

Transcatheter aortic valve implantation: The new option for high-risk patients with aortic stenosis

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Abstract

Calcific aortic valve stenosis is the most common valvular heart disease in developed countries. Without surgery, the prognosis is extremely dismal. Therefore there is general agreement that surgical aortic valve replacement should be offered to patients with symptomatic severe aortic valve stenosis. However, surgery is denied to approx. 30–40% of elderly patients with severe, symptomatic aortic stenosis due to high perioperative risk. Transcatheter aortic valve implantation (TAVI) is a novel and effective procedure which provides a promising treatment option for some of these patients. This review focuses on TAVI systems, the patients who would benefit from TAVI, and the advantages and disadvantages of the procedure. (Cardiol J 2011; 18, 4: 461–468)

Key words: aortic valve stenosis, transcatheter aortic valve implantation

Calcific aortic valve stenosis

Calcific aortic valve stenosis is the most common valvular heart disease in developed countries. Its prevalence increases with age, and it affects 2–7% of the population over the age of 65 [1]. The observed rise in the number of patients with severe aortic stenosis (AS) in recent decades is related to the significant increase in the average lifespan.

Calcific aortic stenosis is a gradually progressive disease. During a long latent period, patients remain asymptomatic. The progressive obstruction in outflow and pressure overload is initially compensated by myocardial hypertrophy without left ventricle (LV) dilatation and normal systolic function is maintained. Once the degree of stenosis becomes severe, even slight changes in the aortic valve area result in a larger rise in pressure gradient. An increase of oxygen consumption due to an increase in systolic blood pressure in the LV,

ventricular mass and ejection time lead to myocardial ischemia and deterioration of LV function. Finally, compensatory mechanisms fail and an imbalance between pump function and LV afterload occurs (afterload mismatch). Ventricular chambers dilate and ejection fraction decreases, and both ventricular filling pressure and pulmonary pressure increase. The onset of clinical symptoms is observed. The development of angina, syncope or heart failure is a critical point, which leads to rapid deterioration, resulting in a high mortality rate within months (approx. 50% in the first two years after symptoms appear) [2, 3]. Patients over the age of 70 have an even worse prognosis, with two- and three-year survival rates of 37% and 25%, respectively [4].

Without surgery, the prognosis is extremely dismal. Therefore there is general agreement that surgical aortic valve replacement (SAVR) should be offered to patients with symptomatic severe aortic

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valve stenosis [1]. Surgery markedly improves symptoms, physical functioning, quality of life and prognosis. However, SAVR is denied to approx. 30–40% of elderly patients with severe, symptomatic AS [1, 5–7]. Operative risk in SAVR is approx. 2–5% in patients under 70 years, and rises to 15% in older adults with co-morbidities [1, 8–10]. According to Guidelines [1] though octogenarians and nonagenarians experience higher perioperative mortality and morbidity, advanced age should not be a contraindication for surgery. Nevertheless, in many reports, older age and LV dysfunction are the most striking characteristics of patients, who were denied surgery, whereas co-morbidities play a less important role [5, 11].

Operative risk score calculators (i.e. EuroSCORE, STS score, ACEF) are used to determine which patients are at a very high or prohibitive surgical risk. However, many elderly patients are deemed inoperable on the basis of co-morbidities not included in surgical risk calculators, such as chest radiation, porcelain aorta and frailty, liver sclerosis, cirrhosis, debility, and nutritional status [5, 9, 10, 12, 13]. Moreover, the STS-PROM score appeared to underestimate mortality [9] and may be unhelpful in identifying patients at high risk of 30-day death after transcatheter aortic valve implantation (TAVI) [12]. In clinical practice, it seems reasonable that high-risk patients should be evaluated using clinical judgment and a combination of several scores [9, 14]. Some authors have suggested that since scores do not take into account some ‘extreme’ risk conditions that may be important in a transcatheter procedure, a new specific risk model for referring patients for TAVI should be established.

TAVI systems

Transcatheter aortic valve implantation is a novel and effective procedure, introduced in 2002 by Alain Cribier [15], which enables treatment of high-risk patients who were denied surgery. Currently, two different TAVI systems are commercially available: Edwards SAPIEN (Edwards Life Sciences, Irvine, CA, USA) and CoreValve ReValving System (Medtronic Inc, Minneapolis, MN, USA).

The CoreValve ReValving System (Fig. 1) consists of three porcine pericardial leaflets mounted in a self-expandable nitinol frame housed within a percutaneous delivery catheter. This system is available in two sizes, 26 mm and 29 mm, for transfemoral or transaxillary/subclavian route. The frame has three distinct functional levels with different radial and hoop strengths. The upper third of the



Figure 1. The CoreValve ReValving System.

frame, positioned within ascending aorta, has low radial force and orients the prosthesis in the direction of the aortic root and blood flow. The valve leaflets are attached to the middle third of the frame; supra-annular valve function delivers optimal hemodynamics. The lower third of the frame, located within the LV outflow tract, has high radial force designed to prevent device migration. Intra-annular implantation and sealing skirt mitigates paravalvular leaks. The self-expandable nitinol frame enables controlled release and partial repositionability, and is designed to maintain coronary perfusion. The 26 mm valve is deployed within a 55 mm stent, and the 23 mm valve within a 53 mm stent. The valve is introduced via an 18 F sheath.

The Edwards SAPIEN System (Fig. 2) consists of three bovine pericardial leaflets mounted within a tubular, slotted, stainless steel, balloon-expandable stent that is placed in the subcoronary position. It is available in three sizes: 23, 26 and 29 mm for transfemoral, transapical or transaxillary/subclavian approach. The 23 mm valve is mounted inside a 14.5 mm long stent, and the 26 mm valve within a 16 mm long stent. The greater part of the stent is covered with a fabric skirt on its outer perimeter to prevent paravalvular leak. Bovine pericardial leaflets are matched for thickness and elasticity and incorporate Thermafix anti-calcification treatment. The geometry and attachment method

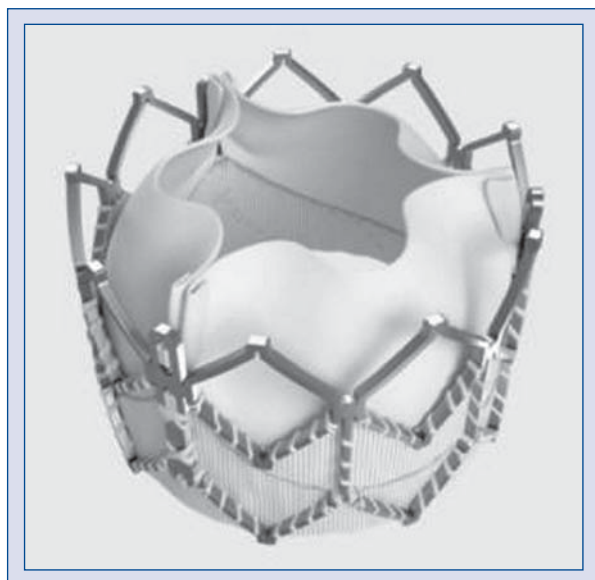


Figure 2. The Edwards SAPIEN XT System.

of the leaflets have been designed to achieve a naturally closed shape and enhance valve durability [16]. The 23 mm valve can be introduced via a 22 F sheath, the 26 mm valve needs a 22 F to 24 F sheath, and the 29 mm valve needs a 18 F to 19 F sheath, depending on the type of catheter.

Several new models of prosthetic valves are under evaluation.

Implantation approaches are the transfemoral and transapical (the most widely used), and the transaxillary/subclavian [17, 18] for patients with significant iliofemoral disease.

The transfemoral approach is simpler and quick to access the aortic valve. The aortic valve is crossed and a stiff wire is placed in the LV with

a large loop. The native aortic valve is dilated using a valvuloplasty balloon with rapid pacing. The prosthetic valve is advanced into position and the native aortic valve is crossed. The device is deployed once the satisfactory position is achieved (Fig. 3). Transesophageal echocardiography and fluoroscopy are necessary for accurate positioning and procedural guidance.

The transapical approach requires mini-thoracotomy. The apex of the heart is punctured using a needle. The aortic valve is crossed antegrade-ly, dilated, and stented under rapid pacing.

Advantages

Several studies have documented a dramatic reduction in the left-aortic gradient and a marked increase in the aortic valve area after the TAVI procedure [12, 16, 19, 20]. Improvement in functional class, quality of life and an enhanced distance in the six-minute walk test have been reported [3, 21, 22] and seem to be permanent. A significant decrease in brain natriuretic peptide has also been observed [21].

The safety of the TAVI procedure is an important consideration. Several studies and registries have been introduced to evaluate mortality rates and risk of the different TAVI systems and accesses, and compare them with standard and surgical therapy (Table 1). Several points are taken into consideration: procedural success, 30-day and long-term mortality, and complications.

Procedural success is defined as the patient leaving the procedure room with an implanted prosthesis without a major complication [13]. It was assessed to be 75% in the initial experience of Cribier et al. [23]. The success rate rises with increas-

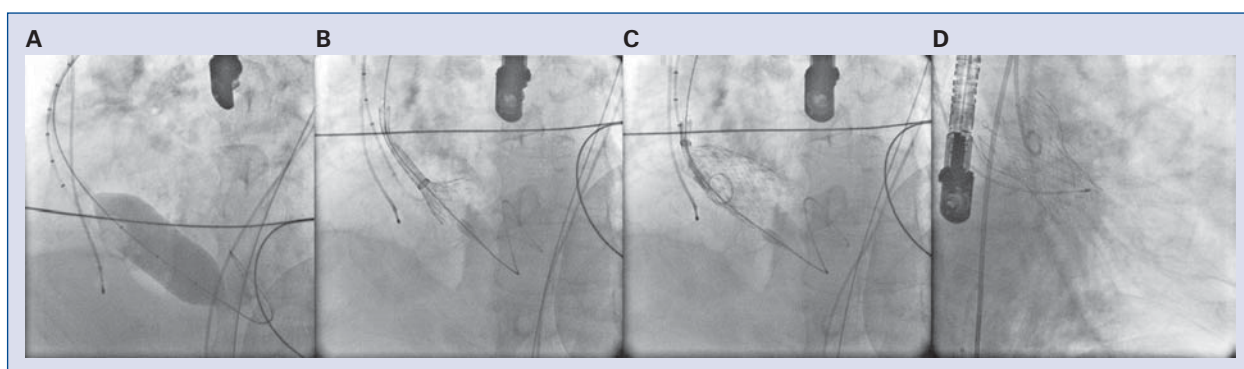


Figure 3. Fluoroscopic images during transcatheter aortic valve (CoreValve) implantation; **A.** Balloon valvuloplasty; **B, C.** Valve deployment in aortic position; **D.** Fluoroscopic aspect of the valve after deployment.

Table 1. Procedural outcome with TAVI in major studies and registries.

Study, year of publication	Patients	TAVI system	Approach	Procedural success	30 day mortality	Other
I-REVIVE and RECAST registries Cribier et al. 2006 [23]	36	Edwards	TF	75%	22.2%	–
Lichtenstein et al. 2006 [24]	7	Edwards	TA	100%	14%	–
US registry Svensson et al. 2008 [25]	40	Edwards	TA	88%	17.5%	–
Piazza et al. 2008 [26]	646	CoreValve	TF	97%	8%	–
Grube et al. 2008 [27]	136	CoreValve	TF/SC	70–91,2%	Total: 12.5%	Total one year mortality 18.4%
Webb et al. 2009 [28]	168	Edwards	TF/TA	94.1%	Total: 11.3% TF: 8% TA: 18.2%	One year mortality 26%
Bleiziffer et al. 2009 [29]	137	Edwards/ CoreValve	TF/SC/TA/ /transaortic	98.5%	12.4%	–
SOURCE registry Thomas et al. 2010 [30]	1038	Edwards	TF/TA	93.8%	Total: 8.5% TF: 6.3% TA: 10.3%	–
Rodés-Cabau et al. 2010 [12] Canadian	339	Edwards	TF/TA	93,3%	Total: 10.4% TF: 9.5% TA: 11.3%	Mean eight month follow-up 22.1% mortality rate
Petronio et al. 2010 [31]	514	CoreValve	TF/SC	TF: 98,4% SC: 100%	TF: 6,4% SC: 0%	–
PARTNER trial Leon et al. 2010 [3]	358 (TAVI: 179, standard therapy: 179)	Edwards	TF	96.6%	6.4%	One year mortality 30.7%
FRANCE registry Eltchaninoff et al. 2011 [32]	244	Edwards/ CoreValve	TF/SC/TA	98.3%	12.7%	–
Belgian registry Bosmans et al. 2011 [33]	328	Edwards/ CoreValve	TF/SC/TA	97%	Total: 11% Edwards: 12%, CoreValve: 11%	One year mortality CoreValve TF: 22% CoreValve SC: 0% Edwards TF: 18% Edwards TA: 37%
PARTNER EU Lefèvre et al. 2011 [20]	130	Edwards	TF/TA	TF: 96.4% TA: 95.4%	TF: 8.2% TA: 18.8%	–
German registry Zahn et al. 2011 [34]	697	Edwards/ CoreValve	TF/SC/TA/ /transaortic	98.4%	12.4%	–

TF — transfemoral; SC — subclavian; TA — transapical

ing experience [16]. In the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry [30], the success rate was 93.8% and comparable to that of other contemporary series (93–98.5%), demonstrating the importance of training and experience.

Similarly, the mortality rate was higher in early reports [23], and has decreased as operators have become more experienced. Nowadays the 30-day

survival rate ranges from 85–95% and a cumulative one-year survival rate from 69–85% (Table 1). These figures differ between the transfemoral and the transapical in some analyses, which depend on patients’ qualifying criteria to both approaches (more diseased patients with severe atherosclerosis in the transapical group) [35]. The survival rate is relatively low, but is primarily the consequence of high preoperative risk and rarely due to the pro-

Table 2. Indications and contraindications for TAVI.

Indications for TAVI	Contraindications for TAVI
Severe symptomatic aortic stenosis in elderly patients at high risk with logistic EuroSCORE > 20 and STS score > 10 or with contraindications for surgery (such as prior chest radiation, previous aorto-coronary bypass with patent grafts, porcelain aorta, liver cirrhosis, severe chest deformities)	<ul style="list-style-type: none"> — Aortic annulus diameter < 18 mm or > 25 mm for balloon expandable and < 20 or > 27 for self expandable devices — Ascending aorta diameter > 43 mm — Severe organic mitral regurgitation — LVEF < 20% without contractile reserve — Atrial or ventricular thrombus — Sub-aortic stenosis — Recent myocardial infarction and cerebrovascular event — Life expectancy < 12 months — For vascular access — vascular diameter < 6 mm or severe ilio-femoral stenosis

LVEF — left ventricular ejection fraction

cedure itself [33]. Mortality is related to the evolutionary stage of disease and co-morbidities, as attested by the predictive value of pulmonary hypertension, severe mitral regurgitation (a three times higher risk of death), post-procedural sepsis, chronic kidney disease, chronic obstructive pulmonary disease and the need for peri-procedural hemodynamic support (a seven times higher risk of death) [12, 36]. Deaths occurring during late follow-up are mainly for non-cardiac reasons [12]. It is worth noting that factors which influence survival after TAVI are also prominent in patients undergoing SAVR [37–40].

Severe pulmonary hypertension is present among one third of patients with severe AS and is associated with end-stage AS, sudden clinical deterioration and sudden death [36]. The prognosis for patients with AS with severe pulmonary hypertension treated conservatively is poor. SAVR is associated with higher than usual mortality, however the potential benefits outweigh the risk of surgery [37]. The same probably applies to patients who undergo TAVI.

Severe hemodynamic impairment is another risk factor for SAVR, and this is an incentive to avoid postponing any intervention until severe hemodynamic impairment, which further increases the risk of all procedures [36].

Functional mitral regurgitation might be expected to improve after TAVI because of the decrease in LV systolic pressure and delayed reverse LV remodeling. Conversely, there is less likelihood of observing an improvement in organic mitral regurgitation [36]. Severe mitral regurgitation, as well as severe pulmonary hypertension, may increase a patient's vulnerability during peri-procedural hemodynamic changes and post-procedural complications [12].

Proper patient selection is crucial for procedure success and increases procedure safety. Thus patients with symptomatic severe AS who are considered inoperable, or at very high surgical risk, undergo a systematic and precise workup protocol including transthoracic and/or transesophageal echocardiography, aortoiliiofemoral and coronary angiography and computed tomography. The current indications and contraindications for TAVI are set out in Table 2. According to the Al-Attar et al. report [35], selection strategy (transapical *vs* transfemoral) is crucial for outcome. Patients in the transapical group had more co-morbidities and consequently a more critical early post-operative period. The respective places of transfemoral and transapical approaches need to be clarified by a random study.

Patients who benefit from TAVI

There are several conditions which significantly increase operative risk, and are acceptable in TAVI procedure. We mention some of them below.

A patient with severe AS and reduced ejection fraction has poor prognosis and despite high peri-procedural risk, surgery is strongly recommended [1]. However, the improvement in ejection fraction varies among patients and apoptosis of a significant proportion of cardiomyocytes induced during open-heart surgery may compromise post-operative recovery of myocardial function [41]. Clavel et al. [41] compared 200 patients undergoing SAVR with 83 patients undergoing TAVI for severe AS with reduced LV systolic function (left ventricular ejection fraction [LVEF] \leq 50%). Despite similar baseline LVEF ($34 \pm 11\%$ *vs* $34 \pm 10\%$), the TAVI patients had faster and better recovery of LVEF compared with SAVR patients and better regression of LV dilata-

tion at discharge and one-year follow up. At the one-year follow-up, 58% of TAVI patients had a normalization of LVEF, as opposed to 20% in the SAVR group. Thus TAVI may provide an interesting alternative to SAVR in patients with depressed LV systolic function considered to be at high surgical risk. The greater increase in LVEF in the TAVI group may be due to the better improvement in aortic valve hemodynamics (i.e. aortic valve area and gradient), and a more complete relief of the valvular obstruction and thereby of the pressure overload imposed on the LV compared with SAVR.

Porcelain aorta is defined as an extensive circumferential calcification of the thoracic aorta as assessed by computed tomography or fluoroscopy [12]. If this condition is present, the ascending aorta cannot be safely clamped and patients are often refused surgery. In the analysis by Rodés-Cabau et al. [12], patients diagnosed with porcelain aorta or frailty had similar 30-day and late results compared with the rest of the study population. Periprocedural stroke rate was relatively low (1.6%), and 30-day mortality was similar to that of the rest of the study group, which may indicate high risk of these patients even though STS-PROM score was lower. Those who survived the procedure tended to have a lower risk of death at one-year follow-up.

A promising indication for the use of a TAVI system is interventional treatment of a degenerated bioprosthesis. In elderly patients, a bioprosthetic device is usually the valve of choice, to avoid the need for anticoagulation with its associated complications. The success of surgical treatment prolongs the lifespan of patients with AS, therefore cases of degenerated valves may be anticipated. Additionally, in parallel with the increasing age of patients operated on due to valve disease, the amount and severity of co-morbidities are increasing steadily [42, 43]. Management of these patients remains a challenge because of the higher surgical risk of repeat SAVR [43]. As a consequence, TAVI as an alternative approach to a re-thoracotomy is likely to be of help to such patients [42]. The 'valve-in-valve' procedures have been performed by several surgeons with favorable hemodynamic and clinical results [17, 42–44].

The TAVI system has also been employed in several cases of patients with co-morbidities or conditions which are very rarely encountered and therefore are an extremely difficult challenge for many medical specialties. Among them are patients with severe aortic stenosis with severe spinal deformities, e.g. extremely severe kyphoscoliosis and thorax deformation in the course of Pott's disease

[45], or heart transplant recipients who need improvement of allograft function long after heart transplantation [46, 47].

Disadvantages

TAVI is an interventional procedure, and is therefore not free from risk of complications. The incidence also depends on the operator's experience and access choice (transfemoral *vs* transapical). The most common complications are described below.

Large femoral access sheaths used to insert a TAVI system (18–24 F sheaths) contribute to the frequent occurrence of major vascular complications and bleeding events (5–16%) [2, 3]. In the SOURCE registry, 10.6% of patients had major vascular complications, although they had no impact on 30-day mortality. Major vascular complications were less frequent in the transapical-approach group (2.4%). However when vascular complications occurred in the transapical group, the mortality was very high, although the nature of the vascular complications was not defined [13].

According to Bagur et al. [48], the occurrence of acute kidney injury following TAVI is associated with a greater than four-fold increase in the risk of post-operative mortality. However, the incidence of acute kidney injury was lower ($p = 0.001$) in patients with chronic kidney disease who underwent TAVI compared with those who underwent SAVR. Potential causes of renal failure are intraprocedural hypotension, contrast load, number of blood transfusions, post-interventional thrombocytopenia, severe inflammatory response syndrome and concomitant medication [13, 49].

Strokes remain a troublesome adverse event following TAVI. According to recent studies [50, 51] conducted with the use of magnetic resonance imaging, there are new perfusion deficits due to atherothrombotic emboli in 58–91% of patients who undergo TAVI. This observation does not appear to correlate with clinical neurological deficits. The PARTNER investigators [3] observed major strokes in 5% of patients and the SOURCE investigators [30] in 2.5% of patients. Emerging emboli prevention devices might provide better protection of the brain during TAVI. Empiric oral therapy with aspirin and clopidogrel for three to six months after procedure, followed by long-term aspirin, is recommended.

Residual aortic regurgitation, mainly in the form of paravalvular leaks, is a frequent complication [35]. However, even moderate aortic regurgitation appears to be well tolerated without heart

failure or hemolysis, and usually remains stable during the one-year follow-up period [3, 13, 52]. In severe regurgitation, valve-in-valve implantation has been described [53]. Excluding patients with an annulus larger than recommended prostheses is prudent to avoid significant regurgitation [52].

High-grade atrio-ventricular block and consecutive pacemaker implantation are frequent complications following TAVI and persist in follow-up [54]. Conduction tissue impairment is probably provoked by mechanical compression with large prostheses in smaller annuli or in the larger area of the CoreValve covering the outflow tract, and may appear instantly during the implantation procedure [52, 55]. Continuous post-operative electrocardiogram monitoring is necessary for at least 2–3 days in all patients after TAVI, and until discharge in patients with increased risk for this complication. Permanent pacemaker implantation is necessary in 18–40% of patients [56], more commonly with CoreValve system. The need for a pacemaker is less than 10% in SAVR [56].

Coronary artery obstruction and/or myocardial infarction during or after procedure occur in 0.4–4.1% of patients [30, 57] and in some cases may require immediate coronary angioplasty [57, 58].

Other, less common, complications or problems concerning the TAVI procedure are pericardial tamponade, valve migration or fracture, need for conversion to surgery, and re-intervention.

Summary

The results of several studies and registries suggest that TAVI may be a good alternative for elderly patients who are not suitable candidates for surgery. Certainly, there are patients still disqualified from any invasive therapy. Hopefully, further improvements in TAVI technique might facilitate the procedure in this 'problematic' group of patients.

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