2023 PCR london valves

One-year outcomes from the ACURATE *neo2* PMCF Post-market Registry

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On behalf of the ACURATE *neo2* Post-Market Clinical Follow-up Study Investigators

PCR

EAPCI
European Society of Cardiology

Potential conflicts of interest

Speaker's name : Won-Keun Kim

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

Receipt of grants / research support: Boston Scientific

Receipt of honoraria or consultation fees: Abbott, Boston Scientific, Edwards Lifesciences, Meril, Shockwave Medical

Why this study?

- ACURATE *neo2* is a 2nd-generation supra-annular valve that features improvements to further reduce PVL compared to the prior-generation ACURATE *neo.*
- The PMCF post-market registry studied *neo2* in routine clinical practice.
- Outcomes at 30 days have been previously presented. Here, we report 1-year outcomes.

ACURATE *neo2*™

CE marked 2020

What did we study?

Prospective multicentre single-arm post-market surveillance study in a routine clinical practice setting

Independent CEC adjudication of safety events

- Primary safety endpoint: 30-day all-cause mortality
- Additional endpoints evaluated through 1 year
  - Death, stroke, bleeding, major vascular complications, hospitalization for valve-related symptoms

Independent core laboratories

- Echocardiography: MedStar Health Research Institute
  - Hemodynamics and PVL at discharge, 30 days, and 1 year
- 4D-CT: The University of British Columbia, Department of Radiology
  - Hypo-attenuated leaflet thickening (HALT) at 30 days [primary imaging endpoint] and 1 year

How was the study executed?

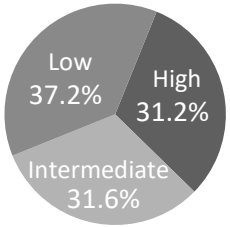
Intention-To-Treat
N=250

Mean Age
80.8 ± 6.2 yrs

36.4% Male
63.6% Female

Mean STS Score
2.9% ± 2.0%

Operative Risk
(per Heart Team)



Successfully Implanted
N=246

Device not in correct position n=4*

30-day
Clinical Follow-up Visit Completed or Death
94% (236/250)

Premature discontinuation
- Withdrawal from study, n=20
- Missed 1y follow-up, n=7 †

1-year
Clinical Follow-up Visit Completed or Death
89% (223/250)

30-day Imaging Data Analyzed

TTE	CT
91% (224/246)	83% (204/246)

1-year Imaging Data Analyzed

TTE	CT
76% (186/246)	62% (153/246)

*In 4 patients, ACURATE *neo2* embolized and patients were implanted with a non-study valve; these patients were followed for safety only through 30 days
†Patient survival confirmed, but no additional follow-up data collected.

What are the essential results?

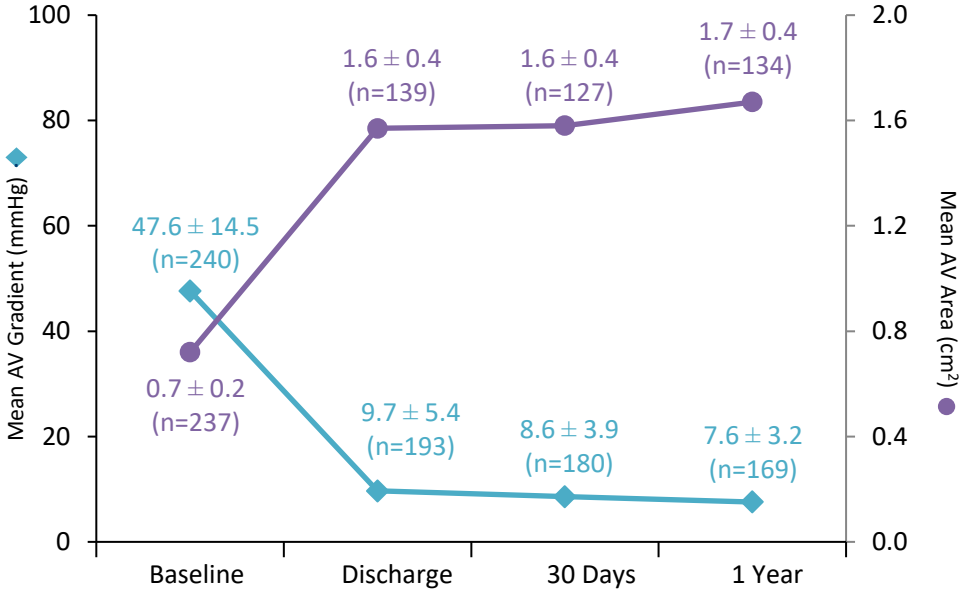
Key Safety Events	Discharge	30 Days	1 Year
All-cause mortality	0.4% (1)	0.8% (2)* 1° Safety Endpt	**5.1% (12)**
Cardiovascular mortality	0.4% (1)	0.8% (2)	**3.4% (8)**
All stroke	0.4% (1)	0.8% (2)	**3.0% (7)**
Major bleeding	2.4% (6)	2.4% (6)	**2.8% (7)**
Hospitalization for valve-related symptoms or worsening CHF	0.0% (0)	0.0% (0)	**1.7% (4)**
Prosthetic aortic valve thrombosis	0.4% (1)^	0.4% (1)	**0.9% (2)‡**
Prosthetic aortic valve endocarditis	0.0% (0)	0.4% (1)	**1.7% (4)**
Valve-related repeat procedure (BAV)	0.4% (1)*	0.4% (1)	**0.8% (2)†**
Newly implanted permanent pacemaker	5.2% (13)	6.1% (15)	**7.8% (19)**

*Deaths: 1 patient experienced life-threatening bleeding (admitted to secondary hospital, source of bleeding not recorded) and hemodynamic instability leading to circulatory arrest and death; 1 patient died post index procedure following valve embolization and unsuccessful TAV-in-TAV with non-study valve leading to coronary obstruction and procedural myocardial infarction.
*Surgical removal of embolized ACURATE *neo*2 valve
^Thrombus noted pre-discharge in non-study valve implanted subsequent to ACURATE *neo*2 embolization
‡Diagnosis of HALT at 30 days and 1 year, with oral anticoagulant therapy initiated shortly before 1-year visit

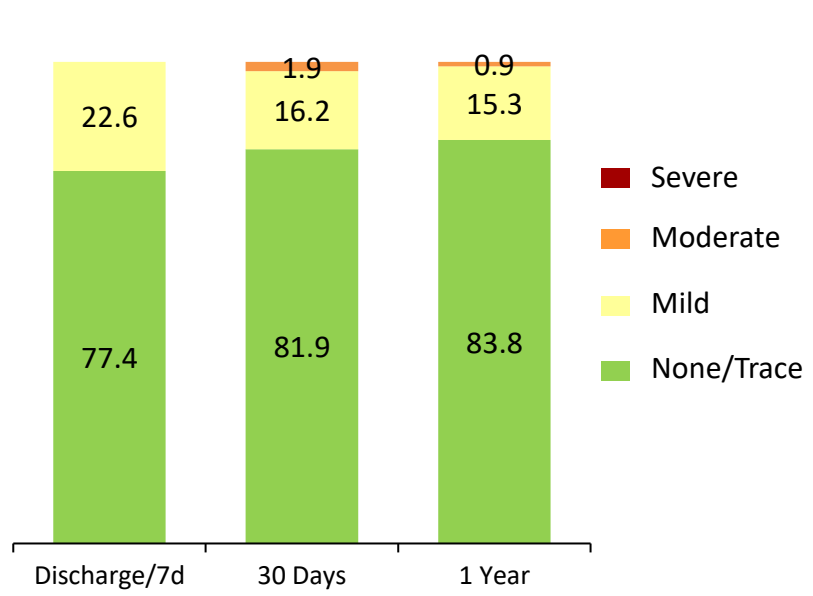
What are the essential results?

Echocardiography Core Laboratory

Aortic Valve Haemodynamics, ITT Population



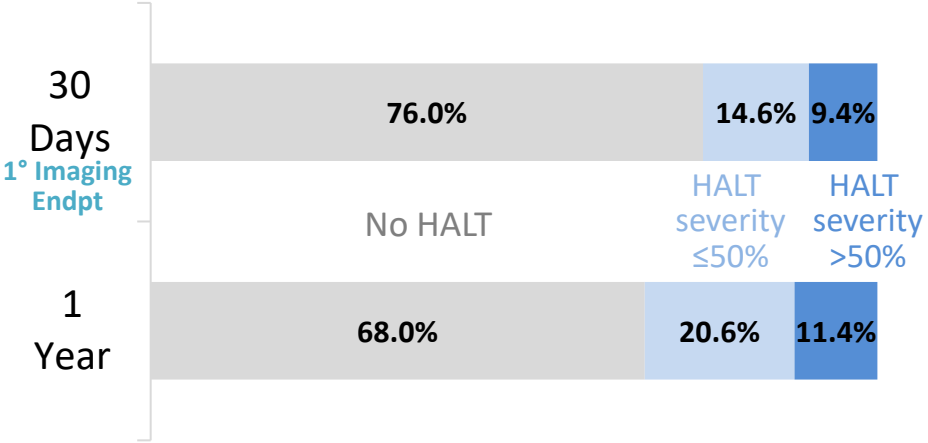
Paravalvular Leak, Paired Analysis (n=116)



What are the essential results?

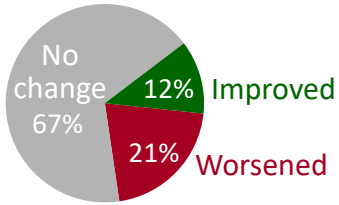
CT Core Laboratory

HALT, Paired Analysis (n=150)



Change in HALT severity from 30 days → 1 year

(n=135, excludes pts on OAC)



1-Year Event Rate	HALT @ 30d or 1y N=72	No HALT @ 30d and 1y N=93	P-value
All-cause mortality	0.0% (0)	0.0% (0)	0.25
CV mortality	0.0% (0)	0.0% (0)	0.25
All stroke	2.2% (2)	2.2% (2)	0.74
Disabling stroke	0.0% (0)	0.0% (0)	--
Valve thrombosis	0.0% (0)	0.0% (0)	0.25
Echocardiography	n=27*	n=91	
AV gradient (mm Hg)	7.1±4.3	7.8±2.7	0.36
AV area (cm^2)	1.6±0.4	1.7±0.4	0.53

*Only subjects with HALT recorded at 30 days *and* 1 year are included in the analysis.

The essentials to remember

This report confirms favorable performance and safety through 1 year in patients with severe aortic stenosis treated with ACURATE *neo2*

- Patients treated with ACURATE *neo2* exhibited early improvement in valve haemodynamics and low rates of PVL through 1 year
  - At 1 year, 99% of patients had mild or no/trace PVL (<1% had moderate PVL)
  - No patients exhibited >moderate PVL at any time
- 1-year rates of all-cause mortality (5.1%) and stroke (3.0%) are comparable to other trials of TAVR patients at intermediate or high surgical risk
- The presence of HALT:
  - Did not impact patient safety at 1 year
  - Did not significantly affect mean AV gradient or mean AV area

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CAUTION: In Europe, ACURATE neo and neo2 Aortic Valve Systems are CE-marked. In the USA, ACURATE neo2 is an investigational device and restricted under federal law to investigational use only. Not available for sale.