Head-to-head comparison of balloon-expandable transcatheter heart valves

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Transcatheter aortic valve intervention (TAVI) is a well established therapy for severe aortic stenosis, demonstrating excellent mid-term outcomes in patients across all surgical risk groups.[1,2] Valve durability and repeatability are key concepts when considering young (ie, aged <75 years) patients with low surgical risk and increased life expectancy, who might therefore outlive their bioprosthetic valve.[3] Short-frame balloon-expandable transcatheter heart valves (THVs) are suitable in most anatomies and offer potential for a second TAVI procedure in most cases.[4] However, randomised trials have shown higher gradients in patients with small annuli treated with balloon-expandable intra-annular SAPIEN 3 THVs than with self-expandable supra-annular THVs, without showing clear clinical impact.[5] Thus, a tailored approach based on patient characteristics and anatomical features from CT scan is required to avoid immediate complications, to ensure optimal THV function and anticipate repeatability.[3]

The SAPIEN 3 THV series is widely used in clinical practice and has shown good outcomes.[2] The newest balloon-expandable THV, Myval, offers intermediate sizes (1·5 mm diameter increments *vs* 3 mm for SAPIEN 3) thus improving sizing accuracy.[6] Furthermore, larger Myval THVs are available to treat large annuli (270–840 mm²), which are often too large for any available THV platforms. Since overexpansion or underexpansion of THVs can affect leaflet function, THV haemodynamics, and valve durability, more appropriate sizing seems desirable. Head-to-head comparisons of new THV platforms and best-in-practice THVs could provide guidance for selecting the most appropriate device for specific patients.

The LANDMARK trial demonstrated non-inferiority of Myval versus contemporary THVs (ie, SAPIEN 3 and Evolut platforms) as well as non-inferiority of Myval versus a SAPIEN 3 platform sharing similar balloon-expanding technologies in a post-hoc analysis.[6,7] In this issue of *The Lancet*, Christian Juhl Terkelsen and colleagues report their findings of a randomised, non-inferiority trial comparing Myval or Myval Octacor THVs and SAPIEN 3 or SAPIEN 3 Ultra THVs in patients undergoing TAVI for severe aortic stenosis.[8] Patients' median age was 81·6 years (IQR 77·6–85·0), 415 (40%) of 1031 patients were female and 616 (60%) were male. Myval THVs were non-inferior to SAPIEN 3 THVs regarding the primary composite endpoint of all-cause mortality, stroke, moderate or severe aortic regurgitation, or moderate or severe valve deterioration at 1 year (71 [14%] of 514 patients *vs* 67 [13%] of 517 patients), which met the prespecified non-inferiority margin (risk difference –0·9% [one-sided upper 95% CI –4·4]; $p_{non\text{-}inferiority}$=0·019).

A higher proportion of patients treated with Myval THVs had first-time pacemaker implantation than those treated with SAPIEN 3 THVs (95 [21%] of 455 *vs* 56 [12%] of 468), especially with the Myval Octacor THV. Although slightly greater oversizing occurred with Myval THVs than with SAPIEN 3 THVs (7·5% *vs* 6·3%), this difference alone does not explain the increased pacemaker rate, suggesting that other factors such as THV design and implantation technique need further investigation. Operators might be less familiar with the new Myval THVs, which might affect implant depth. Moderate or severe paravalvular leaks were also more frequent in patients treated with Myval THVs, suggesting that the skirt used for SAPIEN 3 THVs provides better sealing against paravalvular leaks.

Aortic valve area was smaller and mean gradient were higher in patients treated with SAPIEN 3 THVs, supporting the findings from the post-hoc analysis of the LANDMARK trial.[7] The different design of the Myval THVs that enables a larger effective leaflet opening might explain this finding.[6,7]

Nevertheless, the latest SAPIEN Ultra Resilia technology that is associated with higher effective orifice area than SAPIEN THVs due to different leaflet attachment to the THV frame was not used in the study by Terkelsen and colleagues.[9] Thus, Myval THVs versus SAPIEN 3 Ultra Resilia THV might have yielded different haemodynamics. As in the LANDMARK trial, Terkelsen and colleagues found high predilatation rates in patients treated with Myval THVs versus those treated with SAPIEN 3 THVs (45% *vs* 21%) suggesting lower deliverability of the Myval platform, although predilatation was left to operators' discretion.

The authors acknowledge several limitations including the absence of information on THV balloon filling, which is crucial for the assessment of true valve oversizing, with potential implications on THV haemodynamic performances. Furthermore, the findings were not generalisable to a younger population (aged <75 years).[2] Further analyses are required to determine whether the Myval Octacor iteration affects pacemaker rates and deliverability as it had higher pacemaker and predilatation rates than the previous Myval iteration.

The authors should be congratulated for this trial with unprecedented rates of inclusion (1031 [77%] of 1335 patients treated at participating hospitals) allowing to extrapolate their results to all-comers patients. Furthermore, complex anatomies (bicuspid and valve-in-valve) were not excluded, adding a real-life dimension. Yet, long-term advantages of the more recent Myval THVs over the well established SAPIEN 3 platform requires more data, especially in a younger population for whom lifetime management of aortic stenosis is crucial. Future post-TAVI studies with CT analysis might provide insightful data on expansion of THV frames, implantation depth, and commissural alignment that was intended with the Octacor THV and might affect repeatability, future coronary access, and THV expansion.[10] Further analyses are required to elucidate whether Myval THV might provide favourable haemodynamics in small annuli regarding its unique design and sizing features.

I report consultancy work for Edwards Lifesciences, Medtronic and Abbott.

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