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Commentary: Long-term outcomes of surgical aortic valve replacement: Difficult to match!

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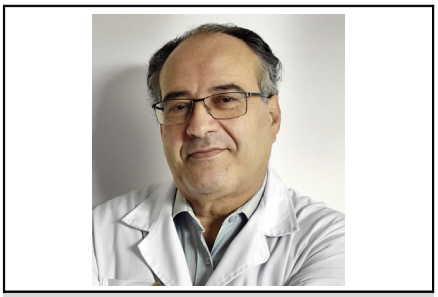

Manuel J. Antunes, MD, PhD, DSc

CENTRAL MESSAGE

AVR remains the gold standard for aortic valve treatment. Further reliable and unbiased comparative studies between TAVI and AVR are required to define the role of TAVI as a long-term alternative.

Aortic valve replacement (AVR) has been performed routinely since the appearance of the valve prostheses in the late 1960s and early 1970s.[1] The procedure is now one of the most frequent, in some centers the most frequent, cardiac surgery performed, essentially due to the "epidemic" of aortic stenosis in elderly patients. More than 2 million patients may have had the procedure in the last half century. Despite the many types of prostheses created, some never used, the surgical procedure has remained essentially the same, but improvement in the management of cardiopulmonary bypass and of myocardial protection has made AVR very secure, with some groups claiming close-to-zero mortality rates. It is so safe that it is usually one of the first procedures given to trainees. Hence, the results of AVR and the durability of current prostheses are now well established.

Nonetheless, there remains a significant number of patients who are either inoperable or very-high-risk for operation, especially in the elderly population. It was for these patients that transcatheter aortic valve implantation (TAVI) was introduced a decade ago (it received Food and Drug Administration approval in November 2011 for use in inoperable patients only).[2] Since then, the use of TAVI has been expanded to less risky and younger patients, based on the favorable early results obtained in many randomized studies, usually designed to prove noninferiority

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(not superiority) of TAVI, which may generate some doubts in terms of methodology and statistical analysis. Recently, several papers raised serious questions about the way these studies are being conducted, some highlighting important ethical concerns.[3] However, more importantly, there remains a yet-unanswered question: the durability of the transcatheter valves, which is still very far from reaching the values set by the surgical prostheses. This is especially important with younger patients. Still, TAVI has gained a fast-growing number of supporters, especially among interventional cardiologists, whose most important dream seems to be to get the surgeons out of the field!

For all these reasons, the article published in this edition of the *Journal* by Çelik and colleagues,[4] from the Erasmus University Medical Center, Rotterdam, is timely. The authors retrospectively analyzed temporal changes in baseline and procedural characteristics, and long-term survival of 4404 adult patients undergoing AVR over a 30-year period, from 1987 to 2016, divided into 3 successive decades (A-C), comparing the survival after AVR with that of the age-, sex-, and procedural year-matched general population. From deciles A to C, the mean age rose from 63.9 to 66.2 years, as did the prevalence of diabetes mellitus, hypertension, hypercholesterolemia, previous myocardial infarction, and previous stroke at baseline. The prevalence of concomitant procedures increased from 42.4% to 48.3%. Hence, the predicted risk of the operation has gradually increased. Yet, perioperative mortality decreased from 2.7% to 1.8%. Mean survival after AVR was 13.8 years. Relative 20-year survival of the overall cohort was 60.4% and 73.8% in isolated primary AVR. Hence, the authors concluded that "while patient complexity is continuously increasing over the last 30 years, long-term survival after AVR remains high when compared to the age-, sex- and year-matched general population."

This conclusion is really not new, having already been reported by many others, but it significantly adds to the evidence. In the initial version of the manuscript, the authors called theirs a "real-world" experience. The use of this term has become fashionable (I came across it in 5 papers that I reviewed in the last 4 months). In fact, their yearly volume of cases is not exceptional (91, 163, and 187 from deciles A to C), which cannot really configure a "high-volume" center. There are many European centers currently doing more than 400 to 500 cases per year. Some report a perioperative mortality around, or less than, 1% for isolated AVR. The term "real-world" was dropped in a subsequent revised version of the manuscript but, retrospectively, it might have been correct, as it may be representative of the mean for most centers.

Nevertheless, the current study is important, as it highlights the excellent current results of AVR. Perhaps, the very long follow-up, up to 30 years and a mean of close to 14 years, together with the very large number of patients, is one of the most important attributes of this paper. The authors believe that these outcomes should serve as a benchmark for TAVI, especially when applied to younger, lower-risk patients. Difficult, because no TAVI series has reached this size and this length of follow-up. And, as the latter increases, the complications of TAVI are coming to surface. TAVI still is a long way to match these surgical results.

Naturally, the study is not perfect. As one of the reviewers stated during the editorial process, "the authors assume that operative techniques remained fairly stable over the study period, but myocardial protection and other changes in surgical technique or in patient selection may have impacted the surgical results." But as the authors also point out, "the advent of TAVI dramatically changed the risk profile of patients presenting for AVR. And it is difficult to evaluate how the introduction of TAVI impacted the AVR outcomes." How did the increasing risk profiles in patients with AVR relate to lower-risk patients having TAVI procedures? Surprisingly, the number of patients older than 80 years of age subjected to AVR increased from 2.6% in decile A to 9.0% in decile C. One would have expected exactly the opposite, these older patients being preferentially referred for TAVI.

Obviously, this patient cohort is different from any TAVI group. The number of concomitant procedures, in addition to AVR, reached 48%. I do not know of any TAVI study with similar numbers. However, mean survival in patients having isolated AVR was 74% at 20 years after operation, which is close to that of a normal population. Naturally, thus, the authors suggest that "the excellent long-term results of AVR over 30-years might influence the preferences for use of AVR over TAVI." They further suggest that future comparative studies between TAVI and AVR might need to be done to refine the role of TAVI as a long-term alternative.

We certainly need better-designed studies, absolutely independent of commercial interests. However, the answer will take a very long time to reach us. Until then, I know well where my preference lies. I leave it to the readers to guess…What I believe is that some of the current guidelines were negatively influenced by many of these questionable studies that "downplay a crescendo body of evidence for adverse outcomes associated with transcatheter therapies, aggravated by the manifest conflict of interest of the writing committee authors and reviewers included in the final version of the document."[3]

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