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Transcatheter aortic valve implantation – new era in treatment of aortic stenosis

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Abstract

Background: The presence of aortic narrowing is common in the elderly and the prognosis is very poor in symptomatic patients. Prior to the era of percutaneous treatment of aortic stenosis, surgical aortic valve replacement (SAVR) was considered the "gold standard" of symptomatic aortic stenosis treatment. However, the records have shown that about 40% of patients at that time were not operated due to their age and their cardiac and non-cardiac comorbidities. The subsequent work was the implantation of aortic valve by transfemoral approach – transcatheter aortic valve implantation (TAVI). Several studies have acknowledged the place of aortic valvuloplasty which has become the reference technique for patients with contraindications or high surgical risk and even recently appeared as at least equivalent to, or even superior to, the surgery in patients at intermediate risk. This development was accompanied by a renewed interest in aortic valvuloplasty, a TAVI that cannot reasonably be executed at first attempt in some patients. In Europe, where this technique was born, the great experience that has been gained has led to a gradual simplification of the procedure. The purpose of this article is to describe the state of the art of TAVI and to discuss its future.

Conclusions: The aortic stenosis disease affects a large scale of people across the globe. The appearance of a new treatment method TAVI opens new era of treatment of this disease. The new TAVI method is a less invasive procedure than an open heart surgery and can be used in almost all the cases of patients with an aortic stenosis.

Key words: aortic stenosis, transcatheter aortic valve implantation, surgical aortic valve replacement.

Cite this article

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Introduction

Calcified aortic stenosis is the most severe form of aortic valve disease and it is characterized by fibrocalcic remodeling. This remodeling process begins with a deposition of lipoproteins and chronic inflammation, resulting in osteogenic differentiation of valvular interstitial cells and active calcification of the layers [1, 2]. Despite similarities with the atherosclerotic process, no pharmacological treatment slowed the progression of the aortic stenosis. Large-scale epidemiological studies have shown an annual incidence of calcific aortic stenosis in the range of 0.36 and 0.37 per 1000 hospital-treated patients [3, 4]. In the general population, the incidence is higher (4.9 per 1000) when calculated on the basis of systematic echocardiographic examination. The prevalence of calcific aortic stenosis is estimated at 0.4% in the general population and between 1.3 and 1.7% in patients over 65 in developed countries [5-7]. The prevalence of calcified aortic stenosis increases significantly after age of 65 and it reaches its severe form of 3.4% after the age of 75, with 75% of symptomatic patients [8]. The natural course of severe symptomatic calcific aortic stenosis is particularly dark, as shown by the 5-year mortality rate of 60% after the initial hospitalization. Mortality is increased in cases of heart failure or in octogenarians with comorbidities [9, 10]. The reliability of the epidemiological data of valvulopathy has important implications for the planning of therapeutic resources. The number of patients with aortic stenosis is expected to triple in the next 50 years [11-13].

History of transcatheter aortic valve implantation (TAVI)

The development of TAVI has been a long odyssey since the birth of the concept in the early 90s. The history began in 1985 in Rouen with the introduction of the aortic dilatation balloon by Alain Criber. After considerable international interest in this technique, its limitations, particularly early valvular restenosis, led to the development of the "percutaneous aortic valve" concept. Faced with the absence of any industrial support, a start-up, "Percutaneous Valve Technologies", was created which allowed the development and testing on animals of the first balloon-expandable dentures in 2000, before the first human implantation took place at the University Hospital Center on 16 April 2002 in Rouen [14]. The 2004 acquisition of this start-up by Edwards Lifesciences was the starting point for significant technological improvements and increasing interest in TAVI, while two years later a competing self-expandable prosthesis was introduced the Medtronic Core Valve. Multiple controlled registers and studies with these two prostheses have resulted in the extraordinary expansion of the TAVI that we know today, with inclusion in the European and American recommendations since 2012 and a gradual and recently validated expansion of indications to patients with less risk [15]. Pre-

TAVI Patient Assessment and selection is a key step in the implementation of a TAVI and should involve a multidisciplinary team of cardiologists, imaging specialists, cardiac surgeons and geriatricians if needed or other specialists [16-21]. The investigations prior to TAVI should include: Echocardiography to confirm the severity of aortic stenosis, analyze aortic valve and ascending aortic morphology, size and function of the left ventricle to rule out dynamic ventricular obstruction and evaluate the mitral valve; coronary angiography to determine revascularization options. The multi-cut coronary computer tomography (CT) is essential to the therapeutic decision, especially for the selection of the best approach in terms of vessel size, tortuosity and calcification. When the indication of a TAVI is retained, a scan of the arteries is performed from the ascending thoracic aorta to the arteries of the lower limbs [22].

For the femoral approach, the ratio of the outer diameter of the vest to the minimum diameter of the vessel should be less than 1.1 in the absence of calcification. When the femoral approach is not feasible, the scanner can make it possible to evaluate the feasibility of another pathway (transcarotide, transaortic, subclavian or transapical).

Transfemoral approach after the initial approach combining a surgical and percutaneous approach is the approach currently entirely percutaneous. This is often the preferred approach because it offers the largest arterial diameters and has a lower rate of complications.

Left subclavian / transaxillary approach: it allows TAVI with the CoreValve prosthesis in patients who cannot benefit from a femoral approach, without requiring thoracotomy. Nevertheless, surgical exposure is required, with a procedure frequently performed under general anesthesia.

Transapical approach: it allows a direct anterograde access via the tip of the VG, without passing through the aorta. This is a surgical approach that requires a left anterolateral intercostal incision, under general anesthesia. It is associated with higher mortality compared to the transfemoral route.

Transaortic approach: this approach consists of a ministernotomy at the level of the ascending aorta, under general anesthesia. The aortic puncture site and the thoracic wall are surgically sutured at the end of the procedure. Other approaches have been developed more recently, such as the transcarotid approach or the brachiocephalic arterial trunk (fig. 1) [23-26].

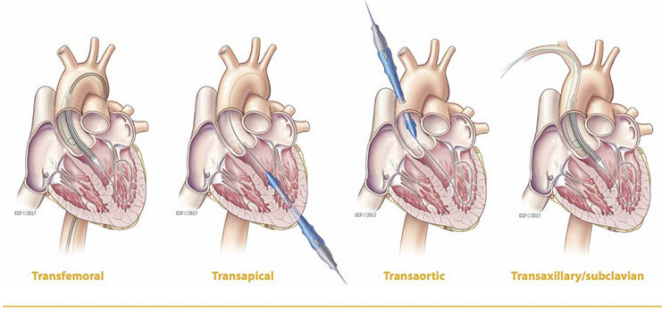


Fig 1. Different approach of TAVI.

In addition, in terms of calibration and selection of the appropriate valve type, CT has become the method of choice for assessing horizontal and ascending aorta, Valsalva sinus size, diameter and shape of the aortic annulus, the volume of calcifications, the bi- or tricuspid nature of the valve, the distance between the valvular ring and the ostium of the coronaries, the presence of a septal margin and possible calcifications in the flush chamber. These explorations make it possible to choose the most appropriate calibers and types of valve and the best incidence for the positioning of the prosthesis. For patients with coronary disease and severe aortic stenosis, the strategy is most likely to allow complete vascularization.

Patients treated with TAVI should be evaluated on a case-by-case basis by the multidisciplinary team, in the extent and complexity of the coronary lesions, the risk of myocardial infarct (risk of myocardial ischemia) and the potential complexity of the angioplasty, as well as the presence of any comorbidities. It should be emphasized that the recently published European Society of Cardiology (ESC) recommendations on myocardial revascularization advocate angioplasty in patients with TAVI-treated coronary artery disease who have a stenosis greater than 70% in the proximal coronary segments [27-29].

The angioplasty and TAVI performed separately, or the two procedures performed concomitantly are strategies considered acceptable with respective advantages and disadvantages that must be carefully considered on a case-by-case basis.

Technique of prosthesis implantation

Long considered to be at high risk of complications, percutaneous aortic valvuloplasty has become a relatively simple act of interventional cardiology, well tolerated, requiring only local anesthesia and short hospitalization.

When the transfemoral route is chosen, a "crossover" technique (involving a wire placed in the contralateral artery to allow delivery of a balloon or stent to treat the access vessel in case of injury) is usually performed to "protect" the artery in case of vascular complication [30].

A temporary pacing wire (TPW) is positioned in the right ventricle via the jugular or femoral vein and may be required during balloon aortic valvuloplasty (BAV), implantation of the TAVI prosthesis, post-dilatation or if the patient develops significant conduction disturbance following valve deployment.

The aortic valve is usually crossed with the aid of a Judkins right 4 (JR4) or Amplatz left 1 (AL1) diagnostic catheter and a soft straight-tipped wire. This is then exchanged for a stiffer wire taking care to ensure that this is free of the mitral valve apparatus. Originally, wires (e.g., Amplatz Super Stiff™, Boston Scientific, Marlborough, MA, USA) were manually shaped to create a curve at the end to reduce the risk of ventricular injury during valve deployment. However, dedicated pre-shaped wires (e.g., the Safari™ pre-shaped TAVI guidewire; Boston Scientific)) have more recently been developed that have better memory (and therefore maintain their shape) to further reduce the risk of ventricular injury

(fig. 2). Stiffer wires, including the Lunderquist® Extra Stiff wire (Cook Medical, Bloomington, IN, USA) or the Back-up Meier™ guidewire (Boston Scientific), may be used when greater support is required to deliver the TAVI device (e.g., in the setting of severe aortic tortuosity).

The aortic valve is initially crossed with a soft-tipped straight wire with the aid of an Amplatz left 1 catheter (fig. 2 A). Once the valve is crossed (fig 2 B), the wire is exchanged for a stiff wire with a curved tip (white arrow) to minimise ventricular injury (fig. 2 C) over which the TAVI device is then advanced.

Transcatheter valves are positioned prior to deployment with the aid of aortography, fluoroscopy and, in some instances, transoesophageal echocardiographic guidance. Balloon expandable valves require rapid ventricular pacing (180-220 beats per minute) for deployment to reduce cardiac output and avoid inaccurate valve implantation [31]. Other devices may not routinely require ventricular pacing, although this may still be useful in instances when valve positioning is challenging (e.g., horizontal aorta).

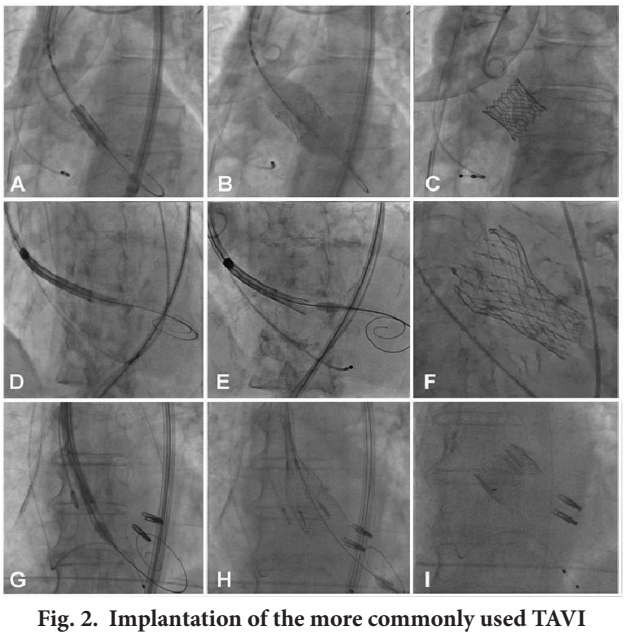


Fig. 2. Implantation of the more commonly used TAVI prostheses.
Initial position of the balloon-expandable Edwards SAPIEN 3 valve (A), deployment (B) and final appearance (C). Initial position of the self-expanding Medtronic Evolut R valve (D), deployment (E) and final appearance (F). Appearance of the mechanically deployed Boston Scientific Lotus valve (G), deployment (H) and final appearance (I).

The goal is to achieve a reduction of the transvalvular aortic gradient of approximately 50% (if possible, less than 25 mm Hg) and an increase of the aortic surface of 100% (example: 0.5 to 1 cm^2).

If the result is insufficient, a larger diameter balloon catheter is used. At the end of the procedure, arterial vascular hemostasis is provided by a percutaneous Angio-Seal 8-Fr (Terumo) or Proglide (Abbott) arterial closure system. The patient can usually leave the hospital the day after the procedure [32].

Current indications of TAVI

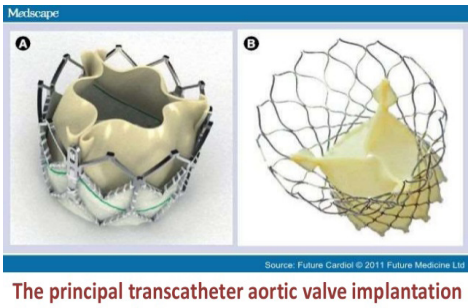
Aortic valve replacement surgery has been the standard treatment for many patients with aortic stenosis for many years and provides symptomatic relief and increased survival. Over the past 15 years, more than 400.000 percutaneous aortic valve implantations have been performed in more than 75 countries. The TAVI technique has now reached maturity, the intervention being standardized and the results predictable.

In high risk patients

According to European (2012) and North American (2014) recommendations, TAVI is currently indicated in inoperable patients or is considered an alternative to surgery in high-risk patients [6, 33-36].

These indications are based on the results of the PARTNER 1 studies with balloon deployed valves (Sapien, Edwards Lifesciences) and the US CoreValve study with self-expanding valves (CoreValve, Medtronic). The PARTNER 1B study, published in 2010, randomized 358 patients, with tight RA and considered inoperable, between a transfemoral TAVI with the 1st generation Sapien valve and medical treatment. The primary outcome (death) at 1 year was 30.7% in the TAVI group and 50.7% in the medical group ($p < 0.001$). The PARTNER 1A study, published in 2011, is a randomized non-inferiority study comparing in 699 patients with tight RA and considered to be at high risk for TAVI transfemoral (2/3 of patients) or transapical with valve 1st generation Sapien and AVR. The primary outcome (death) at 1 year was 24.2% in the TAVI group and 26.8% in the AVR group ($p = 0.62$). Therefore, the PARTNER study had indeed shown that in nonoperable patients with severe aortic stenosis, a TAVI significantly reduced mortality at one year compared to drug treatment3 and that in patients at very high risk of surgery. TAVI and conventional surgical replacement had a mortality rate comparable to one year [37, 38].

In 2014, another study conducted with the 1st generation CoreValve valve was also published. This study compared TAVI and surgical therapy in 795 patients with aortic stenosis and considered at high surgical risk. The primary outcome (death) at 1 year was 14.2% in the TAVI group and 19.1% in the AVR group ($p = 0.04$) [39] (fig. 3).



The principal transcatheter aortic valve implantation devices currently in use:
(A) Edwards Sapien XT bioprosthesis and
(B) Medtronic CoreValve® bioprosthesis

Fig. 3. The TAVI devices.

The results of these pivotal studies have therefore allowed the entry of TAVI into the European recommendations for the management of patients with aortic stenosis (2012). TAVI is limited to inoperable patients and is considered an alternative to surgery in high-risk patients. Patients must have a life expectancy greater than 1 year, procedures must be validated by a medical-surgical meeting (Heart Team) and performed in experienced centers with on-site cardiac surgery [40-42].

Scores to predict surgical risk

The operative risk of aortic valve replacement (AVR) in a patient with severe aortic stenosis is usually assessed by risk scores.

In Europe, the most used score is the recently updated EuroSCORE (European System for Cardiac Operative Risk Evaluation) in the form of EuroSCORE2, while in the United States, the most commonly used score is STS (Society of Thoracic Surgeons score). The validity of these risk scores is usually assessed by their calibration (ratio of observed mortality to expected mortality) and their performance (area under the ROC curve). The first-generation logistics EuroSCORE is poorly calibrated (because it overestimates mortality) and the area under the ROC curve (0.62) is imperfect to discriminate at-risk patients. On the other hand, the EuroSCORE 2 and the STS are better calibrated (ratio between the observed mortality and the expected mortality close to 1) and more discriminating (area under the ROC curve between 0.73 and 0.75) [43-48].

EuroSCORE 2 and STS are scores to assess the risk of cardiac surgery before surgery, and the expected mortality in this type of patient. The higher the score, the higher the risk.

Patients whose EuroSCORE2 or STS score is >8% are considered at high risk and those for whom these scores are <4%, are at low risk.

Patients are usually considered to be at intermediate risk when the EuroSCORE2 or STS score is between 4 and 8% (This means that the risk of death expected at 30 days in case of RVA is between 4 and 8%).

These risk scores have many limitations because they do not take into account a certain number of cardiac or extracardiac co-morbidities that will also impact on the operative risk. Patients with a porcelain aorta (massive circumferential calcification of the ascending aorta), regardless of the level of risk, are usually excluded from surgery because it is impossible to perform aortic clamping during the procedure.

In addition, patients with a hostile chest due to deformities or a history of radiotherapy are also usually considered by surgeons as high-risk patients. Some extracardiac comorbidities, such as advanced hepatic cirrhosis and severe chronic respiratory insufficiency are also not taken into account. Finally, the fragility, autonomy, and cognitive functions of the patient, well known to geriatricians, are not taken into account by these risk scores even though it has been well demonstrated that they have a major impact on morbidity-operative mortality.

Outcomes in intermediate risk patients

Interestingly, the PARTNER 2 study included patients with a low STS score (5.8%) thus presenting a surgical risk this time intermediate. In this study, patients with severe aortic stenosis had comparable mortality or stroke rates after two years, regardless of technique.

However, comparing only those patients who received TAVI transfemoral to surgical patients, the two-year mortality was significantly lower in the TAVI arm (p = 0.05). These results were confirmed in 2017 by the SURTAVI study, which also included patients at intermediate risk (STS score 4.5%) and in which TAVI and conventional surgery were equal to two years in terms of mortality and stroke [49-51].

Three major studies have been reported in patients with tight RA and lower surgical risk. The first study (NOTION), conducted in Denmark and Sweden, involved a reduced population of 280 patients (70 years old), regardless of the level of surgical risk. Patients were randomized for TAVI with a CoreValve valve or surgery. The primary endpoint at 1 year (associating death, heart attack and stroke) was similar in both groups (13.1% vs. 16.3%; p - 0.43).

The second study was conducted with the 2nd generation Sapien valve (model XT, PARTNER 2) and was published in 2016. This study randomized 2032 patients, considered intermediate risk, between TAVI and conventional surgery. The primary endpoint for 2-year judgment (combining death and stroke) was similar in the two groups (19.3% vs. 23.1%; p - 0.25) in the whole group studied. In contrast, the occurrence of death or stroke was significantly lower in the transfemoral TAVI group compared to surgery (16.8% vs. 20.4%; p - 0.05).

The latest study involves the 3rd generation Sapien valve (Sapien 3). This valve has the peculiarity of having an external shell in its ring portion to greatly reduce the incidence of paravalvular leaks. In addition, the size of the catheter allowing implantation has been significantly reduced to 14-16 F, reducing vascular complications. This is a registry comparing 1.077 intermediate-risk patients treated with TAVI and 944 patients treated with RVA paired with the surgical cohort of the PARTNER 2 study. The primary endpoint (combining death, stroke) at 1 year was significantly lower in patients treated with TAVI (10.8% vs. 18.8%; p - 0.001) [52].

Thus, between 2012 and 2017, large randomized studies have demonstrated the value of TAVI in intermediate-risk patients, so it is logical that the number of TAVIs doubled between 2012 and 2015, essentially, since the reimbursement of TAVI by Social Security [53] (fig. 4).

Taking these recent studies into account, the new recommendations of the European Society of Cardiology, published in 2017, have evolved quite a bit in favor of TAVI. These are patients with a risk score (EuroSCORE 2 or STS score) of between 4 and 8%. These new recommendations include promoting the TAVI approach to any intermediate-risk patient 75 years of age or older.

Finally, various studies are currently looking at TAVI in low-risk patients. The NOTION study (280 low-risk pa-

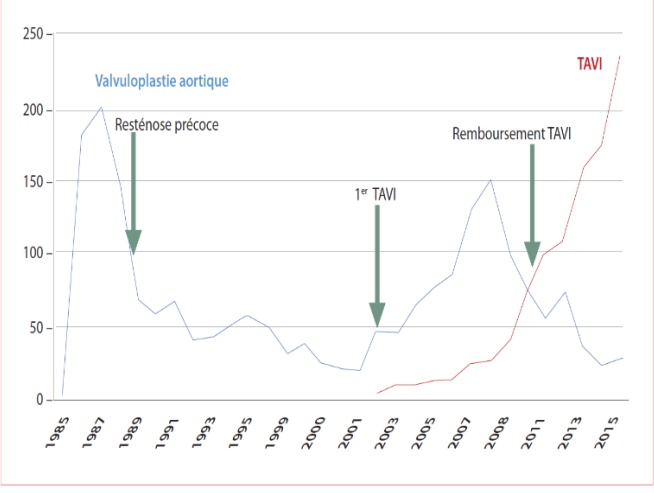


Fig. 4. The decrease in the number of surgical aortic valvuloplasties performed at the University Hospital in Rouen, France, since the TAVI reimbursement in 2010.

tients), whose results at five years have just been presented, thus observed a similar mortality between the two strategies. New data specific to patients at low risk of surgery is therefore to be expected soon [54-56].

For low risk patients (EuroSCORE 2 or STS score – 4%), but with other risk factors for conventional surgery such as significant fragility, aorta "porcelain" or radiation sequelae, different criteria should be taken into account when choosing between conventional surgery or TAVI during a Heart Team were listed (tab. 1).

In addition, it is important to know the theoretical life expectancy of patients according to their age before making a choice between a TAVI and an SAVR (tab. 1).

Evolution of anesthesia

Historically, local anesthesia with conscious sedation had been used during the very first TAVI in 2002 but, at present, practices depend mainly on the experience and habits of the medical hospitals.

General anaesthesia (GA) is required for surgical access sites (e.g., transapical or transaortic). However, improvements in pre-procedural assessment (particularly using advanced imaging of the aorta and peripheral vasculature using computed tomography and echocardiography) and engineering advances in prosthesis delivery systems (e.g. smaller delivery sheaths) have enabled the increasing use of conscious sedation and local/regional anaesthesia. Whilst no randomized studies have been conducted to ascertain if these are superior to GA, the advantages include shorter procedure times, the elimination of risks associated with GA and faster patient recovery [57, 58]. However, due to the better profile of the equipment and the ever-increasing experience of the different teams, local anesthesia is increasingly used during the TAVI and convincing data support feasibility and safety. In terms of differences in prognosis between these two approaches, the data is still unclear. Systematic reviews of the literature and meta-analyses did not observe differences in mortality or stroke incidents, but two more recent studies, based on records of 1737 and 16543 patients, suggest that local anesthesia with conscious sedation may be associated with lower hospital mortality [59].

Table 1

Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a]		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a]	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty[b]	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

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CABG – coronary artery bypass grafting; CAD – coronary artery disease; EuroSCORE – European System for Cardiac Operative Risk Evaluation; LV – left ventricle; SAVR – surgical aortic valve replacement; STS – Society of Thoracic Surgeons; TAVI – transcatheter aortic valve implantation.

TAVI for the treatment of aortic bioprosthesis degenerations

The new 2017 recommendations also enthrone TAVI as a therapeutic modality for the treatment of aortic bioprosthesis degeneration. Aortic replacement with bioprosthesis, about one in two patients will have degeneration with a necessary surgical reintervention rate in 10-30% of cases. As patients with aortic bioprosthesis degeneration are generally frail, elderly and that, by definition, they have a history of heart surgery, a percutaneous approach by a TAVI called valve-in-valve is at first sight attractive. Since the first case described in 2007, this procedure has been increasingly used in inoperable or very high-risk surgical patients with encouraging results. In the largest international registry of patients with aortic bioprosthesis degeneration at very high surgical risk, the one-year survival rate after a TAVI valve-in-valve is indeed greater than 80%. This new indication to achieve a TAVI is now recognized in the guidelines of the European Society of Cardiology for inoperable or considered to be at high risk of surgical re-intervention. However, because the TAVI valve-in-valve situation is more complex than the management of a conventional aortic stenosis, it needs, more than ever, to be the subject of a multidisciplinary discussion within the Heart Team [60-64].

Futility of TAVI?

The identification of patients in whom a TAVI may be futile also remains an open question in 2018. Classically, futility is defined as a death or lack of functional improvement in the short term (6 to 12 months). The potential futility of TAVI is mainly evoked in patients with extreme fragility, chronic renal failure or chronic obstructive pulmonary disease (COPD). In a study based on more than 300 consecutive patients, about one-third of whom had COPD, was observed that a TAVI had proved futile in more than one third of the cases. This excess mortality was also observed in other studies. The full clinical control is expected to help Heart Team members distinguish patients for whom symptomatic benefit is expected from patients for whom the intervention will not improve quality of life or independence. Pragmatically however, Mok et al. propose performing a six-minute walk test and identify a distance of less than 170 meters as a good predictor of futility [65, 66].

Heart team

Finally, remember that according to the new recommendations, to define in a personalized way the most appropriate treatment for a patient, each case must be assessed in a multidisciplinary way by specialists, the Heart Team, already mentioned several times in this article. If the concept was developed long ago in the treatment of coronary heart disease, its use for the treatment of valvulopathies is recent and follows the advent of percutaneous therapeutic approaches. According to the European recommendations, this Heart Team brings together a panel of specialists, such as a cardiac surgeon, an interventional cardiologist, a non-invasive cardiologist, imaging specialist, a radiologist, a cardiac anesthesiologist and a geriatrician to be able to establish an individualized therapeutic project, taking into account all the dimensions (anatomical, functional and human) of the pathology of the patient with the ultimate goal of establishing if the patient is a candidate for a conventional surgical treatment or if his case is more a transcatheter or medical approach.

Conclusions

1. There is no doubt that TAVI is superior to medical treatment in inoperable patients.
2. In operable patients, TAVI is not inferior to surgery in high-risk patients and in intermediate-risk patients and even superior to surgery when a transfemoral route is feasible.
3. It is also important to consider comorbidities not taken into account by their risk scores and geriatric status in order to make the best decision for our patients.
4. The extension of indications to low-risk patients is already being evaluated ("PARTNER 3" and "CoreValve low risk" studies) and the results are expected in 2019-2020.
5. In parallel, it is important to collect as much information as possible about the durability of percutaneously implanted bioprostheses.

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