At a time when the value of performing aortic valve replacement surgery on elderly patients with aortic stenosis (AS) was being questioned, we reported our findings of a formal decision analysis entitled “You’re Never Too Old” (1) that revealed survival benefit of surgical aortic valve replacement (SAVR) in symptomatic elderly AS patients. SAVR is currently widely accepted as a treatment of otherwise healthy patients in the upper decades of life who are suffering from severe symptomatic AS. In such patients SAVR improves survival, symptoms, and quality of life associated with this disease (2). With an increasingly aging population, aortic valve replacement is now the most common reason for valve replacement in Europe and North America. However, approximately one-third of otherwise eligible patients for SAVR do not undergo this procedure, due to increased surgical risk with advanced age and baseline comorbidities (3,4).

To address this unmet need for a less-invasive solution, transcatheter aortic valve implantation (TAVI) was pioneered in the last decade as a treatment alternative for inoperable or high-risk patients with severe AS. Since it was first performed in 2002 (5), several international registries have consistently demonstrated that TAVI is feasible and provides at least favorable short- and medium-term procedural, clinical, and hemodynamic results (6–10).

Comparative data between standard medical therapy (MT), TAVI, and SAVR has so far been limited. Previously nonrandomized registry data have shown comparable results between TAVI and SAVR at 1, 6, and 12 months (11–13). Recently, results from the randomized PARTNER Cohort A (Placement of Aortic Transcatheter Valves) trial showed that TAVI was noninferior to SAVR in terms of 1-year mortality in a high-risk group of patients with severe symptomatic AS (14). These very encouraging results from the first randomized clinical trial comparing TAVI to SAVR are difficult to extrapolate when applied to what is encountered in a real-world group of patients that are not selected according to strict protocol-mandated criteria. In addition, comparative mortality and clinical results between the different treatment strategies available beyond 1 year has so far been very limited.

For these reasons, the prospective single-center registry study reported by Wenaweser et al. (15) in this issue of the journal is of significant importance, because it provides short-, medium-, and long-term clinical outcomes of standard MT, SAVR, and TAVI with 1 of the 2 European commercially available percutaneous aortic valves. Although self-reported and descriptive, this study provides important comparative results on major clinical endpoints in 452 consecutive and unselected, mostly octogenarian patients with symptomatic severe AS and multiple high-risk comorbidities for surgery followed up to 30 months. At 30 days and 12 months, both SAVR and TAVI similarly improved survival dramatically compared with standard MT alone. More importantly, this study demonstrated that the large mortality benefit for TAVI persisted beyond 12 months with an all-cause mortality at 30 months which was lower for both TAVI (22.6%) and SAVR (22.4%), compared with standard MT alone (61.5%, p < 0.001). Furthermore, not only did TAVI and SAVR improve survival, but symptoms were improved as well, with more than 90% of patients undergoing either intervention reporting New York Heart Association functional class I or II symptoms at 1 year, compared with only 70.8% of patients treated medically (p = 0.003).

These striking results highlight several important points. First, they reaffirmed that standard MT in patients with severe symptomatic AS is associated with poor long-term survival (16). Second, these findings demonstrated that, in an unselected high-risk population with severe symptomatic AS, TAVI or SAVR had resulted in similar rates of survival up to 30 months. Third, in agreement with recently published series (7,8), the majority of patients after TAVI have significant symptom improvement at 1 year, which suggests that not only is survival improved but quality of life as well. Finally, this report showed that older age and comorbidities were the main predictors of late mortality, which implies that if TAVI use is expanded to a younger and healthier population the outcomes will also be expected to be very good.

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However, before expanding the use of TAVI in a younger population we need to address the 2 main reservations with the procedure. One major concern with previous TAVI experience is an associated stroke rate that has ranged from 0.6% at 30 days (7) to 13.5% at 2 years (10). More worrisome is the finding that approximately two-thirds of patients who undergo TAVI will develop new and primarily clinically silent cerebral lesions detected by diffusion-weighted magnetic resonance imaging (17). In the study by Wenaweser et al. (15), major stroke occurred with similar frequency in all 3 groups at 30 months, which seems to suggest that long-term major stroke is probably related to the multiple comorbidities that are usually associated with advanced age. Therefore, it is difficult to predict the rate of clinical and the effect of subclinical strokes if TAVI is used in a younger population.

Post-procedural aortic paravalvular regurgitation with TAVI is relatively common, is usually trivial or mild in nature with little clinical effect, and seems to remain stable over time (6–8,10,14,16). Moderate and severe aortic valve regurgitation after TAVI has been shown to correlate with mortality and is usually due to technical difficulties (9,18). In this report by Wenaweser et al. (15), despite 28.3% of patients undergoing TAVI developing moderate or severe aortic regurgitation, the overall long-term mortality and major adverse cerebro-cardiovascular event rates with TAVI remained excellent. Further research on the role of moderate and severe aortic insufficiency after TAVI is paramount before recommending its expanded use in patients with longer life expectancies.

If and when it is approved by the U.S. Food and Drug Administration, TAVI is expected to emerge as a valuable treatment option in inoperable patients with symptomatic severe AS and become an acceptable alternative to SAVR in a select group of patients with high surgical risk. Nonetheless, we need to be very careful before recommending TAVI use in younger patients for 2 reasons. First, peri-procedural complications, especially major stroke and severe conduction abnormalities, need to be further reduced. Such complications can possibly be reduced with additional expertise, refinement of the procedure, and improvement of the delivery systems. Second, long-term percutaneous valve durability similar to SAVR needs to be demonstrated before it can be recommended in patients with longer life expectancies. In conclusion, large randomized clinical trials are needed to address these concerns with TAVI, but until then... “you are too young for TAVI.”

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