



Multicenter comparison of latest generation self-expanding versus balloon-expandable transcatheter aortic valves

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Potential conflicts of interest

Speaker's name : Won-Keun Kim

I have the following potential conflicts of interest to declare:

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

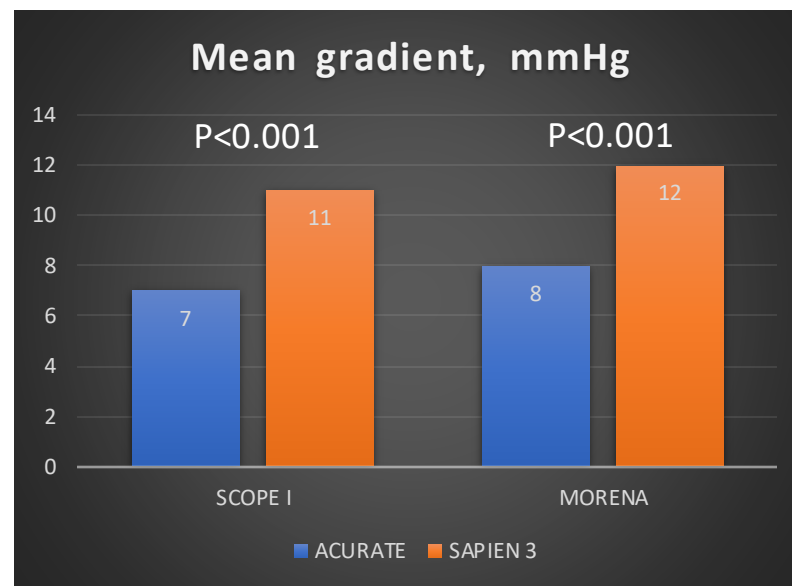
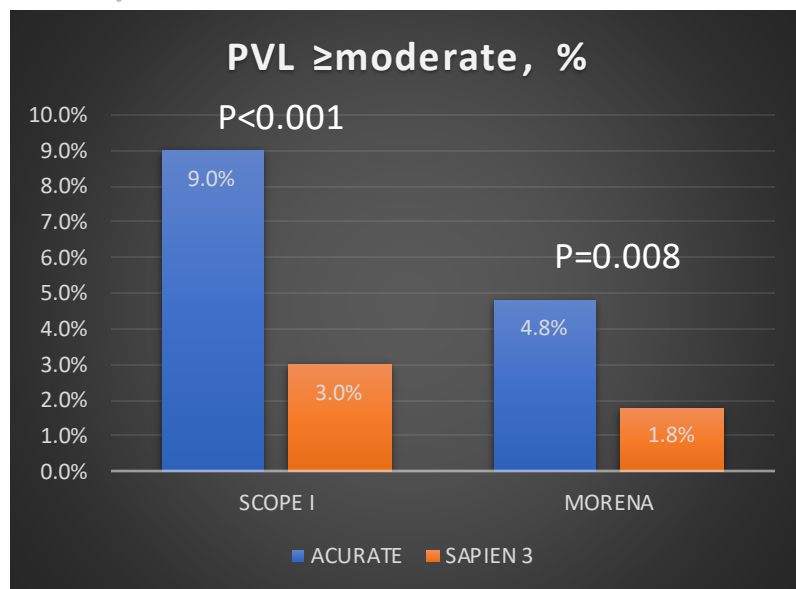
Why this study?



ACURATE *neo* (first gen)



SAPIEN 3



Lanz et al., *The Lancet*, 2019
Husser et al., *JACC Interv*, 2017

- No comparative data on latest generation transcatheter heart valves.

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What did we study?

- New iterations for both valves are now available

SCOPE I MORENA

ACURATE neo 1



(CE 2014)



ACURATE neo2 1



(CE 2020)

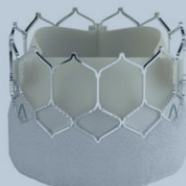
SAPIEN 3 1



(CE 2014)



SAPIEN 3 Ultra 1



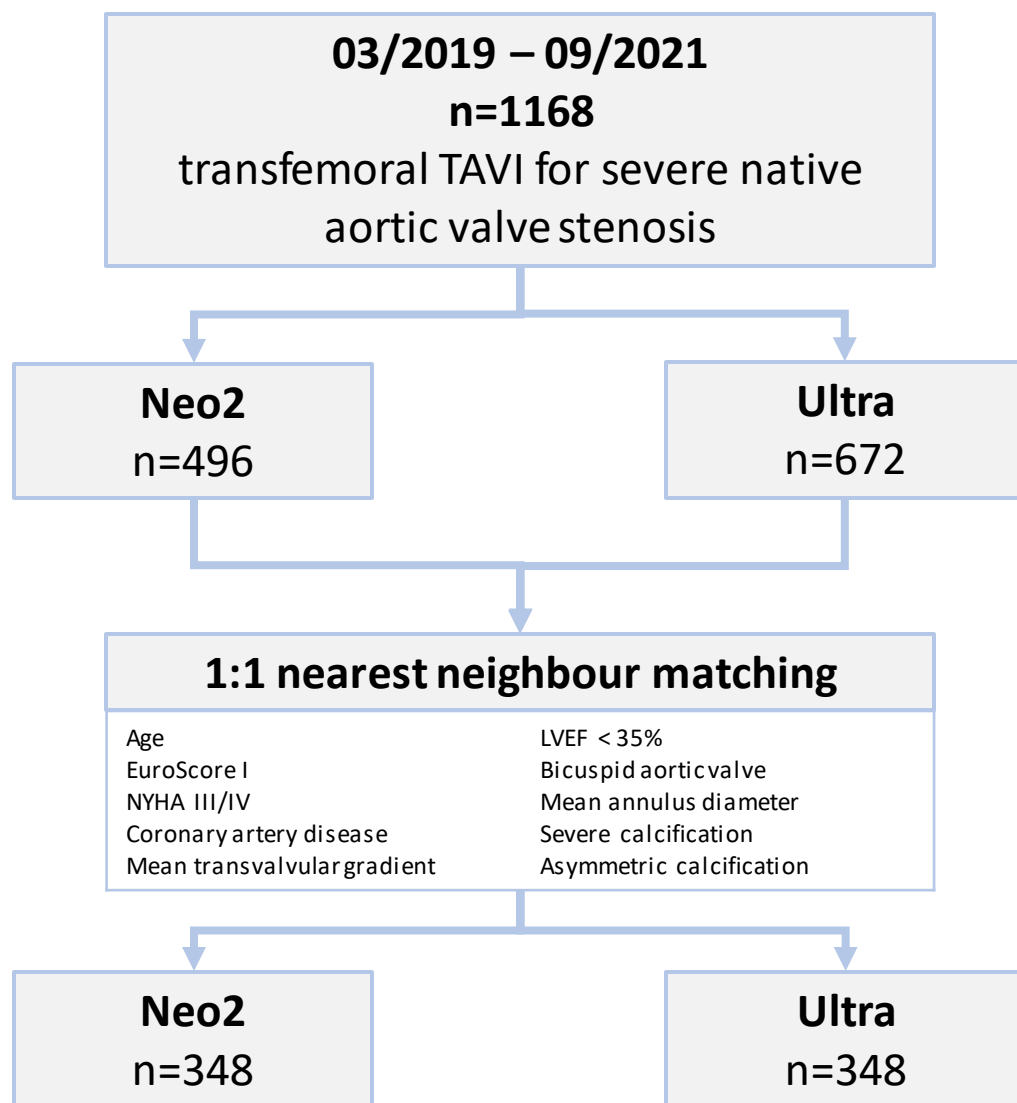
(CE 2018)

Frame	Nitinol
Leaflets	Porcine, supra-annular
Expansion	Self-expanding (top-down)
Valve sizes	S, M, L
Annulus range	21 to 27 mm
Sheath inner diameter	14-French
PVL reduction	Augmented Outer & inner skirt of 60%
New features	Radiopaque positioning markers for placement accuracy

Frame	Cobalt-chromium
Leaflets	Bovine, intra-annular
Expansion	Balloon-expandable
Valve sizes	20mm, 23 mm and 26 mm
Annulus range	18.6 to 26.4 mm
Sheath inner diameter	14-French expandable
PVL reduction	Outer cuff & inner skirt

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How was the study executed?



- **Primary endpoint:**
Device success (VARC-3)
- **Secondary endpoints:**
VARC-3 criteria

What are the essential results? (1)

- No significant baseline differences after 1:1 matching

	Entire population			Matched population		
	Neo2 n=496	Ultra n=672	p-value	Neo2 n=348	Ultra n=348	p-value
Age, years	82 [79 - 85]	81 [77 - 85]	0.026	82 [79 - 85]	82 [78 - 85]	0.657
Female gender	240 (48.4)	351 (52.2)	0.214	180 (51.7)	188 (54.0)	0.595
Logistic EuroScore, %	14.4 [8.1 - 23.1]	12.5 [7.7 - 21.1]	0.028	14.2 [8.2 - 23.1]	13.1 [7.9 - 21.9]	0.285
Coronary artery disease	303 (61.1)	504 (75.0)	<0.001	247 (71.0)	254 (73.0)	0.613
Previous myocardial infarction	44 (8.9)	74 (11.0)	0.240	36 (10.3)	37 (10.6)	0.999
Previous stroke	63 (12.7)	87 (12.9)	0.930	47 (13.5)	44 (12.6)	0.822
COPD	64 (12.9)	73 (10.9)	0.312	49 (14.1)	41 (11.8)	0.429
Peripheral artery disease	72 (14.5)	119 (17.7)	0.150	50 (14.4)	63 (18.1)	0.217
eGFR, ml/min	65 [48 - 84]	64 [48 - 80]	0.395	65 [47 - 84]	63 [48 - 79]	0.375
Previous pacemaker	58 (11.7)	66 (9.8)	0.337	38 (10.9)	35 (10.1)	0.805
Atrial fibrillation	203 (40.9)	264 (39.3)	0.587	152 (43.7)	139 (39.9)	0.356
Right bundle branch block	52 (10.5)	78 (11.6)	0.573	39 (11.2)	43 (12.4)	0.724
LVEF <35%	14 (2.8)	37 (5.5)	0.029	14 (4.0)	11 (3.2)	0.685
Mean gradient, mmHg	42 [32 - 50]	44 [37 - 54]	<0.001	42 [32 - 50]	42 [35 - 50]	0.552
Bicuspid aortic valve	18 (3.6)	91 (13.5)	<0.001	16 (4.6)	22 (6.3)	0.404
Severe aortic valve calcification	53 (10.7)	278 (41.4)	<0.001	53 (15.2)	65 (18.7)	0.266
Asymmetric calcification	95 (19.2)	310 (46.1)	<0.001	90 (25.9)	93 (26.7)	0.863

What are the essential results? (2)

	Neo2 (n=496)	Ultra (n=672)	p-value	Neo2 (n=348)	Ultra (n=348)	p-value
Pre-dilatation	430 (86.7)	234 (34.8)	<0.001	312 (89.7)	97 (27.9)	<0.001
Post-dilatation	202 (40.7)	94 (14.0)	<0.001	150 (43.1)	50 (14.4)	<0.001
Procedural time, min	44 [35 - 60]	45 [35 - 57]	0.605	44 [35 - 60]	45 [36 - 57]	0.981
Fluoroscopy time, min	9.5 [6.9 - 13.3]	10.2 [7.0 - 14.3]	0.128	9.6 [7.1 - 13.3]	10.2 [6.9 - 14.0]	0.354
Moderate to severe PVL*	3 (0.6)	5 (0.8)	0.999	2 (0.6)	4 (1.1)	0.686
Mean gradient ≥ 20mmHg	10 (2.0)	66 (9.9)	<0.001	9 (2.6)	34 (9.8)	<0.001
Severe PPM**	8 (2.1)	38 (16.0)	<0.001	6 (2.3)	18 (15.5)	<0.001
Device success (VARC-3)	455 (91.7)	559 (83.2)	<0.001	324 (93.1)	289 (83.0)	<0.001
Multiple valves	2 (0.4)	1 (0.1)	0.578	0 (0)	1 (0.3)	0.999
Annular rupture	1 (0.2)	1 (0.1)	0.999	0 (0)	0 (0)	0.999
Stroke	15 (3.0)	23 (3.4)	0.704	13 (3.7)	9 (2.6)	0.516
Acute kidney injury St 2-4	17 (3.4)	21 (3.1)	0.773	13 (3.7)	10 (2.9)	0.525
30-day Pacemaker implantation	34/429 (7.9)	63/596 (10.6)	0.154	23/304 (7.6)	36/308 (11.7)	0.084
30-day mortality	10/488 (2.0)	17/660 (2.6)	0.561	9/343 (2.6)	9/341 (2.6)	0.990

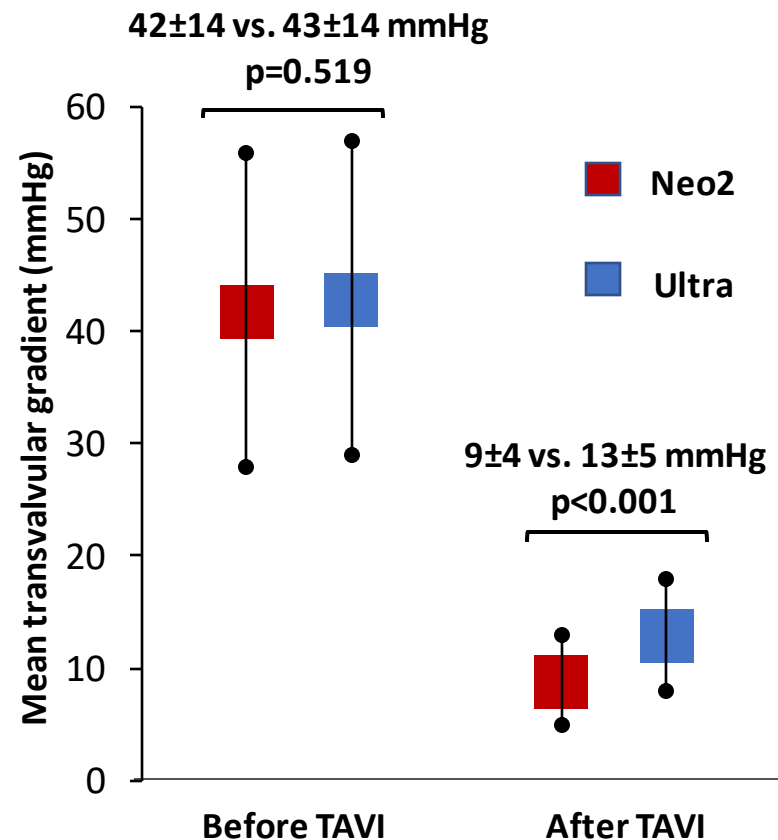
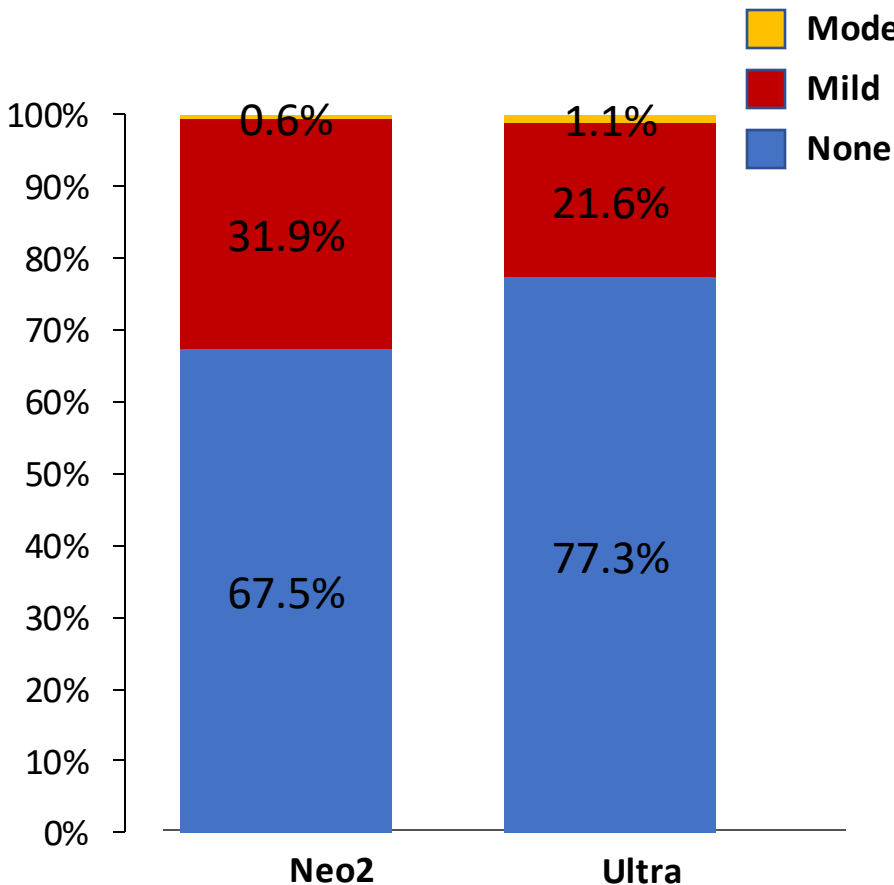
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What are the essential results? (3)

- Lower rates of mild paravalvular regurgitation in the Ultra group
- Lower transvalvular gradients in the Neo2 group



Why is this important?

- Rates of moderate or severe paravalvular leakage were overall low and comparable with both THVs, but mild paravalvular leakage occurred less frequently with the Ultra
- Transvalvular gradients were lower for Neo2 => higher device success!
- Our results emphasize the need for a patient-tailored differential selection of THVs.

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The essentials to remember

- **why?** After the randomized SCOPE I trial, novel iterations of the ACURATE neo and the SAPIEN 3 became available
- **what?** First direct comparison of the ACURATE neo2 and the Ultra valves
- **how?** Multicenter propensity matched comparison including >1100 patients
- **what are the results?** Both valves showed excellent clinical results at 30 days, the ACURATE neo2 showed lower transvalvular gradients, whereas the Ultra showed lower rates of mild paravalvular regurgitation.
- **why is this important?** Patient-tailored valve selection may help to optimize outcomes.

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