased valve were declined for surgery or were never considered as surgical candidates, due to an expected short life expectancy and associated comorbid conditions [4]. Alternative techniques for treatment of high-risk patients are therefore needed.

Percutaneous treatment of aortic valve disease with implantation of a stent-based valve prosthesis has been evaluated in animal models over the past decade [5–10]. In 2002, Cribier et al. [11] performed the first human implantation of a balloon-expandable aortic valve prosthesis (Percutaneous Valve Therapy, PVT) in a patient with aortic valve stenosis considered inoperable due to severe comorbidities. Initial reports with this new percutaneous valve have been promising, though the optimal device and procedural technique are still evolving, and the restriction of PVT candidates to end-stage inoperable patients has clouded interpretation of the feasibility and safety of this procedure [12, 13].

A self-expanding aortic valve prosthesis intended for retrograde delivery across the aortic valve has been developed (CoreValve Irvine, CA, USA), to facilitate treatment of aortic stenosis. Following evaluation in animal models, this device was subsequently successfully implanted in a human being [14], and since 2004 its use was expanded in clinical use [15, 16]. In 2007 its use received a CE certification.
Patient population

Patients with severe native aortic valve stenosis are eligible for CoreValve implantation if they meet the following inclusion criteria:

- a native aortic valve stenosis with an aortic valve area <1 cm$^2$
- aortic valve annulus diameter $\geq 20$ mm and $\leq 27$ mm, measured by means of echocardiography or CT
- diameter of the ascending aorta 3 cm above the annulus of $\leq 43$ mm;
- high risk for surgery due to concomitant comorbid conditions, assessed and agreed to by both a cardiologist and a cardiothoracic surgeon.

The baseline risk of the patient population is estimated by the logistic EuroSCORE or STS score [1].

The patient selection procedure is given in Table 1.

General exclusion criteria include hypersensitivity or contraindication to any study medication; sepsis or active endocarditis; excessive femoral, iliac or aortic atherosclerosis, calcification, or tortuosity; aortic aneurysm; bleeding diathesis or coagulopathy.

Preinterventional morphological patient screening is carried out by means of transthoracic as well as transesophageal echocardiography, computerized multislice cardiac tomographic angiography (CTA), and an invasive cardiac evaluation with coronary arteriography and left ventriculography.

Device description and procedure

The CoreValve aortic valve prosthesis consists of a trileaflet bioprosthetic valve made originally of bovine and now of porcine pericardial tissue, which is mounted and sutured in a self-expanding nitinol frame (Fig. 1). The prosthetic frame is manufactured by laser cutting of a nitinol metal tube to a total length of 50 mm. The lower portion of the prosthesis has high radial force to expand and keep open the calcified leaflets and avoid recoil; the middle portion carries the valve and is constrained to avoid the coronary arteries; and the upper portion is flared to fixate the stent in the ascending aorta and provide longitudinal stability.

In total, three generation devices have been produced and used, with the differences being mainly the diameter of the upper segment and especially the diameter of the delivery sheath.

The third generation device was characterized by a broader upper segment for more secure fixation in the ascending aorta, which also allowed inclusion of patients with an ascending aorta diameter up to 43 mm. The first and second generation devices are constrained within a delivery