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

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Objectives: To compare outcomes after transcatheter aortic valve replacement (TAVR) using the latest generation self-expanding ACURATE neo2 (Neo2) and the balloon-expandable SAPIEN 3 Ultra (Ultra) transcatheter heart valves (THV).

Methods: 722 patients at 4 centers were included and treated either with Neo2 (n=230) or Ultra (n=492) THV. Using 1-to-1 propensity score matching (PSM), 178 matched pairs were identified.

Results: While rates of moderate to severe paravalvular leakage (PVL II+) were overall low and similar (1.1% vs. 1.1%; p=0.999), elevated transprosthetic gradients (≥20 mmHg) were less frequent with Neo2 (0.6% vs. 7.3%; p=0.003), which translated into a significantly higher rate of device success with Neo2 compared with Ultra (94.9% vs. 84.3%; p=0.002). Overall stroke rates, major vascular complications, life-threatening bleedings and need for permanent pacemaker implantation as well as 30-day mortality were comparable between the two groups.

Conclusions: In this multicenter registry, short-term outcomes after TAVR using the Neo2 or Ultra THV were excellent and overall comparable. However, transprosthetic gradients were lower with the Neo2 platform, which translated into a lower rate of device failure.

Disclosures

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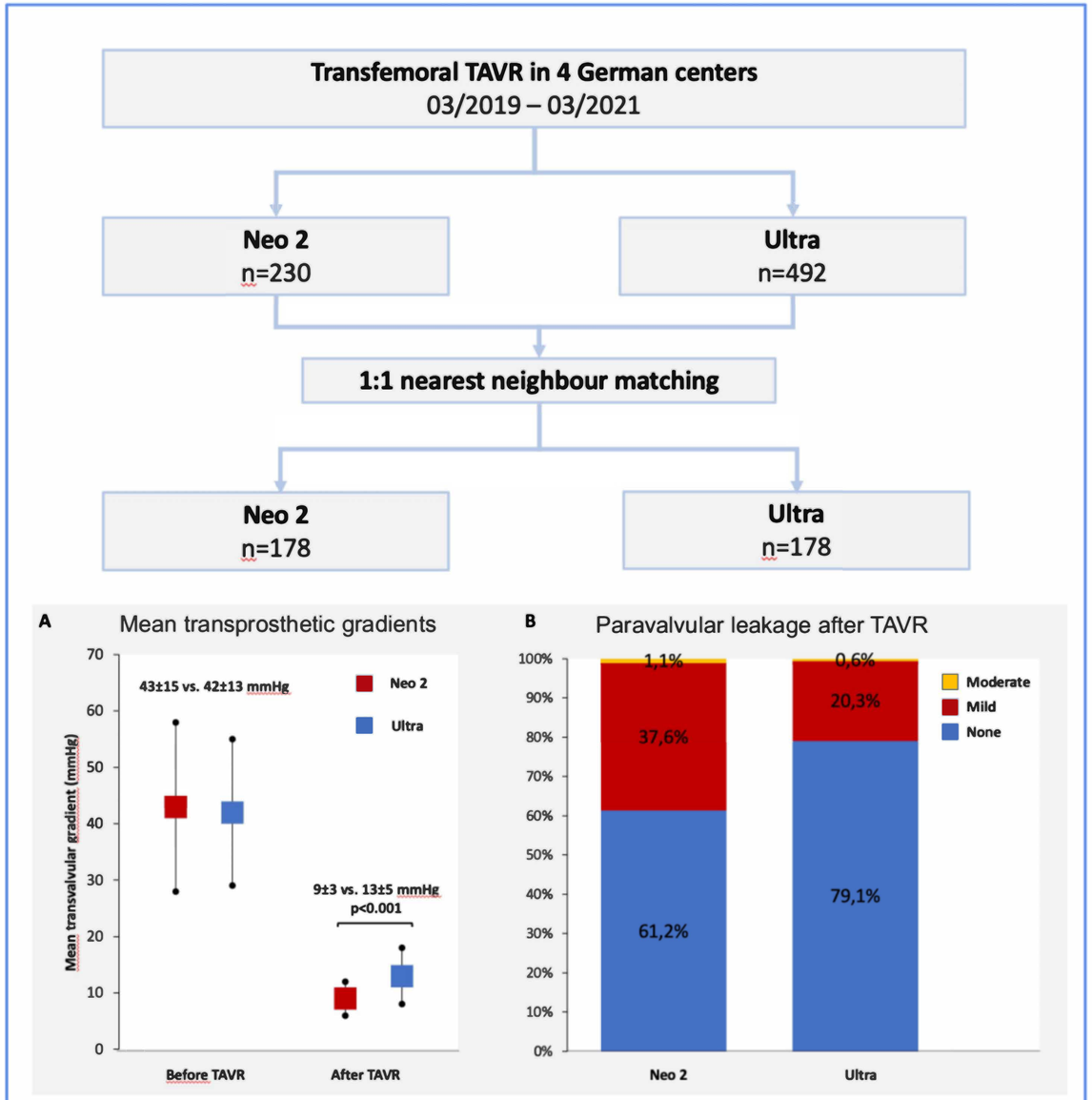

Central Illustration: Study flow and main outcomes in the matched population. Abbreviations: Neo2, ACURATE neo2; Ultra; SAPIEN 3 Ultra.

Table 1 – Procedural outcomes in the matched population

	Neo2 (n=178)	Ultra (n=178)	p-value
Conscious sedation	177 (99.4)	176 (98.9)	0.999
Pre-dilatation	147 (82.6)	45 (25.3)	<0.001
Post-dilatation	71 (39.9)	22 (12.4)	<0.001
Procedural time, min	47 [36 - 64]	44 [35 - 57]	0.056
Contrast agent, ml	40 [20 - 105]	110 [50 - 150]	<0.001
Fluoroscopy time, min	10 [7 - 13]	10 [7 - 14]	0.340
Cover index by area, %	7.20 [5.20 - 9.49]	2.87 [-0.28 - 6.14]	<0.001
Cover index by perimeter, %	5.38 [3.48 - 7.78]	1.26 [-2.73 - 4.42]	<0.001
Device success (VARC-2)	169 (94.9)	150 (84.3)	0.002
Procedural mortality	0 (0)	1 (0.6)	0.999
Correct implant position	175 (98.3)	178 (100)	0.246
Multiple valves	0 (0)	1 (0.6)	0.999
Conversion to sternotomy	1 (0.6)	1 (0.6)	0.999
Moderate to severe aortic regurgitation on angiography	2 (1.1)	2 (1.1)	0.999
Mean gradient ≥ 20mmHg	1 (0.6)	13 (7.3)	0.003
Severe PPM*	2/144 (1.4)	11/68 (16.2)	<0.001
Annular rupture	0 (0)	0 (0)	NA

Data are mean ± standard deviation, median [interquartile range] or n (%). Abbreviations: PPM, patient prosthesis mismatch; VARC-2, updated Valve Academic Research Consortium.

Table 2 – In-hospital and 30 days clinical outcome in the matched population

	Neo2 (n=178)	Ultra (n=178)	p-value
All stroke	8 (4.5)	7 (3.9)	0.999
New pacemaker implantation*	13 (8.2)	16 (9.7)	0.699
Major vascular complication	10 (5.6)	18 (10.1)	0.167
Life-threatening bleeding	7 (3.9)	8 (4.5)	0.999
Myocardial infarction	0 (0.0)	1 (0.6)	0.999
Coronary obstruction	1 (0.6)	1 (0.6)	0.999
Acute kidney injury 2/3	3 (1.7)	3 (1.7)	0.999
In-hospital mortality	1 (0.6)	1 (0.6)	0.999
30 days clinical outcome	n=171**	n=177**	
All-cause mortality	4 (2.3)	5 (2.8)	0.999
All-stroke	8 (4.7)	7 (4.0)	0.796
Rehospitalization for CHF	0 (0)	2 (1.1)	0.499
Repeat procedure	0 (0)	0 (0)	0.999

Abbreviations: CHF, congestive heart failure. *excluding patients with pacemaker at baseline