JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 21, 2016
© 2016 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2016.08.014

Pushing the Limits in Transcatheter Aortic Valve Replacement

High-Volume Center's Effect, Overconfidence, or Something Else?

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ABSTRACT

The recent literature on transcatheter aortic valve replacement (TAVR) is shedding new light on the perspective to extend this procedure to other lower risk-category of patients, leading in fact to a potential erosion of the current guidelines. Notwithstanding the warnings provided in the literature regarding the risk of severely impairing complications, unclear survival advantage, and cost-inefficiency, many observational studies, especially performed in high-volume centers, support a general drive toward the recruitment of intermediate-low risk patients in the expectation of clinical advantages versus standard surgical replacement. It appears that, in combination with the development of more refined technologies, medical groups with matured experience and centers able to successfully manage patients with different profiles have been progressively "selected" and emerged pushing further the limits of the procedure itself. On the surgeon side, involved in the surgical assistance of TAVR procedures or in the standby-coverage in case of major complications, the expansion of indications and the interventionists' overconfidence have relevant implications. Considerations on the actual long-term effectiveness of the procedure on younger lower-risk patients in terms of actual hemodynamic durability and inability to deal with functional and morphological aspects of annular calcifications should be made. Also, it seems that other technologies enabling annulus decalcification, such as sutureless valve, have been totally overlooked and trials sponsored by industrial leaders in the market have taken the lead. Such a rapid expansion of TAVR indications should be better understood considering that in the surgical field valve bioprostheses needed to undergo a much longer validation period and the appearance of data on their 20 years follow-up after implantation was required before the application in younger patients. (J Am Coll Cardiol Intv 2016;9:2186–8) © 2016 by the American College of Cardiology Foundation.

The excellent results obtained in randomized studies of transcatheter aortic valve replacement (TAVR) has led in recent years to a reassessment of the clinical recommendations for treatment of aortic stenosis in the United States and Europe. TAVR has been considered as a valid substitute for aortic valve replacement in inoperable and high-risk patients and the most recent literature is shedding new light on the exciting perspective to extend TAVR to other risk-category patients (1–3), leading to a potential "revision" of the current guidelines. Many observational studies, especially those performed in high-volume centers, support a general tendency toward the recruitment of intermediate- and low-risk patients in the expectation of clinical advantages in comparison with standard surgical replacement. Additionally, data arising from large national registries and from multicenter collaborative studies are pointing at the possibility of extending the indications to replacement for degenerated bioprostheses and are driving toward a widespread use of expandable valves (2,4,5). It seems that the procedural risk associated with TAVR is offset by a maturing experience of clinicians that has translated into the observed clinical benefit over the first 5 years (6). Clearly, the rapid technological advancement and the refined management achieved in highly qualified centers has played a role in the favor of the procedure. Indeed, valve design is improving, development of smaller delivery systems is a concrete reality, and

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Manuscript received May 27, 2016; revised manuscript received June 28, 2016, accepted August 10, 2016.

the introduction of improved mechanisms for steering, correctly and stably placing, and recapturing the valve have given large safety margins to the procedure. However, according to recent literature originating from high-volume centers, we might glimpse an excess of confidence in expanding indications of TAVR.

As surgeons involved in the surgical assistance of TAVR procedures or in the standby coverage in case of major complications, we have been reflecting on the implications of the interventionists' "overconfidence" and on the potential drawbacks and real-life applicability of TAVR in patients at lower risk. These reflections are shared with some sharp and discouraging considerations by relevant investigators in the field regarding the risk of complications, unclear survival advantage, and cost inefficiency in low surgical risk patients (7). On a side note, the expansion of indications is the economic drive and industrial interest in this field. The expansion of the eligible population also triggered the development of more and more refined technology and encourages selected medical groups with mature experience to manage patients with different profiles. However, we feel there are some "jangled nerves out" in TAVR that might hinder the widespread use of the technology in patients at lower risk and produce major complications, especially when adopting an "all-comers" policy in centers not exposed to the same volume of cases. Despite the current advances in technology and design, the TAVR concept was intended initially to force a new prosthesis in to the pulmonary artery, which has a much higher degree of extendibility and distortion compared with the aortic root (8). This achieves important significance in consideration of the annulus calcification and its impact on the procedure outcomes. In this context, we believe that further studies are needed to analyze the distribution of calcification not only from the morphological point of view (9), but also from its functional aspect and in relation to the dynamics of the annulus and of the aortic root.

Also, the hemodynamic behavior of TAVR valve is another important question to be addressed considering the desire to extend this approach to younger patients who are at lower risk with relatively scarcity of long-term data on this young technology. In this regard, Del Trigo et al. (10) demonstrated a significantly increased transvalvular gradient and valvular hemodynamic degeneration in a large cohort of patients within just 2 years (minimum follow-up of 6 months) after implantation and showed the occurrence of patient prosthetic mismatch ranging between 40% and 55%, regardless of the appearance of valvular hemodynamic degeneration in those patients. The authors of this study found the occurrence of valvular hemodynamic degeneration to be statistically associated with specific subcategories of patients (<23 mm sized valve, high body mass index, absence of anticoagulation, valve-in-valve procedures). These findings might also lead one to question the effective durability of the valves, especially when implanted in younger, low-risk patients. Should we therefore consider with caution the expansion of a "not entirely known" technology to this category of patients (11)? Are we not rushing too quickly in to this "TAVR revolution," especially considering that the application of bioprosthetic surgical valves to younger patients needed to wait the appearance of data on the 20-year follow-up of these devices? What is underneath this rapidly changing scenario? The interesting field of sutureless surgical valves, although supported by consistent body of evidence (12,13), seems to have been overlooked or at least have struggled for respect compared with the attention given to TAVR. All the major randomized TAVR studies published disclosed sponsorships by the companies in the market and, considering the non-negligible financial interest and role of industries in this field, one could provocatively think that transcatheter devices companies have been effective in "conquering" the cardiovascular departments of the hospitals around the world. This line of thinking might lead to even more provocative considerations: To what degree is the clinical decision on TAVR actually influenced by the industrial push and financial injection? Could economic considerations be a driving force guiding the clinical indications? Does this explain the nonuniform geographical distribution across Europe (Germany, France, Italy, Spain Portugal, Greece) of TAVR procedures?

We hope that these considerations will not be viewed as a criticism or an obstacle to the TAVR expansion, but might invite a careful consideration of the real-life scenario in this field and foster the scientific debate on the problems that might arise from an incautious push of the indications. Also, we hope that with the expansion of TAVR procedures, more investigator-driven investigations will be produced in order to obtain less biased and more balanced comparisons.

ABBREVIATION AND ACRONYM

TAVR = transcatheter aortic valve replacement

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KEY WORDS high-volume center, TAVR, transcatheter aortic valve replacement