2018 PCR london valves

Transcatheter aortic valve implantation for severe aortic valve stenosis with the ACURATE *neo*2 valve system: 30-day safety and performance outcomes

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Potential conflicts of interest

Speaker's name : Helge, Möllmann; Dortmund

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

Receipt of honoraria or consultation fees from Abbott, Biotronik, Boston Scientific, Symetis, Edwards Lifesciences, St. Jude Medical

The ACURATE *neo*2 Valve

ACURATE *neo*2 maintains key features of the ACURATE neo valve

- Self-expanding nitinol frame with porcine pericardium leaflets
- Supra-annular positioning; two-step top-down deployment
- Treats annuli from 21mm to 27mm

Stabilization Arches

- Axial; self-aligning

Upper Crown

- Captures native leaflets and provides coronary clearance

Lower Crown

- Minimal protrusion into LVOT

ACURATE *neo*2 incorporates "Advanced Sealing" technology

- Inner and outer pericardial skirts (outer skirt covers to waist of stent)
- Designed to improve conformability to irregular, calcified anatomy and enhance reduction of PVL

ACURATE neo AS Study Design & Endpoints

Prospective, single arm, multicentre study of 120 patients at 9 European sites

Primary endpoint: All-cause mortality at 30 days

Key secondary endpoints

- Procedural and device success
- VARC-2 clinical event rates at 30 days
- Hemodynamic function
- Aortic regurgitation
- Functional improvement (as per NYHA Classification)

Independent data assessments

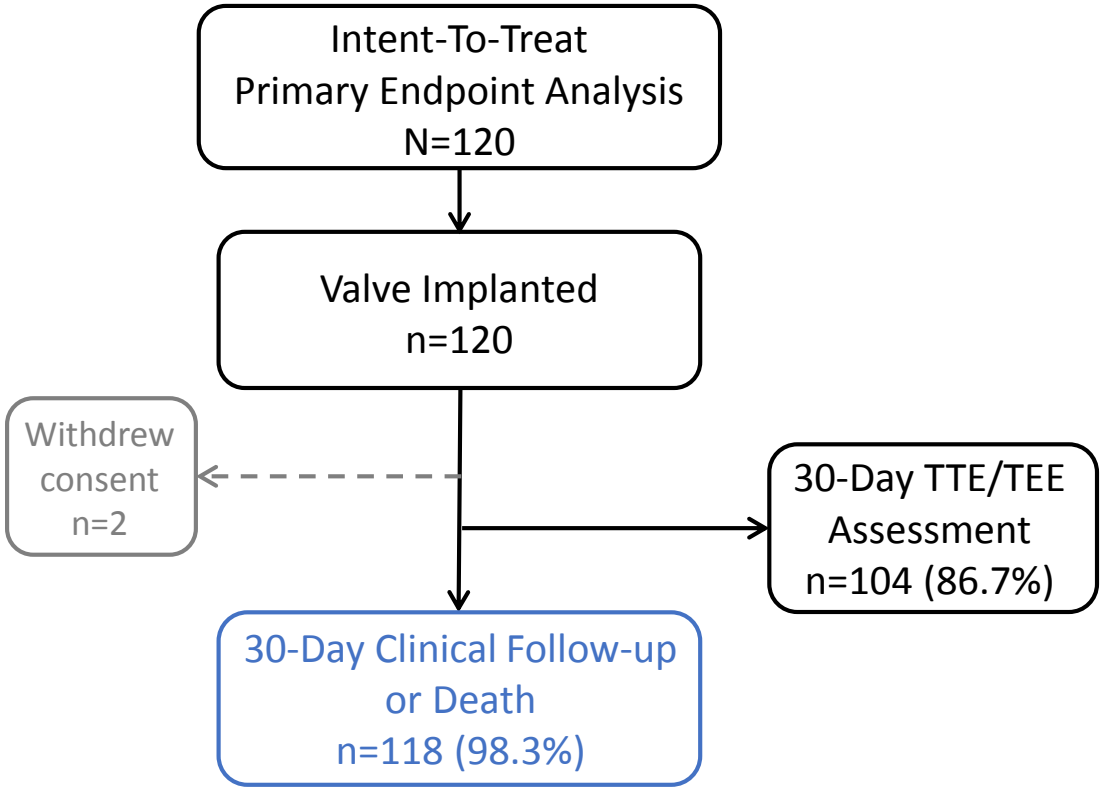
- Echocardiographic data analysed by a core laboratory
  (Neil J Weissman, MD; MedStar Health Research Institute)
- 100% monitoring of all VARC-2 safety events
- Data Monitoring Committee adjudication of all reported VARC-2 endpoint events and review of aggregate safety data

Enrollment

120 patients enrolled between December 2016 & November 2017

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

Study Flow


Intent-To-Treat
Primary Endpoint Analysis
N=120
Valve Implanted
n=120
Withdrew consent
n=2
30-Day TTE/TEE Assessment
n=104 (86.7%)
30-Day Clinical Follow-up or Death
n=118 (98.3%)

Baseline Characteristics

ACURATE neo AS Study subjects were generally representative of patients treated in European contemporary practice

Baseline Demographics & Risk

Age, years	82.1 ± 4.0
Gender, female	67.5%
STS Score, %	4.8 ± 3.8
Logistic EuroSCORE II, %	4.7 ± 3.8
NYHA Class III or IV	99.2%
Baseline PPM	6.7%
History of atrial fibrillation	15.0%
AV block, 1st degree	15.0%
LBBB	10.8%
RBBB	8.3%

Echocardiographic Measurements

EOA, cm^2	0.7 ± 0.2
Mean gradient, mmHg	40.3 ± 14.1
Peak gradient, mmHg	65.9 ± 21.4
LVEF, %	55.8 ± 10.1
AR ≥moderate	6.1%
MR ≥moderate	7.6%

Core laboratory adjudicated data

Procedural Characteristics

Procedural Characteristics

Valve size implanted*	
S	25.8%
M	45.0%
L	29.2%
Balloon pre-dilatation	95.8%
Post-dilatation	32.5%
Correct positioning of a single valve in the proper location	98.3%
Peri-procedural MI (≤ 72h)	0.0%
Coronary obstruction	0.0%
Cardiac tamponade	0.0%
Total procedure time	53.9 ± 31.9 min
Time from femoral insertion to withdrawal of delivery system	3.9 ± 3.5 min

97.5% procedural success
(117/120 patients)

- In 2 patients, valve-in-valve implantation of a non-study valve was required (valve embolization, n=1; valve dislodgement/migration, n=1)
- In 1 patient, post-dilatation resulted in ventricular septal perforation and conversion to open heart surgery

*Size L valve was only available in the second phase of enrollment (ie, after enrollment of initial 30-patient cohort).

Clinical Outcomes at 30 Days

	% (n/120)
All-cause mortality	3.3 (4)
Cardiovascular mortality	3.3 (4)
All stroke	2.5 (3)
Disabling stroke	1.7 (2)
Major vascular complications	3.3 (4)
Life-threatening or disabling bleeding	5.0 (6)
Myocardial infarction (>72h post-procedure)	0.8 (1)
Acute kidney injury (Stage 2 or 3)	0.8 (1)
Permanent pacemaker implantation	
Among all patients (n=120)	15.0 (18)
Among patients without a pacemaker at baseline (n=112)	16.1 (18)
Valve malpositioning*	1.7 (2)
Repeat procedure for valve-related dysfunction	0.0 (0)
Prosthetic aortic valve endocarditis or thrombosis	0.0 (0)

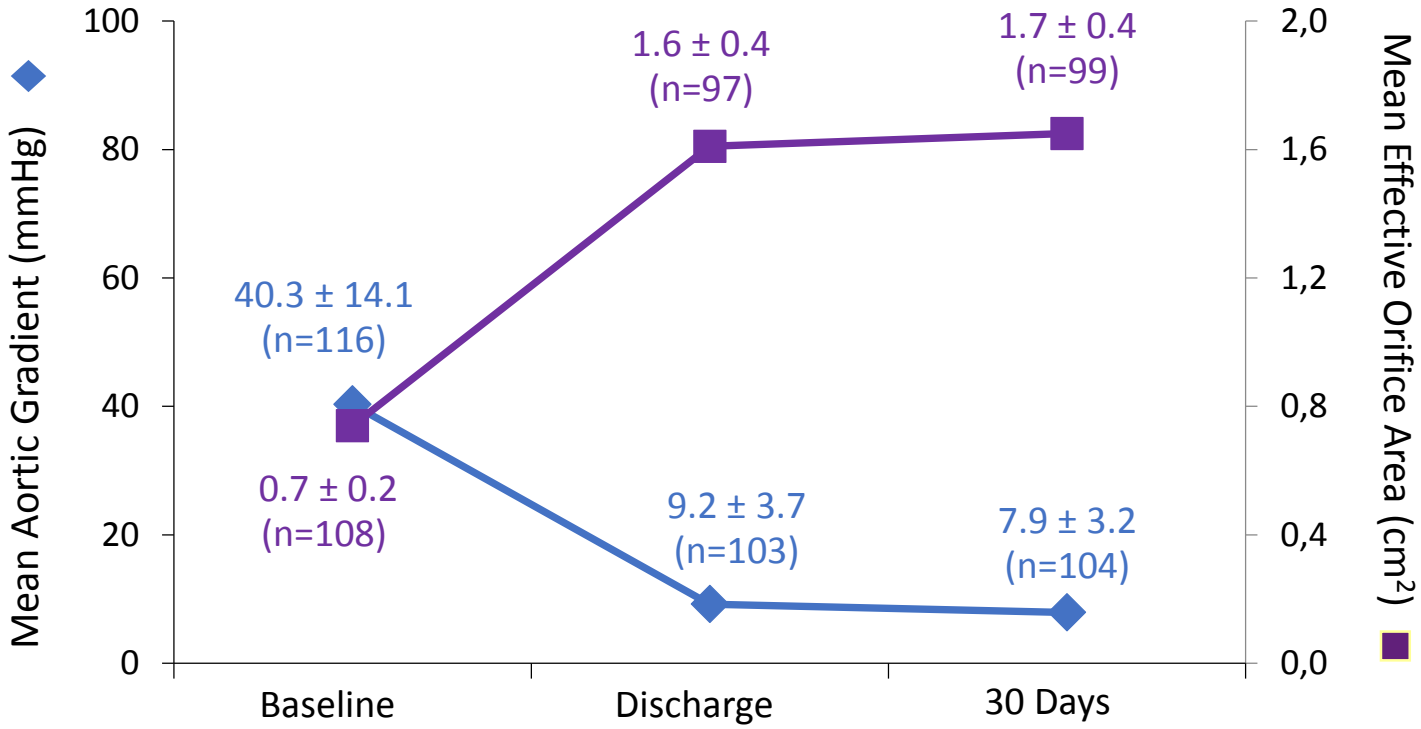
56% of new PPM patients (10/18) had a baseline conduction disorder

- AV block, 1st degree, n=5
- RBBB, n=4
- LBBB (incomplete), n=1

*Includes valve migration, valve embolization, and ectopic valve deployment.

Valve Hemodynamics

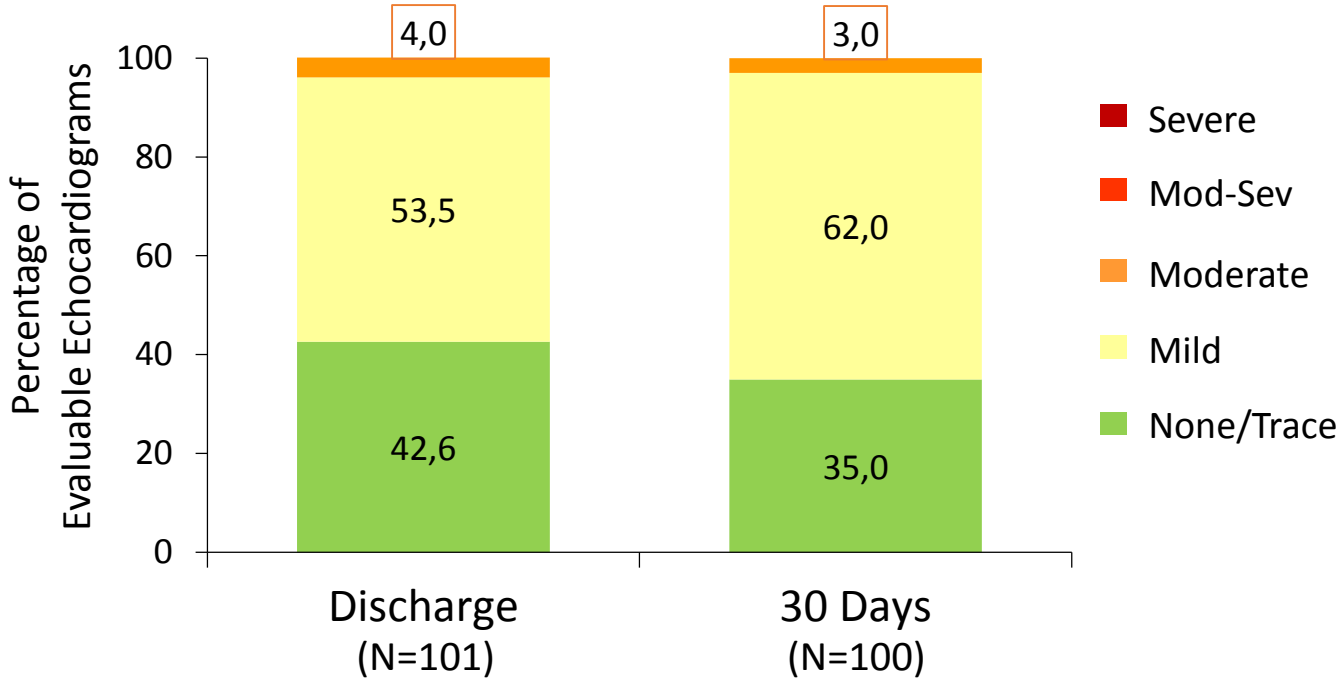
Core laboratory adjudicated data



Paravalvular Regurgitation

Core laboratory adjudicated data

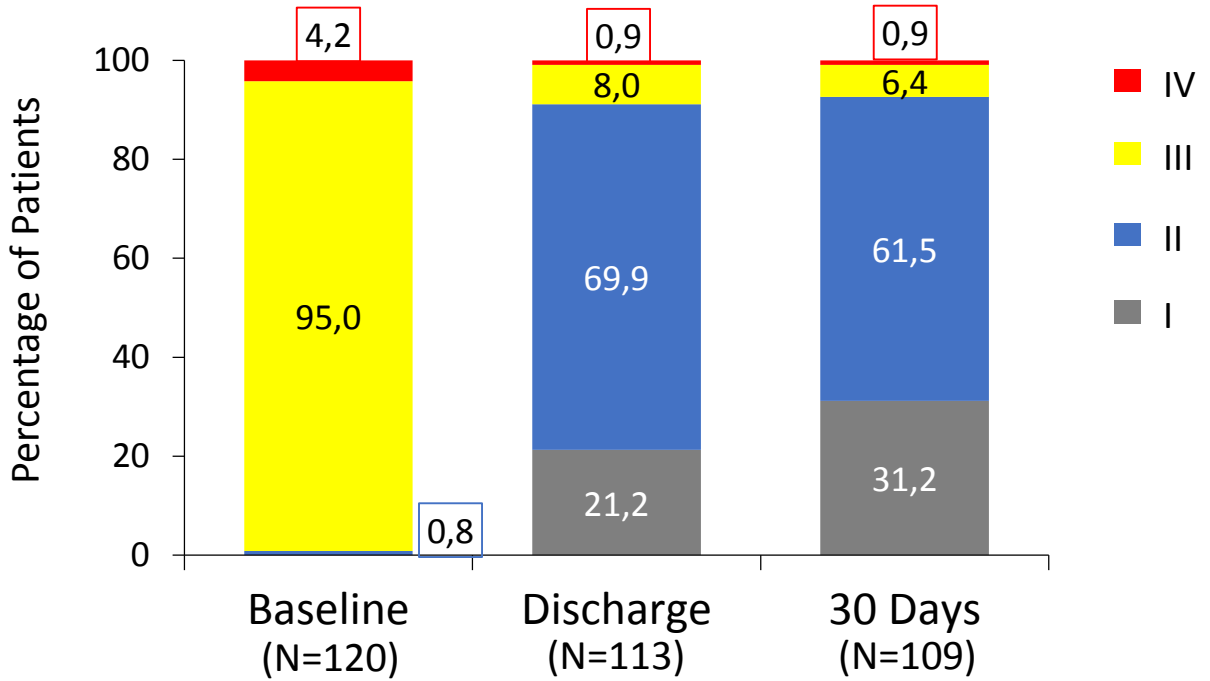
No patients had >moderate PVL; 97% of patients had ≤mild PVL at 30 days



Among patients in whom echocardiography was performed and with follow-up data available for the given time points.

NYHA Functional Class

From baseline to 30 days: 95% of patients improved at least 1 functional class
31% of patients improved at least 2 classes



Among surviving patients in whom NYHA data was collected for the given time points.

ACURATE neo AS Study Conclusions

- 97.5% procedural success with the ACURATE *neo*2 valve
- Low rates of major vascular complications, life-threatening/disabling bleeding, and TAV-in-TAV deployment
- 3.9 ± 3.5 min from femoral insertion to withdrawal of delivery system
- 30-day safety outcomes with ACURATE *neo*2 were comparable to those observed in other TAVI studies in similar patient populations
- Patients experienced marked hemodynamic improvement at 30 days
  - Mean AV gradient: 7.9 mmHg
  - Mean EOA: 1.7 cm^2
- 97% of patients had mild or no/trace PVL at 30 days; no patients had >moderate PVL