

## From gradients to lifetime strategy: rethinking TAVI choice in small aortic roots

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Over the past two decades, transcatheter aortic valve implantation (TAVI) has transformed the management of aortic stenosis and has become the emblem of structural heart innovation. What started as a rescue option for inoperable patients is now a mainstream therapy across the entire risk spectrum<sup>1</sup>. With expanding indications, particularly in lower-risk patients with an expected survival well beyond 10 years, a natural question arises: is the innovation cycle in TAVI complete, or are we just entering a new phase? Can what has been transformational be further refined by incremental innovation?

In the early TAVI era, success meant crossing the valve, avoiding catastrophes and achieving an acceptable gradient. Today, this is no longer enough. For both TAVI and surgical aortic valve replacement (SAVR) operators, the index valve procedure must be planned as the first step of a lifelong strategy. Short-term safety still matters enormously and depends on three elements: patient anatomy and comorbidities, device selection, and operator performance. But current aortic interventions should be planned and performed with a long-term perspective: prosthesis durability, coronary access, feasibility and safety of redo-TAVI or surgical explant, and the impact of prosthesis-patient mismatch (PPM) or conduction disturbances on lifetime management. The device we choose today determines not only early haemodynamics but also what we will be able to offer when the valve inevitably degenerates.

This broader view is reinforced by changes both upstream (timely intervention) and downstream (better follow-up and management) of the procedure. In this continuum, device design remains crucial: it is not a technical detail; it is a major determinant of future options.

Interventions in small aortic annuli remain a challenge. SAVR in this setting frequently yields high postoperative gradients, small effective orifice areas, and a high rate of PPM, all associated with higher mortality, more heart failure hospitalisations, and accelerated bioprosthetic degeneration<sup>2,3</sup>. TAVI is not the final solution; in fact, small annuli magnify the trade-offs between different device platforms. A recent trial did not find different clinical outcomes between TAVI and SAVR in patients with small aortic annuli<sup>4</sup>.

Registry and randomised data have consistently shown that in small annuli, supra-annular self-expanding valves (SEVs) tend to provide lower gradients and fewer PPM than intra-annular balloon-expandable valve (BEV) platforms but at the cost of more paravalvular leaks, and higher rates of permanent pacemaker implantation. The SMART trial<sup>5</sup> and TAVI-SMALL<sup>6</sup> registries have made many operators favour self-expanding valves in this anatomy when long-term haemodynamics and durability are perceived as the priority, particularly in younger patients. Conversely, BEVs are often preferred when paravalvular leak, coronary access, or precise positioning are the main concerns, accepting higher gradients as the price to pay.

In this issue of EuroIntervention, De Backer and colleagues<sup>7</sup> challenge the previous dichotomy, where, in small roots, the choice had been “better gradients” versus “more controlled implant and fewer pacemakers”.

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The DurAVR transcatheter heart valve (Anteris Technologies) introduces two relevant concepts: a short-frame balloon-expandable platform and a single-piece biomimetic leaflet made from bovine pericardium treated with an anticalcification

process. The leaflet is moulded to mimic native aortic cusp geometry, with long coaptation and the promise of more physiological opening and closing, more laminar ascending aortic flow and, ultimately, better durability.

In their pooled analysis of 100 patients with small annuli treated with the “small” DurAVR size, the authors report Valve Academic Research Consortium 3 technical success of 93% overall, and 100% in the last 50 cases; with no deaths and 2% stroke at 30 days. Haemodynamic performance was outstanding with a mean gradient of  $8.2 \pm 3.1$  mmHg and a mean effective orifice area of  $2.2 \pm 0.3$  cm<sup>2</sup>. This resulted in a moderate or severe PPM in only 3%. Such outcomes were achieved with a very reasonable permanent pacemaker rate of 6%.

For a balloon-expandable valve in a small annulus cohort, these figures are striking. The profile is SEV-like haemodynamics with BEV-like control and a low pacemaker rate. The short frame with large open cells and the possibility of commissural alignment may also help preserve coronary access and future TAVI-in-TAVI options. All these features are crucial in small roots, where the risk of sinus sequestration and coronary obstruction during redo procedures is intrinsically higher.

Of course, this is early, non-randomised, industry-sponsored evidence in a relatively small and highly selected population, with limited follow-up. But as a proof of concept, it suggests that thoughtful, “incremental” device innovation can soften, if not fully erase, the historical BEV-SEV trade-off.

A large number of new TAVI devices are entering the market, with unique features<sup>8</sup>. More options should reinforce an anatomy and lifetime-based decision algorithm rather than promote device enthusiasm. For older, frailer patients with limited life expectancy, well-established TAVI platforms (either SEV or BEV) already offer excellent outcomes, and the incremental benefits of a novel valve are less clear. On the other hand, there are several unmet needs including the management of small aortic roots, repeat procedures, longer durability, coronary access and several other challenges that will benefit from future innovation in the field. These results should push both surgeons and interventionalists to discuss lifetime management upfront: mechanical versus bioprosthetic choice, aortic root enlargement versus TAVI in very small roots, the likelihood and sequence of future redo procedures, and how each device option aligns with the patient’s age, comorbidities and preferences.

Innovation in TAVI is far from finished: there is still a need for refinements in valve design and material science to improve durability and haemodynamics, along with the introduction of smart devices and advanced pharma integration to improve long-term clinical outcomes. Outcomes in the future can be improved by upstream strategies for early detection of disease and timely treatment, as well as innovative gene and ribonucleic acid therapies to delay or stop progression of the disease. Artificial intelligence in all its possible declinations, from big data management, real data online contributing to real-world decision-making, to robotics, automation, and real-time copiloting will flood our field and improve practice.

Incremental innovation will pursue the objective of better lifetime management: the key question is no longer “which valve gives the lowest gradient today?” but rather “which strategy keeps the most doors open for this patient over the next 20 or 30 years?” Innovative new devices like the

biomimetic balloon-expandable DurAVR may become valuable tools in that strategy, provided we remain rigorous, cautious, and patient-centred as we test their promise.

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