

# Transcatheter Aortic Valve Replacement:

## What Really Matters for Women?

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**T**he prevalence of senile calcific aortic stenosis, a degenerative disease, mirrors the portion of the population that survives other processes to reach an advanced age. Thus, because of longer life expectancy, increasing numbers of women are candidates for aortic valve replacement (AVR). In current cardiovascular medicine, transcatheter AVR (TAVR) has proved to be suitable in the elderly and in those otherwise at high risk for surgical AVR (SAVR).

Early TAVR trials appeared to harbor a recruitment bias against women—related, in part, to the use of large-profile devices, which precluded insertion in smaller femoral arteries. Even so, sex-specific examination of TAVR in early cohorts suggested distinct profiles of outcome for men and women, including an apparent survival advantage for women.

In the PARTNER high-risk trial, sex-specific all-cause mortality rates at 2 years were reported.<sup>1</sup> The investigators concluded that early and late mortality rates in women were better with TAVR than with SAVR; in contrast, there was no late survival benefit with TAVR in men, although their general clinical outcomes from both methods were similar. Thus, in the high-risk cohort, late mortality rates with TAVR were lower in women than in men, especially in women who underwent transfemoral TAVR.

In a patient-level meta-analysis that included 47,188 subjects, women who underwent TAVR had more strokes, major bleeding, vascular complications, and need for transfusion within 30 days than did men, but lower mortality rates at one year.<sup>2</sup> Likely factors contributing to complications were older age, lower body surface area, and vessels of smaller diameter. Increased occurrences of bleeding and vascular complications in women did not negatively affect their long-term survival benefit. Women had a lower risk of permanent pacemaker placement after TAVR; however, their increased 30-day risk of stroke and transient ischemic attack remained significantly higher after one year.

The investigators<sup>2</sup> concluded that women had better one-year and long-term survival prospects (mean follow-up duration,  $3.28 \pm 1.4$  yr) than did men, despite more risk of early (30-d) postoperative bleeding and vascular complications and a greater long-term risk of stroke. The long-term survival advantage in women was consistently observed in multiple sensitivity and subgroup analyses of the cohorts, vascular access methods, geographic variations, and valve types.

Smaller annular size in the women probably reduced the incidence of prosthesis undersizing. In comparison, the men tended to receive undersized valves, which resulted in more paravalvular leaks. In addition, the men had markedly worse baseline vascular disease and comorbidities than did the women, including hypertension, diabetes mellitus, coronary artery disease, prior revascularization, lower left ventricular ejection fraction, and higher risk scores. Of note, women's hearts may exhibit more favorable remodeling when hemodynamically stressed by aortic stenosis, mainly through less fibrosis and collagen deposition, thus enabling the reversal of cardiac remodeling after TAVR.

One-year outcomes were recently reported in the Women's International Transcatheter Aortic Valve Implantation Registry.<sup>3</sup> The investigators noted that baseline characteristics differ in men and women who undergo TAVR, and that these can affect short- and long-term events. Women have smaller peripheral vessels and aortic valve annuli, lower origins of the coronary arteries, more prevalent osteoporosis and frailty, greater risk of bleeding, and more prevalent concomitant valve disease and heart failure.

Composite TAVR efficacy in women at one year was reported.<sup>3</sup> The rate of all-cause death, and of all stroke, myocardial infarction, and hospitalizations for valvular symptoms or worsening congestive heart failure or valve-related dysfunction, was 16.5%. The rate for composite all-cause death or stroke was 13.9%; for death alone, 12.5%; and for stroke, 2.2%. EuroSCORE I, baseline atrial fibrillation, and prior percutaneous coronary intervention (PCI) were independent predictors of one-year death or stroke. Independent predictors of the Valve Academic Research Consortium-2 efficacy endpoint were EuroSCORE I and prior PCI or coronary artery bypass grafting.<sup>3</sup>

Other investigators studied sex-related outcome differences with the use of lower-profile devices, specifically the Edwards SAPIEN 3 valve (Edwards Lifesciences) in intermediate and high-risk cohorts.<sup>4</sup> At one year, the rates of death, disabling stroke, and repeat hospitalization were 22.4% in women and 20.9% in men. Even so, the one-year all-cause mortality rate slightly favored the women (9.4% vs 10.4%).

Like the outcomes in earlier patient cohorts, these recent trial results continue to suggest a slight survival advantage for women after TAVR, especially when devices compatible with their physical characteristics are implanted.

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