Commentary: Who needs evidence when patient preference is a Class I indication?

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Disclosures: Authors have nothing to disclose with regard to commercial support.

Received for publication May 20, 2019; accepted for publication May 21, 2019; available ahead of print June 18, 2019.

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J Thorac Cardiovasc Surg 2020;159:430-502

0022-5222/\$36.00

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<https://doi.org/10.1016/j.jtcvs.2019.05.021>

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Central Message

We need robust evidence to inform prosthesis choice in young patients.

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Tam and colleagues¹ use the Society of Thoracic Surgeons Adult Cardiac Surgery Database to show how far, in the absence of any supporting evidence, clinical practice has shifted. The authors explore national trends in aortic valve prosthesis choice from 2004 to 2016 and reveal the remarkable decline in the use of mechanical prostheses from 2004 (well before the approval of transcatheter aortic valve replacement) with an increase in implanted bioprosthesis size over the same period of time.

The trend toward bioprostheses has been described in single centers and registries from Europe, and the United States.¹⁻⁵ Although the advantages of bioprosthesis use in older patients are well established, the switch to bioprostheses described here in much younger patients defies guideline recommendations and observational data suggesting mechanical prostheses are associated with better outcomes in adults older than age 50 years.⁵⁻⁸ This analysis lays to rest any illusion that the radical practice change followed transcatheter-based interventions, because the trend started years before these were available.

The superb analysis beautifully frames fundamental questions: Why are we using so many more biological valves; and, Why are we using larger ones? The second question is easier to answer. Because transcatheter valves claim the majority of patients with aortic stenosis, the growing proportion of patients with aortic regurgitation in the surgical aortic valve cohort likely explains the larger bioprosthetic surgical valves—the authors could confirm this by evaluating valve etiology.

The first question, regarding the shift to bioprosthesis use in younger patients without supporting evidence, is harder to address. Patient preference is a Class I indication for either prosthesis type,^{7,8} but recent data suggest that patients' involvement in valve choice is suboptimal.⁹ Navigating the complex balance of stroke, bleeding, and reoperation risk is challenging for patients, who commonly center

their immediate preferences around avoiding anticoagulation therapy. Surgeons seem more inclined to avoid anticoagulation and to choose a biological valve than cardiologists,¹⁰ which brings us again to this question: In the absence of clear evidence, guideline recommendations, informed patient preference, and major technical or safety advantages, should we be choosing biological valves for young patients as often as we are?

A registry analysis cannot answer this question because it contains no long-term outcome data for young patients. A randomized trial would require decades, thousands of patients, and enough surgeons with the clinical equipoise needed to randomize. Most retrospective analyses are plagued by selection bias, thanks to prior decades where only the least compliant patients with the shortest life expectancy and the poorest access to health care received a bioprosthesis. Meta-analyses of nonrandomized data simply compound the problems.

But there are important questions we can answer now. We increasingly pin young patients' hopes on transcatheter and valve-in-valve replacement—but what are the 5-year outcome data in low- and intermediate-risk transcatheter populations? Can anticoagulation therapy reduce bioprosthetic valve thrombosis and structural degeneration? Why is anticoagulation as unthinkable for some patients as stroke or open-heart surgery—do we need a better framework for these conversations? Tam and colleagues¹ highlight how far our practice has moved without evidence. We owe it to our patients to find strong evidence for our next move.

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