Large Aortic Annulus in TAVR with Newer Generation Valves: An Entropy-Balanced Comparison of Balloon-Expandable Versus Self-Expanding Devices

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Background

TAVR is increasingly offered to lower-risk and anatomically complex patients, making device-specific performance in underrepresented subgroups increasingly relevant. Large aortic annuli pose distinct technical challenges: BEV risk incomplete annular conformability, while SEV depend on radial force and frame adaptation for sealing. Early comparative data from the CHOICE trial showed significantly higher moderate-to-severe PVL with older-generation SEV versus BEV in large annuli, a gap that narrowed substantially with next-generation platforms. Despite these advances, device-specific outcomes in large annuli with contemporary valves remain incompletely characterized, making these device-specific outcomes clinically relevant.

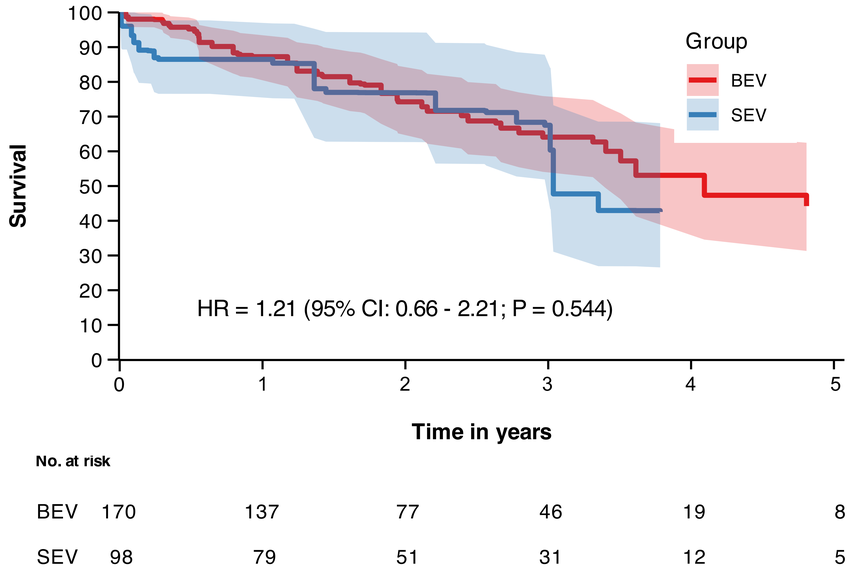
Methods

We retrospectively analyzed consecutive patients undergoing TAVR between January 2018 and December 2023. A large annulus was defined as a CT-derived annular area >575 mm² and/or perimeter >85 mm. Emergency procedures, endocarditis, active or prior cancer, immunocompromised status, redo aortic interventions, predominant aortic regurgitation, and bicuspid valves were excluded.

Entropy balancing was applied to achieve comparable baseline characteristics between BEV and SEV groups. Weighted categorical variables were expressed as sums of weights. Comparisons were performed using survey-adjusted statistical tests: design-adjusted t-tests for continuous variables, Rao–Scott chi-squared tests for categorical variables, and rank-based methods for non-parametric comparisons. Survival was assessed using weighted Kaplan–Meier analysis.

Results

A total of 268 patients were included (170 BEV, 98 SEV). After weighting, mean age was 80.7 ± 7.4 years in both groups. Only 1 female was present in the BEV group compared to 27 in the SEV group (SoW: 2.31 [1.4%] vs. 12.45 [12.7%], SMD=0.320). All other baseline characteristics were well balanced.



Conclusions

In patients with large aortic annuli undergoing TAVR, BEV and SEV demonstrated comparable 30-day clinical outcomes and mid-term survival. SEV was associated with lower rates of acute kidney injury and annular rupture, as well as superior hemodynamic performance, at the expense of increased resource utilization.

Outcome	BEV, SoW=170	SEV, SoW=98	p-value
Transfemoral, n (%)	166.54 (98.0)	90.76 (92.6)	0.052
Pre-dilatation, n (%)	17.13 (10.1)	77.81 (79.4)	**<0.001**
Post-dilatation, n (%)	4.03 (2.4)	13.17 (13.4)	**0.003**
Device size (%)			-
26	5.62 (3.3)	0 (0.0)	
29	164.38 (96.7)	31.06 (31.7)	
34	0 (0.0)	66.93 (68.3)	
Device (%)			-
Evolut FX	-	21.86 (22.3)	
Evolut PRO	-	37.07 (37.8)	
Evolut PRO Plus	-	39.08 (39.9)	
SAPIEN 3	163.25 (96.0)	-	
SAPIEN 3 Ultra	6.75 (4.0)	-	
Unplanned MCS, n (%)	0.47 (0.3)	2.98 (3.0)	**0.025**
Procedural cardiac arrest, n (%)	1.80 (1.1)	1.85 (1.9)	0.654
Intraoperative transfusion, n (%)	3.81 (2.2)	3.18 (3.2)	0.732
Valve malposition, n (%)	0 (0.0)	0 (0.0)	>0.999
2nd Valve implanted, n (%)	0 (0.0)	0 (0.0)	>0.999
Annulus rupture, n (%)	2.69 (1.6)	0.02 (0.02)	**<0.001**
Cardiac tamponade, n (%)	0 (0.0)	0.02 (0.02)	0.201
Coronary obstruction, n (%)	0 (0.0)	0 (0.0)	>0.999
Overt bleeding, n (%)	0 (0.0)	0 (0.0)	>0.999
Major vascular complication, n (%)	1.33 (0.8)	1.02 (1.0)	0.806
Minor vascular complication, n (%)	7.53 (4.4)	9.62 (9.8)	0.209
Creatinine, mg/dL, median [IQR]	1.2 [1.0, 1.6]	0.9 [0.8, 1.3]	**0.003**
Acute kidney injury, n (%)	4.77 (2.8)	0.41 (0.4)	**0.013**
New dialysis, n (%)	0 (0.0)	0.50 (0.5)	0.200
Stroke, n (%)	0 (0.0)	2.58 (2.6)	0.217
TIA, n (%)	0.66 (0.4)	0.45 (0.5)	0.903
Postoperative AMI, n (%)	0 (0.0)	0 (0.0)	>0.999
POAF, n (%)	1.72 (1.0)	2.70 (2.7)	0.353
New LBBB, n (%)	44.24 (26.0)	18.72 (19.1)	0.424
Postoperative transfusion, n (%)	10.96 (6.4)	4.70 (4.8)	0.769
LOS, days, mean (range)	1.8 (1-15)	2.1 (1-28)	**0.020**
LVEF, %, mean (SD)	57.4 (13.3)	58.9 (14.4)	0.580
EOA, cm², mean (SD)	2.53 (0.69)	2.44 (0.79)	0.554
iEOA, cm²/m², mean (SD)	1.20 (0.42)	1.26 (0.40)	0.528
Mean PG, mmHg, median [IQR]	10.0 [7.1, 12.5]	7.0 [5.0, 8.0]	**0.002**
PVL > Mild, n (%)	0.0 (0.0)	4.43 (4.5)	0.084
Central AR, n (%)			0.440
None/Trace	167.38 (98.5)	98.0 (100)	
Mild	2.62 (1.5)	0 (0.0)	
30-day new PMK, n (%)	34.51 (20.3)	22.51 (23.0)	0.739
30-day mortality, n (%)	3.32 (2.0)	5.91 (6.0)	0.195
30-day readmission, n (%)	21.79 (12.8)	16.01 (16.3)	0.603
30-day CV readmission, n (%)	17.41 (10.2)	8.22 (8.4)	0.737