EDITORIAL

# Transcatheter aortic valve implantation. The prodigious decade

*Implante transcatéter de la válvula aórtica. La década prodigiosa*

JOSÉ-MARÍA HERNÁNDEZ-GARCÍA[1], ANTONIO J MUÑOZ-GARCÍA[2]

Transcatheter aortic valve implantation (TAVI) has revolutionized severe aortic valve stenosis treatment. It was unimaginable, both in 2002 -when Cribier described the technique- as in 2007 when the first self-expanding (Corevalve®) and balloon expandable (Edwards®) devices were authorized for use in Europe, to presume the unstoppable development of TAVI in the upcoming years. From 2010 to 2019 randomized studies have compared successive generations of Edwards® (Sapien, Sapien XT and Sapien S3) and Medtronic® (Corevalve, Evolut-R and Evolut-PRO) valves with aortic valve replacement surgery.

Percutaneous valves have shown to be superior, or at least not inferior, to surgery in all the range of patients, from high to low surgical risk. A recent meta-analysis demonstrated a consistent reduction in mortality and stroke independently of risk and the type of valve used, though this benefit was applicable to the transfemoral, but not the transapical procedure. (1)

The generation of this knowledge and device improvement, has produced an exponential increase of treated cases together with a very important decrease in mortality and the increased ratio of the transfemoral approach to the detriment of other procedures, especially the transapical approach. More than 100,000 cases were treated in the compulsory German Registry (2), with a decrease in mortality from 10.4% in 2008 to 3.1% in 2017, without changes in the mean age of patients treated during that period (81 years). Conversely, the number of patients treated with surgery decreased by 23% since 2008, as well as the mean age of these patients (from 69.8 to 67.2 years).

In the US Nationwide Inpatient Sample (3), carried out in the United States between 2003 and 2016, the number of patients above 60 years of age treated for aortic stenosis rose from 96 to 137 per 100,000 population, with great increase of TAVI procedures since its availability in that country (11.9% in 2012 to 43.2% in 2016) and an important reduction in mortality (4.7% in 2012 and 2.2% in 2016). This increase of treated cases seems to correspond, rather than to an "epidemic" of calcific aortic stenosis, to the inclusion of patients who were not previously treated due to age, risk or comorbidities. (4)

Given the relevance of knowing the indication and situation of TAVI from randomized studies, it is not less important to have information on each country and each hospital to establish local indications based on these data. In this sense, the studies published in this issue of the Argentine Journal of Cardiology are highly significant.

In the first study, Nau et al. (5) publish a registry carried out in five Latin American hospitals, including 770 patients consecutively treated between 2009 and 2018, with group assignment according to the STS-PROM risk score. It is worth noting that despite the registry started in 2009, 95% of patients were treated by transfemoral approach.

The study revealed a difference per subgroup in 30-day mortality, which was higher in high-risk patients and lower in low-risk patients. Over time, a very significant reduction in mortality was observed, decreasing from 13.7% in high-risk and 11.76% in low-risk patients in the 2009-2010 period, to 6.35% and 0%, respectively, between 2014 and 2018. Undoubtedly, this was due both to device improvement as to the experience acquired by the intervening teams. This decrease was not reported in patients at intermediate risk, which was not clarified in this article, although this subgroup started with surprisingly low figure in the first years of the registry.

Borracci et al. (6) publish in the same issue of this Journal a meta-analysis of four observational, single-center studies recently published in the Argentine Journal of Cardiology in intermediate-risk patients treated with TAVI. A total of 494 patients were included in the analysis with average STS score of 6.3% and 30-day mortality of 4.5%.

It should be pointed out that the clinical results are excellent, although the learning curve starting in 2009 was included in all of them and, in some cases, a vast heterogeneity of models was used and not only the first generations of percutaneous prosthesis. Both articles will be very useful for decision-making, without need of resorting to randomized studies or registries from other countries as reference that might not

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[1] Clinical Cardiac Management Unit, Hospital Universitario Virgen de la Victoria, Universidad de Málaga (UMA)
[2] Biomedical Research Institute of Malaga (IBIMA)
[3] Biomedical Research Networking Center on Cardiovascular Diseases (CIBERCV), Malaga, Spain

accurately reflect the local reality.

In the study of Borracci et al. the percentage of pacemaker implantation and moderate or severe aortic regurgitation seems penalized by the device used: the first generation of percutaneous valves. In a great percentage of cases the self-expanding Corevalve® was used, without possibility of recovery and no external pericardial wrap of the prosthetic structure found in later generation valves (Evolut R and PRO), with the concomitant reduction both in the ratio of pacemaker implantation as in significant residual aortic regurgitation these advances have provided.

The PARTNER 3 and Evolut low risk studies report that the mildest regurgitation at 30 days was 0.8% and 3.4%, and the ratio of permanent pacemaker was 6.5% and 17.4%, respectively. (7, 8) Due to the new recommended implantation techniques to position the device at a depth of less than the membranous septum length, the percentage of pacemaker implantations reported with the Medtronic® self-expanding valve is lower (3%). (9) It should be noted that in the practice all the experience accumulated with TAVI versus surgery has been reported with successive generations of Edwards® and Medtronic® valves, and that the "non-inferiority" objective has not been fulfilled when other device has been compared with with the Sapien-3 valve. (10)

Once TAVI is known to be non-inferior -when not directly superior- to surgery at all risk levels (from very high to low-risk) the question would be: should surgical risk be discussed by the Heart Team when considering whether the patient is a candidate or not for TAVI? And probably the answer should be "no".

Prior to surgical risk, what should be considered is whether or not the patient is a candidate for TAVI, taking into account clinical, anatomical and access route criteria, as the benefit of TAVI is limited to transfemoral access, currently involving more than 95% of patients. Among the anatomical criteria we should consider whether the valve is bicuspid, which would not rule out the percutaneous treatment but would place it behind surgery in low-risk patients, calcium distribution, an origin of the coronary arteries that might anticipate their occlusion, something exceptional about the native valve, or the presence of other comorbidities requiring cardiac surgery during the same procedure.

Although the information published with the European consensus definitions is very favorable, there is still unknown data regarding TAVI durability. A structural valve deterioration (SVD) of 3.3% and bioprosthetic valve failure (BVF) requiring intervention of 0.58% has been reported at 8 years with the Edwards® valve. (12) In the NOTION study no differences were found in BVF between TAVI and surgical bioprosthesis during a 6-year follow, and very favorable SVD data for TAVI (4.8% vs. 24%) at 6 years with Corevalve®. (13) The durability of each valve in particular, knowledge of the best antiplatelet or anticoagulant regime (14), ease of coronary artery catheterization, the ratio of pacemaker implantation and residual aortic regurgitation, will be vital at the time of decision-making and of extending TAVI to younger patients. In this same line and for decision-making, the excellent articles by Nau and Borracci provide essential information on TAVI results in Argentina.

## Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material)

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