CLINICAL RESEARCH

Transcatheter aortic valve implantation: Our vision of the future

Implantation valvulaire aortique par cathéter : le futur

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Summary Transcatheter aortic valve implantation (TAVI), introduced 10 years ago by Alain Cribier, has now been performed in more than 50,000 patients worldwide. Our vision of the main directions for the future are fourfold. Firstly, the ‘Heart Team’ is and will remain, essential for patient selection and the performance of the procedure. Careful training and controlled diffusion of the technique to medico-surgical centres are also keys to success. Secondly, patient selection must be refined, in order to predict the risk of surgery and that of TAVI. The technique is currently limited to very high-risk patients or those with contraindications to surgery. It will be extended to include lower risk patients once there are adequate trial data, the safety of the procedure has been improved and better knowledge of long-term outcomes from the procedure has been obtained. Thirdly, the procedure will be simplified, and should also be safer with an expected decrease in the occurrence of strokes, vascular complications and perivalvular regurgitation. Fourthly, the devices will also improve, with the addition of the potential for repositioning and improvement in durability. The role of imaging with the use of multimodality techniques will no doubt increase and ease the efficacy and safety of the procedure. Overall, the use of TAVI will undoubtedly increase over time, enabling a larger number of patients with severe aortic stenosis to be treated in an effective and safe way, in complement to surgical aortic valve replacement.

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KEYWORDS
Future;
Heart Team;
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Abbreviations: CT, computed tomography; EAPCI, European Association of Percutaneous Cardiovascular Interventions; MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention; PROM, Predicted Risk Of Mortality; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium.

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**Background**

Transcatheter aortic valve implantation (TAVI) was introduced by Alain Cribier 10 years ago [1] and is now an accepted treatment for high-risk patients with severe aortic stenosis. Since the approval of both the Edwards SAPIEN and the Medtronic CoreValve in Europe in 2007, TAVI has been performed in more than 50,000 patients worldwide [2–6]. The current results of the technique are described in the other articles of this issue.

Today, TAVI has become the standard of care for inoperable patients with aortic stenosis and acceptable life expectancy. TAVI is also an alternative to aortic valve replacement in selected high-risk operable patients [7,8]. The aim of this review is to forecast what may happen in the future, starting with patient selection and then examining technical aspects.

**Patient selection**

First of all, it should be stressed that today and in the future, the TAVI Heart Team approach is and will remain, essential for the management of patients with severe aortic stenosis and TAVI should be restricted to high-risk patients [9]. This will apply at each step of the procedure: patient selection, performance of the procedure, post-procedural care and evaluation of the results.

The Heart Team is comprised of clinical cardiologists, interventionists, surgeons, anaesthesists and imaging specialists, all with expertise in the treatment of valve disease. The participation of other specialists, such as geriatricians, will be increasingly sought.

It is essential to assess both the risk of surgery and the risk of TAVI. Firstly, we need better scores to assess the risk of surgery. The current scoring systems, EuroSCORE or Society of Thoracic Surgeons Predicted Risk Of Mortality (STS PROM) [10,11], are limited in their prediction of outcomes in high-risk patients. New scoring systems should be based on a limited number of variables; aimed at the specific evaluation of valvular patients; elaborated from a broad spectrum of operative risk; externally validated in high- and low-volume centres; and updated on a regular basis. Besides evaluating cardiac and extracardiac factors, it is mandatory to include indices of functional and/or cognitive capacity and frailty. We need better definition and further evaluation of this last parameter [12].

Secondly, we need scoring systems that predict the outcome of TAVI, both in the immediate and the long term. Even with refined scoring systems it is likely that it will never be ‘magic numbers’. Assessment by the Heart Team, based primarily on clinical judgment, will remain critical, but will be supported by a certain degree of quantification using better scores.

The use of TAVI is limited to patients at high risk or with contraindication(s) to surgery. In this category, a number of subgroups require more-precise evaluation:

- associated coronary artery disease: only data from retrospective studies involving a limited number of patients exist; we therefore lack the solid evidence necessary to guide our strategy. It is likely that randomized studies will be the best way to decide when percutaneous coronary intervention (PCI) should be performed and the timing of the procedure [13];
- bicuspid valves are a classic contraindication for TAVI. Here again, we have very limited data to guide us, but this feature will but this feature will become increasingly important with the consideration of lower-risk patients (i.e. younger patients). It may be that a specific valve design is needed in patients with bicuspid valves [14];
- the strategy in patients with severe left ventricular dysfunction is also a matter of debate. We should identify those patients unlikely to benefit from TAVI because of their low likelihood of a good outcome and in those we are willing to treat, we should compare a strategy of balloon aortic valvuloplasty as a bridge versus TAVI as a first intervention;
- transcatheter ‘valve in a valve’ is an attractive alternative in bioprosthesis failure. Preliminary results have

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**MOTS CLÉS**

Futur ; Heart Team ; Imagerie ; Implantation valvulaire aortique par cathéter ; Sélection ; Technologie

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**Résumé**

L’implantation valvulaire aortique par cathéter (TAVI), qui a été introduite par Alain Cribier il y a dix ans, a été réalisée chez plus de 50 000 patients dans le monde. Les principales directions dans le futur pourraient être les suivantes : la « Heart Team » est et restera essentielle pour la sélection des patients et la réalisation de la procédure. L’entraînement soigneux et la diffusion contrôlée de la technique à des centres médicochirurgicaux sont aussi des clés du succès ; la sélection des patients doit être améliorée, tant en ce qui concerne la prédiction du risque chirurgical que celui du TAVI. Actuellement, la technique est limitée aux patients à très haut risque et à ceux ayant une contre-indication à la chirurgie. Elle sera étendue à des patients à plus faible risque après la réalisation des essais adéquats, lorsque la sécurité de la procédure sera améliorée et son évolution à long terme mieux connue ; la procédure va se simplifier et devrait devenir plus sûre, avec une probable diminution du risque d’accident vasculaire cérébral, de complication vasculaire et de fuite péri-valvulaire ; les dispositifs s’amélioreront aussi grâce à la capacité de reposicionnement et à la prolongation de leur durabilité. Avec l’utilisation de techniques multimodales, le rôle de l’imagerie augmentera certainement la simplicité et la sécurité de la procédure. Globalement, avec le temps, l’utilisation du TAVI va croître sans aucun doute, permettant à un plus grand nombre de patients porteurs d’un rétrécissement aortique sévère d’être traités de façon efficace et sûre, en complément de la chirurgie de remplacement valvulaire aortique.

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been reported from observational studies, but more data are needed to better define: which valve prostheses are suitable for valve-in-valve implantation; sizing and the theoretical risk of thrombosis due to dual prosthetic implantation; and durability. It is possible that a new valve design will be needed [15,16].

With improved identification of the predictors of outcome after TAVI and thanks to the involvement of other specialists in patient selection, it is likely that we will be able to better define which patients should not be treated, either by surgery or by TAVI because of their life expectancy and expected quality of life are too limited [17,18].

The most important issue for the future is to know when to treat lower risk patients. This has already happened in practice, as illustrated in a German registry, where as many as 16% of patients were treated as a result of patient choice while being at only intermediate risk for surgery [3]. However, before moving towards lower risk patients we should accumulate evidence on the long-term results of the procedure. We currently have only anecdotal cases of valve dysfunction, but the available follow-up is seldom longer than 3–4 years and we need longer-term data to better define the timing and the mode of failure [19,20].

Due to the similarity of the valves implanted surgically and using the transcatheter, it is likely that both are similar with regard to long-term outcomes, but this has yet to be proven. In addition, when structural dysfunction occurs, it is likely that in most cases it will be possible to put a ‘valve in a valve’ and then further delay conventional operation. The best way to assess whether to move towards lower risk patients is to perform randomized studies, such as the SURTAVI and Placement of Aortic Transcatheter Valves (PARTNER) II trials, which will include patients with a STS predicted mortality rate of 3–8%.

Finally, it is unlikely that TAVI will be used in a large number of patients with aortic regurgitation; most of these individuals have dystrophic disease with dilatation of the ascending aorta, which should be cured at the same time as aortic stenosis [21].

Sizing of the valve
In the future we should be able to solve the challenge of the proper sizing of the valve [22]. Measurement of the aortic annulus was initially done by echocardiography alone. Three-dimensional echo or computed tomography (CT) provides more accurate measurements, but it remains to be established whether a strategy based on CT is more effective and safer than an echo-based strategy [23]; this should be proven by appropriately designed studies. It is likely that in the future, CT or magnetic resonance imaging (MRI) will be the best methods because they can be reproduced more easily and are also better suited to the assessment of the aorta and the peripheral vessels. The role of other factors such as distribution of calcium and the size of the sinus of Valsalva should also be assessed [24,25].

Performance of the procedure
The current recommendation is to perform the procedure only in cardiology and cardiac surgery centres. This will probably remain the case because if we lower the risk of the patients, a higher degree of safety will be even more important and the feasibility of conversion to surgery in the case of a complication will become mandatory. Perhaps more importantly, only large centres will be able to provide appropriate preoperative, perioperative and postoperative care [9].

Currently, the procedure is most often performed in a catheterization laboratory. This will probably remain the case in the near future, the use of hybrid rooms is desirable, however economic constraints could limit their use. Wherever the procedure is performed, imaging will play an increasing role in navigation and the positioning of the devices. Miniaturization of the transoesophageal echocardiographic probes is expected. However, it is likely that the positioning method will mainly use fluoroscopy and CT. This will help in choosing the most appropriate type of device (best suited to the individual anatomy) and then evaluating the position of the prosthesis in relation to the coronary arteries (Fig. 1). First experimental attempts of an MRI-guided procedure have been performed and this strategy will become an attractive option when MRI-compatible devices become available [26].

The Heart Team in a given institution should decide on the precise organization of the procedure. One potential strategy is that interventionists could be trained to perform surgical access or surgeons could be trained to perform catheterization; then these ‘multifunctional’ individuals could perform the whole procedure. However, we do not think that this is the best solution. We are more in favour of ‘cross-fertilization’ and a team approach, with each member bringing his or her expertise and adding to the expertise of others. We feel that it is important for an anaesthesiologist to be present. It is likely that the use of general anaesthesia will decrease in the future and be replaced by local anaesthesia, but management of haemodynamic changes and complications should still be harmonized with anaesthesiologists specialized in cardiac surgery. They should always be available, especially if the procedure is performed in lower-risk patients.

The individuals and, more generally speaking, the team performing the procedure should be carefully trained. Their training should cover: disease, technique and device-orientated training. All of the modern tools should be used (i.e., simulator training, proctoring and teaching courses). Most of the current training is provided by companies, but in the future, scientific societies and associations such as the European Association of Percutaneous Cardiovascular Interventions (EAPCI) should play an increasing role in designing standards for training in TAVI [27].

Currently, the most frequently used approach is transfemoral and this will probably increase in popularity with further miniaturization of the devices. The transapical approach also has a future, although this is more limited [28]. The precise roles of transaxillary and direct aortic access need to be studied in greater detail. In the future, it will be desirable for teams performing TAVI to be able to propose the most appropriate approach for the individual patient. This will increase the number of patients who can be treated and also the safety of the procedure, in particular by decreasing the incidence of vascular complications. Introducers will become smaller and will be available for the transapical approach. Closing devices will be refined;
valve prostheses will also be improved. Today, the valve prostheses available are becoming increasingly similar to the surgically implanted valve. The main advantages of the new over the existing prosthesis designs (Fig. 2) are their repositionability and retrievability [29]. The question of the durability of the valve should also be addressed. Users will then select the type of device used according to the patient’s characteristics. Primary studies have shown the feasibility of valves derived from bone marrow cells for implantation in the systemic circulation [30]. This concept is, of course, of great interest for the future.

Overall the procedure will be greatly simplified, with even wider use of the percutaneous approach. Pre-implantation balloon dilatation may be avoided in selected

Figure 1. New systems for navigation and positioning during TAVI: (A) mini transoesophageal echocardiographic probe; (B) C-THV Paeion System; (C) Dyna computed tomography; (D) three-dimensional template-based planning; (E) Magnetic resonance imaging guidance.

Figure 2. New prosthesis models.
cases, as has been suggested in patients with mild calcification when using self-expandable prostheses [31]. However, this simplification does not mean that all of the necessary team effort and equipment (e.g., cardiac support and immediate access to surgery) should disappear.

The combination of TAVI with other transcatheter interventions will also be performed in the future. We have already discussed the issue of coronary intervention and TAVI. Cerebral protection devices may help to prevent cerebrovascular events. Finally, the potential of combining TAVI with percutaneous mitral valve repair should be studied in selected patients.

It is mandatory to decrease the rate of complications if we want to extend the use of TAVI to lower-risk patients.

Stroke has recently been highlighted as an important issue after TAVI, but more work is needed to better characterize the type and timing of strokes and to find the potential causes [8,32]. It is likely that in the future we will have to pay more attention to the detection of severe aortic debris, which may lead to the postponement of the procedure or to the use of alternative approaches. The role of embolic protection devices also has to be established, but this will not solve the whole issue because a sizable proportion of the strokes occur quite some time after the procedure. The antithrombotic regimen currently uses dual antiplatelet therapy. Studies are ongoing to determine whether one agent is sufficient, which is of crucial importance in the elderly population and in patients on chronic anticoagulant therapy. Finally, the potential role of antiarrhythmic treatment is an important issue, since the role of transient atrial fibrillation has been suggested [33].

Moderate to severe aortic regurgitation carries a poor outcome [3]. Here the solution is to improve the sizing of the prostheses and perhaps also to individualize the choice of the prosthesis. The strategy of post-implantation dilatation should also be refined, balancing the risk of aortic regurgitation against that of aortic rupture.

The incidence of vascular complications should decrease with better screening, with the availability of smaller devices and introducers and the use of alternative approaches, while the refinement of the antithrombotic regimen will also play a role [34,35]. Closure devices will be improved and the management of vascular complications will be better standardized. In particular, the respective roles of stenting and surgery in the case of vascular complication have to be defined.

The need for pacemakers is of less clinical consequence. However, they carry a cost and their use should therefore be decreased [36]. This complication should be dealt more precisely in patients with self-expandable prostheses and tests of possible strategies should be continued, such as higher valve implantation, avoidance of balloon valvuloplasty and performance of post-dilatation. Longer follow-up will also provide information about the incidence and the particularities of other complications such as endocarditis and embolism.

**Evaluation of the results**

Although TAVI is a relatively new technique its evaluation has been performed in an appropriate way—data from randomized studies are already available, which is a positive sign. Precise definitions are mandatory and the Valve Academic Research Consortium effort should be pursued and updated [37]. Mechanistic trials are needed for large single-centre studies. Registries are also very important to show real-life aspects and provide information on temporal changes in the use of surgery, TAVI and medical therapy. However, randomized trials will be key to expand indications and also compare devices in the future. Assessment of cost-effectiveness is important and will be of even greater importance in the future. Finally, it is mandatory that at the level of each single institution, the results of TAVI are carefully followed.

**Conclusions**

A team approach, careful training, good imaging and careful evaluation are and will remain, essential. Today, TAVI is indicated only in high-risk patients. Before extending its use to low-risk patients, further research is needed on: risk stratification models for aortic valve replacement and TAVI, improvements in safety and ease of the procedure, technology and evaluation in comparison with surgery.

Transcatheter treatment after failure of valve bioprosthesis requires careful study. It is most likely that this will become increasingly popular. This new option will have important clinical implications, increasing the number of valve bioprosthesis implantations.

We believe that the use of TAVI will increase over time. It is also likely that the number of surgical aortic valve replacements will decrease. It is difficult to predict when the ‘curves will cross’, but this is not particularly important. What is important is that a larger number of patients with severe aortic stenosis valve disease will be more effectively treated, whatever the approach.

**Disclosure of interest**

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J.-P.D. declares that he has no conflict of interest concerning this article.

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