SCOPE I

A Randomized Comparison of the ACURATE neo versus the SAPIEN 3 Transcatheter Heart Valve Systems in Patients with Symptomatic Severe Aortic Stenosis

Jonas Lanz, Won-Keun Kim, Thomas Walther, Christof Burgdorf, Helge Möllmann, Axel Linke, Simon Redwood, Christian Thilo, Michael Hilker, Michael Joner, Holger Thiele, Lars Conzelmann, Lenard Conradi, Sebastian Kerber, Gerhard Schymik, Bernard Prendergast, Oliver Husser, Stefan Stortecky, Dik Heg, Peter Jüni, Stephan Windecker, Thomas Pilgrim

on behalf of the SCOPE I investigators

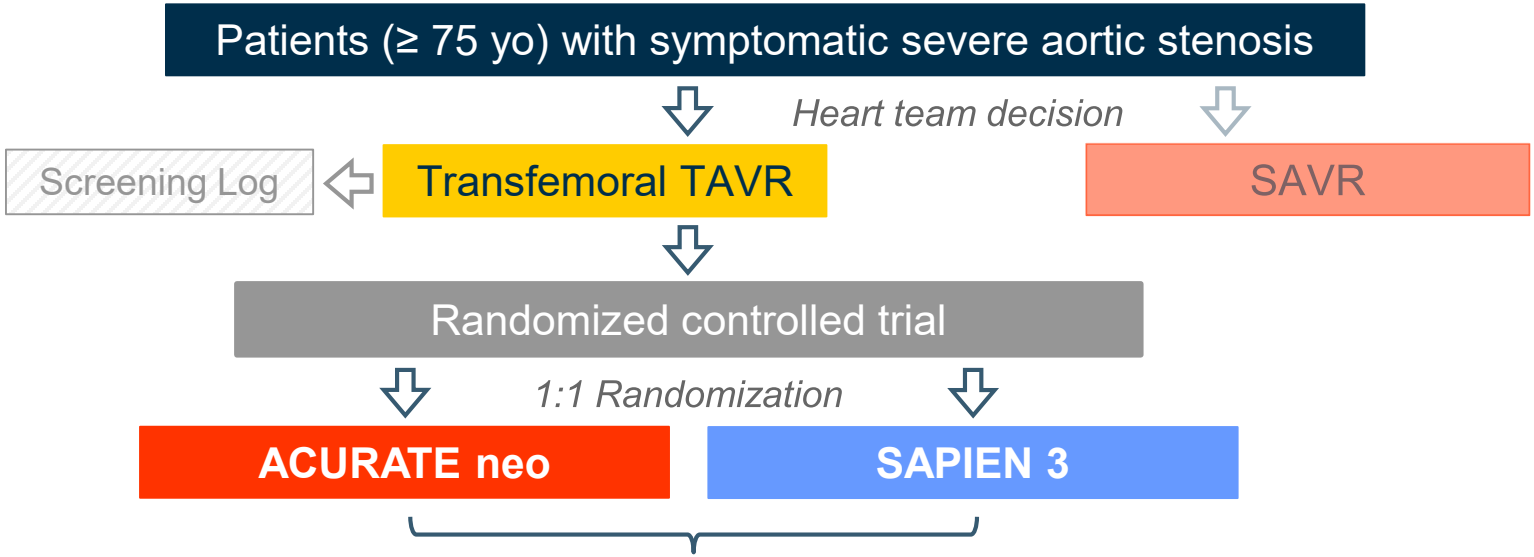
Disclosure Statement of Financial Interest

I, **Jonas Lanz**, DO NOT have a financial interest, arrangement, or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Background

- TAVR has become an indispensable treatment option for patients with symptomatic severe aortic stenosis across all risk categories
- The generalizability of outcomes observed in landmark trials comparing TAVR with SAVR to other commercial TAVR systems is limited by differences in device properties and lack of head-to-head device comparisons
- Iterations of the SAPIEN balloon-expandable TAVR system have been extensively investigated in several large-scale, high-quality randomized trials and registries setting the current benchmark in terms of safety and efficacy
- The ACURATE neo is a novel, self-expanding TAVR system associated with favorable outcomes in non-randomized studies

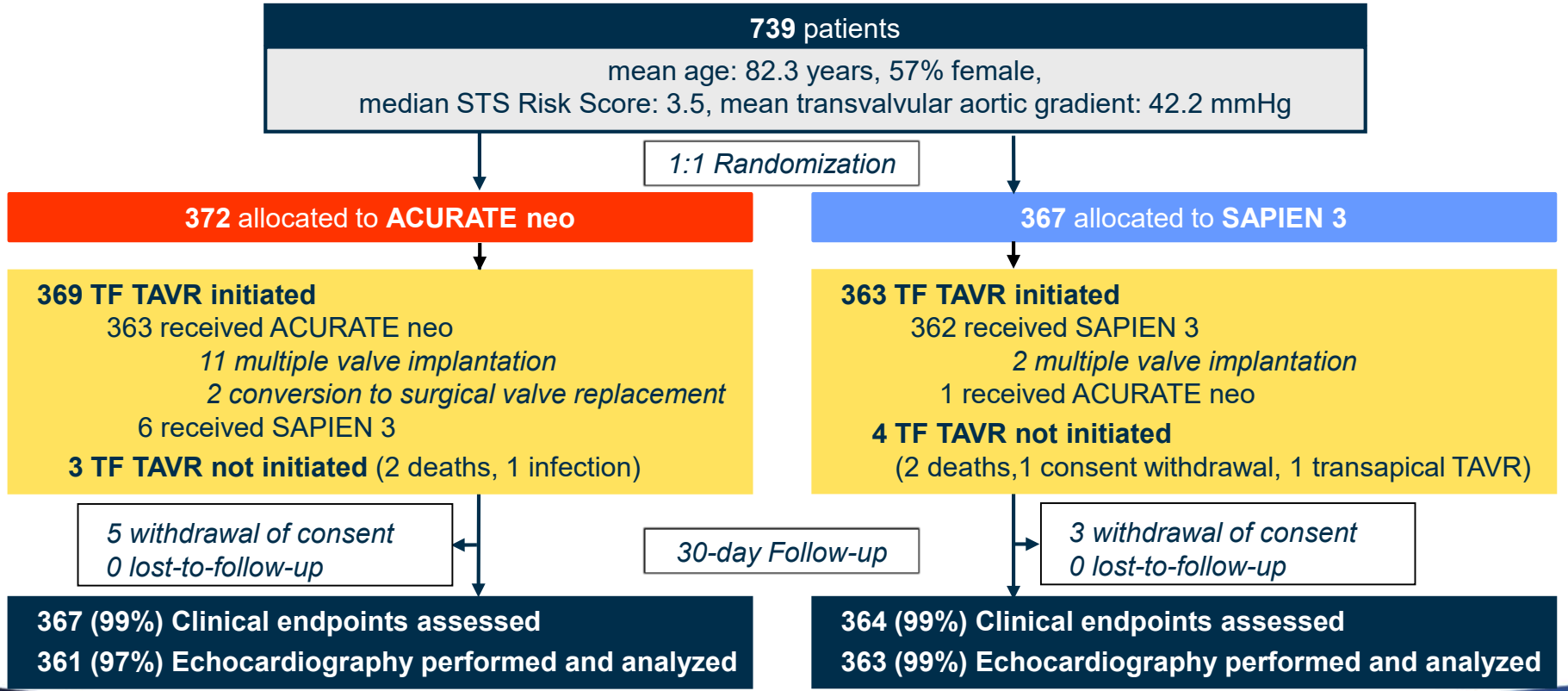
Study Design



Follow-up:
at 30-days, 1 and 3 years

Primary endpoint:
Combined early safety & clinical efficacy (VARC-2) at 30 days
(non-inferiority analysis)

Patient Flow Chart

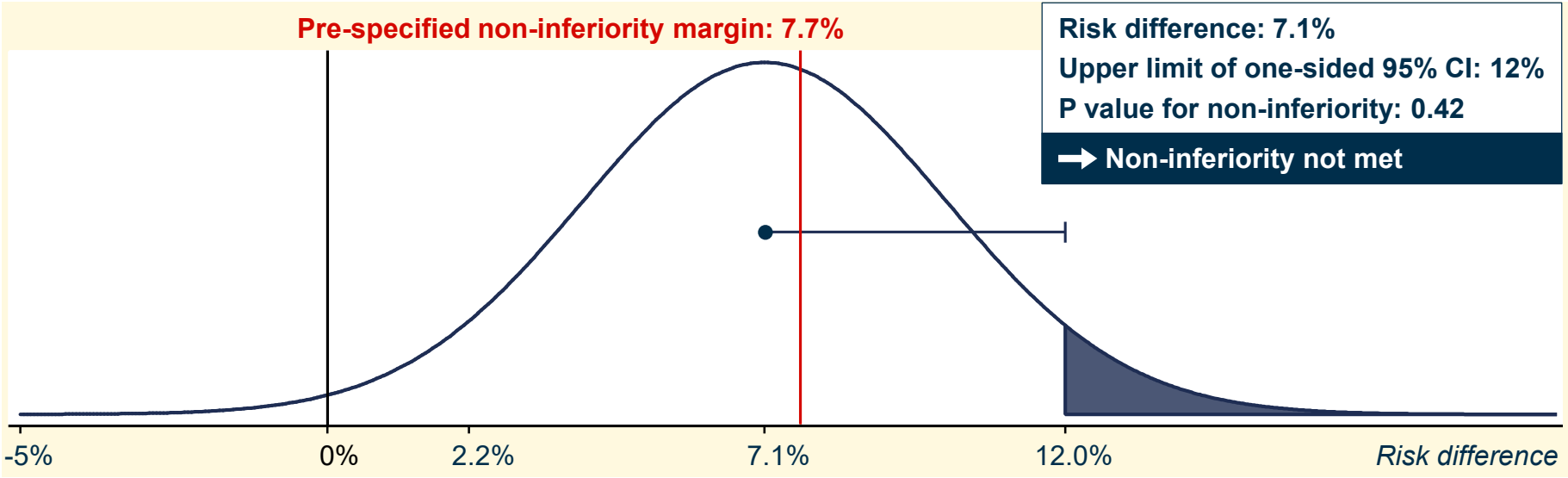


SCOPE I

Primary Endpoint

Primary analysis at 30 days (intention-to-treat)

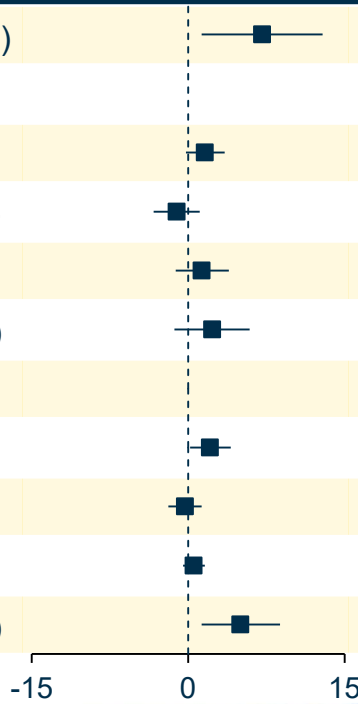
Primary endpoint rates: ACURATE neo 23.7% | SAPIEN 3: 16.5%



ACURATE neo better SAPIEN 3 better

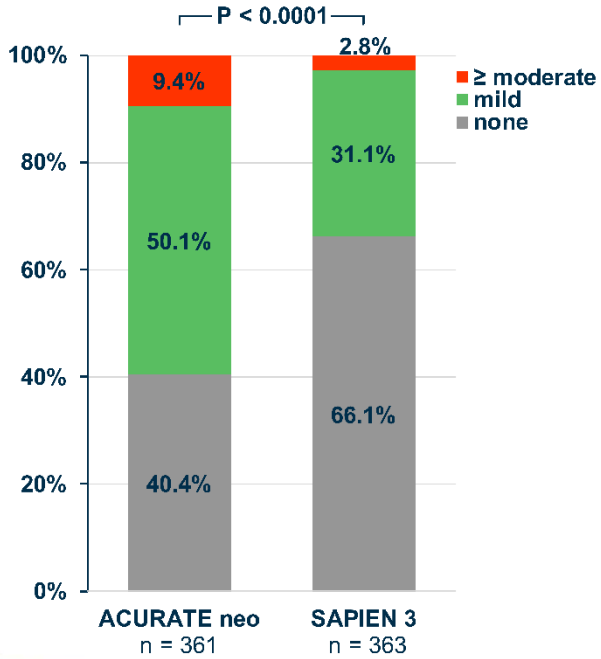
Primary Endpoint - Secondary Analyses

Intention-to-treat cohort at 30 days	ACURATE neo	SAPIEN 3	Risk difference % (95%-CI)	P value
	No. of events/total no. (%)			
Primary endpoint *(superiority analysis)*	87/367 (23.7%)	60/364 (16.5%)		0.0156
Single components of primary endpoint				
All-cause death	9/367 (2.5%)	3/364 (0.8%)		0.09
Stroke (any)	7/367 (1.9%)	11/364 (3.0%)		0.33
Life-threatening or disabling bleeding	14/367 (3.8%)	9/364 (2.5%)		0.30
Major vascular complications	29/367 (7.9%)	20/364 (5.5%)		0.21
Coronary artery obstruction requiring intervention	0/367 (0%)	0/364 (0%)		n/a
Acute kidney injury, stage 2 or 3	11/367 (3.0%)	3/364 (0.8%)		0.0340
Re-hospitalization for valve-related dysfunction or CHF	4/367 (1.1%)	5/364 (1.4%)		0.72
Valve-related dysfunction requiring repeat procedure	3/367 (0.8%)	1/364 (0.3%)		0.32
Valve-related dysfunction *(echocardiography)*	35/361 (9.7%)	17/363 (4.7%)		0.0084

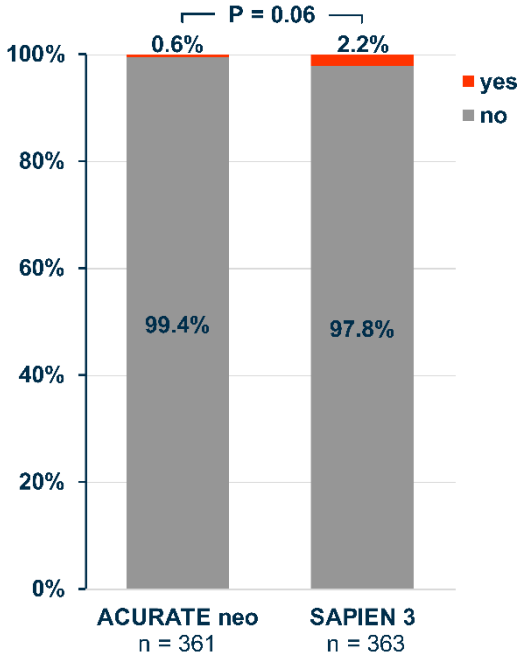


Echocardiographic Valve Performance *(at 30 days)*

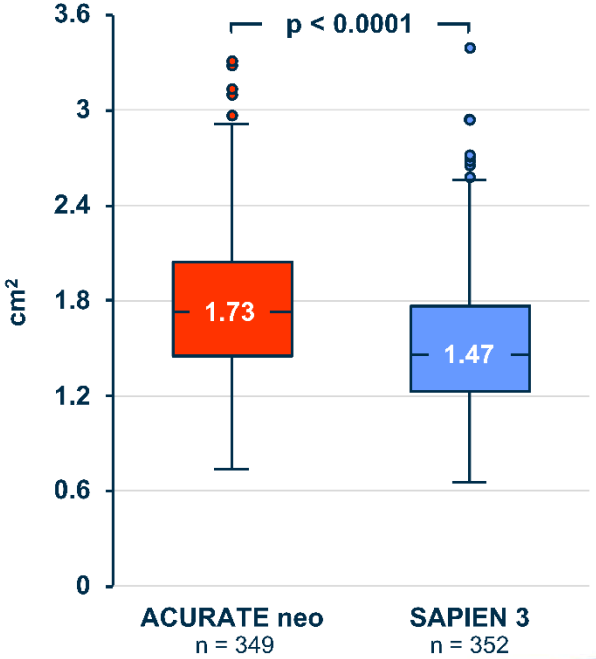
Paravalvular Aortic Regurgitation



Mean Gradient ≥20 mmHg AND EOA ≤ 0.9-1.1 cm² and/or DVI < 0.35



Effective Orifice Area



Conclusions

- **ACURATE neo did not meet non-inferiority** compared to the SAPIEN 3 device **regarding the primary composite safety and efficacy endpoint at 30 days**
- **Differences** between the two TAVR devices were **driven by moderate or severe paravalvular regurgitation** and stage 2 or 3 **acute kidney injury in favor of** the **SAPIEN 3** device
- **An early composite** safety and efficacy **endpoint proved useful in discriminating** the performance of different **TAVR systems**