

EDITORIAL COMMENT

Balloon-Expandable Transcatheter Heart Valve Hemodynamic Parameters

Time to Reconsider What They Mean



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Small aortic annulus (SAA) remains a challenging subset in aortic valve replacement. In surgical aortic valve replacement (SAVR), SAA has traditionally raised concerns regarding prosthesis-patient mismatch (PPM), elevated residual mean pressure gradient (mPG), and adverse late outcomes.¹ In transcatheter aortic valve replacement (TAVR), this issue is more complex. Balloon-expandable (BE) transcatheter heart valves (THVs) are intra-annular devices and may show higher mPGs and more frequent PPM, especially in patients with SAA. Whether these echocardiographic findings translate into worse clinical outcomes or impaired valve durability remains uncertain.

In this issue of *JACC: Cardiovascular Interventions*, Madhavan et al² report an important subanalysis of the PARTNER (Placement of Aortic Transcatheter Valves) 3 trial evaluating BE TAVR vs SAVR according to computed tomography-derived annular size. This is not simply another SAA subgroup analysis. Its key novelty is the randomized comparison between BE TAVR and SAVR while addressing a BE THV-specific question: whether higher gradients and PPM in small annuli should alter the interpretation of clinical risk. In the SAA stratum, BE TAVR showed a higher frequency of mPG ≥ 20 mm Hg than SAVR. However, 5-year death, stroke, or rehospitalization and bioprosthetic valve failure (BVF) were similar across treatment and annular size strata.

These findings are consistent with a growing body of randomized and multicenter BE THV studies with at least 3 years of follow-up (Table 1).²⁻⁶ Across these studies, SAA or 20-mm BEV implantation was associated with less favorable forward hemodynamic status. However, the absolute frequency of mPG ≥ 20 mm Hg and severe PPM varied markedly across cohorts. In Western data sets, elevated gradients and severe measured PPM were often more frequent, whereas Japanese cohorts showed lower severe PPM rates despite similarly small annular anatomy. These differences likely reflect racial and body-size differences, sex distribution, flow state, echocardiographic methodology, and definitions of measured PPM rather than valve design alone.

Table 1 highlights a consistent paradox. Less favorable hemodynamic status is repeatedly observed in SAA or 20-mm BEV recipients, but these findings have not consistently translated into worse mortality, heart failure hospitalization, or BVF. Importantly, in studies that reported BVF, this endpoint was evaluated using Valve Academic Research Consortium 3-based definitions, supporting the clinical relevance and comparability of these durability findings.⁷ This pattern challenges a direct transfer of the surgical PPM paradigm to BE THVs. In the SAVR literature, PPM has been associated with impaired long-term survival in a large systematic review and meta-analysis.¹ After BE THV implantation, however, Doppler-derived mPG and measured PPM may represent a different hemodynamic phenotype rather than a direct marker of clinical failure.

The key contribution of the PARTNER 3 subanalysis is the addition of the SAVR comparator. In SAA, BE TAVR showed more frequent mPG ≥ 20 mm Hg than SAVR, whereas severe PPM, BVF, and clinical outcomes were not worse. This

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TABLE 1 Long-Term Randomized and Multicenter BE THV Studies in Small Annuli or 20-mm Valves

Study	Design	Comparison	n	Definition	Hemodynamic Data	BVF/Durability	Clinical Outcomes
Madhavan et al (2026) ²	RCT subanalysis	BE TAVR vs SAVR; stratified by annular size	Total, 925; small, 293; large, 632	CT area ≤ 430 mm ²	- mPG ≥ 20 mm Hg: small, 14.3% vs 3.8%; large, 3.4% vs 4.3% - Severe PPM: small, 10.1% vs 12.3%; large, 2.1% vs 3.1%	5-y BVF: small, 4.4% vs 6.8%; large, 2.9% vs 2.7%; similar	5-y death, stroke, or rehospitalization: small, 21.2% vs 31.0%; large, 23.5% vs 25.5%; no significant interaction
Hahn et al (2025) ³	RCT + multicenter registry	BE TAVR only; small vs large annulus	Total, 1,355; small, 476; large, 879	CT area ≤ 430 mm ²	- mPG: 1 y, 14.7 ± 6.0 mm Hg vs 11.2 ± 4.4 mm Hg; 5 y, 15.4 ± 8.0 mm Hg vs 10.6 ± 4.6 mm Hg - mPG ≥ 20 mm Hg: 11.4% vs 3.5% - Severe PPM: 11.1% vs 4.1%	5-y BVF: 2.9% vs 2.1%; similar	5-y all-cause death, disabling stroke, or heart failure hospitalization: 36.3% vs 35.8%; similar
Yamamoto et al (2025) ⁴	Multicenter registry	BE TAVR only; small vs large annulus	Total, 2,699; small, 1,793; large, 906	CT area ≤ 430 mm ²	mPG: 13.13 ± 4.92 mm Hg vs 10.41 ± 4.23 mm Hg mPG ≥ 20 mm Hg: 8.5% vs 1.8% Severe PPM: 3% vs 1%	7-y BVF: 3.3% vs 2.7%; similar	7-y all-cause death: 55.2% vs 58.6%; similar
Eng et al (2024) ⁵	Multicenter registry	20-mm vs ≥ 23 -mm BEV	Total, 316,091; 20 mm, 8,102; PS matched, 8,100 pairs	20-mm BEV	mPG: 16.2 ± 7.2 mm Hg vs 11.8 ± 5.7 mm Hg mPG ≥ 20 mm Hg: 26.4% vs 6.9% Severe PPM: 20.0% vs 8.2%	Not primary durability endpoint	3-y all-cause death: 31.5% vs 32.5%; similar
Okuno et al (2025) ⁶	Multicenter registry	20-mm vs >20 -mm BEV	Total, 5,086; PS matched, 1,092	20-mm BEV	mPG: 16.9 ± 6.2 mm Hg vs 12.5 ± 4.9 mm Hg mPG ≥ 20 mm Hg: 26.8% vs 6.7% Severe PPM: 4.9% vs 1.5%	Not primary durability endpoint	5-y all-cause death: 34.2% vs 38.0%; heart failure rehospitalization: 15.2% vs 16.3%; similar

^aDerived from the reported overall and small-annulus proportions with 30-day mPG <20 mm Hg. BVF was evaluated using Valve Academic Research Consortium 3-based definitions in studies reporting BVF.
BE = balloon-expandable BEV = balloon-expandable valve; BVF = bioprosthetic valve failure; CT = computed tomographic; mPG = mean pressure gradient; PPM = prosthesis-patient mismatch; PS = propensity score; RCT = randomized clinical trial; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

finding does not mean that hemodynamic status is irrelevant. Rather, it suggests that isolated post-procedural mPG elevation or measured PPM after BE THV implantation should not automatically be interpreted as early valve failure or poor prognosis.

This distinction has practical implications. The PARTNER 3 subanalysis itself provides an important example: stage 2/3 bioprosthetic valve dysfunction was numerically more frequent after BE TAVR, but this signal was driven largely by valve thrombosis, which is often reversible with oral anticoagulation, whereas the more clinically relevant endpoint of BVF remained similar between BE TAVR and SAVR across annular strata.² Therefore, a stable mildly elevated mPG after BE THV in SAA may be acceptable, especially when the patient is asymptomatic and valve morphology is preserved. In contrast, a progressive rise in gradient, new symptoms, reduced leaflet motion, valve thickening, or new or worsening regurgitation should prompt further evaluation for leaflet thrombosis, early structural valve deterioration, or other causes of valve dysfunction. In such cases, serial echocardiography and multimodality imaging, particularly cardiac computed tomography, are

essential to distinguish reversible valve thrombosis from irreversible structural valve deterioration. When valve thrombosis is suspected, oral anti-coagulation may be appropriate; when irreversible valve dysfunction or clinically significant BVF is confirmed, reintervention should be considered. Thus, the clinical message is not to ignore gradients, but to determine why they occur, whether they progress, and whether they represent a treatable or irreversible valve-related process.

Several cautions remain. Current BE THV data in SAA extend mainly to 3 to 7 years, and robust 10-year evidence remains limited. This gap is important as TAVR expands to younger and lower risk patients with longer life expectancy. BVF events are still infrequent, limiting statistical power to detect modest but clinically meaningful durability differences. Cross-cohort comparisons are also vulnerable to differences in body size, race, sex distribution, valve generation, echocardiographic core laboratory use, and postprocedural imaging protocols.

In conclusion, the accumulating BE THV evidence supports a more nuanced interpretation of post-

TAVR hemodynamic status. SAA and 20-mm BEV implantation are associated with higher mPGs and more frequent severe PPM, but these findings have not consistently translated into worse mid-term clinical outcomes or BVF. Madhavan et al² add critical randomized evidence with a SAVR comparator and strengthen the message that, in BE-THV, hemodynamic status requires context. The next step is not to dismiss gradients but to define which gradients matter, in which patients, and over what time horizon.

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