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Editorial

Class effect in TAVI: the time has come to know if they are all the same

Efecto de clase en el TAVI: ha llegado la hora de saber si son todos iguales

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The time has come. Over the past few years, we have been living a constant increase in the number of patients with aortic stenosis who are treated with transcatheter aortic valve implantation (TAVI). Although the latest indications of the clinical practice guidelines from the European Society of Cardiology[1] are somehow more restrictive than those of the American College of Cardiology[2] regarding age cut-offs and surgical risk we've seen a growing demand for TAVI in low-risk patients and, progressively, in younger patients in almost all anatomical settings.

Up until now, randomized clinical trials had mostly focused on comparing the TAVI technique to conventional aortic valve replacement surgery.[3,4] And although these studies with different models of transcatheter aortic valves laid the foundation for the indications published by the guidelines, very few of them make head-to-head comparisons among the different TAVI models currently available. As a matter of fact, most are observational, non-randomized or non-inferiority clinical trials. On the other hand, the variability of the different models currently available has been growing with technological advances to perform easier, safer, and more durable transcatheter heart valves. However, can we assume that there will be some sort of class effect in all TAVI models currently available?

In an article recently published in *REC: Interventional Cardiology*, Elnaggar et al.[5] compared 2 models of top transcatheter heart valves currently available (the Evolut PRO, Medtronic, United States, and the SAPIEN 3, Edwards Lifesciences, United States) using an easy randomized design. Although the study has significant limitations (a rather clinical compared to methodological protocol), it seems reasonable to start discussing whether the different TAVI models available have similar results in non-selected and randomized populations. As it occurred with coronary stents, presumably in no time, we'll be seeing more comparative trials like this studying not TAVI vs surgery, but TAVI vs TAVI in different clinical and anatomical settings. In the study conducted by Elnaggar et al.[5] no significant differences regarding in-hospital mortality between both models were seen, but a difference regarding paravalvular leak favorable to the SAPIEN 3 vs the Evolut PRO device in a population not previously screened through coronary computed tomography angiography. As described in the methodology and further discussion, the method used in the study to assess annular size and anatomy was unusual. The protocol included an intraoperative transesophageal echocardiography plus in-situ balloon inflation to measure the annulus and select the size of the valve based on the coverage index. This may have impacted implantation results following size selection and coronary artery calcium assessment as predictors of paravalvular leak, and not based on today's gold standard (computed tomography). Regarding the need for pacemaker implantation after TAVI, the authors say that this difference was not significant (7.1% vs 5.8% favorable to the SAPIEN 3) although a difference was seen in the rate of baseline right branch bundle block (16.9% in the SAPIEN 3 group vs 0% in the Evolut PRO group). Therefore, we should mention that the baseline population was more favorable regarding the predictors of pacemaker implantation in the Evolut PRO compared to the SAPIEN 3. The latter, however, showed a lower—although not statistically significant—absolute rate of pacemaker implantation. Finally, the composite endpoint defined by the authors as device success was favorable to the SAPIEN 3 (98%) vs the Evolut PRO (86%) and included lack of mortality, paravalvular leak grade ≥ II at discharge, the need for a second valve, conversion to surgical aortic valve replacement or valve embolization. The study focused on procedural results with a follow-up limited to the length of stay (median of 7 days).

In any case, and beyond any methodological constraints, comparative trials show the strengths and weaknesses of different transcatheter aortic valve models even with experienced operators, which probably debunks the theory that a single model in expert hands fits every patient. If we want excellent results in patients and longer life expectancies, we'll probably need to profit from what each model has to offer depending on the patient's anatomy. Also, in high-volume centers that treat young or low-risk patients, the use of different TAVI models should be mandatory for better valve selection regarding the patients' clinical and anatomical characteristics. As a matter of fact, there is compelling evidence that the hemodynamics of supra-annular models is better compared to that of annular coaptation models, especially, in small annuli[6,7] or that, with a significant load of calcium, latest generation balloon-expandable models have better results regarding paravalvular leak,[8] etc. Still, several questions remain unanswered that can all be summarized in the headline of this editorial: is there a class effect in all TAVI models currently available?

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In view of the reports that compare the results of different models,[9,10] similar immediate results are likely during primoimplantation with all of them since the technique is highly reproducible. However, like we said before, the population where indications are trying to be expanded requires excellent results and small differences that seem irrelevant in absolute terms but are very important in this context of excellence if we want TAVI to become the gold standard to treat aortic stenosis regardless of age and surgical risk. Considering the durability data available to this date (median of nearly 8 years)[11] when offering this therapy to young patients with longer life expectancies compared to this expected durability, the term «lifetime plan» comes into play. Now the index TAVI needs much more than excellent results regarding severe cardiovascular complications, paravalvular leak, need for pacemaker implantation or rate of stroke. Now, valve selection needs to be planned and carefully individualized to better suit the patient's anatomy anticipating a possible second TAVI in the future (TAVI-in-TAVI). Come to this point, very few will still advocate for class effect. The different designs and adaptations made to the patient's anatomy will be key in a crucial aspect regarding planning a second procedure years after the index one: access to coronary arteries following the risk of sinus sequestration or occlusion due to outer skirts and height of the first and second valves. This is where intra- or supra-annular designs, the valve total height, strut amplitude, the possibility of commissural alignment, laceration techniques, prosthesis-patient mismatch, etc. come into play. In conclusion, a significant combination of factors that still need to be studied before answering some of these questions. Undoubtedly, virtual, and three-dimensional simulation technologies play a key role in research and clinical application with decision-making algorithms to choose the best alternative for our patients. Therefore, former studies have already discussed these aspects while trying to elucidate how different models behave in this complex TAVI-in-TAVI setting.[12] Also, comparisons have been made with surgical explantation of TAVI with structural failure.[13,14] Currently, the rate of these events is not high, but the most plausible thing is that as the patients' mean age drops, the rate of valve degeneration will increase parallel to the need for dealing with this problem.

All things considered it seems highly likely that there will be no class effect in TAVI considering how different the designs currently available behave beyond implantation. There is, however, great reproducibility of the transfemoral transcatheter technique with excellent short- and mid-term results. Some questions remain, though, on the long-term outcomes that will surely be answered as scientific evidence as it has been the case since this technique was born 20 years ago.

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C.A. Urbano Carrillo is a proctor for Edwards Lifesciences and participates in consulting groups for Medtronic España.

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