



CLINICAL INSIGHTS
PORTICO™ WITH FLEXNAV™ TAVI SYSTEM

TAVI and Prosthesis-Patient Mismatch (PPM) in the Small Aortic Annulus (SAA)



Publication Background¹

Title: Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves

Journal: *Clinical Research in Cardiology*

Authors: Lisa Voigtlander et al.

Background:

- Prosthesis-patient mismatch (PPM) is associated with increased morbidity and mortality after TAVI including a 12% higher risk of heart failure rehospitalization and 19% higher risk of death (severe PPM vs. no or moderate PPM).²
- Study investigated whether specific transcatheter heart valves (THVs) yield superior hemodynamics in small anatomies.

Methods:

- Retrospective, multicenter study (four German centers) of 8411 consecutive patients from (May,2012 – April,2019).
- 1069 patients had small aortic annulus (SAA) defined as CT derived annulus area < 400 mm² (focus of study).
- PPM defined as indexed effective orifice area ≤ 0.85 cm²/m²; severe ≤ 0.65 cm²/m² (VARC-2 definition).
- Five specific THVs investigated – Portico™, Evolut[†], Accurate Neo[‡], Sapien[†] 3 and Lotus[†] (discontinued).

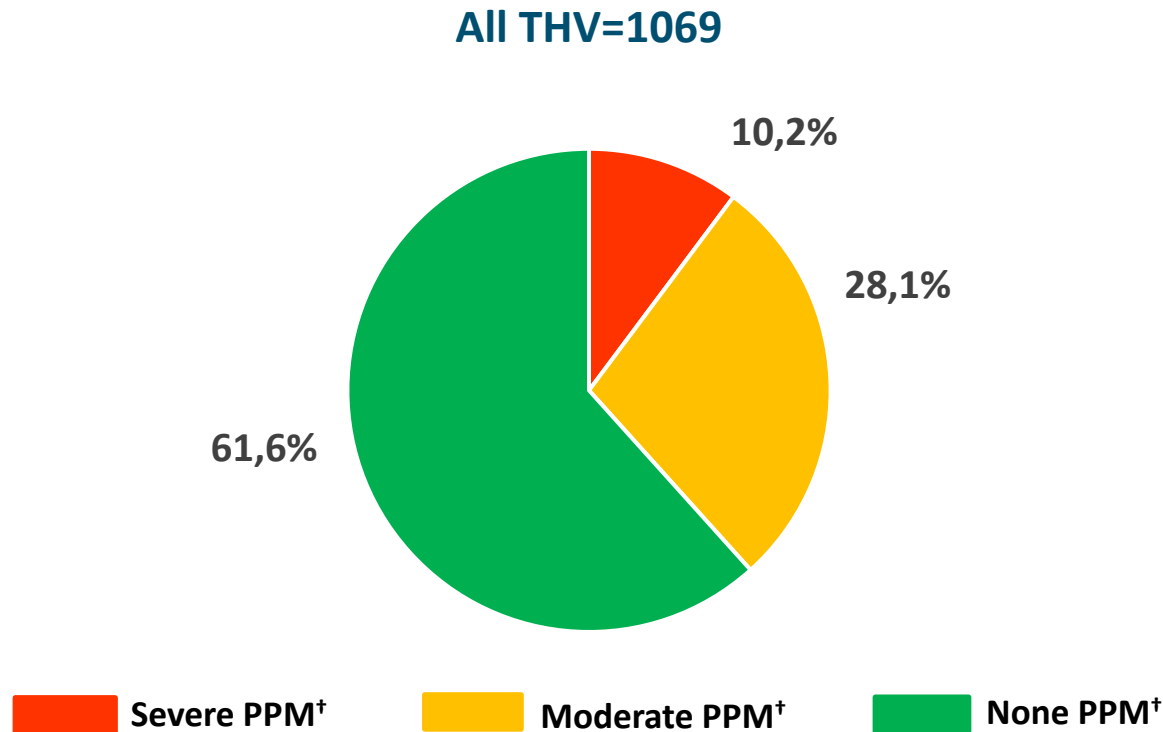
1. Voigtländer L, et al. Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves. *Clin Res Cardiol*. 2021 Aug 13. doi: 10.1007/s00392-021-01918-8. Epub ahead of print.
2. Herrmann HC, et al. Prosthesis-patient mismatch in patients undergoing transcatheter aortic valve replacement: from the STS/ACC TVT Registry. *J Am Coll Cardiol*. 2018 Dec 4;72(22):2701-2711



PPM in Small Aortic Annulus (SAA) (%)

Results (All):

- Among all THV SAA patients, the prevalence of PPM was 38.3% overall; moderate PPM = 28.1% and severe PPM = 10.2%.¹

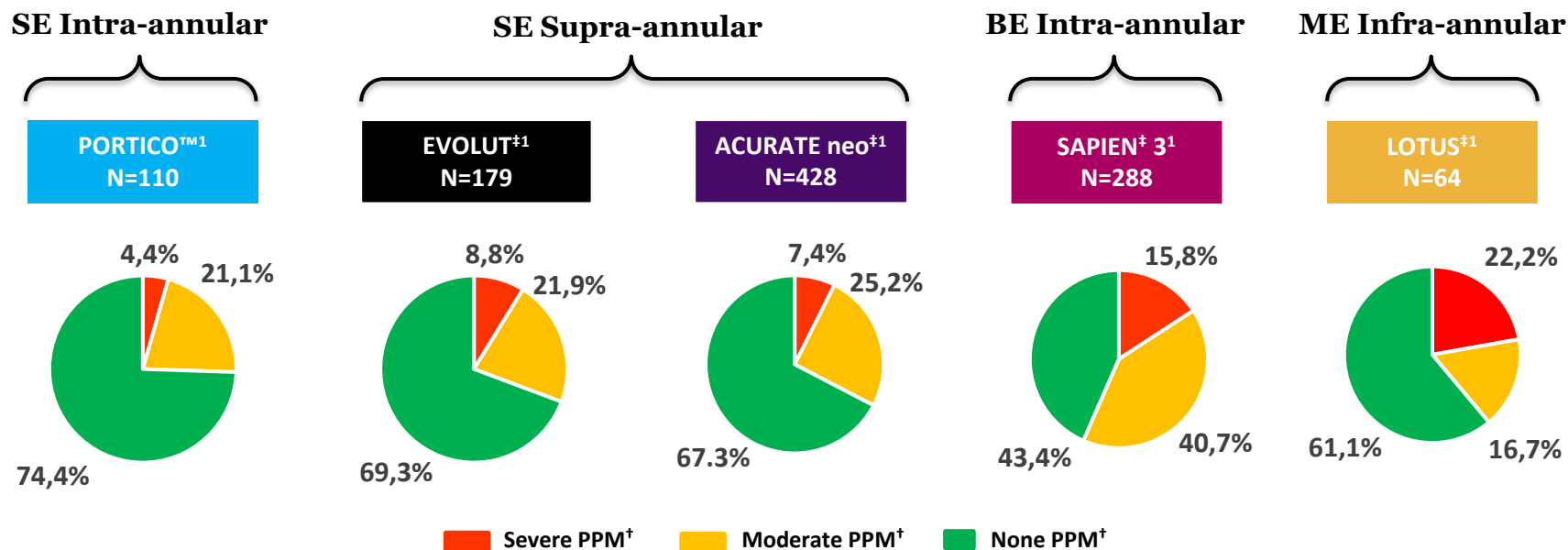


1. Voigtländer L, et al. Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves. *Clin Res Cardiol.* 2021 Aug 13. doi: 10.1007/s00392-021-01918-8. Epub ahead of print. †Patient-prosthesis mismatch (PPM) classified according to VARC 2 criteria and adjusted for BMI.

Comparative PPM in Small Aortic Annulus (%)

Results (Specific THV):

- Portico™ valve demonstrated the lowest rate of PPM (25.5%) including the lowest rate of severe PPM (4.4%) in the SAA series.¹
- The authors' note: "Interestingly, we did not observe any differences between SE supra- or intra-annular THV design, contradicting the idea that supra-annular seating alone yields improved hemodynamics. Even though Sapien[†]-3 and Portico THV both feature intra-annular designs, the latter revealed lower rates of PPM."¹



1. Voigtländer L, et al. Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves. Clin Res Cardiol. 2021 Aug 13. doi: 10.1007/s00392-021-01918-8. Epub ahead of print. †Patient-prosthesis mismatch (PPM) classified according to VARC 2 criteria and adjusted for BMI.

Comparative Clinical Outcomes

- SE supra- and SE intra-annular THV demonstrated superior hemodynamics and consequently lower rates of PPM but showed increased residual PVL.¹

Rate	All ¹ N=1069	PORTICO™ ¹ N=110	EVOLUT ^{†1} N=179	ACURATE neo ^{†1} N=428	SAPIEN ^{‡ 3} ¹ N=288	LOTUS ^{†1} N=64
30-Day Mortality (%)	3.2	4.6	4.0	2.2	3.2	4.8
12-Month Mortality (%)	9.9	10.1	9.1	9.1	11.0	12.9
Disabling Stroke (%)	0.7	0.9	0.7	0.7	0.3	1.6
Major Vascular Complications (%)	7.3	9.1	2.2	10.3	4.9	9.4
Acute Kidney Injury* (%)	8.3	10.0	10.3	7.6	8.3	4.8
Major Bleeding	6.3	8.2	2.8	7.0	5.9	9.4
New Permanent Pacemaker Implantation (%)	13.8	17.8	9.8	10.6	16.5	27.6
Reintervention** (%)	0.3	0	0	0.5	0.4	0
PVL > Mild (%)	4.8	5.5	3.9	7.0	2.4	1.6
iEOA (cm ² /m ²)	0.9	0.9	1.0	0.9	0.8	0.9
Mean Gradient (mmHg)	10.0	9.0	7.0	9.0	12.2	12.9

iEOA=indexed effective orifice area, *AKI stage 1-3, ** reasons for reintervention: relevant aortic regurgitation after post-dilatation.

- Voigtländer L, et al. Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves. *Clin Res Cardiol*. 2021 Aug 13. doi: 10.1007/s00392-021-01918-8. Epub ahead of print.

Key Takeaways

- The belief that SE supra-annular positioning yields improved hemodynamics over SE intra-annular positioning is not supported in this large clinical series.
- A substantial number of patients (12.7% in this large clinical series) presented with small aortic annulus (SAA).¹
- Prevalence of PPM was high, especially in patients treated with BE and ME (Lotus[†]) THV.¹
- SE supra- and SE intra-annular THV demonstrated superior hemodynamics and consequently lower rates of PPM but showed increased residual PVL.¹
- This series excludes outcomes with the Portico™ with FlexNav™ TAVI system which has shown improved rates of PVL (4.1 % moderate or greater PVL at 30 days) and other key clinical outcomes including PPI over the first- generation Portico DS.²
- Portico™ valve has shown favorable hemodynamic performance with single-digit gradient and large EOA reported at 30 days.²

1. Voigtländer L, et al. Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves. *Clin Res Cardiol*. 2021 Aug 13. doi: 10.1007/s00392-021-01918-8. Epub ahead of print. [†]Indicates a third-party trademark, which is property of its respective owner.
2. Fontana GP, et al. Safety profile of an intra-annular self-expanding transcatheter aortic valve and next-generation low-profile delivery system. *JACC Cardiovasc Interv*. 2020 Nov 9;13(21):2467-2478.

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