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VALVULAR HEART DISEASE (V NKOMO, SECTION EDITOR)

Transcatheter Aortic Valve Replacement: Current Application and Future Directions

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Abstract During the last decade, the rapid evolution of transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of severe aortic stenosis. Since the PARTNER A and B trials, this technique has become the treatment of reference for inoperable patients, and an attractive alternative to surgical aortic valve replacement in those at high risk for surgery. Large multicenter registries conducted since 2007, mainly in Europe, confirmed the excellent hemodynamic performances of the 2 percutaneous valves currently available on the market, the Edwards SAPIEN, and the Medtronic CoreValve, as well as their benefits in terms of symptom relief and survival. The whole process of TAVR, from patient selection to post-procedural care and result evaluation, should be conducted by a dedicated multidisciplinary "heart team," within centers with expertise in valve disease. Though currently limited to those deemed at high risk for surgery or inoperable, indications for TAVR will likely be extended to a broader spectrum of patients, in particular those with surgical bioprosthetic failure or at intermediate risk for surgery. Beforehand, it will be essential to obtain more extensive data on the durability of percutaneous prostheses, since the available follow-up is seldom longer than 5 years, and in order to further decrease the rate of complications, mainly stroke, paravalvular regurgitation, and access site complications. Furthermore, the use of the transfemoral route will undoubtedly increase because of the miniaturization of the devices, at the expense of other approaches. Above all, multidisciplinary approach, excellent imaging, and careful evaluation will remain key to the success of this technique.

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Introduction

The "first-in-man" transcatheter aortic valve replacement (TAVR) was performed by Alain Cribier in 2002 [1]. Thereafter, this technique has undergone rapid developments and refinements during the last decade (Table 1). Since the Edwards SAPIEN transcatheter heart valve and the Medtronic CoreValve System have become available on the market, more than 50,000 patients have undergone TAVR around the world [2, 3•]. TAVR is now considered as the treatment of choice for inoperable patients with severe aortic stenosis (AS) and an attractive alternative option in those at high surgical risk. The aim of this review is to present the current application of the technique and discuss its future directions.

Current Application

Technical Aspects [4]

Two devices are commercially available at present time (Fig. 1): (1) *The Balloon expandable Edwards SAPIEN XT Transcatheter Heart Valve* (Edwards Lifesciences Inc, Irvine, California). It consists of 3 bovine pericardial leaflets, mounted within a tubular Cobalt-chromium balloon expandable stent. Four diameters (20 mm, 23 mm, 26 mm, and 29 mm) are currently available. The leaflets are constructed using the Leaflet Matching technology, and treated by the ThermaFix anticalcification process. The transfemoral NovaFlex catheter requires sheath introducer diameters of 18 Fr for the 20 and 23 mm valves, 19 Fr for the 26 mm valve, and 22 Fr for the 29 mm valve. The transapical access is performed through the

Table 1 Historical steps of TAVR

16 April 2002	«First-in-Man», Rouen.
2002-2004	Feasibility studies with compassionate implantations (I-REVIVE, RECAST), Rouen.
2004	Acquisition of Percutaneous Valve Technologies by Edwards Lifesciences and development of the Edwards SAPIEN.
	Development of the transfemoral approach, Canada.
	First implantations of the CoreValve.
2006-2007	Feasibility studies in Europe (REVIVE-II, PARTNER, TRAVERSE).
2007	CE mark for CoreValve and Edwards SAPIEN.
	Start of European post-marketing registries.
2009	Acquisition of CoreValve by Medtronic.
	Start of the PARTNER study in the US.
2010	Publication of the PARTNER B study (inoperable patients) showing the superiority of TAVR over medical treatment.
2011	Publication of the PARTNER A study (high-risk patients), showing non-inferiority of TAVR in comparison with surgery.
	Approval of the Edwards SAPIEN valve by the FDA for treatment of inoperable patients.
2012	More than 50,000 patients implanted in the world.

26 Fr Ascendra 2 catheter. The frame height is 14–19 mm; (2) *The Self expanding Medtronic-CoreValve System* (Medtronic Inc, MInneapolis, Minesota). It consists of 3 porcine leaflets mounted into a long self-expanding multi-level nitinol frame with 3 different areas of radial force. Due to its specific design, the bioprosthesis is implanted intra-annularly but functions supra-annularly. The Medtronic CoreValve bioprosthesis is currently available in 4 diameters 23, 26, 29, and 31 mm. The transfemoral and transaxillary approaches are commonly used. The sheath diameter is 18Fr for all valve sizes. The catheter is the AccuTrack System .The frame height is 50–53 mm.

Patient selection is a crucial process, of which every single detail counts. It should involve a "heart team" which includes cardiologists, cardiac surgeons, imaging specialists, anesthesiologists with experience in valve disease, and other specialists such as geriatricians if necessary [5, 6••, 7••]. To begin with, it is necessary to determine the indication for the procedure, that is to say, to evaluate the level of surgical risk. This evaluation is based on clinical judgment, supported by quantitative predictive risk scores, mainly the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) and the EuroSCORE. Although these scores provide precious guidance for patient selection, they tend to overestimate operative mortality in high-risk patients, and do not take into account many

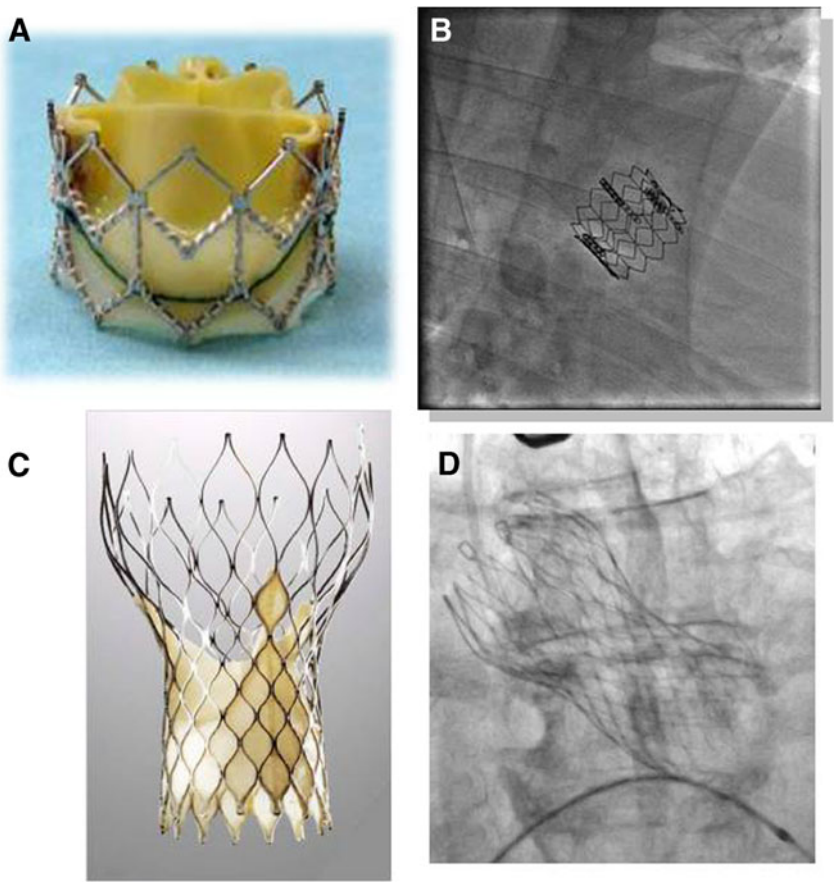

Fig. 1 Transcatheter heart valves commercially available at present time: **a**, Edwards SAPIEN XT; **b**, implanted Edwards SAPIEN XT on fluoroscopy; **c**, Medtronic CoreValve; **d**, implanted Medtronic CoreValve on fluoroscopy

important comorbidities (porcelain aorta, liver cirrhosis, etc.) as well as patient frailty, whose prognostic impact is significant in this elderly population [8]. Secondly, it is necessary to assess the technical feasibility of TAVR, which is conditioned by the patient's anatomy. This evaluation is based on multimodal imaging combining transthoracic (TTE) and/or transesophageal echocardiography (TEE), multislice computed tomography (MSCT), and conventional angiography [9–11]. The main targets are the arterial access sites (diameters, calcification, tortuosity) and the aorto-valvular complex, consisting of the aortic root, the aortic annulus, and the left ventricular outflow tract. The information obtained from this evaluation will allow to determine the best approach (transfemoral, transaxillary, transapical, or direct transaortic) and the most suitable type and diameter of valve, and to anticipate possible strategies or complications during the procedure. Finally, the patient's coronary status should be assessed, although there is currently no specific recommendation concerning coronary revascularization in this setting. Indeed, such a decision should take into account symptoms, clinical condition, extent of myocardium at risk, and coronary lesion characteristics. Performance of TAVR should be restricted to high-volume medico-surgical centers with expertise in valve disease [7••]. All the physicians involved in TAVR programs should have previously received specific training. Ideally, TAVR should be performed in "hybrid" rooms, combining the specific characteristics of both the catheterization laboratory and the operating room, with the immediate availability of circulatory assistance if needed. The decision to perform TAVR under general anesthesia depends mainly on the need for TEE guidance, the requirement for surgical arterial or thoracic access, or local preferences. However, with the increasing experience of the operators and the reduction of the introducer diameters, the proportion of transfemoral procedures performed under sedation, and locoregional anesthesia tends to increase. A strict hemodynamic monitoring is crucial, with the objective of maintaining a systolic aortic pressure between 110 and 130 mmHg throughout the procedure; this justifies the presence of an anesthesiologist in all the cases. Prophylactic antibiotics are given at the beginning of the procedure and intravenous anticoagulation with unfractionated heparin is administrated, with a target Activated Clotting Time between 250 and 300 seconds. Heparin can be antagonized at the end of the procedure. By default, the access is most often transfemoral. If this is not possible, the alternative approach depends on the type of the prosthesis used and local preferences. The transaxillary route is elegant and simple, but can be performed only with the CoreValve System [12]. The transapical route is possible with the SAPIEN valve. More recently, there has been an increasing interest for the direct transaortic access, which is possible with both the SAPIEN and the CoreValve prostheses and avoids the drawbacks of the ventricular puncture required for transapical TAVR [13].

The different steps of the procedure have been described in detail previously [4]. Briefly, after obtaining arterial or thoracic access, the main steps include retro- or antegrade crossing of the aortic valve, placement of a stiff wire through the valve, and predilatation of the valve with an undersized balloon. Then, the prosthesis is placed at the level of the aortic orifice and deployed. Precise positioning of the prosthesis warrants prior identification of the plane of the annulus, which is usually represented by the projection where the 3 cusps are seen on the same line. Optimal projection can be determined by conventional angiography or by using software allowing for the identification of a perpendicularity line. The modality of deployment depends on the prosthesis. The SAPIEN valve is deployed by inflation of the balloon under rapid ventricular pacing (usually 180 to 220 bpm), with the objective to decrease aortic pressure below 50 mmHg in order to avoid cardiac motion, transaortic flow, and ejection of the prosthesis towards the ascending aorta. The CoreValve is deployed by progressive removal of the shaft of the delivery catheter. This removal is guided by iterative angiograms in the aortic root, and allows for readjustment of the position and recapture of the prosthesis during the first two-thirds of the deployment. Immediate assessment of the result is crucial and involves an accurate analysis of the ECG (possible rhythm and conduction disturbances and myocardial ischemia), the TTE/TEE (possible pericardial effusion, left ventricular function, detection of a possible central, or paravalvular regurgitation) and the angiogram (prosthesis positioning, coronary patency, and potential aortic regurgitation).

Although complication management cannot be detailed here, it can be summarized by the following five points: (1) their prevention, allowed by a meticulous screening; (2) their anticipation, achieved through a thorough multidisciplinary evaluation; (3) their immediate identification; (4) the training of the teams to deal with bail-out equipment and procedures; (5) when necessary, the immediate availability of cardiopulmonary support and surgical conversion.

Post-procedural care is also crucial. Patients are transferred to an intensive or coronary care unit for at least 24 to 48 hours, and can be discharged between day 5 to day 10, if no complication occurs. In addition to standard clinical and biological parameters, post-procedural monitoring should focus on vascular or thoracic access sites, conduction disturbances (which may be delayed) and arrhythmias (in particular atrial fibrillation with its inherent risk of stroke) and on valve function, which should be carefully assessed by TTE before discharge.

Unless oral anticoagulant therapy is needed, a combination of aspirin and clopidogrel is empirically recommended for 3 to 6 months. The duration of treatment may be shortened for patients at high risk of bleeding.

The definitions proposed by the Valve Academic Research Consortium (VARC) should be used for the assessment of patient's follow-up, in order to provide consistency across studies and facilitate the evaluation of the technique [14].

Results

The PARTNER study, which is the only randomized trial currently available, was conducted in 25 North American and 1 German centers using the SAPIEN valve. It provided the first evidence of the superiority of TAVR on medical treatment in inoperable patients, and of the noninferiority in comparison to conventional surgery in high-risk patients [15, 16]. The trial included 1056 high-risk patients in 2 different cohorts: operable patients (cohort A) were randomized to TAVR (transfemoral or transapical according to their vascular access) vs conventional surgery; inoperable patients (cohort B) were randomized to transfemoral TAVR vs medical treatment (including balloon aortic valvuloplasty). In the latter, TAVR was clearly superior to medical treatment, with an important reduction of all-cause mortality and hospitalizations. One-year mortality was 30.7 % in the TAVR group, vs 50.7 % in the medical group ($P<0.001$). In the high-risk group, TAVR was non-inferior to conventional surgery with regards to 1-year all-cause mortality (24.2 %, vs 26.8 %, $P=0.44$). One-year stroke rate was 5.1 % in the TAVR group, vs 2.4 % in the surgical group ($P=0.07$) and 30-day major vascular complication rate was 11.0 %, vs 3.2 % ($P<0.001$). Conversely, major bleedings were more frequent after surgery (19.5 %, vs 9.3 %, $P<0.001$), as was new atrial fibrillation (16 %, vs 8.6 %, $P=0.006$). These findings led the Food and Drug Administration to approve TAVR for inoperable patients and more recently for high-risk patients. Thus, hundreds of US centers should initiate a TAVR program within the near future. Furthermore, the results of the study at 2 years confirmed the absence of any statistical difference between TAVR and surgery with regards to mortality (33.9 % after TAVR, vs 35.0 % after surgery, $P=0.78$), functional improvement, and hemodynamic performances [17]. Paravalvular aortic regurgitations were more frequent after TAVR and seemed to be correlated with late mortality.

Furthermore, since 2007, several multicenter registries using either or both of the commercially available transcatheter heart valves have been conducted [18–22]. These registries have contributed to technological improvements as well as increased knowledge concerning patient selection and prevention and management of complications. This was accompanied by an increase of procedural success, up to 97 %. The excellent hemodynamic performances of the valves have been confirmed, as well as their favorable impact on symptoms and survival. Among them, the largest 3 European registries are particularly interesting: SOURCE, ADVANCE, and FRANCE 2. Their results are presented in Table 2.

The SOURCE registry used the SAPIEN valve and included 1038 patients among 32 centers [18, 19]. Overall, patients treated with the transapical approach represented a higher-risk population in comparison to those treated with the transfemoral approach. Immediate success rate was 94 %. Thirty-day mortality was higher among the transapical group (10.3 %) in comparison with the transfemoral group (6.3 %). Furthermore, occurrence of vascular complications was not associated with an increase of 30-day mortality in the transfemoral group. At 1-year, survival was 76.1 % in the whole cohort (72.1 % in the transapical group and 81.1 % in the transfemoral group). Deaths were cardiac-related in 25.1 % of the cases, non-cardiac in 49.2 % and unexplained in 27.7 %. Moreover, the most frequent causes of non-cardiac death were pulmonary or renal disease, cancer, and stroke. Finally, multivariate analysis identified the EuroSCORE, renal failure, liver disease, and smoking as the most important predictors of mortality.

The ADVANCE study used the CoreValve and included 1015 patients among 44 centers [20]. The methodology was strict, as all events were analyzed according to the definitions from the VARC [14] and adjudicated by an independent committee. Procedural success rate was high (98 %). In addition, 30-day all-cause mortality was 4.5 %, while the incidence of stroke was <3 %. Consistent with previous studies using the CoreValve, the rate of new pacemaker implantation was 26.3 %. Moreover, 6-month survival was 87.2 %. Unfortunately, there was no data on post-implantation aortic regurgitation, with the exception of the cases where surgery was required. Overall, this study shows that in a real-life setting, TAVR using the CoreValve is safe, with low rates of mortality and major complications, in particular stroke.

Finally, the FRANCE 2 registry included all the 3195 patients who were treated by TAVR in France from January 2010 to October 2011 [21]. It is the largest registry carried out so far. The SAPIEN and CoreValve prostheses were used in 66.9 % and 33.1 % of the cases, respectively. Approaches were transfemoral in 74.9 % of the cases, transaxillary in 5.8 %, and transapical in 17.8 %, while other routes (transaortic or transcarotid) were used in 1.8 %. Procedural success was achieved in 96.9 % of cases. Thirty-day and 1-year mortality rates were 9.7 % and 24.0 %, respectively. Furthermore, the rate of stroke at 1 year was 4.1 %, while paravalvular aortic regurgitation was observed in 62.9 % of the patients (grade 1, 46.0 %; grade 2, 16.1 %; grade 3, 0.8 %). On multivariate analysis, a high EuroSCORE, a NYHA functional class III or IV, the use of the transapical approach and a higher grade paravalvular aortic regurgitation were associated with a higher mortality.

Which Vision for the Future?

Toward a Better Identification of Patients at (too) High Risk

The predictive scores of surgical risk currently used, such as the EuroSCORE and the STS-PROM, suffer from important limitations in high-risk patients. Therefore, new scores specifically dedicated to valvular diseases are warranted [23]. Such scores should be based on a limited number of variables, adapted to a

Table 2 Results from main multicenter registries

	SOURCE (n=1038)		ADVANCE (n=1015)	FRANCE 2 (n=3195)
	Transfemoral (n=463)	Transapical (n=575)		
Clinical characteristics				
Age, years	82±7	81±7	81±6	83±7
EuroSCORE, %	26±14	29±16	19±12	22±14
NYHA III/IV, %	NA	NA	80	76
Coronary artery disease, %	47	56	58	48
Prior CABG, %	18	27	21	18
COPD, %	25	29	23	25
Cerebrovascular disease, %	NA	NA	13	10
Peripheral artery disease, %	11	27	20	21
Chronic renal failure, %	26	33	15	3[a]
Immediate outcome				
Procedural success, %	94		98	97
Implantation of 2 valves, %	2		4	2
Conversion to open surgery, %	3		0.1	0.4
Coronary obstruction, %	0.6		0.1	NA
Valve embolization, %	0.3		0.3	NA
Aortic regurgitation >2+, %	2		2	NA
30-day outcome				
Death, %	8.5		4.5	10
Aortic regurgitation >2+, %	NA		NA	1[b]
Stroke %	2.5		3	NA
Major vascular complications, %	7		11	NA
Dialysis, %	4		0.4	NA
New pacemaker implantation, %	7		26	NA
1-year outcome				
Death, %	24		NA	24
Stroke, %	NA		NA	4
Myocardial infarction, %	NA		NA	1
Major vascular complications, %	NA		NA	5
Valve migration, %	NA		NA	1
New pacemaker implantation, %	NA		NA	16

[a] Requiring dialysis.

[b] Requiring surgery.

CABG coronary-artery bypass grafting, *COPD* chronic obstructive pulmonary disease, *NYHA* New York Heart Association

large scale of surgical risks, validated in centers with various patient volumes, and regularly updated. Most importantly, it will be necessary to establish other risk scores for short and long term results of TAVR. The analysis of large databases, such as the FRANCE 2 registry, should help to indentify discriminating variables. This will allow a more accurate identification of patients who should not be treated due to insufficient life expectancy or quality.

Toward the Extension of Indications

Currently, the use of TAVR is restricted to patients suffering from severe degenerative aortic stenosis considered at high-risk or inoperable for surgery. Other populations are potentially candidates for the technique and should be evaluated.

"Valve-in- valve" implantation is an attractive alternative to redo surgery in elderly patients with failed surgical

bioprosthesis. The first results from observational studies are promising [24–28], but more information is needed in order to better determine the types of bioprostheses suitable for this intervention, as well as the thrombotic risk related to the double valve implantation and the durability of transcatheter valves in this setting. Moreover, the elaboration of specific prostheses will likely be necessary for this setting of patients.

Bicuspid aortic valves represent a classic contraindication to TAVR due to the risk of prosthesis deformation and dysfunction. While the current literature on this matter is relatively scarce [29, 30], the issue of treating this specific sub-group will become more commonly raised as indications of TAVR are extended to younger and lower-risk patients.

TAVR for aortic regurgitation also raises various technical concerns in relation with the absence of calcification, annulus size, and possible concurrent aortic root dystrophy. In addition, ventricular hyperkinesia may complicate positioning and anchorage of the prosthesis in the adequate position. A European registry using the CoreValve for patients with aortic regurgitation is currently ongoing.

Patients at intermediate risk also represent a major issue for the future. In clinical practice, a temporal shift towards lower-risk populations was observed in the FRANCE 2 registry as well as in most European registries. In the German registry, 16 % of indications were motivated by the wish of intermediate-risk patients [31]. However, before this trend becomes common practice, longer-term follow-up concerning the durability of the transcatheter heart valves is mandatory. Indeed, while case reports of transcatheter valve failure are anecdotic, the current follow-up does not exceed 5 years and neither the time nor the modalities of prosthetic degeneration are known at present time. The only acceptable way for progressing in this direction is to carry out randomized trials in intermediate-risk patients. The SURTAVI and the PARTNER II trials, which will respectively use the CoreValve and the SAPIEN XT, will include patients with a surgical predicted mortality between 4 % and 10 %, according to the STS PROM [32].

Toward a More Precise Measurement of the Aortic Annulus

Measurement of the aortic annulus is one of the most challenging steps of the screening process, and its implications are crucial. Measurements obtained by CT are closer to the 3-dimensional anatomy of the annulus than those drawn from TTE or TEE. However, there is yet no evidence that the choice of the prosthesis size guided exclusively by CT rather than by echocardiographic measurements is more effective and safe. In the future, CT or magnetic resonance imaging will probably allow more precise and reproducible measurements.

Toward a Safer and Simplified Procedure

The current recommendation is to restrict the ability of performing TAVR to high-volume centers. This will likely remain unchanged in the future because of the increased need for safety, as the practice will shift towards treatment of lower-risk populations. Most procedures will probably be performed in catheterization laboratories because of economic constraints, which will unfortunately limit the diffusion of hybrid rooms. Multimodality imaging, mainly with fluoroscopy and CT, will play an increasing role for prosthesis delivery and positioning. The use of the transfemoral approach will become even more frequent with the miniaturization of the devices, resulting in a lower use of the transapical approach. The exact role of the transaxillary and direct aortic approaches will also be better determined. New prostheses will be commercialized, most of them autoexpandable, repositionable and retrievable [33]. The issue of durability will be crucial as indications will be extended to younger populations. Overall, the procedure will be simplified, the predilatation step will be suppressed in certain cases [34], but the major issue will be to decrease the complication rate, most importantly the risk of stroke [35–38]. In this view, a better comprehension of the timing and the potential causes of this complication will be necessary. Moreover, the role of embolic protection devices will have to be assessed [39], and the optimal antiplatelet therapy will have to be determined, as current treatment regimens are purely empirical. In addition, the role of atrial fibrillation in the occurrence of stroke following TAVR and the potential benefit of antiarrhythmic treatments in this setting will have to be evaluated.

The issue of paravalvular leak will also need to be addressed, as it has been suggested that even mild degrees of regurgitation could be associated with a poor prognosis. The prevention of this complication will require more precise measurements of the aortic annulus, an adequate adaptation of the type of prosthesis to the anatomy, and the reassessment of the benefit/risk ratio of post-dilatation. The ability to reposition the prosthesis will probably limit the risk of paravalvular aortic regurgitation.

Vascular complications will decrease with the reduction of the size of delivery systems and the technical improvements of percutaneous vessel closure devices.

Finally, although the consequences of conduction defects leading to new pacemaker implantation following TAVR are relatively minor among the patients currently treated, technological improvements will be warranted to reduce the incidence of this complication, as this carries a financial burden and may also prove to be more harmful in a younger patient population [40].

Conclusion

During the last decade, the development of TAVR has not only revolutionized the management of aortic stenosis, but has also led to an improved collaboration between specialists treating patients with heart disease, emphasizing the need for a team-approach strategy. In addition to this multidisciplinary approach, high-quality imaging and careful evaluation will be key to success in the future [41]. There is no doubt that the number of TAVR procedures will increase, at the expense of surgical aortic valve replacement. The issue is not to discuss if, or when the curves will cross, but to be able to provide the best treatment to every patient, whatever the modality.

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- •• Of major importance

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