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ACURATE *neo2*™
Aortic Valve System

ACURATE *neo2* CE-Mark Study

Transcatheter Aortic Valve Implantation for Severe Aortic Valve Stenosis with the ACURATE *neo2* Valve System: 30-day Safety and Performance Outcomes
Möllmann H; Presented PCRLV 2018, London, September 10, 2018

Transcatheter Aortic Valve Replacement with the ACURATE *neo2* Valve System: 1-Year Clinical and Hemodynamic Outcomes
Möllmann H; Presented TVT 2019, Chicago, June 13, 2019

Study Design

Prospective, single-arm, multicenter study of 120 patients at 9 European sites evaluating the safety and performance of the ACURATE *neo2* Aortic Valve System (device in study named "ACURATE *neo* AS").

Primary endpoint was all-cause mortality at 30 days; key secondary endpoints include VARC-2 clinical events at discharge, 30 days, and 1 year as well as hemodynamic function and aortic regurgitation. Independent assessment of clinical data including core-laboratory analysis of echocardiographic data.

Procedural Characteristics

Procedural efficiency demonstrated with high rate of procedural success (97.5%), and short device usage time (3.9 min) with no incidence of coronary occlusion.

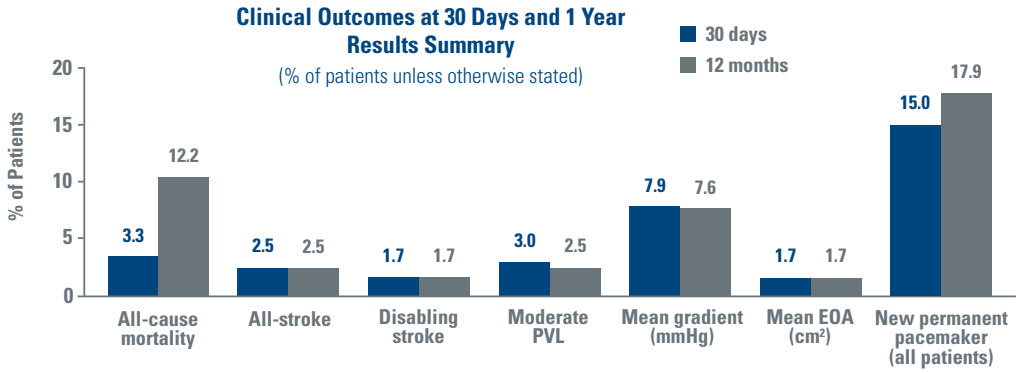
Procedural Characteristics	
Procedural success*	97.5%
Peri-procedural MI (≤ 72h)	0.0%
Coronary occlusion	0.0%
Device usage time**	3.9 ± 3.5 min

* 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
** Time from femoral insertion to withdrawal of delivery system

Clinical Highlights

Low complication rates, in line with other third-generation TAVI systems.

Single-digit transvalvular gradients and large EOAs demonstrated at discharge and further improved at 30 days and 1 year. Most pacemaker recipients (56%) had conduction system disturbances already at baseline.

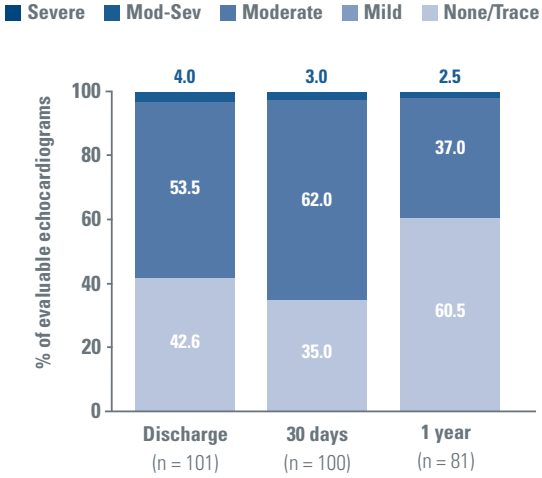


Low PVL rates and excellent hemodynamic performance.

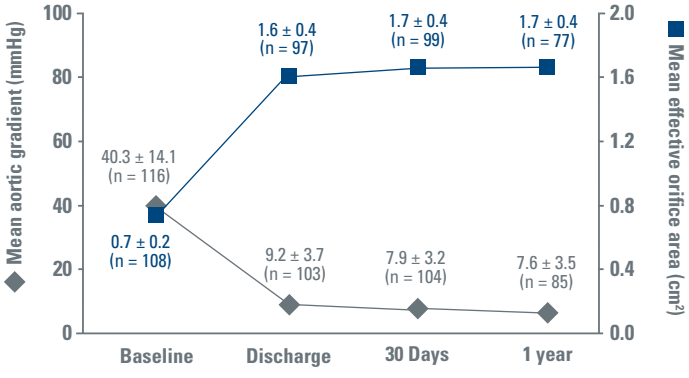
Core-lab-adjudicated PVL rates are lower with ACURATE *neo2* than previously reported with ACURATE *neo*

- 97% of patients with None/Trace or Mild PVL, 3% of patients had moderate, and no PVL more than moderate was observed at 30 days
- Results confirmed at 1 year with 97.5% of patients Mild or less PVL (60.5% none/trace, 37% mild) and only 2.5% of patients with moderate PVL; no patients with severe PVL

Paravalvular Leakage (PVL)
at 7-day/discharge, 30 days, and 1 year



Hemodynamic Performance
at 7-day/discharge, 30 days, and 1 year (mmHg/cm²)



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