

Editorial

A Decade of Experience With Transcatheter Aortic Valve Replacement: Now Is the Time to Resolve Doubts About Long-term Effectiveness



Una década de experiencia con el TAVI, el momento de resolver las dudas sobre su efectividad a largo plazo

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In the past decade, transcatheter aortic valve replacement (TAVR) has become the treatment of choice for patients who are inoperable or at high surgical risk and who have severe and symptomatic aortic stenosis. According to clinical practice guidelines,¹ TAVR has a grade IB indication for patients deemed inoperable by a multidisciplinary team due to extreme surgical risk. For high-risk patients, the guidelines consider that the TAVR procedure should be individualized (IIa B). These indications are based on the results of the 2 PARTNER studies,^{2,3} which were randomized clinical trials reporting improved survival and functional class with TAVR compared with standard therapy in inoperable patients² and similar results to those obtained with surgical valve replacement in high-risk patients.³

In recent years, the use of TAVR has grown exponentially. The procedure is now being used in patients at intermediate surgical risk, because international registries and new clinical trials^{4–6} have reported very good outcomes and a reduction in the number of its complications; in addition, initial concerns regarding valve durability and long-term complications are being resolved.^{7,8} Lately, 5-year outcomes have been published for patients after TAVR procedures that showed favorable clinical effects and a low rate of valve deterioration.^{9,10} In addition, comparisons between the types of prostheses most commonly used (Edwards-SAPIEN and CoreValve) do not appear to have revealed any relevant differences.¹¹

In Spain, Salinas et al.¹² recently published a long-term follow-up study after percutaneous implantation of the Edwards-SAPIEN valve. In this series of 79 patients, 4-year survival was 50%; prosthetic valve dysfunction occurred in 15.3% but did not lead to new valve replacement.

An article by Avanzas et al.¹³ published in this issue of *Revista Española de Cardiología* reports the long-term results of CoreValve self-expanding valve implantation at 3 Spanish hospitals. A total of 108 patients underwent surgery between December 2007 and May

2009, with a median cohort follow-up of 6.1 years. Survival outcomes were 84% at 1 year and 52% at 6 years, and prosthetic dysfunction was detected in 5.5%, although this finding may be underestimated due to the sample size.

The results of both studies are similar to those of other published series and further confirm that TAVR is an appropriate procedure and a major advance in the treatment of serious symptomatic aortic stenosis in patients at high surgical risk.

However, there are still several issues and questions regarding the disease. During follow-up, both studies observed high mortality, primarily of noncardiac cause. Avanzas et al. showed that 43% of patients included had survived and were in functional class I-II at 6 years postimplantation, which is a good outcome, as the patients were elderly and at high-risk. Nevertheless, 57% had died or had major limitations in their daily life. This underscores the need for a comprehensive individualized study of patients potentially eligible for the procedure, as they are almost always elderly. It is important to assess heart disease correctly: *a*) to ensure that any severe aortic stenosis is diagnosed, which is not always easy, particularly in patients with ventricular dysfunction and low gradients; *b*) to analyze ventricular function and pulmonary pressure carefully; *c*) to document the existence and severity of other valve lesions, in particular mitral regurgitation, and *d*) to study any associated coronary heart disease. In summary, examinations are needed to ensure that the patient's symptoms are clearly attributable to aortic stenosis and, therefore, that the procedure will improve the patient's symptoms. Additionally, any comorbidities and effects thereof on the patient's symptoms and life expectancy should be properly assessed, and the utmost care should be taken to clearly identify the patient's real expectations and to offer accurate information on the procedural risks and possibilities for symptomatic improvement.

The debate on the possible futility of some procedures is still ongoing and difficult to appraise. The long-term results of the PARTNER trial in inoperable patients show very high mortality during the follow-up of patients who have undergone TAVR (although it is important to remember that these patients were at very high risk); frailty, kidney failure (creatinine), and lung disease are the main factors for poor outcomes, defined as the combined event of death plus lack of improvement in quality of life.¹⁴

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As stated at the recent European Society of Cardiology congress by Dr C. Otto, Director of the Valve Clinic at the University of Washington and a leading voice in the field of valve disease, the decision not to indicate TAVR in a patient is an active one and is more difficult to take than to move forward with an inconclusive indication.

At the other end of the spectrum, it is possible to broaden the indications for TAVR to patients at intermediate or even low surgical risk. There is no question that studies conducted in coming years will shed light on these possible new indications and that new guidelines on valve disease will broaden the indications. Studies such as that by Avanzas et al.¹³ contribute to these changes.

Although increasingly better outcomes are obtained with TAVR, it is also true that surgical outcomes are good and virtually identical to those of TAVR in high-risk patients.¹⁵ The comparison between TAVR and surgery is further influenced by ongoing improvements in surgical techniques. Last, economic efficiency issues should be taken into consideration, particularly in health care systems such as ours. For instance, it has recently been shown that the high cost of TAVR valves vs total hospitalization cost in patients at intermediate surgical risk means that the cost-effectiveness results are more favorable for surgery.¹⁵

In short, in view of the above, it is essential for clinical and interventional cardiologists to work together with surgeons in a difficult task: selecting patients, evaluating the best treatment for each individual (whether medical therapy, surgery, or TAVR) and, in the case of TAVR, deciding on the most appropriate access route and prosthetic valve. Prospective and detailed clinical studies such as that by Avanzas et al. will enhance our know-how and aid in decision-making. In forthcoming years, TAVR outcomes should be further reported and assessed, as further technical advances can be expected to improve devices.

CONFLICTS OF INTEREST

None declared.

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