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EDITORIAL COMMENTARY

A game of millimeters

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See related article on pages 163-73.

The current issue of the *Journal* includes a report by Thalji and coauthors¹ on a prospective, randomized trial of isolated aortic valve replacement with 3 commonly used bioprostheses. Early and 1-year echocardiographic data showed that the Magna valve (Edwards Lifesciences Corporation, Irvine, Calif) had a small (<4 mm) but persistent and significantly lower transvalvular gradient than either the Epic valve (St Jude Medical, Inc, St Paul, Minn) or the Mitroflow valve (Sorin Group USA, Inc, Arvada Colo). This intriguing potential benefit, with attendant calculated increase in indexed valve area, was confined to sizes larger than 23 mm. Early similar gradient differences noted in the 23-mm group did not persist at 1 year. Not surprisingly, clinical outcomes including early

and midterm mortality and morbidity, left ventricular mass regression, and valve durability or need for reintervention (N = 0) have been equivalent for these 3 popular and well-known valves. Thalji and coauthors¹ emphasize that the small hemodynamic benefits at this point in the follow-up have no corresponding demonstrable clinical or physiologic findings, and this report should reassure the patients and doctors using any of the 3 valves. As increasing relative numbers of bioprostheses are implanted each year, further information on these 3 commonly used valves is welcome.

The study's strength is clearly the randomization format enforced at the time of implantation. This was likely very achievable because of the tertiary referral center of Thalji and coauthors,¹ and most surgeons as well as patients enrolling in this trial (mean 75 years) would view these 3 valves as providing equivalent outcomes. On the other hand, challenges imposed by the large tertiary nature of their institution, the natural history of these elderly patients, and the "confidence" level of the patients in receiving the assigned valve has resulted in the major weakness of this trial, and that is the relatively large percentage of patients (30%) without 1-year echocardiographic data who were effectively lost to follow-up (LTF). Because of the small hemodynamic differences and the relatively small trial, the availability of complete data for only 71% of the patients should cause readers to view the findings as preliminary at most and warranting

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Disclosures: Author has nothing to disclose with regard to commercial support.

Received for publication Sept 22, 2014; accepted for publication Sept 22, 2014; available ahead of print Oct 22, 2014.

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J Thorac Cardiovasc Surg 2015;149:173-4

0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2014.09.083>

future attempts to recapture these patients as part of a long-term review in an ongoing randomized trial. Thalji and coauthors¹ have confirmed the mortality and the nonintervention rate by telephone contact with the surviving 45 patients in the LTF group. Thalji and coauthors¹ further attempt to address the LTF issue by using imputational values (Table E1) to repopulate the missing echocardiographic data by statistical technique. The study's findings were not changed by the addition, and the reader can decide whether absence of actual hemodynamic data constitutes true LTF. To their credit, Thalji and coauthors¹ state their determination to acquire additional funding to facilitate the necessary hemodynamic tests in the future.

Although users and manufacturers of these popular bioprostheses will be very interested in a prospective, randomized trial that shows any hemodynamic difference, albeit modest, several significant caveats in addition to the flaw of incomplete follow-up need emphasis. First, the equivalent clinical outcomes in this early review are to be expected from the 3 commonly used and reported on valves. A longer follow-up will be needed to provide valuable information on both valve durability and reintervention rates. Thalji and coauthors¹ appropriately propose future long-term follow-up. Second, it should be emphasized that in the group of patients receiving valves smaller than 23 mm

and at greatest risk for patient-prosthesis mismatch, there was no difference among the three valves in either hemodynamic performance or the incidence of patient-prosthesis mismatch. The study did show acceptably low gradients in the aggregate, with a 4% root enlargement rate that was evenly used among the 3 valves. Left ventricular mass regression was equivalent among the valves at 1 year, again underscoring the relatively small hemodynamic differences. One might have expected any specific valve's design-related benefit to be accentuated in this group with smaller valve sizes, but this was clearly not the case.

Surgeons and manufacturers will, it is to be hoped, avoid "a game of millimeters" sparked by making overreaching conclusions from the modest early findings presented in this report. Thalji and coauthors¹ strike the right note, stressing the equivalence of important clinical parameters among the 3 valves and the need to perform a long-term review. They are to be commended for initiating a prospective, randomized trial that can provide useful information in the future.

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