EDITORIALS

Informed Shared Decisions for Patients with Aortic Stenosis

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Valve replacement is the only effective treatment for adults with severe, symptomatic aortic stenosis. The ideal prosthetic valve would be associated with minimal risk and discomfort at implantation, would have hemodynamics similar to those of a normal valve, would not require anticoagulation, and would be durable for the patient's lifetime. We are moving closer to this goal, as evidenced by sequential randomized clinical trials of transcatheter aortic-valve replacement (TAVR), initially in patients at prohibitive or high estimated risk for death with surgical aortic-valve replacement, then in patients at intermediate risk, and now — in the trials by Mack et al.[1] and Popma et al.,[2] the results of which are reported in this issue of the *Journal* — in patients at low risk, defined as a risk of less than 3 to 4%.

In the trial by Mack et al., among patients with severe aortic stenosis, death, stroke, or rehospitalization at 1 year (the primary composite end point) occurred in 8.5% of the patients who were randomly assigned to undergo TAVR with a balloon-expandable prosthesis, as compared with 15.1% of those who were randomly assigned to undergo surgical aortic-valve replacement.[1] In the trial by Popma et al., death or disabling stroke at 2 years (the primary composite end point in that trial) occurred in 5.3% of the patients who were randomly assigned to undergo TAVR with a self-expanding prosthesis, as compared with 6.7% of those who were randomly assigned to undergo surgery.[2] The two trials provide strong evidence that TAVR is noninferior, and even superior, to surgery over 1-year and 2-year time frames. In addition, TAVR resulted in fewer strokes, less bleeding, and less atrial fibrillation than surgery, as well as a shorter hospital stay and faster recovery.

Thus, it is time for a paradigm shift in how we approach decisions about valve type in patients with aortic stenosis. Estimated surgical risk no longer dictates the choice between surgery and TAVR; instead, the primary considerations are life expectancy and valve durability, both of which are related to the patient's age.[3] For example, in the United States, women who are 70 years of age have an average life expectancy of 16 years, whereas women who are 50 years of age have a life expectancy of 33 years. Conversely, the durability of surgical aortic-valve replacement is inversely related to the patient's age at the time of valve replacement; the 15-year risk of reoperation is approximately 5% among patients who are 70 years of age at the time of surgery, as compared with 25% among patients who are 50 years of age.[4,5]

Because of these considerations, current guidelines recommend the use of a mechanical valve in adults younger than 50 years of age, unless long-term anticoagulation is contraindicated or declined by the patient.[6] Among adults 50 to 70 years of age, long-term outcomes are similar with mechanical and biologic valves; the risk of bleeding and thrombosis associated with mechanical valves is balanced against the risk of valve deterioration and reintervention associated with bioprosthetic valves. In most patients older than 70 years of age, the use of a bioprosthetic valve is appropriate; in this group of patients, TAVR is likely to become the preferred option over surgery. Even so, caution is needed, because robust data regarding the durability of the transcatheter bioprosthetic valve beyond 5 years are not yet available.[7]

We also need to consider how many patients with severe aortic stenosis are similar to the pa-

tients enrolled in these two trials. Nearly all the patients in these trials had high-gradient severe aortic stenosis with normal ventricular function, and none had a bicuspid valve, even though this condition accounts for nearly half of all aortic-valve replacements. In addition, aortic-valve, coronary, and peripheral vascular anatomy was suitable for the transcatheter approach. In terms of demographics, the mean age of the patients was approximately 74 years, and 65 to 70% were men.

Why were so few women included in these trials? Possible explanations include incorrect diagnosis of aortic stenosis in older women, who frequently have low-flow, low-gradient severe aortic stenosis; inappropriate biases in referral; and anatomical factors (e.g., annular size, coronary ostial height, and vascular access) that render current TAVR valves poorly suited to women. Regardless of the possible reasons, the inadequate inclusion of women should be remedied in future studies.

Valve disease is a lifelong condition that is not cured by valve replacement; a dysfunctional native valve is simply replaced with an imperfect prosthetic valve. Nearly everyone would choose a transcatheter procedure over open-heart surgery if they are thinking only about short-term pain, risk, and disability. But many patients, particularly younger ones, might accept greater up-front risk and pain to ensure a better outcome over their lifetimes. In younger patients, concerns include the risk of permanent pacemaker implantation, deterioration of the valve, and associated conditions, such as aortic dilatation, that might be better treated with a surgical approach.

How can we actively involve patients in this decision-making process? My approach is to start with an evaluation of the patient's symptoms, the severity of the aortic stenosis, associated cardiac and noncardiac conditions, and overall health status. The next step is to consider whether a mechanical or bioprosthetic valve is most appropriate, in alignment with the patient's preferences and values. Then, if a bioprosthetic valve is chosen, the discussion focuses on comparing TAVR with surgery in the context of estimated remaining years of life and valve durability, highlighting uncertainties in the current data. This is challenging, given the paucity of reliable information sources for patients.[8-10] Physicians and patients need tools that provide accurate data in accessible, continuously updated, and understandable formats to allow truly informed shared decisions for patients with aortic stenosis.

Disclosure forms provided by the author are available with the full text of this editorial at NEJM.org.

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DOI: 10.1056/NEJMe1903316