The authors reported no conflicts of interest.

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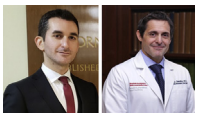

REPLY: ONLY RANDOMIZED TRIALS CAN DEFINE THE GOLD STANDARD

Reply to the Editor:

We read with great interest the letter to the editor authored by Jahanyar and colleagues in response to the article published by the Cleveland Clinic group.[1] In the Cleveland series of 607 patients (92 with bicuspid aortic valve [BAV]), Mokashi and colleagues[1] concluded that aortic root replacement with valve-sparing reimplantation was a reliable option for selected patients with either BAV or tricuspid aortic valve, as a propensity score–based comparison showed no statistically significant difference in death and in-hospital complications. After a follow-up of 8 years, mortality was similar in the 2 groups ($P = .07$), whereas a greater number of aortic valve reoperations were noted in patients with BAV, raising concerns for long-term outcomes.

In contrast, Jahanyar and colleagues cite their experience with BAV repair at a single institution in Brussels, performed with a 180° reimplantation-El Khoury technique.[2,3] In this series, authors reported a freedom from reoperation of 91% at 12 years in the BAV group, greater than that reported in the BAV cohort (77%) analyzed by the Cleveland Clinic group. Jahanyar and colleagues argue that the difference could have been driven primarily by a greater recurrence of aortic regurgitation, even though this remains unclear. Considering the long-term outcomes obtained at their institution, the authors conclude by recommending that their reimplantation technique should be favored over prosthetic valve replacement when feasible.

According to Jahanyar and colleagues,[3] the 180° reimplantation technique is well-thought-out, successfully adapts to the complex anatomy of BAV, and facilitates the surgical repair. While we agree in principle, we also believe that both approaches may be used as long as the surgeon possesses technical experience and expertise. At present, we are lacking sufficient, solid comparative data from large observational studies or, better, randomized clinical trials to make an evidence-based decision on which surgical approach should be preferred. Yet, we certainly agree that there is an unspoken need to provide cardiac surgeons and patients with solid data to inform practice and optimize clinical outcomes.

To accomplish such a goal, our community should in primis avoid estimating treatment effects based on comparisons between observational studies, which are undoubtedly more representative of clinical practice but are intrinsically prone to a greater risk of bias and confounders.[4,5] Second, surgeons should now be aware that answers to long-awaited and unresolved questions can only be derived from appropriately designed and adequately powered high-quality trials, for which specific recommendations to overcome challenges have been developed by experts and trialists in the field.[6,7] In the history of our clinical practice, there have already been plenty of examples of widely adopted treatments based on observational studies that were subsequently found to be ineffective when tested in appropriately powered randomized trials.[5] This is a unique opportunity to not repeat our past mistakes, to come together, and to give our patients an evidence-guided answer. So, let trials have the last word.

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