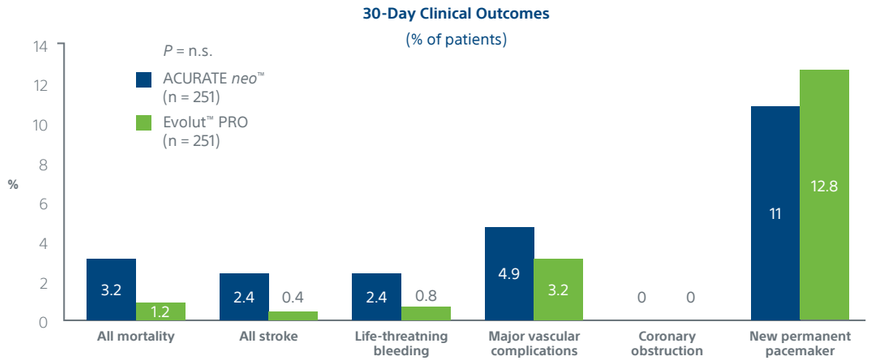
PROPENSITY SCORE MATCHED COHORT CLINICAL OUTCOMES



- In the PS-matched cohort, both devices show similar 30-day clinical outcomes for the VARC-2 device success and also the composite safety endpoint without any significant differences in the 30-day clinical outcomes
- ACURATE *neo* patients in the PS-matched cohort showed a higher rate of moderate and heavy AV calcification at baseline as compared to the overall ACURATE *neo* cohort, leading to higher pacemaker rates as seen in the overall ACURATE *neo* cohort (11% vs. 8.8%)

CONCLUSION

- Transfemoral TAVI with ACURATE *neo* and the next-generation Evolut PRO THVs was associated with high device success, acceptable rates of PVL, and overall good 30-day clinical outcomes
- Subtle differences in procedural characteristics and clinical outcomes highlight the different design features of the two valves
- After adjustment for potential confounders, short-term outcomes were similar between both devices
- The new 14F iSLEEVE Expandable Introducer is designed to further improve the rate of vascular complications with ACURATE *neo*
- The next generation ACURATE *neo2* with an enhanced sealing skirt is designed to further reduce the frequency and severity of PVL

1. Möllmann H et al. EuroIntervention 2017;13:e1040–6;
2. Möllmann et al. EuroIntervention 2018;13:e1764–70
3. Forrest et al. JACC Cv Intv 2018;11:160–8

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TAVI with next-generation self-expanding devices: a multicenter propensity-matched comparison of Evolut™ PRO versus ACURATE *neo*™ bioprostheses – NEOPRO Registry

NEOPRO

STUDY SUMMARY

ACURATE *neo* VS. Evolut PRO

Principal Investigators: Azeem Latib and Matteo Pagnesi, San Raffaele Scientific Institute, Milan, Italy
On behalf of the NEOPRO Registry investigators; Presented TCT 2018

PRESENTATION SUMMARY: NEOPRO REGISTRY, TCT 2018

TAVI WITH NEXT-GENERATION SELF-EXPANDING DEVICES: A MULTICENTER PROPENSITY-MATCHED COMPARISON OF EVOLUT™ PRO VERSUS ACURATE *neo*™ BIOPROSTHESES – NEOPRO REGISTRY

Azeem Latib, et al.; presented September 25, TCT 2018, San Diego, CA, USA

BACKGROUND

Several next-generation Transcatheter Heart Valves (THV) have been developed to minimize TAVI complications and improve outcomes.

The self-expanding ACURATE *neo* (Boston Scientific, 'NEO') and Evolut PRO (Medtronic, 'PRO') THVs have been associated with excellent clinical and echocardiographic outcomes[1-3], but no published data comparing ACURATE *neo* and Evolut PRO exist today.

The objective of this study was to compare short-term clinical and echocardiographic outcomes after transfemoral TAVI with the self-expanding NEO and PRO devices.

STUDY DESIGN AND METHODS

International, multicenter, observational, retrospective NEOPRO Registry.

A total of 1,551 patients (1,263 NEO, 288 PRO) treated at 24 centers between January 2012 and March 2018 were evaluated for this propensity score matching analysis.

All consecutive patients treated with transfemoral TAVI for symptomatic, severe aortic stenosis of the native aortic valve with either NEO or PRO implantation were included.

Propensity Score (PS) matching

1-to-1 nearest neighbor matching was performed without replacement to identify PS matched pairs.

Pseudo-R2 was 0.08 ($P < 0.0001$) before matching and very low (0.007; $P = 0.995$) after matching.

OVERALL COHORT
N = 1,551 (1,263 NEO, 288 PRO)

↓

PS-MATCHED COHORT
N = 502 (251 NEO, 251 PRO)

STUDY ENDPOINTS

Primary endpoint

- Device success according to VARC-2 criteria

Secondary outcomes

- Procedural outcomes (VARC-2 criteria)
- Pre-discharge echocardiographic outcomes
- 30-day clinical outcomes (VARC-2 criteria)

Primary and secondary endpoints were compared between NEO and PRO groups in the entire population and after PS matching.

DEVICES*

Device Characteristics	ACURATE *neo*	Evolut PRO
THV design	Self-expanding Supra-annular porcine pericardial leaflets Pericardial sealing-skirt	
Specific THV features	–	Repositionable Retrievable up to 80%
Easy of use	High	Intermediate
Sizes	23 mm (S) – 25 mm (M) – 27 mm (L)	23 mm – 26 mm – 29 mm
TF introducer sheath used	20F sheath	16F sheathless
Radial strength	Low	Intermediate

*As described by the study authors

RESULTS

PS-MATCHED COHORT: VARC-2 Endpoints and Procedural Characteristics

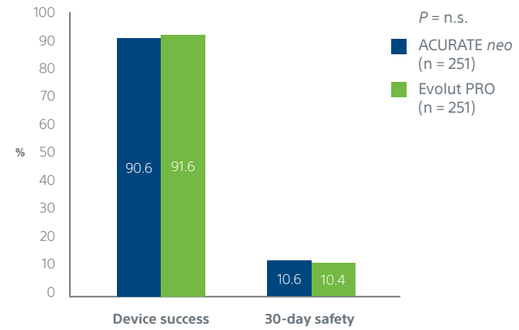
In the PS-matched cohort (N = 251/251), both devices showed similar 30-day clinical outcomes for the VARC-2 Device Success and also the Safety Composite Endpoint without any significant differences in the 30-day clinical outcomes.

Procedural characteristics show a higher rate of pre- and post-dilatation in ACURATE *neo*™ patients.

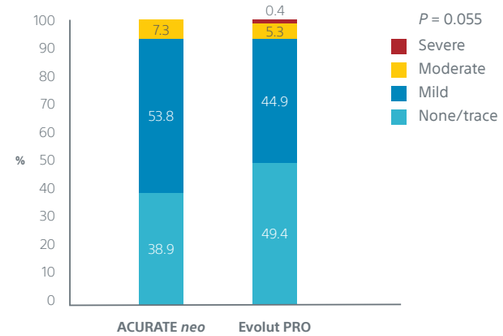
PROCEDURAL CHARACTERISTICS (PS-MATCHED COHORT)

	ACURATE *neo* (n = 251)	Evolut PRO (n = 251)	*P* value
Conscious sedation	96.4%	92.8%	0.112
Valve size			–
S (NEO) or 23 mm (PRO)	**23.9%**	**2.0%**	
M (NEO) or 26 mm (PRO)	41.8%	38.3%	
L (NEO) or 29 mm (PRO)	**34.3%**	**59.8%**	
Predilatation	86.5%	37.9%	<0.001
Postdilatation	41.4%	25.0%	<0.001
Valve repositioning	–	8.6%	–
Second THV implanted	0.8%	1.2%	1.000
Valve embolization	0.4%	0.8%	1.000
Annular rupture	0.0%	0.0%	–
Pericardial tamponade	2.0%	0.0%	0.061
Conversion to surgery	0.8%	0.0%	0.499
Mean AV gradient (mmHg)	8.3 ± 4.0	7.3 ± 3.6	0.003

VARC-2 Endpoints
(PS-matched cohort, % of patients)



Paravalvular Leak Rates
(PS-matched cohort, % of patients)



In the PS-matched cohort, ACURATE *neo* patients showed higher PVL rates greater than mild as compared to the overall ACURATE *neo* cohort (7.3% vs. 5.2%) due to the higher rate of moderate and heavy AV calcification at baseline in the PS-matched cohort.