Comparison of earlier- vs. latest generation self-expanding and balloon-expandable valve platforms for TAVI in large aortic annuli

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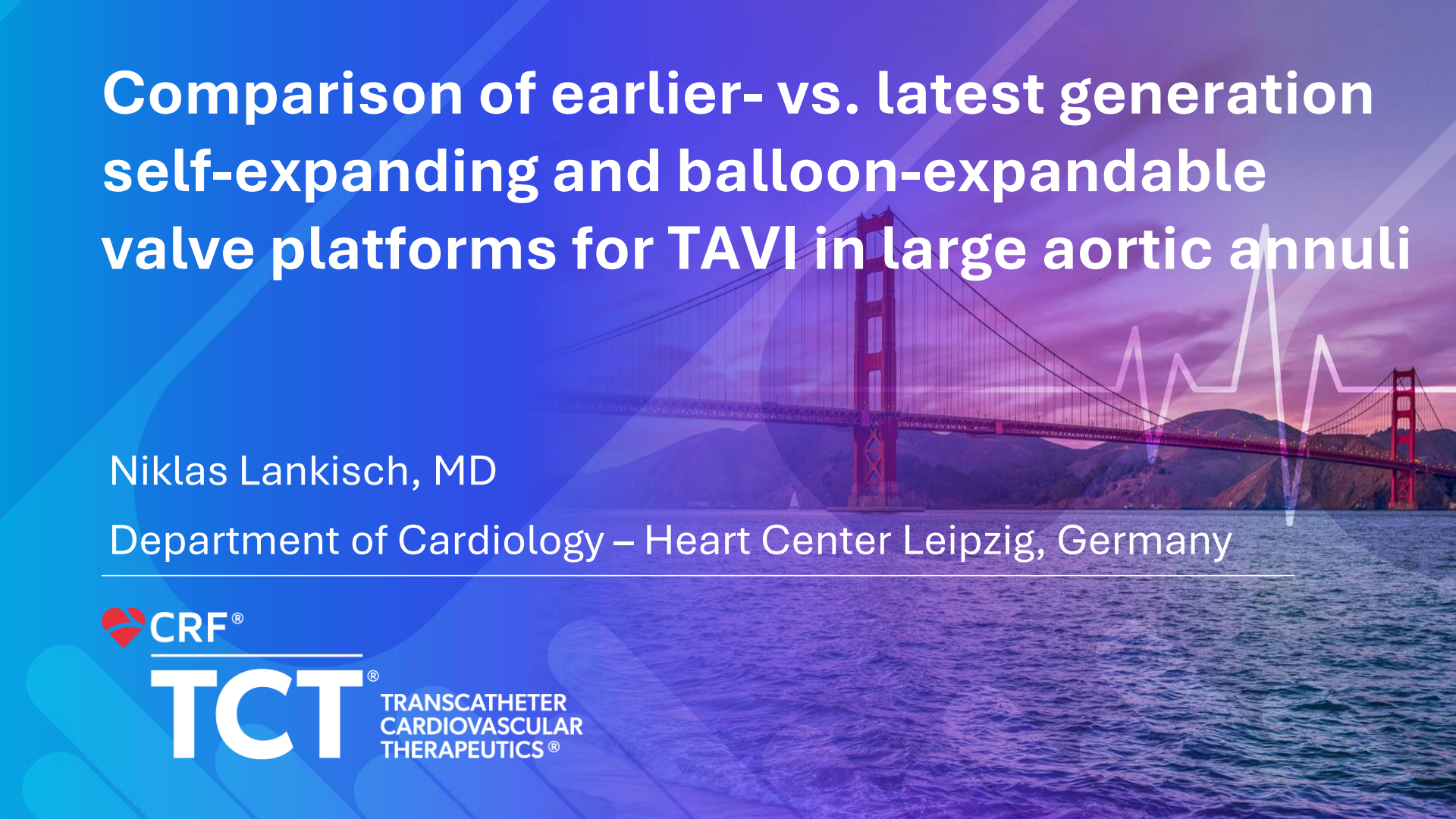

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Disclosure of Relevant Financial Relationships

I, Niklas J. M. Lankisch, DO NOT have any financial relationships to disclose.

Introduction - Definition of large aortic annulus

- Inconsistent definition of *large aortic annulus* in previous literature

Area >430 mm^2
- ➢ used in sub analysis Partner 2S3i and Partner 3[1]

Diameter of > 26 mm
- ➢ used in various retrospective studies[4,5]

Area of ≥ 548 mm
- ➢ determined by measuring quintiles of patients treated in 3 German centers[6]

Area ≥ 500 mm^2
- ➢ used in the OCEAN-registry[2] (Japan)

Perimeter > 80 mm
- ➢ used in a retrospective US-study[3]

Area >575 mm^2
- ➢ used in various retrospective head-to-head comparisons of S3 and EV-platform[7,8]

540 mm^2 chosen cut-off for the present study

S3	**26 mm**												**29 mm**									
EV FX+	**29 mm**											**34 mm**										
Area (mm^2)	**430**	**440**	**450**	**460**	**470**	**480**	**490**	**500**	**510**	**520**	**530**	**540**	**550**	**560**	**570**	**580**	**590**	**600**	**610**	**620**	**630**	**640**
Perimeter (mm)	**75.3**	**74.3**	**75.2**	**76**	**76.8**	**77.6**	**78.4**	**79.2**	**80**	**80.8**	**81.6**	**82.4**	**83.1**	**83.9**	**84.6**	**85.4**	**86.1**	**86.8**	**87.5**	**88.2**	**89**	**89.7**
Diameter (mm)	**23.4**	**23.7**	**23.9**	**24.2**	**24.5**	**24.7**	**25**	**25.2**	**25.5**	**25.7**	**26**	**26.2**	**26.5**	**26.7**	**26.9**	**27.2**	**27.4**	**27.6**	**27.9**	**28.1**	**28.3**	**28.6**

Introduction – Characteristics/Challenges

- Patients with large aortic annuli exhibit unique characteristics:
  - Predominantly male
  - Often associated with aorthopathies and horizontal aorta[1]
  - Higher incidence of bicuspid aortic valves[2]

- These characteristics impose significant challenges for TAVI procedures resulting in:
  - High rates of moderate-severe PVR, valve embolization and need for a second valve
  - Lower rates of device success

1)Gorla, R. et al. In-Hospital Outcomes and Predictors of Paravalvular Leak and Deep Implantation With the Evolut R 34-mm Device: A Comparison With Smaller Evolut R Sizes. Cardiovascular Revascularization Medicine 35, 19–26 (2022).
2) Higginson, C. et al. Prevalence and Phenotypic Characterization of Patients with Bicuspid Aortic Valve and Large Aortic Annular Diameter. J Am Soc Echocardiogr 36, 436–437 (2023).

Introduction - previous head-to-head comparisons (BEV vs. SEV)

Conclusion of published *head-to-head* comparisons in large aortic annuli:

	Device success	Valve embolization	Second valve required	Annular rupture	Mean gradient at discharge	moderate – severe PVR	Clinical endpoints
BEV	+	+	+	(-)	-	+	=
SEV	-	-	-	(+)	+	-	=

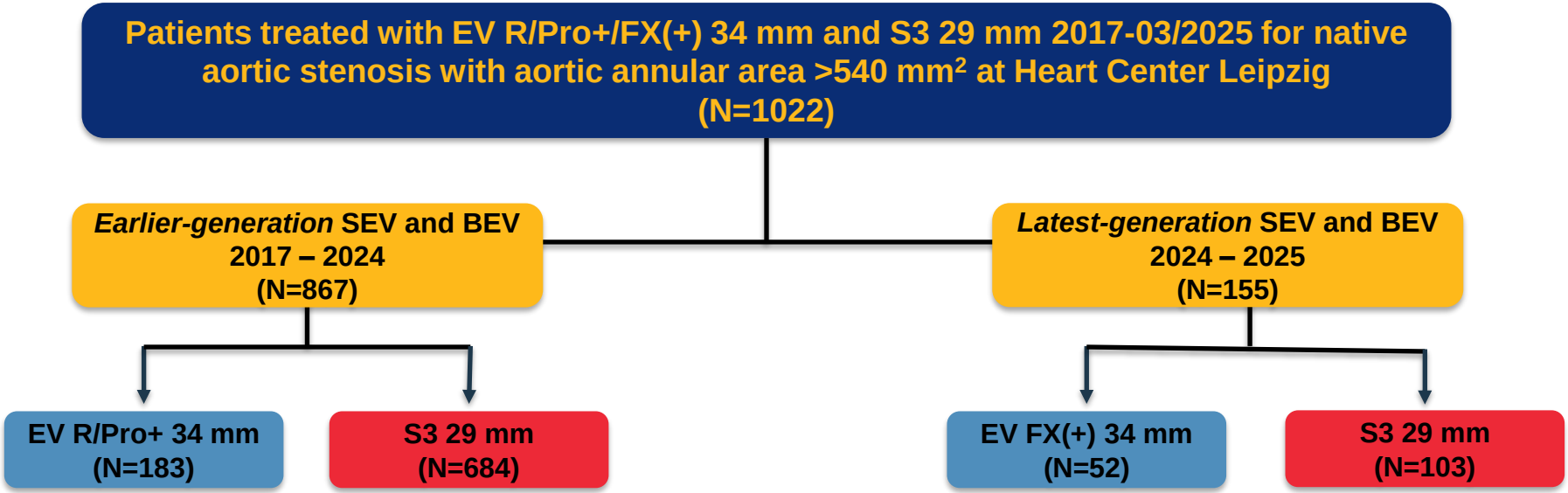
1) Hahn RT, Late Clinical Outcomes of Balloon-Expandable Valves in Small Annuli: Results From the PARTNER Trials. JACC Cardiovasc Interv. 2025
2) Onishi, K, Mizutani, K, Fujita, K. et al. Transcatheter Aortic Valve Implantation in Japanese Patients With Large Annulus: The OCEAN-TAVI Registry. JACC: Asia. 2024
3) Choice of Balloon-Expandable Versus Self-Expanding Transcatheter Aortic Valve Impacts Hemodynamics Differently According to Aortic Annular SizeRogers, Toby et al.American Journal of Cardiology
4) Dalian LAP, Tang G, Forrest JK, Reardon MJ, Sseto WY, Kodali SK, Baeza C, Eisenberg R, Attizzani GF. Transcatheter Aortic Valve Replacement in Large Annuli Valves With the Supra-Annular, Self-Expandable Evolut Platform in a Real-World Registry. Circ Cardiovasc Interv. 2023
5) Eitan A, Witt J, Stroppa J, Haselbach T, Rieß FC, Schofer J. Performance of the Evolut-R 34 mm versus Sapien-3 29 mm in Transcatheter aortic valve replacement patients with larger annuli: Early outcome results of Evolut-R 34 mm as compared with Sapien-3 29 mm in patients with Annuli ≥26 mm. Catheter Cardiovasc Interv. 2018
6) Schmidt S, Fortmeier V, Ludwig S, Wienemann H, Körber MI, Lee S, Meertens M, Macherey S, Iliadis C, Kuhn E, Eghbalzadeh K, Bleiziffer S, Baldus S, Schofer N, Rudolph TK, Adam M, Mauri V. Hemodynamics of self-expanding versus balloon-expandable transcatheter heart valves in relation to native aortic annulus anatomy. Clin Res Cardiol. 2022
7) Armijo G, Tang GHL, Kooistra N, Ferreira AN, Toggweiler S, Amat-Santos IJ, Keller LS, Urrera M, Ahmad H, Tafur Soto J, Muñoz-García E, Regueiro A, Leenders GE, Tirado-Conte G, Sengupta A, McInerney A, Couture T, Cuevas Herreros O, Rodriguez T, Kini A, Ahmed M, Zaid S, Gonzalo N, Nuñez-Gil IJ, Muñoz-García AJ, Jimenez-Quevedo P, Fernández-Ortiz A, Himbert D, Nietlispach F, Stella P, Dangas GD, Escaned J, Macaya C, Rodés-Cabau J, Nombela-Franco L. Third-Generation Balloon and Self-Expandable Valves for Aortic Stenosis in Large and Extra-Large Aortic Annuli From the TAVR-LARGE Registry. Circ Cardiovasc Interv. 2020
8) Moscarella E, Mangieri A, Giannini F, Tchetchè D, Kim WK, Sinning JM, Landes U, Kornowski R, De Backer O, Nickenig G, De Biase C, Søndergaard L, De Marco F, Bedogni F, Ancona M, Montorfano M, Regazzoli D, Stefanini G, Toggweiler S, Tamburino C, Immè S, Tarantini G, Sievert H, Schäfer U, Kempfert J, Wöehrle J, Latib A, Calabrò P, Medda M, Tespili M, Colombo A, Ielasi A. Annular size and interaction with transcatheter aortic valves for treatment of severe bicuspid aortic valve stenosis: Insights from the BEAT registry. Int J Cardiol. 2022

Rationale of the study

- Latest refinements of the self-expanding Evolut FX + have addressed challenges of TAVI in large aortic annuli
  - Enhanced flexibility of the catheter tip → better control for anchoring the THV at optimal implantation depth

- *Aim of the current study:*
  - To compare the earlier- and latest-generation SEV Evolut 34 mm with the BEV Sapien S3 29 mm platform

Methods – Study design



Primary endpoint:

- Device success as defined by VARC-3-Criteria

Secondary endpoints:

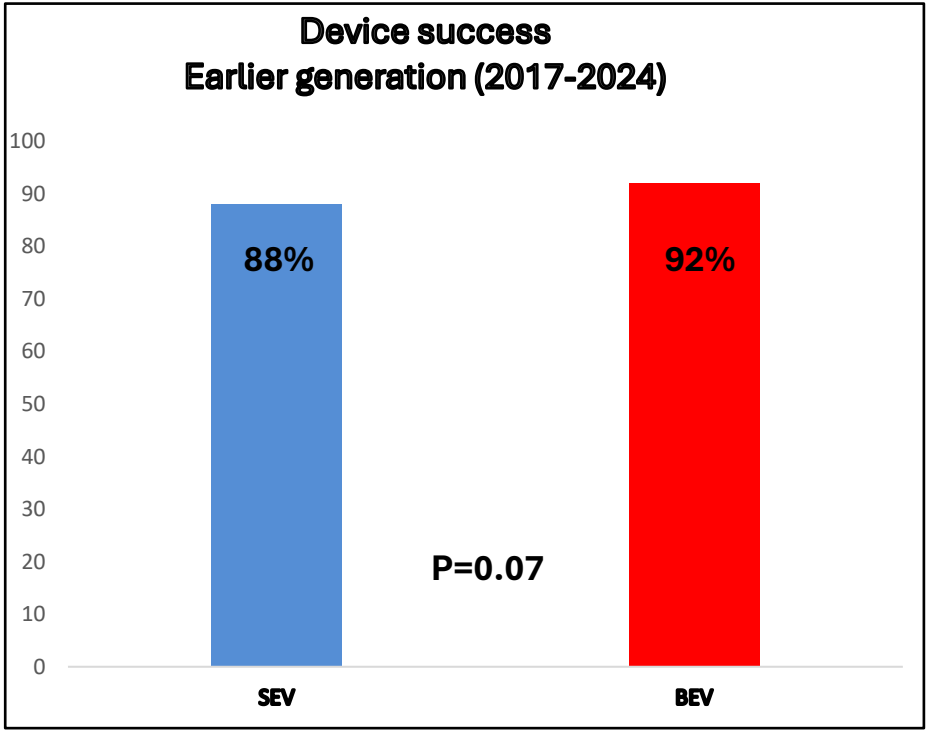
- Hemodynamic performance and clinical outcomes

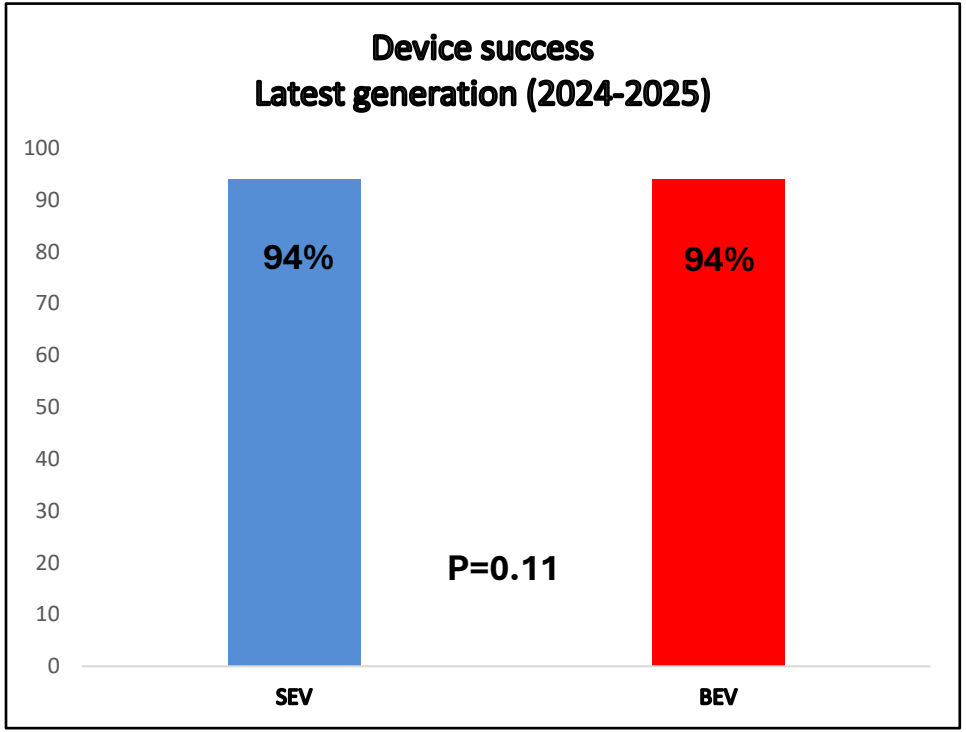
Results - Baseline

	BEV (N=787)	SEV (N=235)	*P* Value
Age (years)	78.4 (±7.8)	81.3 (±4.6)	<0.001
Male (%)	94.5%	94.0 %	0.77
BMI (kg/m^2)	28.8 (±5.0)	28.5 (±4.8)	0.33
STS-score	3.2 (2.1–5.1)	3.7 (2.1-5.1)	0.04
Diabetes	39.8%	41.7%	0.60
PAD	11.3%	10.2%	0.64
CAD	55.4%	61.3%	0.11
- Prior CABG	9.1%	8.9%	0.92
eGFR	59.2 (±19.5)	57.7 (±19.8)	0.30

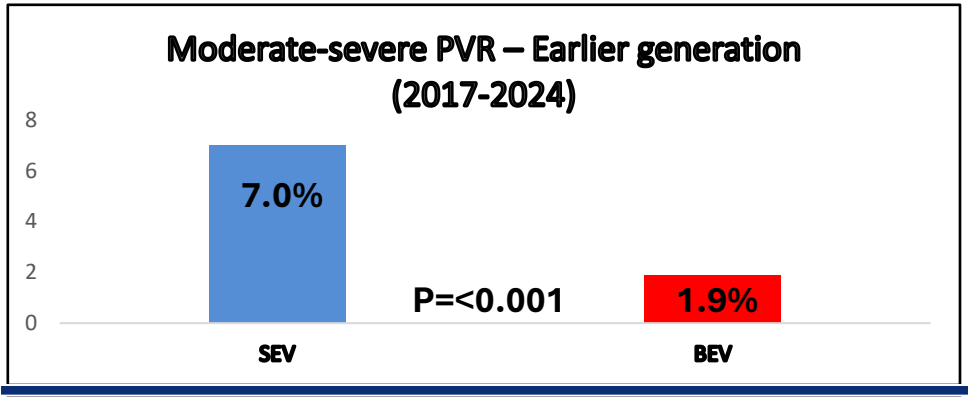
Echo	**BEV**	**SEV**	***P* Value**
LVEF (%)	50.0 (35-58)	55.0 (48-60)	<0.001
Mean gradient (mmHg)	37.0 (28-46)	40 (32-50)	0.003
AVA (cm^2)	0.8 (±0.2)	0.8 (±0.2)	0.32
CT	**BEV**	**SEV**	***P* Value**
Aortic annular area (mm^2)	607 (573-651)	573 (556-585)	<0.001
Bicuspid aortic valve (%)	14.1%	4.3%	<0.001
Procedure	**BEV**	**SEV**	***P* Value**
Transfemoral access (%)	96.3%	99.6%	0.26
Procedure time (min)	50 (40-62)	52 (43-63)	0.16
Use of contrast (ml)	80 (65-105)	107 (84-130)	<0.001

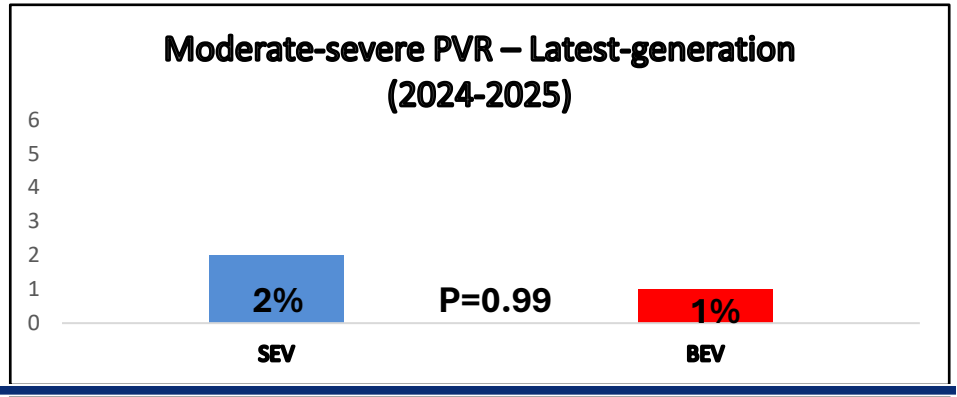
Results – Primary endpoint

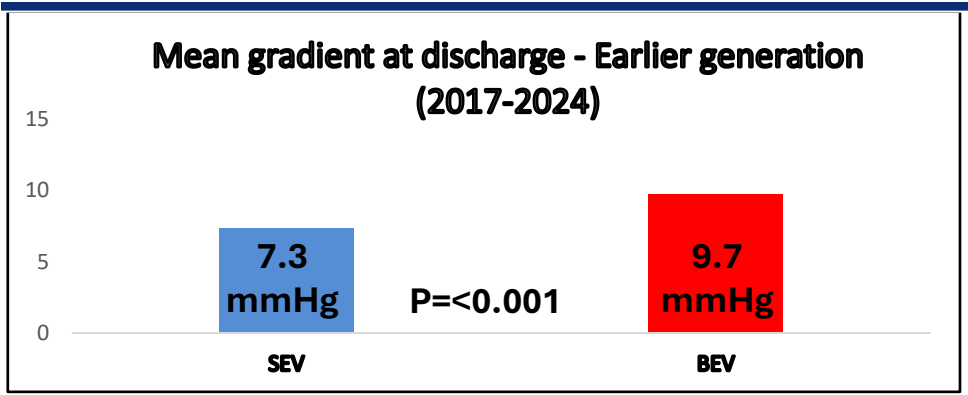


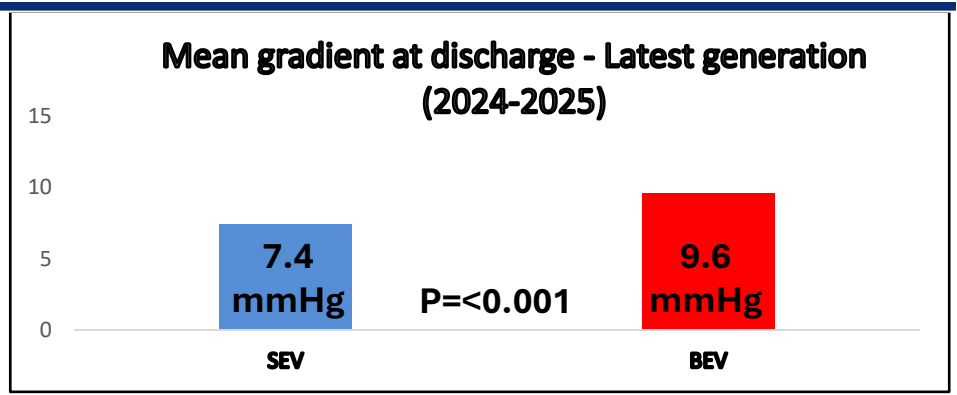


Results – Hemodynamic performance

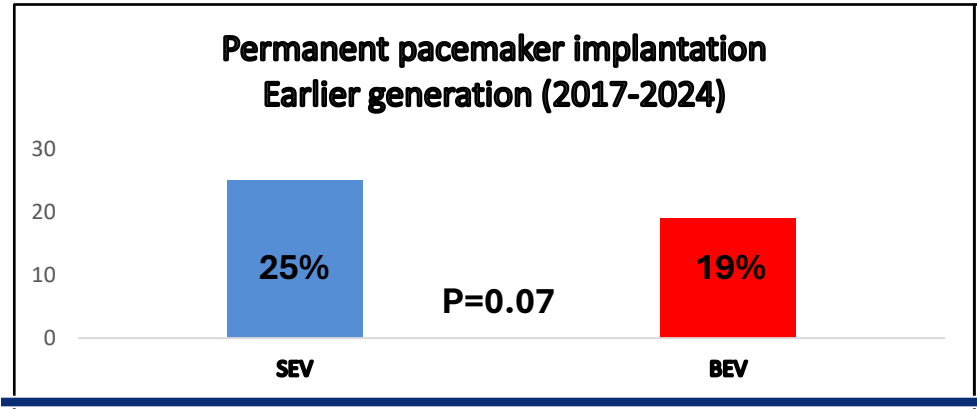


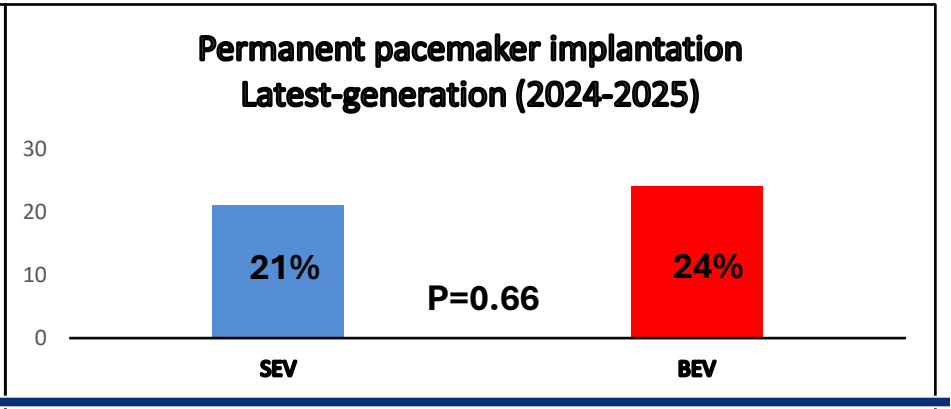


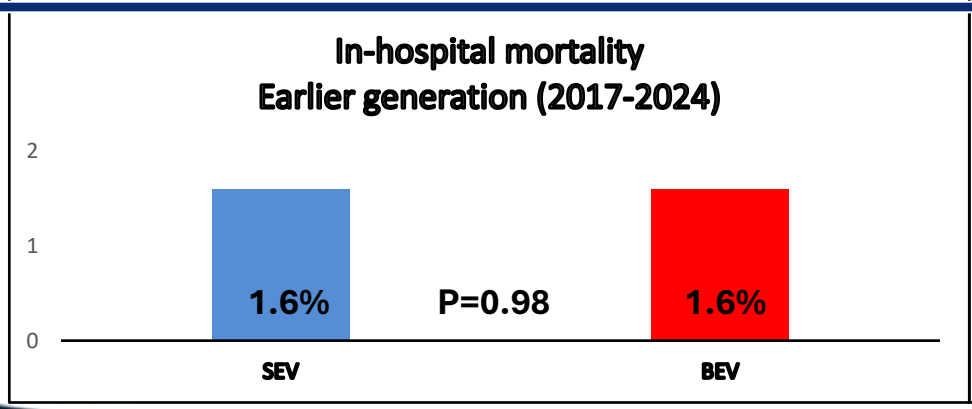


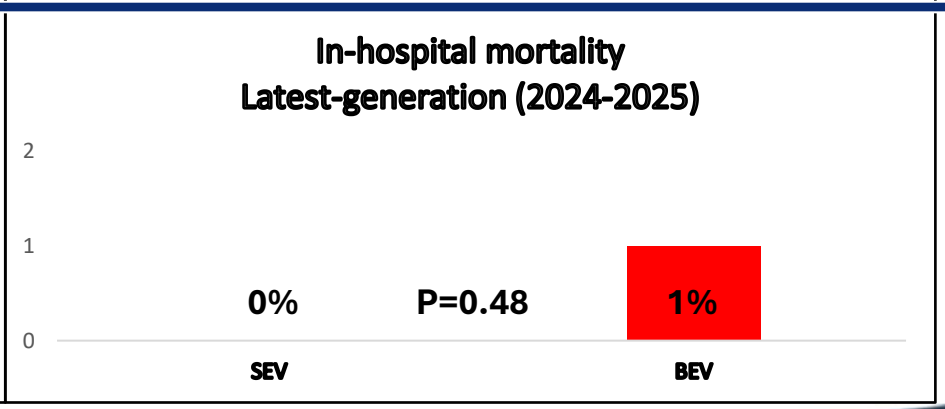


Results – Clinical outcomes









Summary

- Enhanced performance in the latest-generation SEV-group for patients with large aortic annuli undergoing TAVI in this study
  - Higher device success rate and lower rate of moderate-severe PVR as compared to earlier generation SEV (BEV=SEV)

- Limitations:
  - Retrospective design susceptible to confounding
    - e.g. potentially higher calcium burden of the aortic valve/LVOT in the SEV-groups
  - Low sample size in the latest-generation THV comparison

Take-Home Messages

- TAVI for aortic stenosis in patients with large aortic annuli is feasible and safe, especially in experienced centers

- Our analysis suggests that latest-generation SEV demonstrate improved performance in large aortic annuli
  - Especially for device success and moderate-severe PVR

- Further studies are needed for clarification