

Letters

Lack of Clinical Equipoise Renders Randomized-Trial Execution of Ross vs Prosthetic Valves an Impossible Task



The Toronto group has recently published their long-term (20-year) results with the Ross procedure (Ross) vs bioprosthetic aortic valve replacement (AVR) in a propensity-score matched analysis.¹ The authors concluded that Ross was associated with significantly better long-term survival and freedom from adverse valve-related events and should therefore be considered as the primary option for young and middle-age adults undergoing AVR.

This is the latest publication in a recent series of similar papers that have verified earlier results and demonstrated significantly improved outcomes with Ross compared to prosthetic AVR,^{2,3} with the same low perioperative risk although with a lack of clinical equipoise. In particular, Ross achieves long-term survival that mirrors survival of the general population.⁴ These results, to date, have not been achieved with any of the other valve replacement therapies.

In the authors' opinion, there is therefore no need to further tease out differences between the 2 therapies by means of a randomized trial. High-volume Ross centers, such as ours, would likely not even participate in a randomized trial of patients who would normally meet their institutional criteria for Ross. This would thus likely limit trial recruitment to less-experienced Ross surgeons, which may then unfavorably skew results. Based on these grounds, the question also arises whether it is even ethical to randomize a young patient to a treatment when a

therapy with better long-term survival, better quality of life, and the same low perioperative risk already exists and can be safely performed in experienced hands. Similarly, there has never been a randomized trial between mitral valve repair and replacement for mitral valve prolapse, and mitral valve repair is now the standard of care. As clinicians, we must advise our patients based on the most recent available data, and the data consistently favor Ross over prosthetic valve replacement.

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<https://doi.org/10.1016/j.jacc.2022.04.043>

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Dr Said is a consultant for Stryker, Abbott, and Cryolife. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

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