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From gradient reduction to flow restoration: redefining haemodynamic success after TAVI

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This editorial refers to 'Biomimetic transcatheter aortic valve replacement restores ascending aortic flow towards native physiology: A first-in-human prospective imaging study', by P. Garg *et al.*, https://doi.org/10.1093/ehjvshd/xwag011.

Transcatheter aortic valve implantation (TAVI) has profoundly transformed the therapeutic management of severe aortic stenosis (AS). Over the past two decades, technological refinement and procedural standardization have progressively shifted clinical goals from procedural feasibility to early safety and, more recently, to long-term durability.[1] In this evolution, haemodynamic performance has remained a critical marker of success, traditionally assessed through transvalvular gradients, effective orifice area (EOA), and the incidence of prosthesis-patient mismatch.[2] While these parameters remain pivotal, they primarily reflect pressure-based surrogates of valve function and implicitly assume that blood behaves as a passive medium whose motion is entirely governed by upstream and downstream pressure differences: increasing evidence suggests that they capture only part of the physiological complexity underlying ventricular–valvular interaction.[3]

Cardiac magnetic resonance (CMR) has emerged as a comprehensive imaging modality for quantification of valvular disease severity and long-term prognosis in this context.[4,5] In the last years, advances in computational fluid dynamics and four-dimensional (4D) flow by CMR, allowing direct time-resolved visualization of intracardiac flow, have demonstrated that organized vortical structures play a central role in minimizing energy dissipation, facilitating efficient ventricular ejection, and modulating leaflet kinematics. Disruption of these flow patterns has been associated with increased viscous energy loss and impaired ventricular–arterial coupling, even in the presence of apparently preserved conventional haemodynamic indices.[2,6] Of note, even after appropriate pressure gradient restoration following TAVI, abnormal flow dynamics may persist,[7] with perturbation of physiological helical outflow patterns that translates into higher energetic burden on the left ventricle (LV): thus, whether a prosthetic design capable of preserving physiological flow can further improve valve durability and promote favourable LV remodelling remains an intriguing yet unresolved question.

The DurAVR transcatheter heart valve (Anteris Technologies, Eagan, MN, USA) is a novel biomimetic balloon-expandable valve featuring a unique single-piece biomimetic leaflet design that replicates native aortic valve leaflets. In an early bench study, the DurAVR demonstrated excellent hydrodynamic performance in native, valve-in-valve, and redo-TAVI simulations, compared with other commercially available balloon-expandable and self-expanding devices.[8] Furthermore, De Backer *et al.*[9] reported pooled 30-day outcomes from first-in-human and early feasibility studies in severe AS patients with small aortic annuli treated with DurAVR, showing excellent clinical and echocardiographic data at 30 days (EOA 2.2 cm^2, mean gradient 8.2 mmHg), with only 3% of moderate or severe prosthesis-patient mismatch and 6% of new pacemaker implantation. Although limited by sample size and short follow-up, these data suggest that the haemodynamic advantages observed *in vitro* may translate into clinically meaningful benefits in selected populations (*Figure 1*).

Complementing these preliminary data, in this issue of *European Heart Journal Valvular and Structural Heart Disease*, Garg *et al.*[10] explored the efficacy of DurAVR in restoring ascending aorta flow and in leading to LV mass regression, both assessed with CMR. A total of 60 patients with severe symptomatic AS were analyzed: 46 of them underwent TAVI with DurAVR, of whom 39 had paired baseline and 6-month CMR data; the control group was represented by an age-matched cohort of 35 patients without AS from the PREFER-CMR registry (NCT05114785). Ascending aortic flow was analyzed from the phase-contrast plane which allowed quantification of forward and retrograde flow volumes: flow displacement (FD) was used as a marker of systolic flow eccentricity and defined as the systolic-average distance between the geometric centroid of the aortic lumen and the velocity-weighted centre of forward flow, while flow reversal ratio (FRR) was used as a marker of turbulence and defined as systolic retrograde flow divided by systolic forward flow multiplied by 100.

In terms of results, first, compared with baseline CMR studies in AS patients, the DurAVR cohort showed lower LV mass (142 ± 47 to 112 ± 33 g, *P*-value <.0005) and a trend towards smaller LithV end-diastolic and end-systolic volumes, not reaching statistical significance. Interestingly, when correlating DurAVR with non-AS controls, there was no significant difference in LV end-diastolic and end-systolic volumes and mass (all *P*-values >.05). As for flow metrics, both indexed FD and indexed FRR significantly improved following DurAVR compared

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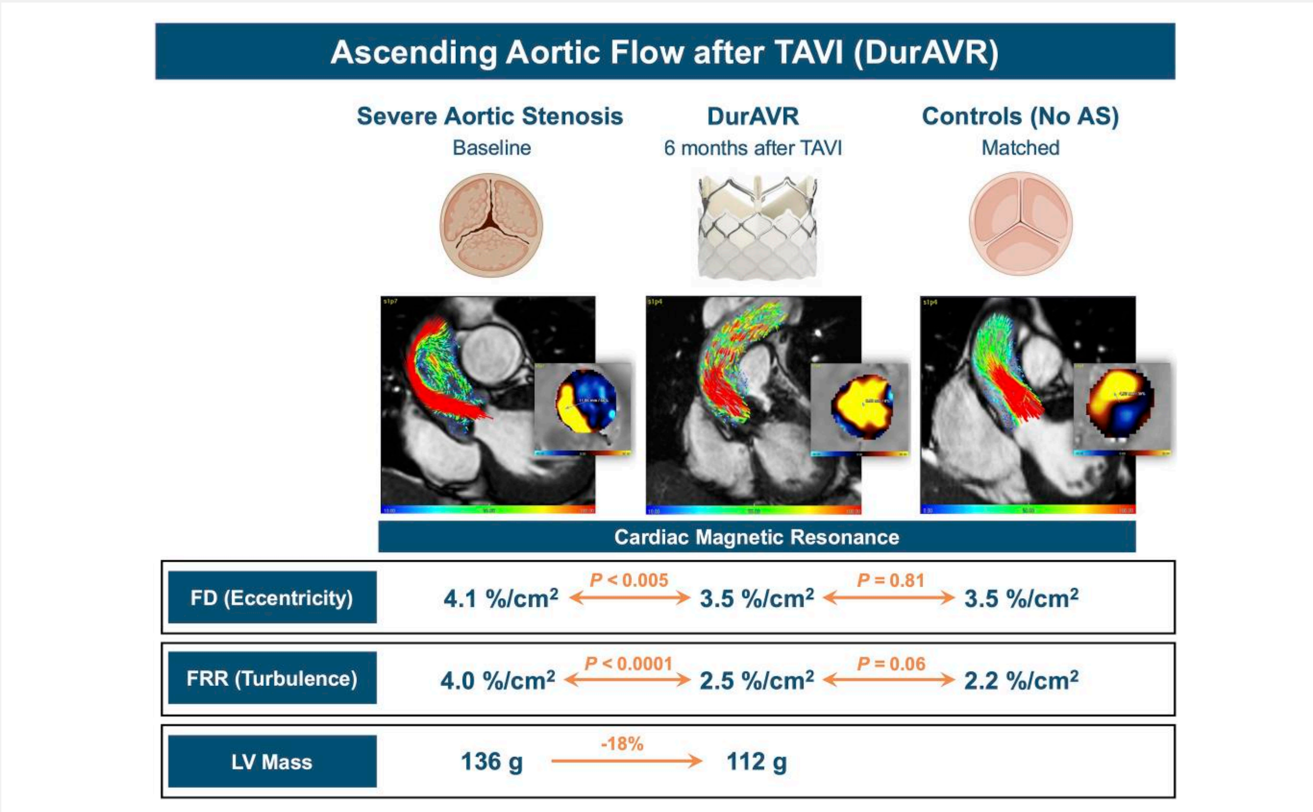

Figure 1 Ascending aortic flow after TAVI (DurAVR). Ascending aorta flow and LV mass were evaluated at baseline in severe AS patients, at 6 months after TAVI with DurAVR, and in the matched non-AS control group; adapted from Garg *et al.*[10] AS, Aortic Stenosis; FD, Flow Displacement; FRR, Flow Reversal Ratio; LV, Left Ventricle; TAVI, Transcatheter Aortic Valve Implantation

with severe AS patients (4.1 ± 1.2 to $3.5 \pm 0.8\%/cm^2$, *P*-value <.05, and 4.0 ± 1.1 to $2.5 \pm 0.7\%/cm^2$, *P*-value <.0001, respectively) and were comparable to non-AS control values at six months (*P*-value =.08 and = .06, respectively). As expected, DurAVR implantation was associated with significant improvement in echocardiographic-derived parameters such as lower mean aortic valve gradient (9.1 mmHg), higher EOA (2.1 cm^2), and higher dimensionless velocity index (0.59; all *P*-values <.0001). Finally, multivariable regression analysis demonstrated the significant association of LV mass regression with the reduction of mean gradient by echocardiography and of FRR by CMR, with variation in the latter providing additional independent explanatory contribution to LV mass regression.

These early observations are encouraging, and the authors are to be commended for exploring the context of flow restoration following TAVI with this novel, promising device. Nonetheless, it is important to underline some points that warrant careful consideration. First, current evidence derived predominantly from bench studies and early-phase, non-randomized clinical investigations: mechanistic hypotheses regarding long-term durability and flow organization remain largely untested *in vivo*. Second, comparative data with contemporary-generation devices are limited, and registry-based controls cannot fully account for residual confounding. Accordingly, the results of the dedicated CMR sub-study of the randomized controlled PARADIGM trial (NCT07194265) comparing flow restoration through the DurAVR system with commercially available TAVI systems in a broad patient population are eagerly awaited. Third, as the authors correctly acknowledge, aortic flow assessment was performed using through-plane phase-contrast imaging at a single proximal ascending aortic level, which is a practical and readily applicable approach to characterize flow, but limited in fully capturing the three-dimensional complexity of aortic haemodynamics, thereby limiting detailed insights into the meticulous evaluation of intravascular energetic phenomena.

So, where do we go from here? The potential significance of these findings extends beyond conventional haemodynamic metrics. Preliminary data from 4D flow CMR studies in native and prosthetic valves suggest that restoration of organized flow may be associated with improved kinetic energy efficiency and reduced turbulent dissipation.[6,7] Although such analyses remain largely confined to research settings, they provide a conceptual framework to interpret why devices with similar gradients might differ in long-term performance. Within this framework, the DurAVR platform can be viewed as novel technology attempting to reproduce native valve geometry and, potentially, physiological flow patterns. As advanced flow imaging techniques are not yet standardized for routine clinical use, their integration into prospective trials will be essential to validate flow-based surrogate endpoints. The evolution of TAVI toward younger and lower-risk populations has intensified the need for devices that combine procedural safety with sustained haemodynamic and structural performance. In this context, design-driven approaches aimed at restoring physiological flow may represent an important strategic direction.

The DurAVR system features a unique leaflet design, but durability data are currently limited to short-term follow-up and warrant cautious interpretation. Although the short-frame valve configuration is intended to facilitate future redo-TAVI, durable leaflet performance remains essential to avoid premature reintervention. If early haemodynamic and flow-organizational benefits are ultimately associated with enhanced long-term durability, this would constitute a paradigm shift in TAVI procedural success, emphasizing lifetime management rather than short-term haemodynamic endpoints.

Ongoing randomized trials and dedicated imaging sub-studies will be critical to determine whether these theoretical advantages translate into durable clinical benefit. Nonetheless, the DurAVR experience illustrates a broader shift in how transcatheter valve performance is assessed: moving beyond a narrow focus on pressure gradients toward a more integrated evaluation of flow physiology and energetic efficiency, underscoring the importance of moving beyond conventional metrics when evaluating next-generation transcatheter valves. Future research integrating long-term outcomes with advanced flow imaging will determine whether restoring physiological flow can become a cornerstone of durable TAVI success.

Author contributions

Davide Margonato (Conceptualization [lead]; Writing—original draft [lead]), and Andrea Scotti (MD (Conceptualization [supporting]; Validation [supporting]; Writing—review & editing [equal]))

Declarations

Disclosure of Interest

Dr A.S. serves as a local Principal Investigator for PARADIGM—Randomized Clinical Trial Assessing the Safety and Effectiveness of the DurAVR System.

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