Editorial

Percutaneous Aortic Valve Implantation: Present and Future. Controlled Clinical Application Before the Results of Randomised Trials

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In recent memory it was not uncommon to encounter elderly patients, with severe aortic valve stenosis and coexistent pathologies that rendered them inoperable because of unacceptably high risk, to whom we were unable to offer any other effective treatment. They were perhaps the second most common group of patients in this age group, after those with end-stage ischaemic heart failure, where the cardiologist felt completely unable to intervene effectively.[1-3] During the last two years we have all been watching how the clinical application of percutaneous aortic valve implantation has been changing the treatment of these patients dramatically. Thus, with an acceptable single-figure interventional mortality,[4-6] an untreatable condition with a very bad prognosis and a poor quality of life has been transformed into a treatable condition that potentially no longer affects expected survival.

Surgical aortic valve replacement dates back to the 1960s and has been shown to improve the symptoms and prognosis of patients with calcific stenosis of the aortic valve, regardless of age.[7] Valvuloplasty was proposed and adopted towards the end of the 1980s and the start of the 1990s as an alternative, less invasive treatment of aortic valve stenosis.[8-11] Its use, however, was not limited exclusively to patients with high surgical risk, and it soon became clear that this treatment could only be considered as palliative, since the relief of stenosis was partial and temporary, with restenosis the method's Achilles' heel.[7-12] The inability of valvuloplasty to improve the prognosis and to change the natural history of the disease confined its application to palliative treatment. During the 1990s, many studies recognised a major deficiency in the treatment of elderly patients with severe symptomatic aortic valve stenosis, since only 50-70% of them finally underwent surgical aortic valve replacement.[13-15] The reasons were many, the main ones being the assessment that the risk of the procedure was unacceptably high, and the reluctance of the patients and/or the treating physicians to proceed to a serious operation. The start of research efforts by various groups seeking to develop a method of percutaneous aortic valve implantation coincided with the above findings.[16-19] It took more than a decade to arrive where we are today, with the method in controlled clinical use, and to have its first meaningful assessments.[4,5]

Evaluation of surgical risk

In the era of evidence-based medicine, the development of this new method required special care. The existence of the tried and tested surgical valve replacement meant that the new method could only be used and

tested initially in patients who had a good reason to be rejected for established treatment. Thus, from the broad spectrum of assessed surgical risk, patients from the high risk end were chosen and were those who in any case are still not treated surgically today (Figure 1).

The precise evaluation of surgical risk in a specific patient is not easy and involves an attempt at individualisation based on statistical data from databases containing a large number of procedures. The most accepted and validated algorithms that are widely available today are the EuroSCORE (www.euroscore.org), the STS score (www.sts.org) and the Parsonnet score (www.sfar.org). These algorithms predict the surgical risk by assigning weight to various factors that affect the clinical result, but it is clear that they can underestimate or overestimate it in certain groups of patients who are not represented satisfactorily in the population used to generate the algorithm.[20,21] The surgical mortality for isolated aortic valve replacement in the database of the Society of Thoracic Surgeons is 3%, and the proportion of patients with a mortality rate higher than twice the mean value is much less than 10%, since such patients do not frequently undergo the operation.[22] Therefore, the accuracy of predicting not only mortality, but also morbidity and quality of life, after the procedure is reduced, and the instincts of the surgeon and treating cardiologist acquire greater importance.

In a few studies where for special reasons patients with a relatively high risk were *selected* to undergo surgical aortic valve replacement, the mortality predicted by the EuroSCORE was higher and by the STS score lower than the rate actually recorded.[23,24]

Apart from age, the EuroSCORE coevaluates 16 dichotomised risk factors. The STS score is a more detailed algorithm that grades with precision the type of planned procedure and 7 grouped categories of characteristics (many with continuously distributed values). In addition to mortality, it predicts morbidity, length of hospital stay and artificial ventilation, the risk of infection, renal failure, stroke, and reoperation. However, no algorithm can include all the rare, but very well known risk factors, such as porcelain aorta, actinic disease, end-stage obstructive pulmonary disease, cirrhosis of the liver, and severe neuromuscular degenerative disorders.

Based on existing surgical databases, as well as in prevailing practice, it is extremely rare for patients with a EuroSCORE >20% and/or an STS score >10% to undergo surgery – obviously because no possible benefit can be considered to compensate for the excessively high risk. The percutaneous valve implantation method is proposed today in just such patients with severe, symptomatic calcific aortic valve stenosis who are not treated surgically.

Technical aspects of the procedure

Of those patients with aortic valve stenosis who are referred for percutaneous implantation, a significant percentage are rejected for various reasons even before the technical check for feasibility begins.[25,26] It is not rare for a detailed examination to reveal that the severity of stenosis or the surgical risk has been overestimated, or that the patient is effectively asymptomatic. Once the criteria of severe symptomatic aortic valve stenosis and high surgical risk are met, the thorough technical check of the patient's suitability for the percutaneous implantation method begins. Given the technological

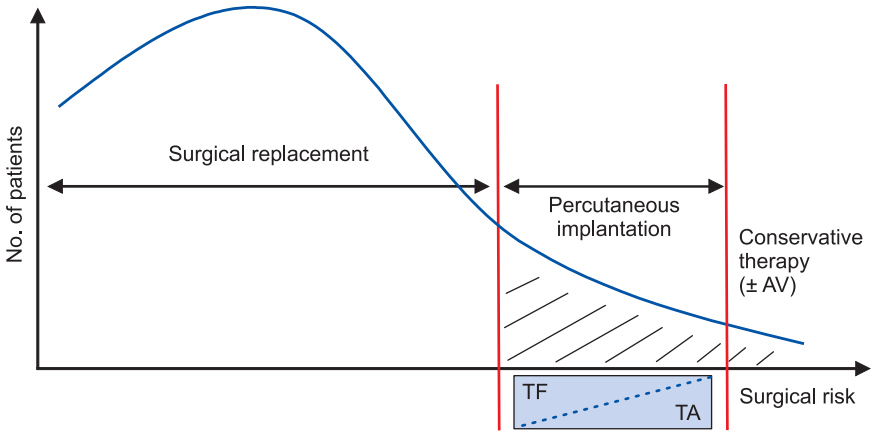

Figure 1. Choice of treatment of aortic valve stenosis according to the predicted risk of surgical replacement. AV – aortic valvuloplasty; TF – transfemoral; TA – transapical.

improvements and the larger range of available sizes expected for existing percutaneous valves, as well as the arrival of new systems, frequent updating of the codification of technical eligibility requirements is essential.

The two most basic parameters are the suitability of the peripheral arterial net (common femoral, external and common iliac arteries) and the size of the aortic valve annulus. Contrast angiography is needed to assess the former, while the latter requires an initial approximate assessment of the diameter of the aortic annulus on a transthoracic echocardiogram. In general terms, a large artery with dominant elastic elements should have a diameter up to 1 mm smaller than the external diameter of the sheath that has to be introduced for the valve implantation.[27] Thus, current systems with an external sheath diameter of 28 F (SAPIEN 26 mm, Edwards), 25 F (SAPIEN 23 mm, Edwards) and 22 F (CoreValve, Medtronic) require minimum diameters in the order of 8, 7 and 6 mm, respectively (Figure 2). Apart from the minimum diameter, the existence of significant vessel tortuosity (>90˚), especially when combined with wall calcifications, makes advancing the large sheath problematic, with a high risk of vascular complications that could potentially affect the final outcome. In addition, the existence of extensive circumferential calcifications limits the elastic dilation of the artery; thus, the minimum diameters referred to above are underestimated. Patients who do not meet the criteria of suitable peripheral arterial access may still be candidates for transapical implantation of the SAPIEN valve, or transaxillary implantation of a CoreValve (though experience with the latter method is limited).

The diameter of the aortic annulus is another very important parameter that determines the eligibility of a patient for percutaneous valve implantation. The range of diameters suitable for a SAPIEN valve is 18-24 mm, while for a CoreValve it is 20-27 mm. For the assessment of aortic annulus diameter we should keep in mind that transthoracic echo underestimates its size by a mean of 1.4 mm compared to the transoesophageal echocardiogram,[28] while the latter method also underestimates the size by 1.2 mm compared with intraoperative measurement.[29] Therefore, in order to avoid undesirable and often catastrophic displacement of the prosthesis, there should be a margin of at least 1-2 mm between the diameter of the valve and the size of the aortic annulus estimated using transoesophageal echocardiography, so that the former may be successfully and safely anchored within the latter. Table 1 shows data concerning the sizes of available percutaneous valves, as well as expected improvements. It is important to stress that implantation of available percutaneous prostheses is contraindicated in the case of a unicuspid or bicuspid aortic valve, because of the risk of incomplete deployment, significant paravalvular regurgitation, and displacement of the prosthesis.[30]

Another very important parameter of the procedure, whose evaluation is often much more difficult, is the risk of obstruction of the coronary ostia by the often bulky and calcified aortic valve leaflets that are expelled around the stent of the prosthetic valve as it is de-

Figure 2. Comparison of arterial dilators with external diameters 28, 24, 22 and 20 F.

Table 1. Sizes of available percutaneous aortic valves and sheaths required. Numbers in parentheses represent improvements announced and new sizes expected (data for CoreValve have not been revealed).

	Prosthesis diameter (mm)	Sheath size (F)	
		External	Internal
SAPIEN, Edwards	(20)	(18)	(16)
	23	25 (20)	22 (18)
	26	28 (21)	24 (19)
	(29)	(22)	(20)
CoreValve, Medtronic	26	22 (?)	18 (?)
	29	22 (?)	18 (?)

ployed. The size of the Valsalva sinuses and the arrangement of the coronary ostia within them, as well as their distance from the aortic annulus in relation to the length of the leaflets, are data that can help in the assessment of this risk. CT scan aortography and angiography of the ascending aorta are the most appropriate examinations for investigating these aspects. Those examinations will also be used for the measurement of the dimensions of the ascending aorta and the aortic arch, which are essential for checking eligibility for the CoreValve (the most important being the diameter of the ascending aorta, which should be <4.3 cm). However, this author's recent personal experience and that of others indicates that perhaps the most effective test for the evaluation of the size of the aortic annulus, as well as the risk of obstruction of the coronary ostia, is valvuloplasty with simultaneous aortography of the ascending aorta. This allows checking for the existence and assessing the degree of insufficiency of the regions of the aortic apparatus that are not sealed by the fully inflated balloon, while the diameter of the functional aortic annulus can be evaluated in relation to the diameter of the balloon. It also provides a way of estimating the risk of obstruction of the coronary ostia by the aortic valve leaflets as they are displaced towards them by the valvuloplasty balloon.

The anatomy of the thoracic aorta (any chance of porcelain aorta) and the abdominal aorta should be studied by some imaging method for the existence of extensive atheromatosis, mural thrombi and aneurysm.

First results

The percutaneous valve implantation procedures that were carried out in Europe during the first year after the acquisition of the CE mark and under controlled clinical application were recorded in registries. Table 2 shows the patient characteristics and clinical results from the recently updated registries with regard to the transfemoral and transthoracic implantation of the SAPIEN valve and the transfemoral implantation of the CoreValve.[4,5,31] It is clear that the patients who underwent the procedures were typically elderly patients with severe symptomatic aortic valve stenosis and multiple concomitant pathologies that rendered the standard surgical treatment practically infeasible. It is also clear that the immediate results were much better than those predicted by the EuroSCORE algorithm. The ratio of the actual to the predicted mortality was 0.25-0.45 for transfemoral implantation and 0.31 for transthoracic implantation (Table 3).

As regards complications, vascular complications in peripheral arteries were directly related to the size of the introducer sheath required (10.6% for SAPIEN and 1.9% for CoreValve implantations); the expected decrease in sizes, especially for SAPIEN valves, should dramatically reduce this kind of complication.

Another notable complication was the high incidence of high-degree atrioventricular block associated with the use of the CoreValve. In the initial European registry permanent pacing was needed during the first month after implantation in 12.2% of cases, but newer reports cite rates as high as 27% with the use of this valve.[32] Atrioventricular block does not seem to be a particular problem when the SAPIEN valve is used, since the need for permanent pacing during the first month after implantation does not exceed 6-7%.[4] The corresponding incidence after surgical aortic valve replacement is 3-8%.[33]

The latest large study to correlate real with predicted surgical mortality after aortic valve replacement in high-risk patients comes from the New York University Medical Centre.[34] In 731 patients with a logistic EuroSCORE >8% (mean 17.2%) who were *selected* to undergo surgical replacement the real in-hospital mortality was 7.8%, and as a result the ratio of actual to

Table 2. Patient characteristics and clinical results from the updated registries of procedures in Europe for the percutaneous valves SAPIEN, Edwards Lifesciences,[4] and CoreValve, Medtronic.[31]

	SOURCE TF N=463	CoreValve TF N=1500	SOURCE TA n=575
Age, years	81.7	81.2	80.7
Women, %	55.2	55	56
EuroSCORE, %	25.7	23	32.9
NYHA III-IV, %	75	70	74
Effective valve orifice, cm^2	0.65	0.64	0.61
Mean transvalvular pressure gradient, mmHg	52.2	49	51.7
Successful procedure, %	95.6	98.2*	92.9
Vascular complications, %	10.6	1.9*	2.4
Cerebrovascular episode, %	2.4	1.9*	2.6
Permanent pacing, %	6.7	12.2*	7.3
30-day mortality, %	6.3	10.4	10.3

TF – transfemoral; TA – transapical. *In 1243 patients.[5]

Table 3. Predicted and observed results of percutaneous implantation and surgical replacement in high-risk patients.

	EuroSCORE %	30-day mortality %	Ratio of observed to predicted mortality
SOURCE TF n=463	25.7	6.3	0.25
CoreValve TF n=1500	23	10.4	0.45
SOURCE TA n=575	32.9	10.3	0.31
Surgical replacement n=731[34]	17.2	7.8*	0.45

TF – transfemoral; TA – transapical. *In-hospital.

predicted mortality was 0.45. If we accept that this series of patients was similar to those in the registries of percutaneous valves, then the ratio of observed to predicted mortality in those procedures was overestimated by up to 50%. However, this is unlikely to be the case, since the patients in the New York University Medical Centre study generally had a lower risk and in any case they had been *selected* by the cardiac surgeons to undergo the operation, which introduced a bias.

The trials

The determination of the benefit of percutaneous as compared to surgical aortic valve implantation, based on algorithms for the prediction of surgical risk, is feasible but not accurate, as analysed above. In any case, if percutaneous implantation is to become the method of choice, this must be supported by well-planned and executed randomised studies. Since in-hospital the durability of percutaneous valves is of little importance in the aged population in whom they have been implanted until now, such studies should concentrate on the short- and mid-term clinical results. If these studies prove that percutaneous implantation is almost always technically feasible, and that its clinical results are superior to or comparable with surgical replacement, the extension of the use of the method to younger patients with a lower surgical risk will be inevitable. Then, of course, there will be a need for studies that focus mainly on the long-term clinical results, which reflect the durability of the valve.

The PARTNER IDE study is the first randomised trial of percutaneous aortic valve implantation; it is in progress in the USA and will include 1040 patients. Soon, the randomisation of patients, which began in 2007, will be completed (the randomisation in the first arm of the study was already completed in March 2009), while the first results will be announced early next year.

In fact, it is really two studies, since one arm includes patients (n=350) who are judged inoperable (STS mortality and morbidity >50%) and are randomised to transfemoral implantation of a SAPIEN valve or to conservative medical treatment (which may include valvuloplasty), while the other arm includes patients (n=690) with a high surgical risk (EuroSCORE >15%) who are randomised to either percutaneous implantation or surgical replacement of the aortic valve. In the second arm of the study there is further stratification of the randomisation, according to whether the patient is eligible for transfemoral or transthoracic valve implantation, so that there will be comparative results for the percutaneous and surgical method also according to the access route used. The results of PARTNER IDE will provide the first data for the practice of evidence-based treatment at this level. The intention to carry out a similar study for the CoreValve was announced before its recent acquisition by Medtronic and that study is expected to commence soon.

New technologies

Percutaneous valve implantation was developed in order to provide an alternative and less invasive method of treating aortic valve stenosis. Given the gap in the treatment of many patients who do not undergo surgical valve replacement, it was inevitable that the initial application of the technique would be in those patients. It has been proven that the method is feasible, with results that were reproduced by many physicians in many centres (approximately 8000 implantations to date). It was also shown that the method has a learning curve, with significant improvements in the success rate and the clinical results after the first 25 and 50 procedures.[35,36] All this has led to wider acceptance of the method and to the appearance of many more suggestions for new designs of percutaneously implantable valves. Industry and market forces also foresaw great opportunities for investment, paving the way for many original and promising ideas. Today there are at least 10 new percutaneous aortic valves that have had their first implantation in humans, many more that have reached the level of animal experiments, and even more that are still in the initial design stage. Figure 3 is a collage of the new percutaneous aortic valves that are already available or are in an advanced stage of development and experimental application; some of them will soon be available for controlled clinical application. It is worth noting that the development of valves with non-biological leaflets, which do not need special preservation and preparation before implantation and can be used off the shelf, is well under way, and their first implantations in animals have already been carried out (Figure 3-14). Also, those systems will need only a 10-12 F introducer sheath, which will simplify the procedure to a great degree.

An important obstacle that must be overcome with new technologies —and there are already positive signs— is the safe implantation of prostheses in pa-

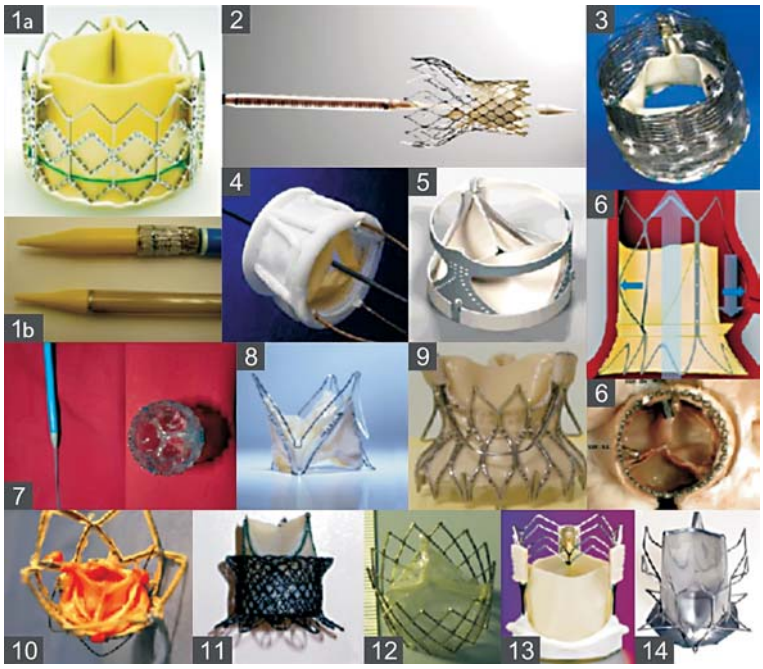

Figure 3. Photographs of some types of percutaneous valves. 1a: SAPIEN, Edwards. 1b: Comparison of SAPIEN (25-28F) and SAPIEN XT (18-21F). 2: CoreValve, Medtronic. 3: Lotus, Sandra Medical. 4: Direct Flow, Direct Flow Medical. 5: AorTx, Hansen Medical. 6: Perceval, Sorin Group. 7: Paniagua, Endoluminal Technologies. 8: Jena, JenaValve Technology. 9: Ventor, Medtronic. 10: DAVR. 11: HTL, Heart Leaflet. 12: Lutter. 13: Enable PHV, ATS (3-F). 14: PercValve, eNitinol.

tients with a unicuspid or bicuspid valve. These patients are not at all rare, since they make up 20-40% of those who undergo isolated surgical aortic valve replacement for aortic stenosis at ages over 70 years, while the percentage rises to 40-60% in younger patients.[37]

Conclusions

After almost 20 years since the conception of the original idea, the controlled clinical application of the percutaneous implantation of a prosthetic aortic valve is a fact. It is directed at patients with severe symptomatic stenosis and coexisting pathologies who are rejected for standard surgical replacement are, because any benefit is not considered sufficient to outweigh the excessively high surgical risk. The first data from registries of more than 2500 percutaneous implantations of these valves show that the procedure is feasible in selected referral centres with a high success rate and acceptable short-term clinical results, clearly superior to those predicted for standard surgical replacement. Thus, there is now the possibility for effective therapeutic intervention in a large group of mainly elderly patients, who until recently were treated conservatively and had a very poor quality of life and prognosis.

This possibility opened a new Pandora's box for interventional cardiology, since treating physicians and patients no longer fatalistically accept conservative treatment, given the low risk of percutaneous intervention. Thus, a significant number of patients who would not in the past have undergone haemodynamic evaluation are being mobilised to undergo an eligibility check for percutaneous intervention, significantly increasing the workload of catheterisation laboratories. Many of these patients are in borderline clinical equilibrium, which even the process of an angiographic examination may overturn, leading to complications and prolongation of their hospitalisation. Also, experience indicates that a percentage of these patients undergo valvuloplasty during their eligibility check for percutaneous valve implantation, because their clinical status demands the performance of valvuloplasty as a bridge to future intervention or as palliative therapy.[25,26]

For the definitive inclusion of percutaneous valve implantation in the treatment algorithm of patients with aortic stenosis, we must await the results of randomised trials that are already under way, with the first results being expected early next year. However, the evaluation of those results in a landscape of continuous technological developments that will simplify percutaneous implantation and have the potential to minimise complications will be extremely difficult.

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