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Prosthesis durability and anatomy in transcatheter aortic valve implantation decision-making

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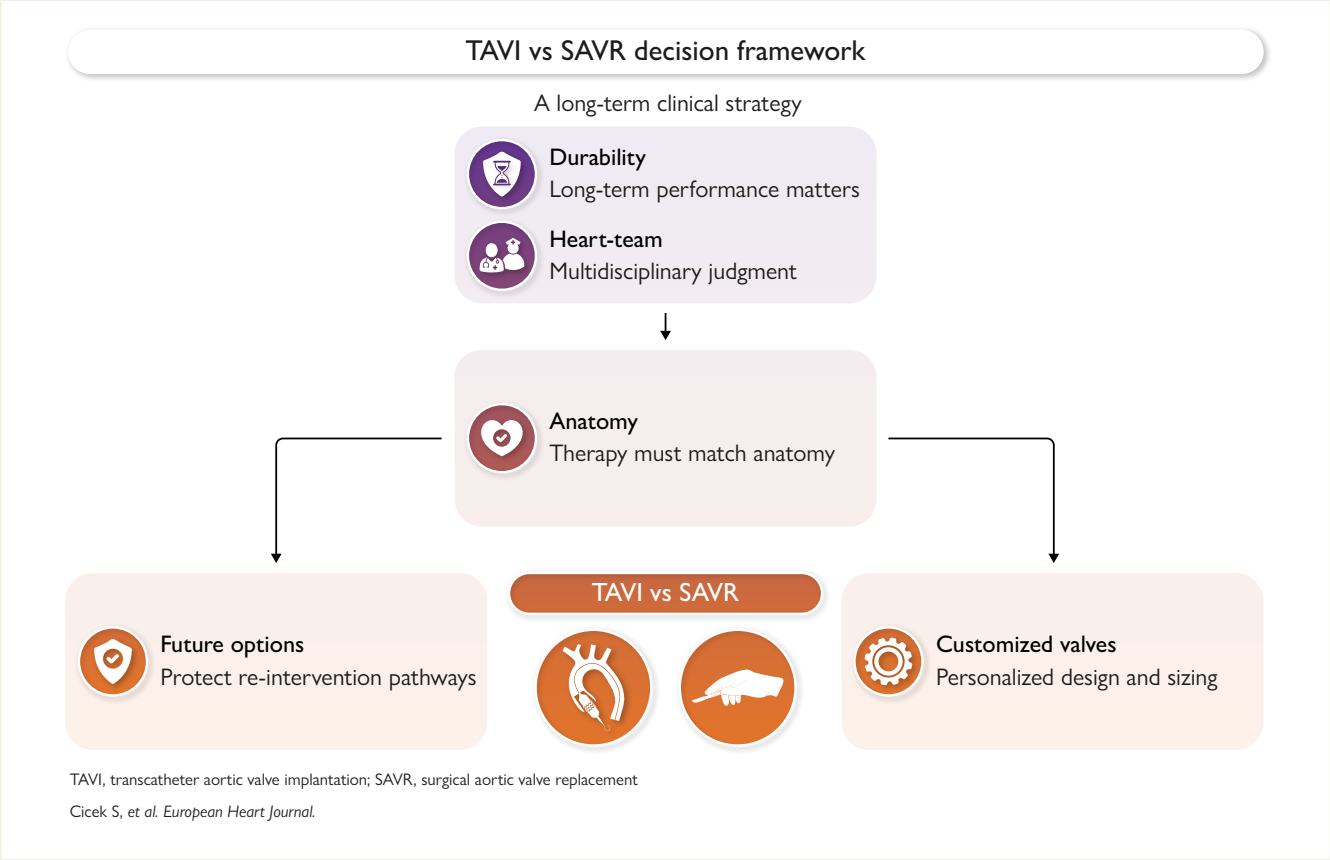
Graphical Abstract



Pillars of TAVI vs SAVR decision-making.

The problem with contemporary transcatheter aortic valve implantation (TAVI) practice is no longer a question of 'high-risk' vs 'low-risk' patients. What began as a carefully defined therapy for inoperable or surgically prohibitive patients has evolved into an almost indiscriminate extension across the risk spectrum. The central question has therefore

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changed: the key determinant is no longer patient risk, but patient anatomy.

The two axes of precision valve therapy

Anatomy governs feasibility. Procedural success depends foremost on anatomic factors: annular geometry, leaflet morphology, coronary height, sinus width, calcification pattern, aortic angulation, and vascular access.[1] A frail octogenarian with favourable anatomy may undergo TAVI safely, whereas a robust younger patient with a bicuspid valve or narrow sinuses may face greater procedural hazard. The heart-team algorithm must begin not with comorbidity but with anatomy; the structural terrain on which all other variables rest. Crucially, today's procedural choices govern tomorrow's possibilities. Surgical decisions such as supra- vs intra-annular positioning, stent height, or annular enlargement determine future valve-in-valve feasibility. Likewise, transcatheter strategies that respect sinus geometry and aim for commissural alignment preserve coronary access in future. Prosthesis selection and implantation technique are therefore acts of long-term planning, not procedural preference.

Anatomy defines the technical terrain; durability defines the temporal horizon. A technically perfect procedure has diminished value if the valve fails within a decade. Long-term follow-up from major low-risk TAVI trials underscores this concern. Midterm results now show early TAVI advantages in low-risk patients do not persist, with equipoise or catch-up by 5 years and fragile meta-analytic signals supporting a recalibration of low-risk recommendations that centres lifetime strategy rather than 1-year endpoints.[2,3]

At present, 5-year data indicate that the actual freedom from structural valve deterioration of transcatheter aortic bioprostheses is comparable to that seen in surgical bioprosthetic valves. Yet the trajectory beyond these years, particularly in younger patients, where accelerated degeneration remains a concern.[4]

The evidence informing valve durability must be interpreted through the structural limitations of its sources. Registries capture real-world practice but remain vulnerable to residual confounding, heterogeneity, and incomplete longitudinal follow-up. Randomized trials, while methodologically rigorous, achieve internal validity by imposing extreme selection—excluding many younger, anatomically complex, and high-risk patients in whom durability is most consequential. As Barili *et al.*[5] have shown, this selection creates systematic distortions in randomized comparisons of TAVI and surgical aortic valve replacement (SAVR). Doenst *et al.*[6] have further demonstrated that contemporary TAVI–SAVR trials are additionally influenced by a powerful technician bias, whereby above-average operators and centres generate outcomes that disproportionately favour TAVI and obscure the long-term survival advantage of surgery consistently observed in large registry-based analyses. The apparent mid-term equivalence between TAVI and SAVR should therefore not be interpreted as biological parity, but rather as an artefact of selectively constructed 'duels' that fail to reflect the true population in whom valve durability ultimately matters most.

Physiological resilience (frailty) modulates both axes, determining whether anatomical feasibility and temporal promise can translate into lasting success. Yet resilience is a modifier, not a third pillar; it defines the horizon of tolerance within which anatomy and durability interact.

The future of valve therapy must therefore rest on anatomy- and durability-based assessment not on arbitrary patient data derived from outdated surgical databases and scoring systems.

The missing comparator

Nearly all TAVI vs surgery trials have compared TAVI with bioprosthetic AVR, not mechanical valves, which biases interpretation. Modern mechanical prostheses, particularly the On-X valve, have demonstrated safe performance under low-INR protocols.[7] Comparing a percutaneous bioprosthesis in a 50-year-old to a surgical tissue valve is methodologically incomplete; comparing it to a modern mechanical valve is the only apple-to-apple evaluation that respects a lifetime horizon.

In the STS-linked analysis of 109 842 patients aged 40–75 years, Bowdish *et al.*[8] found that mechanical AVR conferred a significant survival benefit in patients ≤60 years [adjusted HR 0.69 (95% CI 0.59–0.79) for ages 40–49; 0.87 (95% CI 0.80–0.94) for ages 50–59], with parity emerging at 60–69 years [HR 0.99 (95% CI 0.91–1.08)].

Quality of life and the anticoagulation myth

The debate between mechanical and bioprosthetic valves has long rested on assumptions rather than evidence. To this day, no single study has conclusively demonstrated that quality of life is superior with bioprosthetic valves.[9] Contemporary data show no meaningful difference in health-related QoL between mechanical and bioprosthetic AVR in middle-aged cohorts.[10] Indeed, with modern anticoagulation management, the rates of bleeding and thromboembolic events among mechanical valve recipients are far lower than the historical narrative suggests.[11] The notion that avoiding anticoagulation inherently improves life quality remains more cultural than clinical.

If durability were the only measure of value, the hierarchy would be unambiguous: the mechanical valve remains unmatched. But the problem is not simply the data; it is our collective willingness to ignore them. Durability has been quietly relegated to the background, replaced by early recovery, cosmetic appeal, and the seductive simplicity of a percutaneous option.

Ethics and communication

The notion of 'aligning therapy with patient expectations' has become an ethical shortcut. Alignment cannot substitute for evidence; expectations are shaped by the information physicians provide. Patients must be told, clearly and without euphemism, that 'minimally invasive' does not always mean minimal in consequence and that a bioprosthetic valve in a younger patient will almost certainly fail within their lifetime. To omit this truth is not respect for autonomy; it is a failure of informed consent.

These considerations become even more consequential in low- and middle-income countries, where the clinical question is inseparable from infrastructure, access to surveillance, and cost of repeat interventions. In such settings, durable surgical solutions including mechanical prostheses, may offer the most rationale lifetime value.

Caution is therefore required when extrapolating guideline expansions generated in resource-rich environments to global populations whose risks and treatment horizons are fundamentally different.

Recent long-term data remind us of these boundaries. In low-risk cohorts, 5-year outcomes between TAVI and SAVR show similar survival and stroke rates.[2,3] Yet the same data caution that valve degeneration and reintervention remain poorly characterized in younger patients. PARTNER-3 was, first and foremost, a non-inferiority trial; any 'superiority' claim derives from a pre-specified, hierarchical test applied to a one-year composite that bundled hard outcomes (death, stroke) with a softer one (cardiovascular rehospitalization). It is methodologically and ethically questionable to headline 'superiority' from a non-inferiority framework, particularly when driven by softer endpoints and not sustained over time.

The 7-year PARTNER-3 results provide the longest randomized comparison of TAVI and SAVR in low-risk patients, demonstrating similar rates of death, disabling stroke, rehospitalization, and sustained valve performance.[12] These findings are reassuring for the studies specific cohort with favourable anatomy. However, key asymmetries were identified: one quarter of surgical patients underwent concomitant CABG, while none had PCI; surgical valve types were non-standardized; valve thrombosis (2.8% vs 0.5%) and paravalvular leak (17.7% vs 2.0%) were far more frequent after TAVI. Late mortality drift favoured surgery (19.5% vs 16.8%), and crossing hazard estimates indicated non-proportional risk over time.

An equally relevant real-world signal comes from the independent DEDICATE-DZHK6 trial in low- to intermediate-risk patients.[13] At 12 months, the composite of all-cause death or stroke occurred in 5.4% with TAVI vs 10.0% with SAVR (HR 0.53; 95% CI, 0.35–0.79), reinforcing that TAVI can reduce early major adverse events in well-selected anatomies. Yet like previous trials, DEDICATE remains event-driven and short-term, leaving durability, coronary access, and reintervention risk unresolved in younger patients.

Between precision and enthusiasm

Protecting the integrity of the heart-team model is essential. The expansion of TAVI into centres without on-site cardiac surgery risks transforming multidisciplinary evaluation into unidirectional referral. In such environments, the absence of balanced surgical input can compromise patient autonomy, informed consent, and emergency safety nets that only surgical presence provides.

The authors of this editorial are not opponents of TAVI. On the contrary, we regard it as one of the most transformative advances in modern cardiovascular medicine when used appropriately. Transcatheter aortic valve implantation has saved lives, expanded access, and redefined structural intervention. But the reality today is far more complex. The greatest threat to the future of TAVI is not its limitations, but its uncontrolled practice. The future of valve therapy depends on a compass oriented towards two coordinates: anatomical feasibility and temporal durability, moderated by physiological resilience. The art of decision-making lies not in choosing the faster route, but the one that remains open longest. Lifetime management is therefore the true determinant of value. The first intervention sets the boundaries for every subsequent one.

Valve-in-valve procedures accumulate anatomic penalties: rising gradients, reduced sinus volume, and increasing difficulty of coronary re-access. Redo-TAVI exposes patients to unknown frame-in-frame durability, while SAVR after TAVI can involve complex and morbid explantation of an embedded stent frame. Looking ahead, advances in transcatheter engineering including 3D patient-specific modelling, commissural alignment strategies, and customizable valve architectures may expand the anatomic boundaries and long-term durability of TAVI, but these innovations must be judged by the same lifetime standards that guide today's decision-making. SAVR and TAVI must therefore be viewed not as competing therapies; they should be sequenced components of a lifetime strategy.

Declarations

Disclosure of Interest

Nothing to declare.

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