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## **EDITORIAL**

### TAVR at 5 Years — Rematch or Swan Song for Surgery?

- Eric Van Belle, M.D., Ph.D.

To become the first-line treatment for patients with aortic stenosis,<sup>1</sup> transcatheter aortic-valve replacement (TAVR) must not only mitigate periprocedural events but also be as effective as surgical aortic-valve replacement in the long term.

Makkar et al. examined this question and report in this issue of the *Journal* the 5-year outcomes of the Placement of Aortic Transcatheter Valves (PARTNER) 2 cohort A trial,<sup>2</sup> which involved patients at intermediate surgical risk. A total of 2032 patients were stratified according to intended transfemoral or transthoracic access and randomly assigned to undergo TAVR with the second-generation balloon-expandable SAPIEN XT valve or surgical aortic-valve replacement. The trial showed that TAVR was noninferior to surgery with respect to the primary outcome of death from any cause or disabling stroke at 2 years.<sup>3</sup>

Makkar et al. confirmed that at 5 years there was no significant difference in the incidence of death or disabling stroke between TAVR and surgical aortic-valve replacement (47.9% and 43.4%, respectively; hazard ratio, 1.09, 95% confidence interval [CI], 0.95 to 1.25). Because patients will always prefer a minimally invasive catheter-based therapy to open surgery, this could be seen as a resounding victory. However, a landmark analysis of events occurring between 2 and 5 years after the procedure clearly showed a divergence of event rates in favor of surgery (hazard ratio, 1.27; 95% CI, 1.06 to 1.53) (Table S7 in the Supplementary Appendix of the article, available at NEJM.org). This late increase in risk with TAVR, which was noticeable in both the transfemoral-access and transthoracic-access subgroups and has already been reported with a self-expanding TAVR valve,<sup>4</sup> arouses concerns. Several aspects of the 5-year report are worthy of note.

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First, 8.5% of the TAVR recipients had at least moderate paravalvular regurgitation at 2 years, as compared with only 0.4% after surgery, with the use of multiple imputation to account for missing echocardiographic data (Table S11). Moderate or severe paravalvular regurgitation after TAVR has consistently been associated with an increase in mortality by a factor of 2 to 3 at 1 to 2 years.<sup>5</sup> Makkar et al. found that this risk of death persists at 5 years (hazard ratio for moderate or severe vs. none or trace, 2.44; 95% CI, 1.54 to 3.85).

Second, mild paravalvular regurgitation at 2 years was seven times more frequent after TAVR than after surgery (25.2% vs. 3.5%). The clinical consequences of this finding are debated.<sup>5</sup> Makkar et al. report a higher mortality among patients with mild paravalvular regurgitation (hazard ratio for mild vs. none or trace, 1.25; 95% CI, 0.98 to 1.59), consistent with the findings of the FRANCE-TAVI registry (Registry of Aortic Valve Bioprostheses Established by Catheter) (hazard ratio, 1.13; 95% CI, 1.01 to 1.27).<sup>6</sup> It is interesting that the diverging mortality curves with TAVR and surgery after 2 years mirrored the late increase in deaths among patients with mild paravalvular regurgitation. It also suggests that grading is challenging for “mild-to-moderate” categories and that misclassification could happen.<sup>7</sup>

Third, the protocol of the PARTNER 2 cohort A trial allowed concomitant procedures. Although coronary-artery disease was evenly distributed between the two groups, 14.5% of the patients in the surgery group had concomitant coronary-artery bypass grafting, but only 3.9% of the patients in the TAVR group underwent percutaneous coronary intervention. In addition, 86 patients in the surgery group (9.1%) underwent combined valve procedures (as compared with none in the TAVR group). Therefore, a total of 23.6% of the patients in the

surgery group had “optimized” surgery, which could have reduced the occurrence of late adverse outcomes. These data indicate that surgery offers an all-in-one treatment that could provide long-term benefit for patients with complex conditions.

Fourth, with respect to valve durability, the aortic-valve gradient remained excellent at 5 years in both the TAVR group and the surgery group (11.4 mm Hg and 10.8 mm Hg, respectively), consistent with findings in the French Aortic National CoreValve and Edwards (FRANCE-2) Registry.<sup>8</sup> However, patients in the TAVR group had nearly three times as many valve-related hospitalizations as those in the surgery group (92 vs. 31) (Table S9), and they underwent 21 aortic-valve reinterventions (as compared with 6 in the surgery group). These findings echo the higher incidence of structural valve deterioration with SAPIEN XT than with surgery (8.8% vs. 3.5%) at 5 years reported by Pibarot in the PARTNER 2 cohort A trial.<sup>2</sup>

Fifth, for more than 35% of the patients, echocardiography variables were missing or incomplete at 5 years. In addition, follow-up data at 5 years were not available for 281 patients (13.8%), two thirds of whom were in the surgery group. Although the baseline characteristics of these 281 patients are not reported according to treatment assignment, the comparison with patients for whom complete follow-up data were available and the sensitivity analyses to account for missing data are reassuring.

Sixth, the results of the present trial cannot be extrapolated to current clinical practice because second-generation valves are not implanted any more and alternative transthoracic access has been abandoned for carotid or subclavian approaches. The third-generation balloon-expandable SAPIEN 3 valve combined with computed tomography–based annulus sizing was associated with a 2-year incidence of moderate or greater paravalvular regurgitation as low as 3.7%<sup>10</sup> and a 4-year durability similar to that of surgical valves.<sup>9</sup> The 5-year

durability outcome of the PARTNER 2 SAPIEN 3 intermediate-risk registry is eagerly waited.

The results of the PARTNER 2 cohort A trial showing similar effects for TAVR and surgery with respect to death or disabling stroke at 5 years confirm that TAVR is a game changer. However, this trial also reveals the long-term drawbacks of TAVR technology, which is still relatively new. Whether the refinements of third-generation valves and further iterations will overcome these pitfalls is a question requiring an answer before TAVR can take over as first-line treatment from the well-defined procedure of surgical aortic-valve replacement in intermediate-risk patients. An old fable taught us that “slow but steady wins the race.” Since the journey of TAVR is only starting, the moral may be changing.

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