

## Re: Is valve choice a significant determinant of paravalvular leak post-transcatheter aortic valve implantation? A systematic review and meta-analysis

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**Keywords:** Aortic valve • Replacement • Heart valve • Transapical • Percutaneous

Paravalvular regurgitation (PVR) significantly increases mortality from 35.3% for mild PVR to 60.8% for moderate-to-severe PVR as reported in the PARTNER trial in 3-year transcatheter aortic valve implantation (TAVI) outcomes [1].

PVR results from incomplete apposition of the prosthesis to the aortic annulus. Recognizing the underlying mechanism is important to improve TAVI outcomes further. Understanding the etiology of what might seem a simple equation of two variables—first, the aortic valve and root complex and second, the TAVI device—is a challenging undertaking.

Additional variables add to the complexity leading to PVR after TAVI. Adequate imaging focusing not only on annular diameter, but also on circularity, distribution of aortic valve calcifications or left ventricular outflow tract (LVOT)/aortic root angulation, impacts on the choice of device size and type. Mechanical properties and stent design as well as access direction or delivery strategies are further determinants of PVR and subsequently survival outcomes. Assessment and quantification of PVR are not standardized, and the degree of regurgitation of various studies is difficult to compare. At present, even the adoption of the Valve Academic Research Consortium (VARC) consensus document [2], the standard classification used to describe regurgitation in native valves, does not guarantee comparable PVR assessments. Multi-located eccentric jets make quantitative echocardiographic evaluation difficult. Stent and calcification induced shadowing interfere with flow signals and transthoracic two-dimensional echocardiography might underestimate the degree of regurgitation. When interpreting the present meta-analysis data, those facts need to be considered carefully.

In this issue, O'Sullivan *et al.* [3] reviewed the literature reporting on PVR after TAVI. Nine publications including nearly 6000 patients were identified to report PVR data of either the balloon-expandable Edwards Sapien (ES; four publications) or the self-expanding Medtronic Corevalve (MCV) device (two publications) or both devices (seven publications).

To support their observational conclusion that the self-expanding MCV device has a significantly higher rate of PVR compared with the balloon-expandable ES valve, the authors defined

two variables: first, modifiable factors being technological issues and second, non-modifiable factors being anatomical considerations leading to PVR.

In particular, as modifiable factors were identified: stent design including material properties and construction particularities, deployment position and prosthesis/annulus mismatch including sizing. Non-modifiable factors predisposing to PVR were the angle between LVOT and aortic root as well as aortic valve calcifications. Even though the France 2 register [4] and the UK TAVI registers [5] indicate that the antegrade transapical TAVI approach has a significantly lower incidence of PVR when compared with all retrograde routes, the authors did not analyse the impact of access route on PVR in this paper.

The authors primarily discuss stent designs, material characteristics and deployment technique as modifiable factors for PVR. An MCV self-expanding nitinol stent having continuous radial expansion forces results in higher compliance in the non-circular anatomy. In comparison, an ES stainless steel stent exhibits a higher stiffness better withstanding the compressive forces of the calcified valve resulting in high degree of circularity in 98.5% of implants [6]. Valve positioning and prosthesis/annulus incongruence are further elaborated under valve-related modifiable factors leading to PVR.

Despite the evidence for increased PVR and the intrinsic insight into the mechanistic origin of PVR in the MCV device, there are limitations to be considered. The absence of randomized studies comparing the two devices in all-comers presents an important drawback. The choice of device type might be influenced by anatomical considerations and site-specific consideration, for example favouring a self-expanding device in a massively calcified aortic valve. Accordingly, an ES device is favoured in the hostile setting of strong LVOT/aortic root angulation. Both conditions might lead to increased PVR in either device and induce a device selection bias.

Mechanistic insights into PVR after TAVI set aside, the authors in their meta-analysis found a significant increase in PVR in patients undergoing an MCV implantation compared with those undergoing an ES implantation. Further studies are mandatory to confirm the present findings.

PVR after TAVI remains an unresolved driver of independent significantly higher mortality. All efforts should be made to eliminate PVR before expanding TAVI indication to lower risk and younger patients. The solution to a technical problem often is more technology. Next-generation TAVI devices, improved imaging and a percutaneous antegrade transapical TAVI platform might contribute to reducing TAVI-related PVR.

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