Author receives speaker honoraria for Edwards Lifesciences.

THE BIOPROSTHETIC VERSUS MECHANICAL VALVE DEBATE: UNWINNABLE AND INCREASINGLY IRRELEVANT?

Reply to the Editor:

It is a remarkable fact that surgeons and specialty leaders, including 3 American Association for Thoracic Surgery presidents, are divided between 2 therapies as different as mechanical and bioprosthetic valve replacement—split between stances that range from advocating mechanical valves in the elderly to recommending bioprosthetic valves in the young.¹

It is remarkable, but it is not surprising. The enormous pile of relevant evidence can be selectively quoted or critiqued to support both positions and the entire spectrum in between. Dr Emiliano Rodriguez-Caulo² outlines some of the issues in his critique of the meta-analysis of mechanical versus bioprosthetic valve published recently in the *Journal*,³ and he then goes on to describe ANDAVALVE, a prospective, observational registry trial—but even this methodology cannot adequately address the selection bias that undermines the reliability of every nonrandomized study.

Is a randomized trial the answer? Only if we can wait 20 years for survival data that would inform practice, but obviously that is too long in a specialty where patient preference and rapid advances in technology are the primary drivers of practice change, and where it took less than a decade for transcatheter valve replacement to go from first-in-human to the dominant therapy for valve replacement in aortic stenosis.

The Achilles' heel of transcatheter technology is calcific degeneration of xenografts. Solving this could establish transcatheter aortic valve surgery as the first choice for patients in all age groups. The solution looks increasingly likely to lie in emerging polymer technology, which in initial hemodynamic in vitro testing has shown improved hemodynamics, minimization of platelet activation and thrombosis, and improved strength, mechanical stability, and durability. Recent work suggests that a novel polymeric transcatheter valve outperforms clinically used xenograft transcatheter valves in vitro, and it hints at the possibility of a future new clinical paradigm.⁴

In the interim, producing more nonrandomized data comparing mechanical and bioprosthetic valves just adds to the mounting slush pile of evidence without materially informing or shifting the debate. Knowledge gaps that we

could usefully tackle instead include the incidence of structural valve degeneration at 5 years after transcatheter valve replacement in patients at intermediate and low risk, strategies to minimize the operative mortality of reoperative aortic valve replacement and optimize valve-in-valve outcomes, and the role of novel anticoagulants in reducing bioprosthetic valve thrombosis and structural degeneration.

Wherever we choose to focus, it is time to stop repeating studies with the same methodologic problems. This is an unwinnable debate. And it is one that may soon be irrelevant.

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References

1. Sundt T, Schaff H, Soltesz EG, Uva MS, Adams DH. Mechanical vs biologic valves: our modern day conundrum. *Semin Thorac Cardiovasc Surg*. 2016;28:404-17.
2. Rodriguez-Caulo E. More evidence favoring bioprostheses for patients older than 55 years in aortic valve replacement. *J Thorac Cardiovasc Surg*. 2019;157:e357.
3. Diaz R, Hernandez-Vaquero D, Alvarez-Cabo R, Avanzas P, Silva J, Moris C, et al. Long-term outcomes of mechanical versus biological aortic prosthesis: systematic review and meta-analysis. *J Thorac Cardiovasc Surg*. November 20, 2018 [Epub ahead of print].
4. Rotmen OM, Kovarovic B, Chiu W, Bianchi M, Marom G, Slepian MJ, et al. Novel polymeric valve for transcatheter aortic valve replacement applications: in vitro hemodynamic study. *Ann Biomed Eng*. 2019;47:113-25.

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SHOULD WE MODIFY THE PROTOCOL OF A SYSTEMATIC REVIEW TO INCLUDE A RELEVANT STUDY?

Reply to the Editor:

We thank Rodriguez-Caulo¹ for his letter and Chikwe and Weiss² for their editorial commentary on our systematic review and meta-analysis on mechanical versus biological valves. We concluded that, compared with biological valves, mechanical aortic prostheses provide better long-term survival.

Under ideal conditions, the best evidence comes from the meta-analysis of randomized, controlled trials (RCTs). This is not the case for this issue, however, because there is only a single RCT with small statistical power. Overcoming this limitation is the main goal of any meta-analysis. Propensity score methods are used to deal with the intrinsic biases of observational studies. In addition, propensity score matching allows direct comparison of survival curves.³ So