Uniformity in bioprosthetic mitral valve sizing – when will we get there?

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Abstract

Much has changed since the introduction of surgical valve repair in the 1950s, from the introduction bioprosthetic valves to percutaneous approaches to valve repair. Yet, despite substantial advancements in bioprosthetic valve technology, there has been a lack of direct, independent comparison between bioprosthetic mitral valve devices, accompanied by a marked heterogeneity in approaches to the sizing and selection thereof. Wang et al. have hence endeavoured to evaluate, head-to-head, the technical successes and biomechanical outcomes associated with three different bioprosthetic mitral valves (Epic, Abbott, IL; Mosaic, Medtronic, MN; Mitris Resilia, Edwards Lifesciences, CA) in a porcine model, under standardised haemodynamic and anatomical conditions. With a robust experimental technique, they have made clear the heterogeneity in both sizing and biomechanical properties between bioprosthetic mitral valves, and have further emphasised the need for a uniform approach to the manufacturing and sizing of bioprosthetic valves.

Invited Commentary

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Running head: Bioprosthetic mitral valve sizing

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ASBTRACT

Much has changed since the introduction of surgical valve repair in the 1950s, from the introduction bioprosthetic valves to percutaneous approaches to valve repair. Yet, despite substantial advancements in bioprosthetic valve technology, there has been a lack of direct, independent comparison between bioprosthetic mitral valve devices, accompanied by a marked heterogeneity in approaches to the sizing and selection thereof. Wang et al. have hence endeavoured to evaluate, head-to-head, the technical successes and biomechanical outcomes associated with three different bioprosthetic mitral valves (Epic, Abbott, IL; Mosaic, Medtronic, MN; Mitris Resilia, Edwards Lifesciences, CA) in a porcine model, under standardised haemodynamic and anatomical conditions. With a robust experimental technique, they have made clear the heterogeneity in both sizing and biomechanical properties between bioprosthetic mitral valves, and have further emphasised the need for a uniform approach to the manufacturing and sizing of bioprosthetic valves.

COMMENTARY

We read with great interest the manuscript by Wang, Caranasos, and O'Neill et al. titled '*Comparison of a new bioprosthetic mitral valve to other commercially available devices under controlled conditions in a porcine model*' .[1] The authors astutely identified a gap in existing research concerned with long-term outcomes associated with bioprosthetic mitral valves (particularly, in terms of echocardiographic gradients across the prosthesis, true-annular opening, and propensity for left ventricular outflow tract [LVOT] obstruction).[1] They also highlighted issues with mitral bioprosthetic valve sizing that have been identified by the Valve Labelling Task Force as requiring regulatory evaluation. Manufacturer-labelled dimensions for mitral bioprostheses appear to lack consistency and are not evidence based; further, factors such as device size selection, implantation technique, and instructions for use vary greatly between manufacturers.[1,2] In view of this, Wang et al study sought to address this gap in research by comparing outcomes associated with three different mitral valve bioprostheses.

When anatomically feasible, management of mitral valve pathologies should be geared to securing optimal long-term outcomes. It follows therefore that a robust analysis advocating the use of bioprosthetic mitral valves should be centred on a high-risk population profile (e.g. groups with blunted life expectancy, or incapacity for anticoagulation). Henceforth, an early feasibility experimental study, featuring controlled haemodynamic and anatomical variables, would need to be conducted to allow a head-to-head comparison between commercially available prostheses. To this effect, an evaluation of bioprosthesis efficacy against these portrayed endpoints would facilitate comprehensive appraisal of devices in question.

Wang and colleague's study is, arguably, affected by several limitations. Firstly, the study was carried out using a smaller number of animals, restricting the number of bioprosthesis types and sizes tested, and precluding the statistical analysis of reported outcomes. This low sampling bias permitted a limited scope around the longevity of valve in the face of structural deterioration which could necessitate reintervention. Furthermore, the acuity of the study prevented the long-term outcomes of each bioprosthesis from being evaluated, for example in terms of paravalvular leak, ventricular remodelling, or ejection fraction.[4] These limitations are highlighted and accounted for the in their study.[1]

Undoubtedly, there exists great heterogeneity in bioprosthetic mitral valve sizing and application between manufacturers. This would come as no surprise to the experienced cardiac surgeon or interventionalist – a similar issue has been reported in aortic valve prostheses.[5] Interestingly, Wang et al. found that different bioprostheses of the same size (namely, 27 mm Epic and Mosaic) were associated with drastically different valve gradients, peak velocities, LVOT, and SOA.[1] The extent to which LVOT may be attributed to differences in prosthesis strut protrusion into the LV, or from abnormal subvalvular positioning of the prosthesis, leading to outlflow tract obstruction, is unclear.

Bothe et al. highlight that the bioprosthesis-specific sizers provided by the manufacturer vary greatly,

and indeed, the numbers used to label prosthesis-specific sizers are often arbitrary numbers, rather than metrics – making any effort towards standardisation on this front more complicated yet. For example, some manufacturers base sizer metrics on the external stent diameter, without accounting for the sewing ring, while others do.

A key message highlighted by Wang et al. is that considering the significant heterogeneity between individual patient anatomical and biomechanical characteristics, and between mitral valve bioprosthesis sizing practices, a standardised, evidence-based strategy is required. Yet, the potential for untoward colliding bias between exposure and outcomes in the attribution and confirmation of thereof should be kept in view. Perhaps a concept derived through practiced assessment of annuloplasty rings, as highlighted by Ender et al., would also be a viable option. They suggested an approach using superimposed computer-generated models of annuloplasty rings onto live, 3D echocardiographic images, and thus far have reported good results in terms of correlation with ring size determined intraoperatively.[6] Yet, while these and other observed approaches are novel and require further investigation, they help pave the way for a more evidence-based mitral valve bioprosthesis sizing and selection protocol. This would mandate further efforts to avail against patient-prosthesis mismatch which is detrimental for patient quality of life.

In conclusion, the manuscript by Wang et al. succinctly highlights an area in dire need of further investigation and standardisation. Their clinical feasibility experiment using a porcine model has produced valuable findings towards the development of a standardised approach to mitral valve bioprosthesis sizing and selection.

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