

# TRANSCATHETER AORTIC VALVE IMPLANTATION: REVIEW AND CURRENT STATE OF THE ART

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## ABSTRACT

Since the introduction of transcatheter aortic valve implantation (TAVI) 12 years ago, the treatment options for severe, symptomatic aortic valve stenosis in high-risk patients have significantly increased. Because of the growing implementation of TAVI in clinical practice, knowledge of the outstanding clinical outcome of TAVI and TAVI-related limitations is expanding. In this review, potential complications, including stroke, vascular complications, paravalvular regurgitation, and conduction disturbances, are discussed. To reduce the incidence of these limitations, new valves are being designed and clinically evaluated. The ultimate goal is to reduce potential complications and expand the use of TAVI to lower-risk patient cohorts.

**Keywords:** Aortic valve stenosis, valvular heart disease, prosthetic valves, transcatheter aortic valve implantation (TAVI), stroke, aortic regurgitation, vascular complications, permanent pacemaker.

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## AORTIC VALVE STENOSIS

Aortic valve stenosis is one of the most common acquired valvular diseases in elderly patients (>75 years) in Western countries, with a prevalence of 3.4% of severe aortic valve stenosis.<sup>1</sup> The progressive narrowing of the degenerative aortic valve, due to aortic valve sclerosis, causes an increasing pressure gradient between the left ventricle and the ascending aorta. The left ventricle can compensate to overcome this pressure gradient by progressive myocardial hypertrophy. As long as ventricular compensation is present, symptoms do not occur and patient prognosis remains uninfluenced. However, once hypertrophy reaches its limit by losing compliance, diastolic dysfunction initiates, and further thickening and calcification of the aortic valve - together with progressive myocardial dysfunction - will lead to the onset of symptoms. Once symptoms occur, the prognosis is very poor; the average survival of patients that experience angina, syncope, or heart failure

symptoms due to aortic valve stenosis is only 5, 3, and 2 years, respectively.<sup>2</sup>

The actual gold standard treatment for severe, symptomatic aortic valve stenosis is surgical aortic valve replacement (AVR). The aortic valve is replaced by a mechanical or biological valve prosthesis (depending on the clinical picture and the age of the patient). Absence of important comorbidities leads to low operative mortality, even in elderly patients.<sup>3</sup>

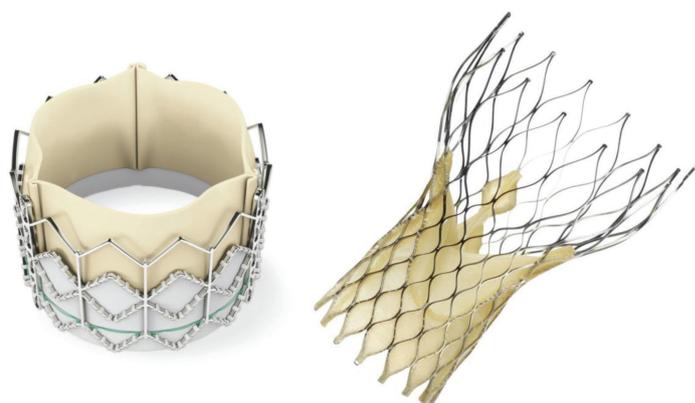
However, one in three patients are rejected for AVR, because of a too high operative risk (e.g. old age, increased surgical risk score such as EuroSCORE) or the presence of important comorbidities (pulmonary hypertension, porcelain aorta, etc.).<sup>4</sup> Until recently, a pending medical therapy (digoxin, diuretics, angiotensin converting enzyme-inhibitors or angiotensin receptor blockers), potentially combined with balloon aortic valvuloplasty, was proposed for those patients.<sup>5</sup> However, prognosis of medically treated patients remains limited.

Non-surgical, percutaneous treatment of patients with severe symptomatic aortic valve stenosis was initiated in 1985, with the introduction of balloon aortic valvuloplasty.<sup>6-8</sup> In 1986, Alain Cribier reported on balloon aortic valvuloplasty carried out in three elderly patients with acquired severe aortic valve stenosis. The transvalvular systolic pressure gradient was considerably decreased at the end of the procedure, during which there were no complications. An increased valve opening was confirmed by angiography and echocardiography. A subsequent clinical course showed a pronounced functional improvement.<sup>6</sup> Unfortunately, a high rate of restenosis, occurring several months to years after balloon valvuloplasty, and the occurrence of aortic regurgitation, remains an important limitation of this technique. In 1987, the development of larger peripheral vascular stents created technical perspectives for the design of a specific 'cardiac' stent to maintain opening of the aortic valve.<sup>9</sup> In 1992, the first stent-based porcine bioprostheses were implanted in animal models.<sup>10</sup> Ten years later (2002), the first-in-man non-surgical aortic valve implantation was performed by Alain Cribier.<sup>11</sup> In 2012, TAVI or percutaneous aortic valve implantation was adopted in the European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines as a treatment for severe, symptomatic aortic valve stenosis in patients with high surgical risk.<sup>5</sup>

### Types of Percutaneous Aortic Valves

To date, a significantly expanding number of percutaneous bioprostheses are approved by the Conformité Européenne (CE). The Edwards-SAPIEN THV™ valve (Edwards Lifesciences, Irvine, California, USA) and CoreValve® (Medtronic, Inc., Minneapolis, Minnesota, USA) are the valves with the most clinical experience and published data to date (Figure 1).

More recently, the following valves also received CE approval: Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, California, USA), JenaClip JenaValve™ (JenaValve Technology GmbH, Munich, Germany), Symetis Acurate™ (Symetis, Lausanne, Switzerland), Direct Flow Medical® Transcatheter Aortic Valve System (Direct Flow Medical, Santa Rosa, California, USA), Portico™ (St. Jude Medical, St. Paul, Minnesota, USA), Medtronic Engager™ (Medtronic, Minneapolis, Minnesota, USA), and Lotus™ Valve System (Boston Scientific, Boston



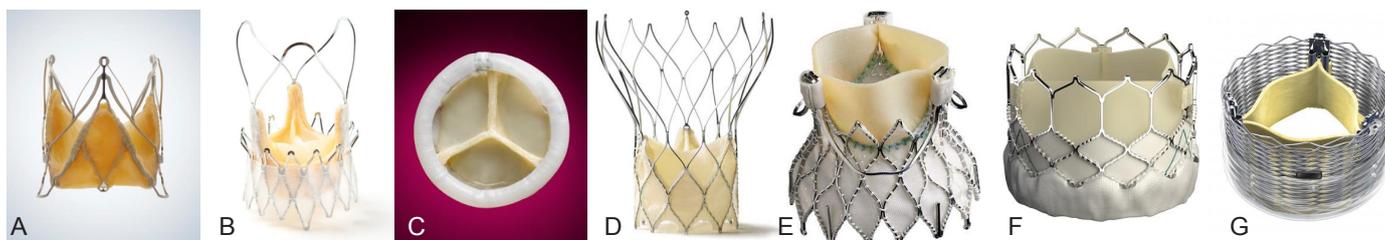
**Figure 1:** Left: Edwards-SAPIEN (Edwards Lifesciences, Irvine, California, USA), and right: CoreValve® (Medtronic, Inc., Minneapolis, Minnesota, USA); the valves with the most clinical experience and published data until now.

Scientific, Natick, Minnesota, USA). These are the most recently approved transcatheter valve types (Figure 2).<sup>12,13</sup>

### Edwards SAPIEN

The Edwards SAPIEN THV™ prosthesis is a balloon expandable valve, consisting of a cylindrical frame of a cobalt chromium alloy. In this stent, three valve cusps of bovine pericardial tissue are sealed. The lower part of the stent frame is covered with a skirt of polyethylene terephthalate. This bioprosthesis is available with a diameter of 23 mm or 26 mm. After nose cone modifications of the delivery system, Retroflex3™ is currently used. The diameter of the delivery system varies from 22 French (Fr) up to 24 Fr. The second generation of this valve, Edwards SAPIEN XT™ is available in 20 mm, 23 mm, 26 mm, and 29 mm, with resp. 16, 16, 18, and 20 Fr delivery sheaths (Novaflex™). Ascendra™ delivery system is used for transapical approach.

The Edwards SAPIEN 3 transcatheter heart valve comprises a balloon-expandable frame with bovine pericardial tissue valve.<sup>14,15</sup> The valve is covered by an outer polyethylene terephthalate cuff to enhance paravalvular sealing. The transfemoral delivery system (Commander, 14 Fr eSheath for the 23 mm and 26 mm valves, and 16 Fr eSheath for the 29 mm SAPIEN 3 valve) enables advancing or retracting the valve several millimetres up or down within the annulus. For transapical implantation, the Certitude is the new corresponding delivery system that also features a smaller nose cone.<sup>16</sup>



**Figure 2:** Most recent CE-approved transcatheter aortic valves.

A: JenaValve™ (JenaValve Technology GmbH, Munich, Germany); B: Symetis Acurate™ (Symetis, Lausanne, Switzerland); C: Direct Flow Medical® Transcatheter Aortic Valve System (Direct Flow Medical, Santa Rosa, California, USA); D: Portico™ (St. Jude Medical, St. Paul, Minnesota, USA); E: Medtronic Engager™ (Medtronic, Minneapolis, Minnesota, USA); F: SAPIEN 3 (Edwards Lifesciences, Irvine, California, USA); G: Lotus™ Valve System (Boston Scientific, Boston Scientific, Natick, Minnesota, USA).

**Table 1: Results of the PARTNER trial (Edwards SAPIEN) and the ADVANCE registry (Medtronic CoreValve).**

	TAVI (n)	30-day outcomes				Longer mortality
		Stroke	New PM	Grade AR ≥II	Mortality	
Edwards SAPIEN PARTNER Cohort A <sup>18,19</sup>	248	5.5%	3.8%		3.4%	1 year: 24.3%, 2 years: 33.9% 1 year: 30.7%, 2 years: 43.3%
Cohort B <sup>17,20</sup>	178	6.7%	3.4%	12.5%	5.0%	
Medtronic CoreValve ADVANCE <sup>21,22</sup>	996	3.0%	26.4%	13.0%	4.5%	1 year: 17.9% 1 year: 24.0%
US Pivotal trial (Iliofemoral) <sup>25</sup>	471	2.4%	22.2%	11.5%	7.9%	

PM: pacemaker; AR: aortic regurgitation.

The PARTNER (Placement of Aortic Transcatheter Valve) trial is a unique randomised trial, designed to evaluate TAVI compared to AVR in high-risk patients (cohort A, n=699), and TAVI compared to conservative treatment in inoperable patients (cohort B, n=358), with the Edwards SAPIEN prosthesis.<sup>17,18</sup> The results of PARTNER cohort A proved that TAVI is comparable to AVR for survival up to 3 years after valve implantation (50%, n.s.). Mortality within 30 days was lower than expected (TAVI: 3.4%, AVR: 6.5%, p=0.070).<sup>19</sup> In PARTNER cohort B, no difference was found for mortality within 30 days after the procedure for patients treated with TAVI or optimal medical treatment, but 2 years mortality after the interventions differed significantly (optimal medical treatment: 2 years mortality 68%, TAVI: 2 years mortality 43%, p<0.001).<sup>20</sup> Within 30 days after TAVI, both in

cohort A and cohort B, the incidence of stroke or transient ischaemic attack (TIA) was resp. 5.5% and 6.7%, and the incidence of new pacemaker implantation was resp. 3.8% and 3.4% (Table 1). Moderate-to-severe aortic regurgitation (AR) was present in 12.5% after TAVI.

### CoreValve revalving system

The CoreValve prosthesis is a self-expandable stent, with a supra-annular porcine pericardium valve. These leaflets form a sealing skirt on the stent frame to reduce paravalvular leakage. The stent is manufactured from nitinol, an alloy of titanium and nickel, which has a temperature-related shape memory. Initial sheaths were 25 Fr, but since 2010 the Accutrack™ delivery system (18 Fr) is available for transfemoral implantation of prostheses of size 26 mm, 29 mm, and 31 mm. Medtronic Evolut™

**Table 2: Overview of current available data of various transcatheter aortic valves.**

	N	30-day outcomes				Longer mortality
		Stroke	New PM	Grade AR ≥II	Mortality	
JenaValve™ Multicentre CE-mark study <sup>26</sup> JUPITER registry <sup>27</sup>	66 101	3.0%	9.1%	13.6% 2.3%	7.6% 14.9%	
Symetis Acurate™ <sup>28</sup>	40	5.0%	7.5%	3.4%	12.5%	6 months: 17.5%
Direct Flow Medical® DISCOVER trial <sup>29</sup>	33			3.0%	3.0%	
Portico™ valve first-in-men <sup>30</sup>	10	10.0%	0.0%	10.0%	0.0%	
Medtronic Engager™ European Pivotal trial <sup>31</sup>	61	3.5%	27.6%	0.0%	9.9%	6 months: 16.9%
SAPIEN 3 <sup>15</sup>	26	0.0%		0.0%	3.8%	
Lotus™ Valve System REPRISE I trial <sup>34</sup> REPRISE II trial <sup>35</sup>	11 60	27% 8.6%	36% 29.3%			

*PM: pacemaker; AR: aortic regurgitation.*

is available in 23 mm size, is 10 mm shorter in height, and is modified to fit better in the aortic root.

The ADVANCE Registry is the best monitored, prospective, multicentre study as regarding to the CoreValve prosthesis, with the inclusion of 1,015 patients in experienced TAVI sites.<sup>21,22</sup> It is important to mention that the clinical endpoints were all defined according to the ‘Valve Academic Research Consortium’ (VARC) and were all monitored by an independent event committee. The 30 day mortality was comparable to the 30 day mortality of the PARTNER trial (4.5%).<sup>23,24</sup> All-cause mortality at 1 year was 17.9%.<sup>21</sup> No differences were found in survival between men and women. Within 30 days after TAVI, the incidence rate of stroke or TIA was 3.0% and the incidence of new pacemaker implantation was 26.4% (Table 1). The need for permanent new pacemaker implantation, however, did not influence 1 year survival. Moderate-to-severe AR was present in 15% after TAVI. The CoreValve US Pivotal trial has two cohorts: the first is a randomised controlled study in high-risk patients (CoreValve versus AVR), and the second is a non-randomised study in extreme-risk patients that can be treated with TAVI by iliofemoral access.<sup>25</sup> In the latter (n=471), a significant reduction in all-cause mortality and in major stroke compared to the objective performance goal (estimated

mortality risk and stroke risk with medical therapy only) was achieved by transfemoral TAVI.

### Other percutaneous aortic valves

The JenaValve™ is a self-expandable nickel-titanium alloy frame with porcine valve. The valve is fixed on the native aortic valve leaflets and there is no high radial force needed to anchor in the aortic root. This valve is specifically designed for transapical approach. The results of the multicentre prospective CE-mark study were promising.<sup>26</sup> The JUPITER Registry, which will provide long-term outcomes of the JenaValve™, is still ongoing.<sup>27</sup>

The Symetis Acurate™ is also a self-expandable nickel-titanium alloy frame with porcine valve.<sup>28</sup> The conical form during the implantation centres the valve in the correct place. The upper part of the cone anchors itself, and the skirt seals the valve in the native annulus to minimise paravalvular leakage.

The Direct Flow Medical® consists of bovine pericardium to form leaflets and has a plastic polymer frame.<sup>29</sup> The Portico™ resembles the Medtronic CoreValve, but has more open cells. In order to prevent suboptimal positioning of the prosthesis, this transcatheter valve is fully re-sheathable and repositionable, until fully deployed.<sup>30</sup> Bovine pericardium leaflets are used in the design

of the Medtronic Engager™ for transapical TAVI.<sup>31</sup> The Multicentre European Engager Pivotal trial is still ongoing.<sup>32</sup> A central marker in the nitinol frame (including bovine pericardium) of the Lotus Valve helps positioning of the valve.<sup>33-35</sup> A novel Adaptive Seal™ technology leads to minimised AR, and the device can be fully retrieved, redeployed, or repositioned, even after full valve deployment and prior to release. An overview of the current available data of these newer transcatheter aortic valves is given in [Table 2](#).

## Patient Selection

Due to the complex condition of high-risk patients, the final clinical decision for an individual patient to be suitable for undergoing AVR/TAVI/medical treatment relies on a multidisciplinary heart team discussion, with (interventional) cardiologists, cardiac surgeons, and other involved specialists.

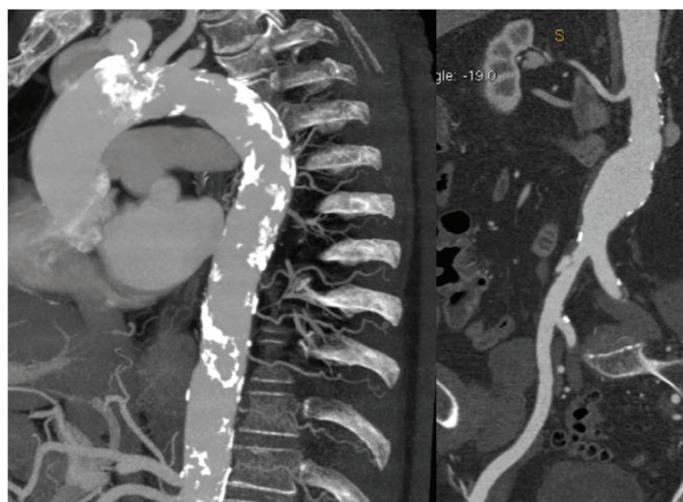
### Anatomical factors

There are several necessary anatomic evaluations specific to TAVI.<sup>36</sup> Non-invasive evaluation of the dimensions of the aortic annulus, such as transoesophageal echocardiography, magnetic resonance imaging, and multidetector computed tomography (MDCT, [Figure 3](#)), must be carried out in order to select the optimal size of the valve.<sup>36</sup> Arterial access is generally assessed with angiography or contrast MDCT. Most arteries are compliant and can accommodate slightly larger sheaths, but this is not always the case in diffusely diseased, tortuous, or calcified arteries. The aorta should be evaluated with angiography or contrast MDCT to assess delivery and implantation of the specific valve type, aortic root, and calcification, together with the risk of coronary obstruction.

### Clinical factors

Not only is technical and anatomical evaluation necessary in the discussion of whether TAVI has to be performed, but also the likelihood of functional and survival benefit. Patients in whom a significant improvement in quality and duration of life is likely have to be distinguished from those in whom the intervention will not be beneficial due to advanced age and comorbidities.

Surgical risk scores (e.g. EuroSCORE, Society of Thoracic Surgeons mortality score) could be helpful in patient selection; however, they do not take TAVI-related risk factors into account, are in general not accurate enough to predict prognosis



**Figure 3:** Evaluation of aorta and calcifications and tortuosity of peripheral arteries by computed tomography.

after TAVI, and are not based on elderly patients (75 years and older).<sup>37</sup> Geriatric syndromes (falling, dementia, malnutrition), together with frailty, which are frequently seen in elderly patients and remain an important preoperative risk factor, are not included in these surgical risk scores, although frailty is significantly related to functional decline and prognosis.<sup>38,39</sup> Therefore, multidimensional geriatric evaluation of these patients may be useful in predicting outcome and optimal patient selection.<sup>36</sup>

### Procedure

In general, TAVI is performed under general anaesthesia or sedation.<sup>39</sup> Femoral access remains, until now, the preferred and most frequently used approach. The native valve can be predilated by balloon valvuloplasty during rapid ventricular pacing. The transcatheter valve is deployed by angiographic or echographic guidance ([Figure 4](#)). Successful implantation of the valve will immediately decrease the pressure gradient over the aortic valve. Guidewires and catheters are withdrawn, and the femoral artery is sealed surgically or by use of a specific closure device.

The femoral artery has been the most popular access site. Although originally requiring a surgical cut-down, most experienced groups now utilise a percutaneous puncture and suture pre-closure technique, avoiding the need for open surgical access. Current consensus, with some exceptions, strongly favours transfemoral arterial access as the preferred, default approach for TAVI.<sup>36</sup>

## Complications

Acute periprocedural and late complications may occur. Left ventricular rupture, tamponade, and coronary obstruction can be fatal complications during the TAVI procedure, but are fortunately rare. Stroke, vascular (access-related) complications, AR, and conduction abnormalities are more frequently occurring adverse events; their specific definitions are recently described in the Valve Academic Consortium-2 Consensus Document.<sup>24</sup>

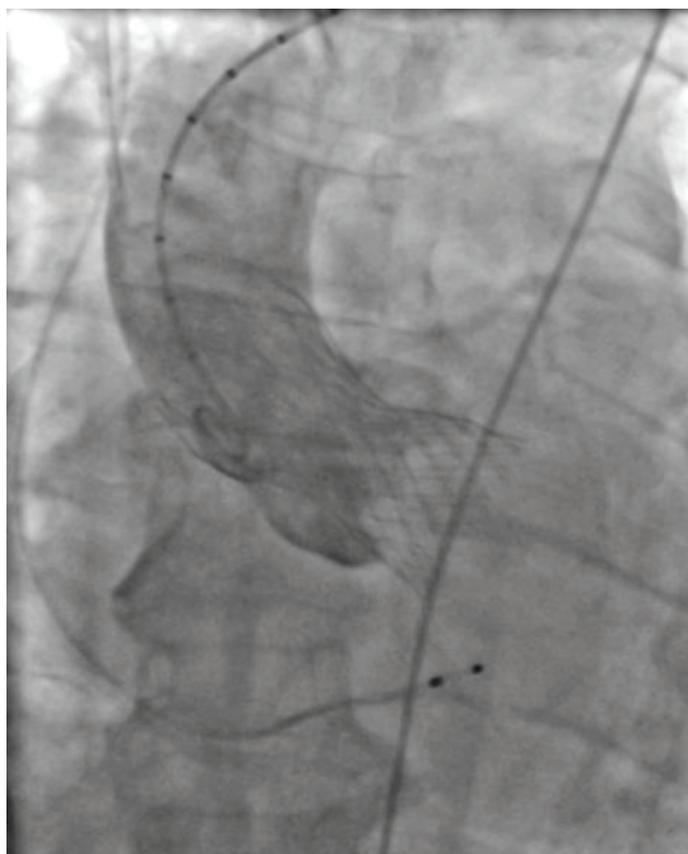
### Stroke or TIA

The definition of stroke according to VARC is 'an acute episode of focal or global neurological dysfunction caused by the brain, spinal cord, or retinal vascular injury as a result of haemorrhage or infarction.'<sup>24</sup> Another type of ischaemic event is TIA, which is a transient type of dysfunction, without acute infarction.

Procedural stroke (acute, <24 hours) has an incidence of 1.5% after TAVI. During the first month after TAVI (subacute), stroke and TIA have an incidence of resp. 3-6.7% and 0.9%, and resp. 10% and 2.3% 1 year after TAVI (late).<sup>19-21,40,41</sup> If stroke occurs, this has a negative impact on the prognosis and the quality of life of patients who underwent TAVI.<sup>41</sup>

The aetiology of neurological events during or after TAVI is clearly multifactorial. Embolic causes of these cerebrovascular events are, however, often assumed, with material of the native aortic root dislodged by introduction and control of the guidewire, balloon valvuloplasty, manipulation of the delivery system, and by the deployment of the transcatheter valve. Embolic protection devices are developed to avoid stroke.<sup>42,43</sup> Deflection shields are used to cover supra-aortic arteries, and intraluminal filters can retrieve embolic debris in the carotid arteries. These devices are, however, also introduced by catheterisation, which can, in turn, increase embolisation of calcified material. Available data supporting their evidence are limited.

Thrombin or platelet deposition before endothelialisation of the prosthesis can occur after TAVI and might be a risk for embolisation. Duration and type of antithrombotic therapy after TAVI is not clearly defined. Also post-procedural (new or continued) atrial fibrillation is a proven risk factor for post-procedural stroke or TIA and was related to anticoagulant therapy. Nuis et al.<sup>44</sup> reported five patients developing new onset atrial



**Figure 4:** Implantation of CoreValve™, guided by aortography.

However, many patients have small or diseased femoral arteries. On occasion, surgical retroperitoneal approach is utilised to gain access to the larger iliac artery in patients with femoral disease. Subclavian (transaxillary) access has gained popularity as an alternative access. Importantly, the subclavian route can damage the left internal mammary artery, which is important to patients with previous coronary artery bypass graft.

Antegrade implantation of the aortic transcatheter valve has several advantages, due to transapical approach, with direct access to the left ventricle through an intercostals thoracotomy: a low risk of vascular complications, a direct pathway to the aortic valve, and easier crossing of the diseased aortic valve. Nevertheless, direct myocardial/mitral injury, bleeding, haemodynamic instability, and postoperative respiratory and thoracotomy pain, remain points of concern. The transapical procedure is generally associated with the Edwards SAPIEN valve and newer valves (JenaClip JenaValve™, Medtronic Engager™, Portico™, Symetis Acurate™).

fibrillation without anticoagulant therapy, suffering strokes. Amat-Santos<sup>45</sup> reported a stroke incidence of 40% (no anticoagulants) compared to 2.9% in those who did receive anticoagulant therapy. Therefore, sustained anticoagulant therapy, mostly consisting of clopidogrel/aspirin during 3-6 months after TAVI, is recommended. In case of atrial fibrillation, coumarin is combined with aspirin or clopidogrel.

### Vascular complications

Vascular access-related complications occur most following transfemoral approach, leading to potentially serious arterial bleeding and increased patient mortality. The rate of vascular complications varies from 9.5-51.6% of TAVI patients.<sup>46</sup> Early vascular complications are related to increased late mortality after TAVI, due to haemodynamic instability, increased transfusion need, and longer hospitalisation.<sup>47</sup> Therefore, evaluation of iliofemoral vasculature on tortuosity, calcifications, and diameters is important to determine if femoral approach is safely feasible.

An important risk factor of the development of vascular complications is the sheath size. The development of smaller sheaths (from 22 Fr to 18 Fr), and smaller delivery systems, is important to decrease the incidence of major vascular complications. Also, improved design of closure devices for sealing the access site puncture is important.

### AR

Moderate-to-severe AR (Grade  $\geq 2/4$ ) occurs in around 15-20% of the TAVI patients and, as described in several papers, has a significant negative impact on survival.<sup>48,49</sup> During TAVI, the native valve is crushed between the aortic wall and the prosthesis. This debris of calcifications can prevent appropriate sealing of the prosthesis in the aortic root, which increases the risk of paravalvular AR. Also, malpositioning of the valve (too high, too low under the native annulus) and incorrect sizing of the prosthesis (annulus - prosthesis mismatch) cause AR after TAVI.<sup>48-51</sup>

Quantification of AR after TAVI can be done by angiography, by echocardiographic evaluation, and by invasive haemodynamics. Angiographic evaluation is based on grading the amount of contrast regurgitating into the left ventricle, which relates to the severity of the leakage (Grade I to IV).<sup>52</sup> This technique is very easy to use but

remains a subjective evaluation depending on the observer, the amount of contrast used, and overlapping structures. Non-invasive transthoracic echocardiographic evaluation of AR in non-TAVI patients is typically done by integrating colour flow, vena contracta, and pressure half-time, together with signs of haemodynamic impact of AR (LV size, LV function, LV pressures).<sup>24</sup> However, in TAVI patients, assessment of AR by echocardiography usually appears to be much more difficult because of the echo reflections of the stent and the frequent presence of multiple (excentric) jets (valvular, paravalvular, multiple locations).<sup>51</sup>

Haemodynamic evaluation of AR post TAVI is suggested by AR index, defined as '(diastolic blood pressure - left ventricular end diastolic pressure)/systolic blood pressure x 100'.<sup>53,54</sup> This objective parameter is available during the TAVI procedure but it is based on invasive pressures, which can be influenced by age and procedural factors. Validation of this method is necessary. Which of these techniques is preferred for AR quantification after TAVI remains a matter of debate.

Reduction of the grade of AR might be done by post-balloon dilatation (increasing the expansion of the valve), snaring of the valve (adaptation of the implantation depth), or implantation of a second valve (valve-in-valve).

### Conduction disturbances

Left bundle branch block (LBBB) and atrioventricular block (AVB), with the need for permanent pacemaker implantation, are the most important and the most frequently observed new conduction disturbances after TAVI. The occurrence of conduction disturbances depends on valve design and valve position. LBBB is reported in 29-65% of the patients implanted with Medtronic CoreValve®, in contrast to 4-18% of the patients treated with Edwards SAPIEN.<sup>55</sup> The assumed cause of this difference relies on the difference in design of the valves: Edwards SAPIEN includes only the native aortic valve, in contrast to CoreValve, which overlaps left ventricular outflow tract (LVOT) and the aortic sinuses. The overlap of LVOT could potentially cause damage to the underlying conduction tissue of the heart. Inconsistent data have been published on whether LBBB after TAVI increases the risk of mortality.<sup>55-58</sup> Most conduction abnormalities occur during balloon aortic valvuloplasty before the effective

TAVI (46%), 25% with the crossing of the aortic valve with guidewires and delivery systems, and the other 29% during expansion of the prosthesis.<sup>59</sup> In line with LBBB, high degree AVB after TAVI is more frequent after CoreValve implantation (14-44%, Edwards SAPIEN: 0-12%). This leads to more pacemaker implantation in patients with CoreValve implanted (18-49%), in contrast to Edwards SAPIEN treated patients (0-12%).

Deep implantation of the prosthesis under the native annulus and pre-existing right bundle branch block are risk factors to total AVB, and therefore, to the need for permanent pacemaker implantation.<sup>60</sup>

## In the Future

The most challenging aspect of TAVI for high or very high-risk patients is optimal patient selection. Geriatric aspects have an influence on patient outcome and can be useful in determining whether or not a patient is capable of undergoing AVR or TAVI.<sup>39,61</sup> Therefore, a specific TAVI-score to evaluate this, taking into account a frailty index, imposes itself.<sup>62</sup>

With the scope to reduce complications - such as paravalvular leakage and conduction disturbances - other transcatheter valves, guidewires, and delivery

systems are designed with the ability of the valve being retrievable to allow optimal deployment. Bourantas et al.<sup>43</sup> made an overview of these second-generation transcatheter valves.

The experience of TAVI in high-risk patients is helpful in expanding the use of TAVI to treatment for medium-risk patients suffering from aortic valve stenosis (PARTNER II, SURTAVI), or patients with bicuspid aortic valve.<sup>63</sup> Also, TAVI may be used in patients with a degenerative bioprosthesis or in patients suffering from AR.<sup>64,65</sup> The TAVI-experience is also useful in expanding transcatheter approaches to pulmonary and mitral valve interventions.<sup>66</sup>

## CONCLUSION

TAVI is an outstanding, relatively new treatment for high-risk patients with severe, symptomatic aortic valve stenosis. Although there were excellent results from the PARTNER and the ADVANCE studies, important complications including stroke, vascular complications, paravalvular AR, and conduction disturbances may occur after TAVI, and so need to be considered. The development of adapted transcatheter valves and devices will reduce these complications.

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