Five-year outcomes with the ACURATE *neo*2 valve: the Neo AS CE-mark study

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Potential conflicts of interest

Speaker's name : Helge Möllmann

☑ I have the following potential conflicts of interest to declare:

Proctor and/or speaker fees from Abbott, Boston Scientific, Edwards Lifesciences, Medtronic, SMT

What did we study?

ACURATE *neo*2 Transcatheter Heart Valve

ACURATE *neo2*™

CE marked 2020

An evolution of the prior-generation ACURATE *neo* valve

- Supra-annular leaflet positioning yields favorable haemodynamics
- Maintains the ease of use, good coronary access, and low pacemaker rate of ACURATE *neo*
- Compatible with 14F iSLEEVE introducer sheath

➢ New marker band for precise alignment

➢ Enhanced ACURATE *neo2* sealing skirt is 60% larger, resulting in improved mitigation of PVL

How was the study executed?

Prospective, single-arm study of TAVR patients with symptomatic AS at high risk for surgery and implanted with ACURATE *neo*2

PRIMARY ENDPOINT

All-cause Mortality at 30 days

SECONDARY ENDPOINTS

- Device & procedural success
- VARC-2 safety events through 5 years
- Haemodynamic function, evaluated at discharge/7d, 30d, and 1y

INDEPENDENT ENDPOINT EVALUATION

- Data Monitoring Committee (DMC) review / Clinical Events Committee (CEC) adjudication of VARC-2 endpoints
- Echocardiographic data evaluated by a core laboratory (MedStar Health Research Institute) at baseline, discharge, 30d, and 1y

How was the study executed?

120 patients were enrolled at 9 European sites between December 2016 & November 2017

Investigator	Clinical Centre	City, Country	Subjects (N=120)
Won-Keun Kim, MD	Kerckhoff Heart Center	Bad Nauheim, Germany	35
Helge Möllmann, MD	St. Johannes Hospital	Dortmund, Germany	33
Thilo Noack, MD	Heart Center Leipzig University	Leipzig, Germany	20
Michael Hilker, MD	University Hospital Regensburg	Regensburg, Germany	16
Lenard Conradi, MD	University Heart Center Hamburg	Hamburg, Germany	4
Stefan Toggweiler, MD	Luzerner Kantonsspital	Lucerne, Switzerland	4
Britt Hofmann, MD, PhD	University Hospital Halle	Halle, Germany	3
Michael Joner, MD	German Heart Center Munich	Munich, Germany	3
Lars Søndergaard, MD	Rigshospitalet, University of Copenhagen	Copenhagen, Denmark	2

Essential results: Patient population

Baseline Demographics & Risk

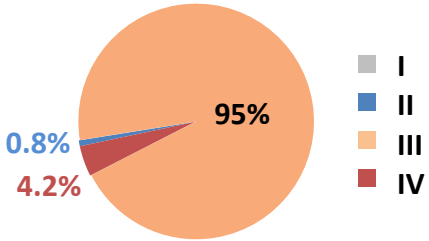
Age
82.1 ± 4.0 yrs

Gender


67.5% **32.5%**

Mean STS Score
4.8% ± 3.8%

EuroSCORE II
4.7% ± 3.8%

NYHA Class at Baseline


Medical History

COPD	10.0%
Diabetes	27.5%
Prior CAD	69.2%
Prior stroke/TIA	10.8%
Baseline conduction abnormality	47.5%
Prior pacemaker	6.7%

Echocardiographic Measurements
(Core laboratory adjudicated)

Mean AVA	0.74 ± 0.2 cm^2
Mean AV gradient	40.3 ± 14.1 mmHg
Aortic regurgitation ≥ moderate	6.1%

Essential results: Study follow-up

ACURATE *neo2* Implanted n=120

Clinical Follow-up or Death

30 Days: 98% (n=118) ----------> 2 patients withdrew consent

- Echo at 30d: 87% (n=104)

1 Year: 93% (n=111) ----------> 7 patients withdrew consent

- Echo at 1y: 74% (n=89)

2 Years: 92% (n=110) ----------> 1 patient withdrew consent

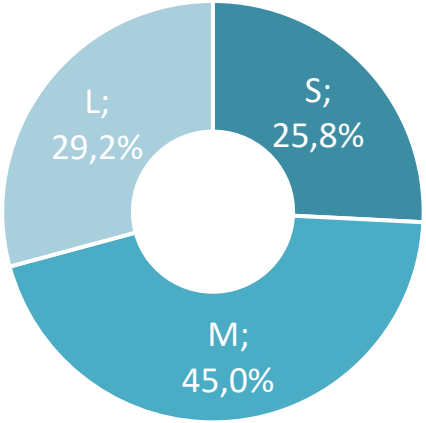
3 Years: 92% (n=110)

4 Years: 92% (n=110)

5-Year Follow-up: 91% (n=109) ---> 1 patient lost to follow-up

Essential results: Early outcomes

Valve size implanted



KEY PROCEDURAL OUTCOMES

- Procedural success: 97.5%*
- No periprocedural deaths
- No MI ≤72h post-procedure
- No cases of coronary obstruction or cardiac tamponade
- Major vascular complications: 2.5%
- New PPI at discharge: 13.3%
  - 56% of new PPI patients (10/18) had a baseline conduction disorder†

PRIMARY ENDPOINT

All-cause Mortality at 30 days

3.3%

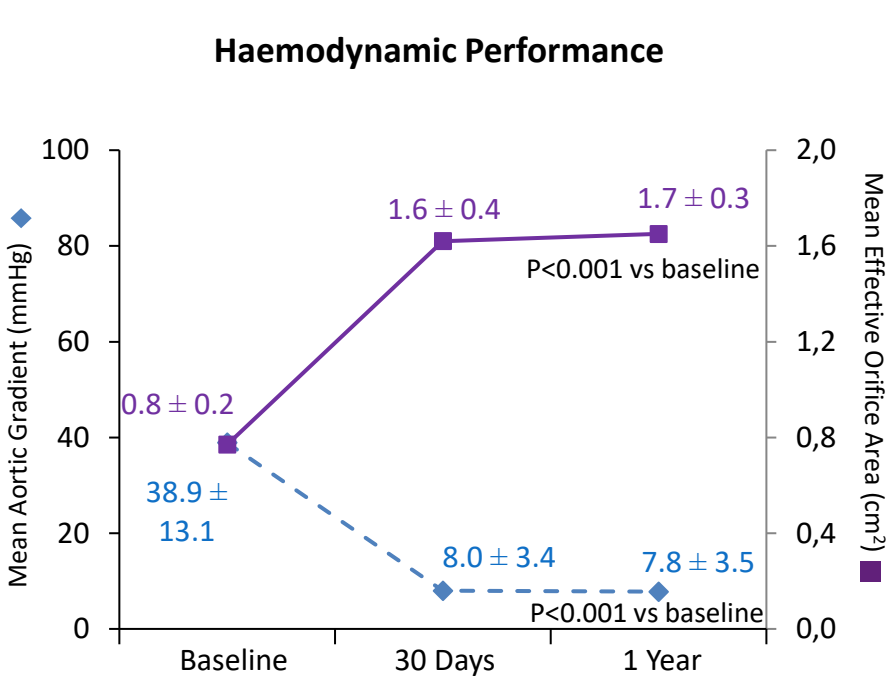
Möllmann H, et al. *Clin Res Cardiol*. 2021 Dec;110(12):1912-1920.

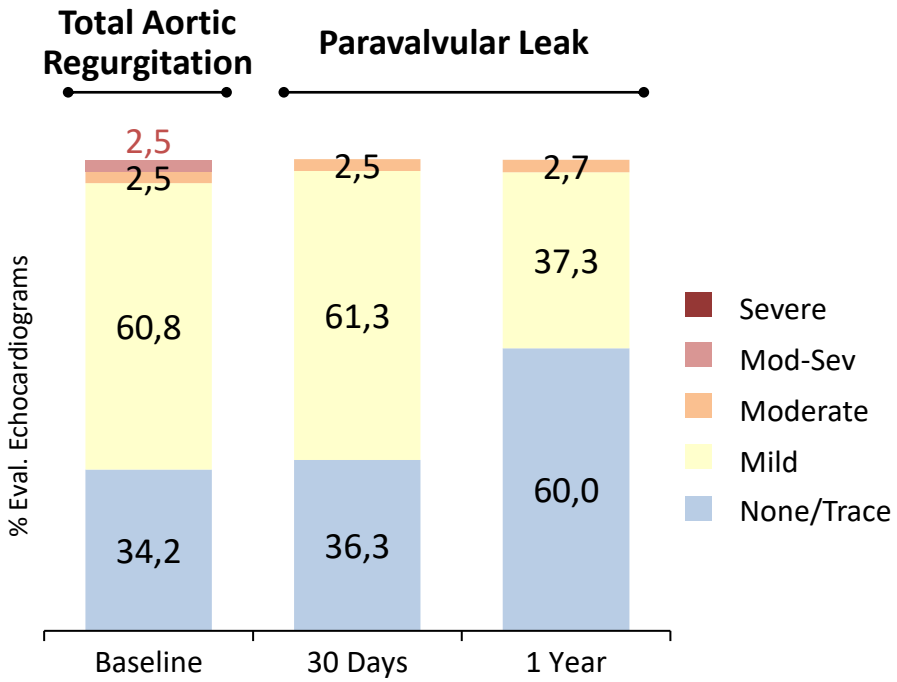
*Procedure was considered successful in 117/120 patients (valve embolization, n=1; valve migration, n=1; conversion to open-heart surgery, n=1)

†AV block, 1st degree, n=5; RBBB, n=4; LBBB (incomplete), n=1; Other, n=1

Essential results: Echocardiographic outcomes

Paired analysis (n=80); core-laboratory adjudicated



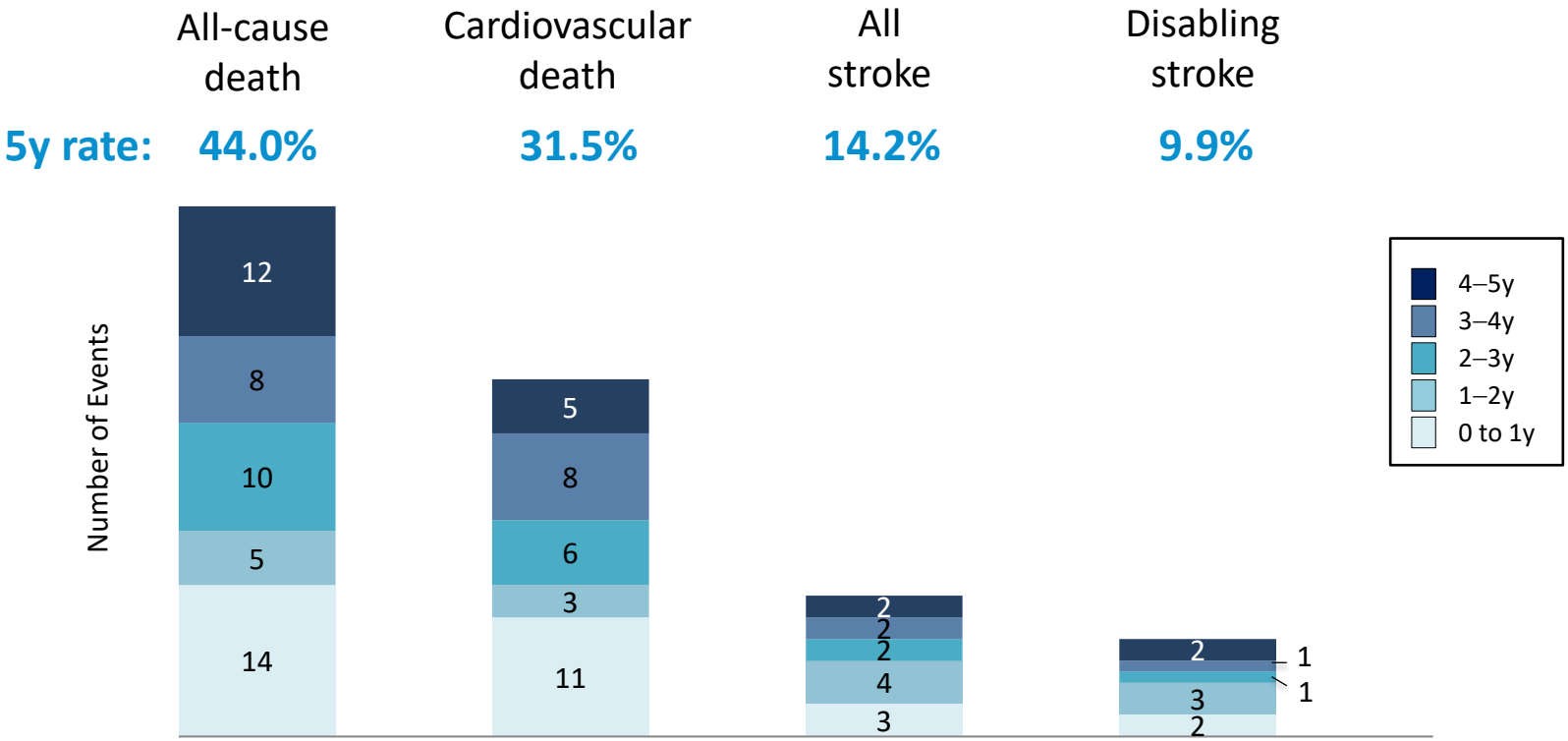


Core laboratory adjudicated data; mean effective orifice area is reported as time velocity integral (TVI) ratio

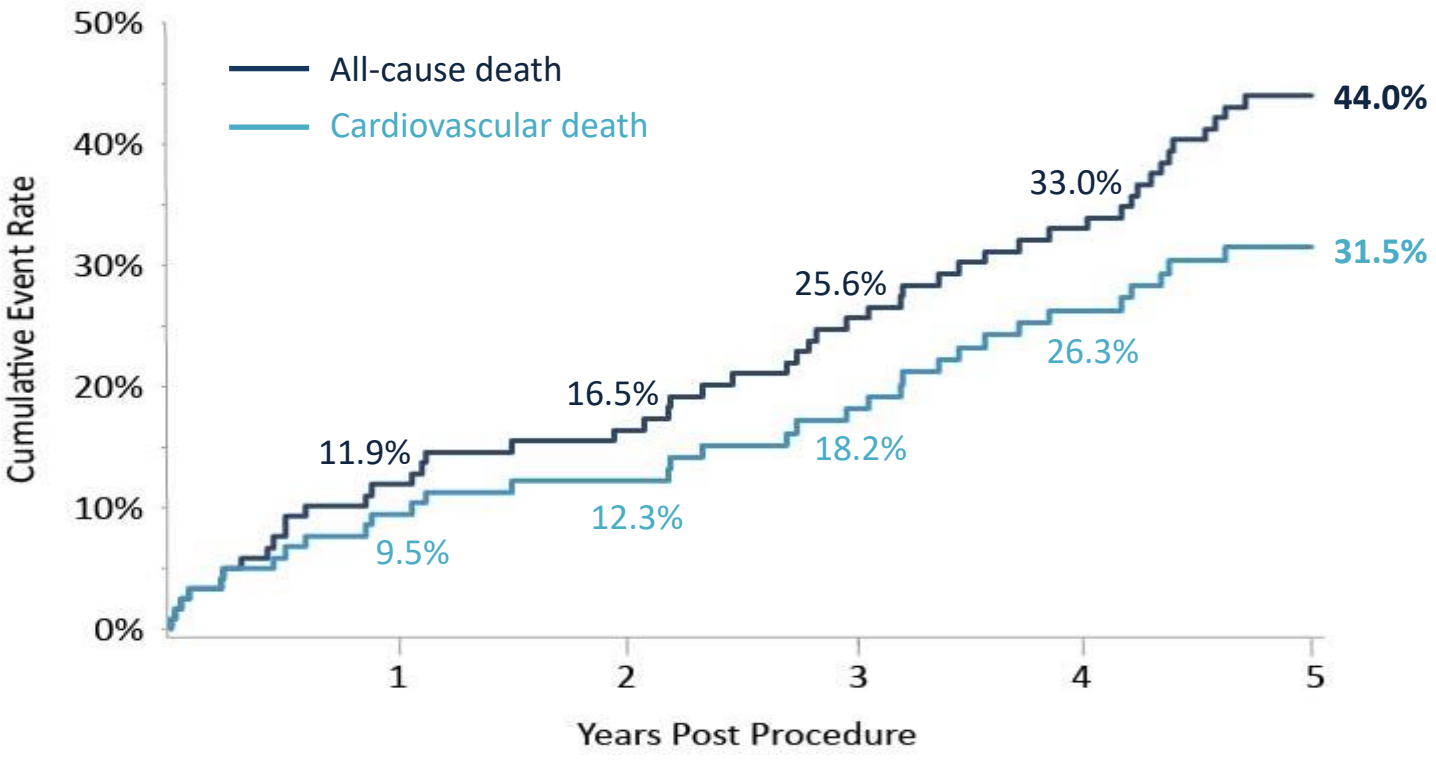
Möllmann H, et al. *Clin Res Cardiol*. 2021 Dec;110(12):1912-1920.

Essential results: Mortality & Stroke through 5 years

ITT population (N=120); time-to-event analysis



Essential results: Death through 5 years



At risk:						
	All death	104	98	91	81	47
	CV death	104	97	89	81	44

Essential results: VARC-2 Safety through 5 years

ITT population (N=120); time-to-event analysis

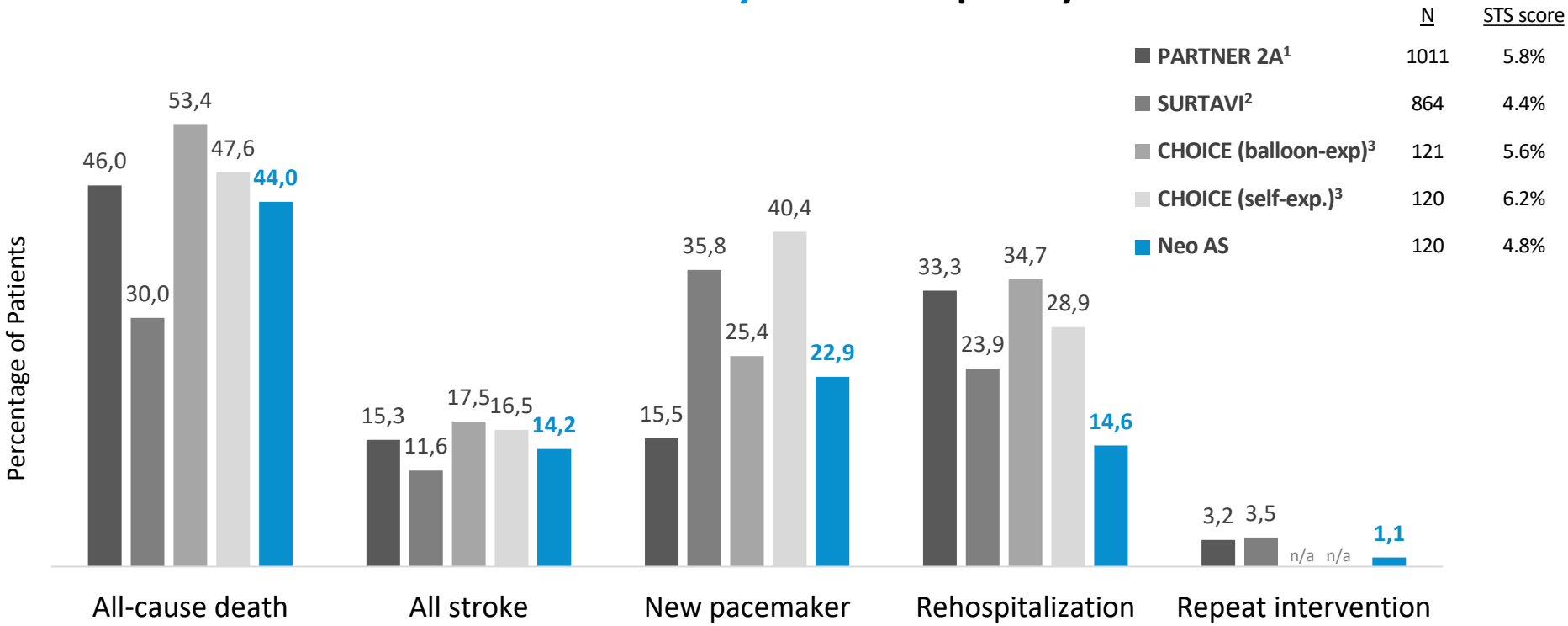
	Cumulative Event Rate				
	1y	2y	3y	4y	**5y**
Hospitalization > 30 days (for valve-related symptoms or worsening congestive heart failure)	4.6%	9.9%	13.2%	13.2%	**14.6%***
Repeat intervention post index procedure	0.0%	1.1%†	1.1%	1.1%	**1.1%**
Clinical valve thrombosis	0.0%	0.0%	0.0%	0.0%	**0.0%**
Endocarditis	0.0%	0.0%	0.0%	0.0%	**0.0%**

* Heart failure-related, n=13; Mitral insufficiency, n=1

† n=1; patient presented with mild-to-moderate paravalvular leak and was treated with balloon valvuloplasty.

Why is this important?

5-Year Clinical Outcomes: Neo AS Study vs contemporary studies



[1]Makkar R, et al. N Engl J Med 2020;382:799-809. [2]Van Mieghem NM, et al. JAMA Cardiol 2022;7:1000–1008. [3]Abdel-Wahab, et al. JACC CI 2020;13:1071-1082.

The essentials to remember

- Patients treated with ACURATE *neo*2 exhibited early improvement in valve haemodynamics and low rates of PVL through 1 year
  - No patients exhibited >moderate PVL at any time
  - PVL at 1y was evaluated as none/trace in 60.0% of patients, mild in 37.3%, moderate in 2.7%
- 5-year rates of all-cause mortality (44.0%) and stroke (14.2%) are comparable to other trials of TAVR patients at intermediate or high surgical risk
- Patients treated with ACURATE *neo*2 had low rates of rehospitalization and re-intervention through 5 years

This first report of longer-term outcomes with ACURATE *neo*2 confirms favorable performance and sustained safety in a high-risk population of patients with severe aortic stenosis

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