New-generation Myval transcatheter heart valve in severe aortic stenosis

Transcatheter aortic valve implantation (TAVI) has become a well established treatment option in patients with severe aortic stenosis, regardless of the surgical risk spectrum.[1,2] The refinement of techniques and broadening of indications have meant complication rates—including death, strokes, and vascular complications—have drastically decreased over time,[1,2] without serious concerns regarding transcatheter heart valve (THV) durability.[3] The current focus lies on a tailored approach, aiming to offer each patient the most suitable THV based on their specific anatomy and ensuring optimal haemodynamic performances after the index procedure and potential for repeatability in patients with increased longevity. In an effort to help physicians to select the most appropriate device for their patients, there have been four head-to-head comparisons of THVs since 2020.[4-7]

The two most used contemporary THVs in clinical practice are the self-expandable Evolut THV, with supra-annular design, and the balloon-expandable Sapien 3 THV, with intra-annular design. The randomised SOLVE-TAVI trial showed the equivalence of Evolut R to Sapien 3 in 447 participants with symptomatic severe aortic stenosis undergoing TAVI,[6] although the Evolut platform recently showed haemodynamic superiority using echocardiographic criteria at 1 month in patients with small annuli.[4]

Device selection and sizing, based on standardised CT analysis, are crucial to ensure optimal outcomes and decrease complication rates. Oversizing can result in aortic rupture or conductance disturbances, whereas undersizing can lead to paravalvular leak or even THV embolisation. The traditional sizing of existing balloon-expandable and self-expandable THVs, with step-ups of 3 mm in nominal valve size, could pose challenges in clinical practice when native annular area dimensions fall between two THV sizes. Currently, to address this gap, the balloon of the label-sized balloon-expandable THV is generally overfilled or underfilled. The Myval balloon-expandable THV represents a novel and tailored approach that has diversified and bridged an important gap in THV sizing. The Myval THV enables precise and more accurate matching of the device with the aortic annulus, with a 1·5 mm diameter increment between each nominal device size (eg, 20·0 mm, 21·5 mm, or 23·0 mm) to cope with the wide variety of aortic annulus dimensions (area ranging from 270 to 840 mm²).[8]

Until now, comparative studies between Myval and other types of THV have been mainly observational and with small sample sizes. In *The Lancet*, Andreas Baumbach and colleagues[8] present new, important data from the LANDMARK trial, which is a head-to-head comparison of Myval and contemporary THVs (Sapien 3 and Evolut series). In this multinational, randomised trial (31 sites across 16 countries), 768 participants with severe symptomatic aortic stenosis were randomly assigned (1:1), 384 to the Myval THV series and 384 to contemporary THV series, between Jan 6, 2021, and Dec 5, 2023. 369 (48%) participants had their sex recorded as female, and 399 (52%) as male. The primary outcome of non-inferiority of the Myval THV was tested in the intention-to-treat population (non-inferiority margin of 10·44%, assuming an event rate of 26·10%). This study highlights several findings that have important implications in a contemporary TAVI population (mean age 80 years; Society of Thoracic Surgeons score 2·6%).

The LANDMARK trial establishes the non-inferiority of Myval compared with contemporary THVs (25% *vs* 27%; risk difference –2·3% [one-sided upper 95% CI 3·8%], $p_{non\text{-}inferiority}<0·0001$) for the 30-day composite endpoint (all-cause mortality, stroke, major bleeding, acute kidney injury, major vascular complications, moderate or severe prosthetic valve regurgitation, and permanent pacemaker implantation according to third Valve Academic Research Consortium criteria). Another important finding is that 48% of Myval THV implants were intermediate-size devices, emphasising that the Myval THV allows for a more tailored and accurate THV sizing, translating into less immediate paravalvular leak and better effective orifice area than contemporary THVs on 30-day follow-up echocardiography. Although these findings are promising, the effect of the more appropriate sizing provided by the Myval THV on long-term outcomes and valve durability still needs to be evaluated.

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Despite a more accurate sizing in the Myval group, the permanent pacemaker rate was relatively high and similar between groups. However, no information was provided on the implantation technique—which might affect the incidence of conduction disturbances—or on permanent pacemaker indications, which might widely vary across sites. Similarly, the rate of predilatation, up to 43% in both groups, with no additional information on its indication, appears higher than one would expect for current practice.

The study by Baumbach and colleagues has some limitations, the main one being that their results might not be generalisable to daily practice for all patients. Although the investigators should be congratulated for having included participants with greater anatomical complexities, reflecting real life, and the extending indication for TAVI (ie, small annulus in 32% and bicuspid aortic valve in 7%), it is important to emphasise that all participants included in this study had to be considered suitable for self-expandable, balloon-expandable, and Myval valves, which excludes patients for whom balloon-expandable or self-expandable valves might be preferable. The global inclusion rate of participants in this trial was only 15%, indicating high selection bias.

Moreover, whether this new Myval THV offers long-term advantages over contemporary THVs is not yet established, especially for younger individuals, for whom repeatability and coronary access are key for lifetime management given the expected steady increase in the number of individuals with increased longevity.[9] Although commissural alignment does not seem feasible with the Sapien THV, recent promising data were published with Myval,[10] which could give it a valuable advantage for long-term outcomes.

Baumbach and colleagues should be congratulated for their well conducted randomised controlled trial, providing additional evidence to strengthen the case for an individualised approach with more tailored THV sizing. Nevertheless, the potential advantage of Myval THV tailored sizing through the availability of intermediate sizes requires further investigation in future clinical trials and long-term follow-up to integrate this new tool into the current TAVI landscape.

We declare no competing interests.

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