ACURATE NEO2:
Features and Benefits for Optimized TAVR

Young-Guk Ko, M.D.

Severance Cardiovascular Hospital, Yonsei University Health System,

Seoul, Korea

Disclosure

- Consulting:
  - Genoss, S&G
- Research grants:
  - Medtronic, Cook Medical, Boston Scientific, Otsuka Korea, Dong-A ST, Samjin Pharm
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  - Medtronic, Cook Medical, Abbott, Cordis
- Proctor:
  - Medtronic, Edwards

ACURATE NEO 2:
Improved Design to Reduce Paravalvular Leak

ACURATE *neo*

CE mark 2014
for transfemoral TAVR

Porcine pericardium leaflets

ACURATE *neo2*

CE mark 2020
(Investigational device in the USA)

Nitinol frame
- Self-expanding; top-down, two-step deployment
- Low radial force reduces mechanical injury

Supra-annular positioning
- Large effective orifice areas and low gradients

Stabilization arches
- Axial self-alignment of valve within native annulus
- Open cells facilitate coronary access

Upper crown
- Supra-annular anchoring
- Captures native leaflets to provide coronary clearance

Pericardial sealing skirt
- Compared with *neo*, the skirt on *neo2* is 60% larger and features 'active sealing'

Lower crown
- Minimal protrusion into LVOT
- Low risk of conduction system interference

Transfemoral Delivery System

14F iSLEEVE Expandable Introducer

Flexible Delivery Catheter
- Reduced risk of vascular complications
- Full range of ACURATE neo2 valve sizes

Radiopaque Positioning Marker
- Enables high placement accuracy

Atraumatic Tip
- Reliable tracking
- Smooth guidewire transition

Top-Down Deployment
- Stable and preditable valve release
- No requirement for rapid pacing during deployment

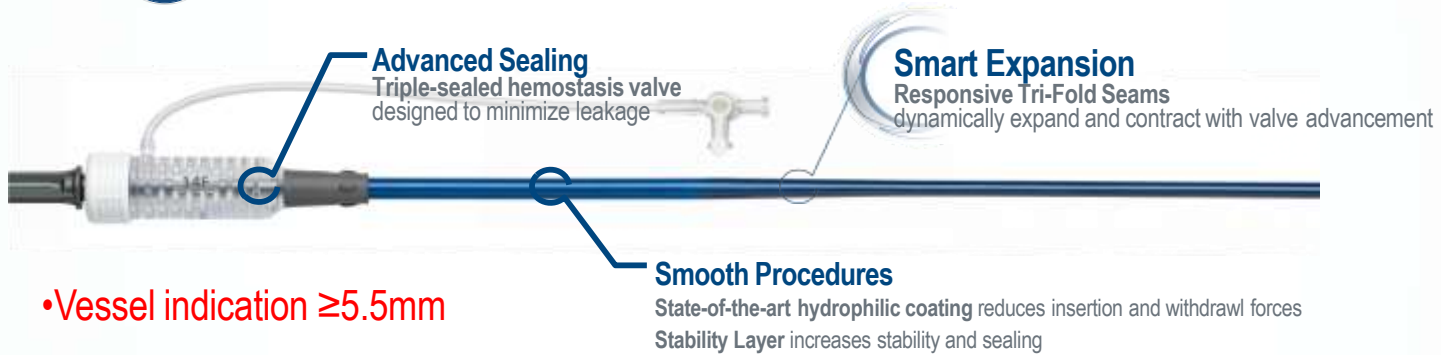**Two Rotation Knobs**
- Intuitive step-by-step implantation

Safety Button
- Prevents premature implantation

# Expandable Introducer

14F iSLEEVE™ Expandable Introducer

Advanced Sealing
Triple-sealed hemostasis valve
designed to minimize leakage

Smart Expansion
Responsive Tri-Fold Seams
dynamically expand and contract with valve advancement

• Vessel indication ≥5.5mm

Smooth Procedures
State-of-the-art hydrophilic coating reduces insertion and withdrawl forces
Stability Layer increases stability and sealing

Stable and Predictable Deployment

Top-Down Deployment delivers the hemodynamic stability and positioning accuracy needed for high procedural success and low complication rates

Valve Positioning
- Flexible delivery system
- Accurate positioning
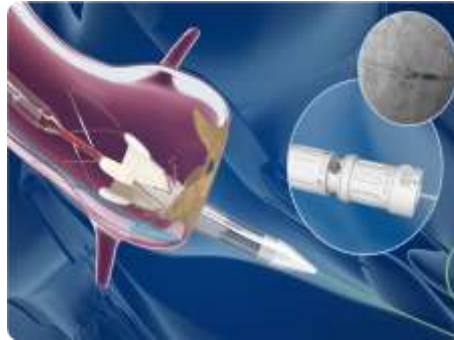
Top-Down Deployment
- Co-axial self-alignment
- Hemodynamic stability
- No requirement for rapid pacing*
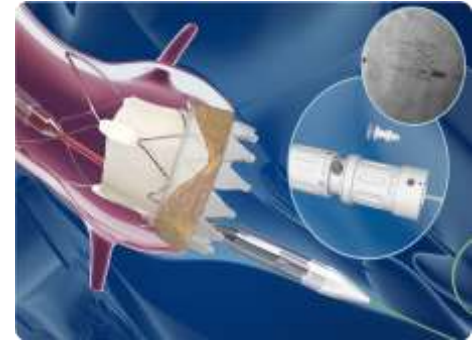
Valve Release
- Controlled release
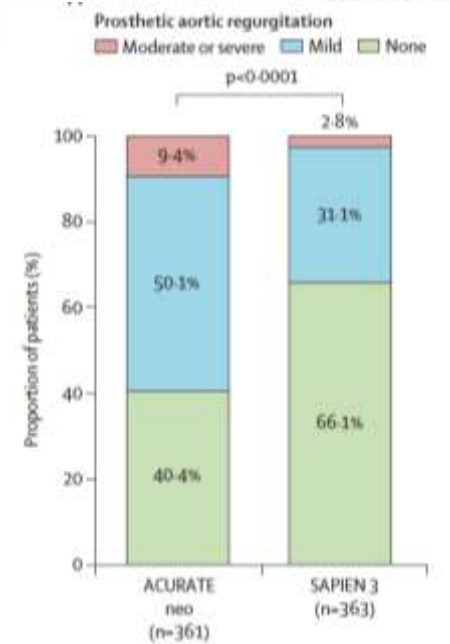- Predictable deployment

ACURATE Neo2: Valve Sizing

S – 23 mm   **M – 25 mm**   **L – 27 mm**

ACURATE neo2 ™ Aortic Valve			
Aortic annulus diameter*	21 mm ≤ annulus diameter ≤ 23 mm	23 mm < annulus diameter ≤ 25 mm	25 mm < annulus diameter ≤ 27 mm
Aortic annulus perimeter (mm)	66 mm ≤ annulus perimeter ≤ 72 mm	72 mm < annulus perimeter ≤ 79 mm	79 mm < annulus perimeter ≤ 85 mm

SCOPE 1: ACURATE Neo vs SAPIEN 3

Primary endpoint: VARC 2 safety & efficacy endpoints including all-cause death, any stroke, life-threatening or disabling bleeding, major vascular complications, coronary artery obstruction requiring intervention, AKI (stage 2 or 3), rehospitalisation for valve-related symptoms or CHF, valve-related dysfunction requiring repeat procedure, moderate or severe prosthetic valve regurgitation, or prosthetic valve stenosis within 30 days of the procedure.
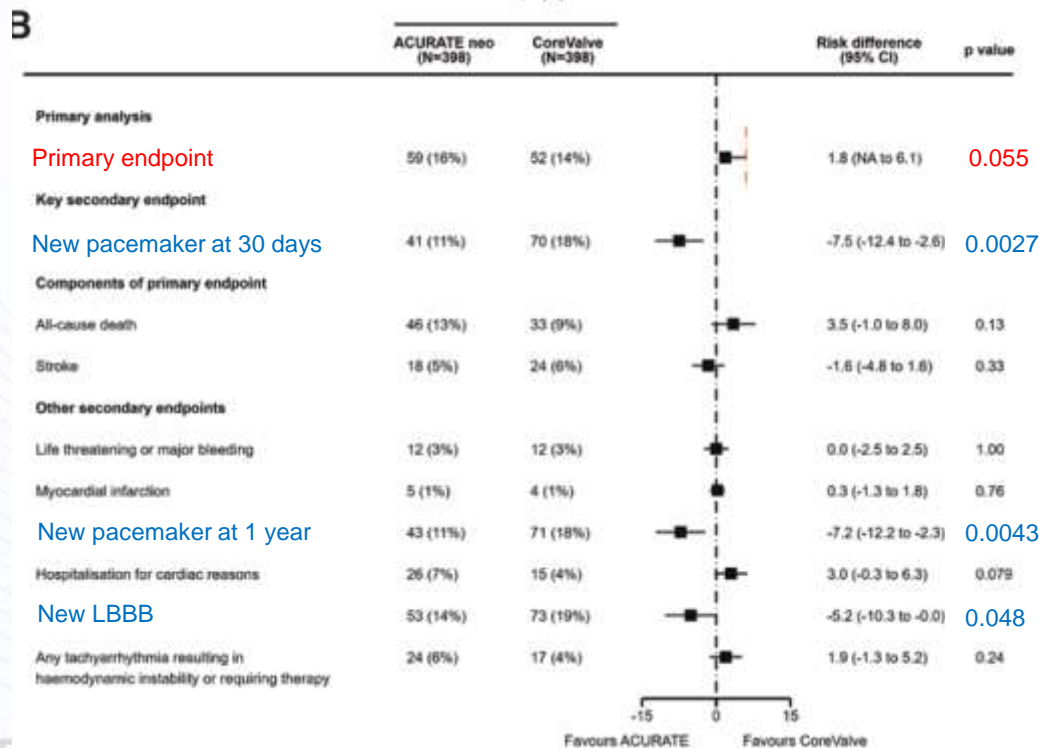
SCOPE 2: ACURATE Neo vs EVOLUT
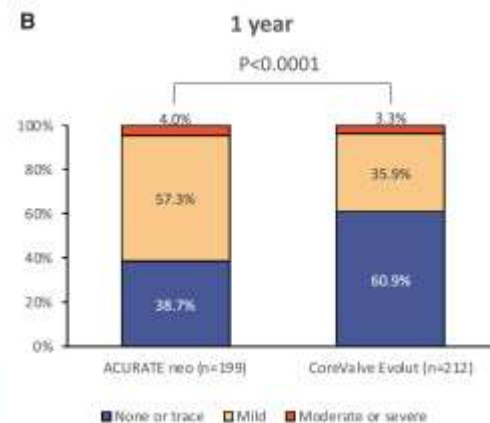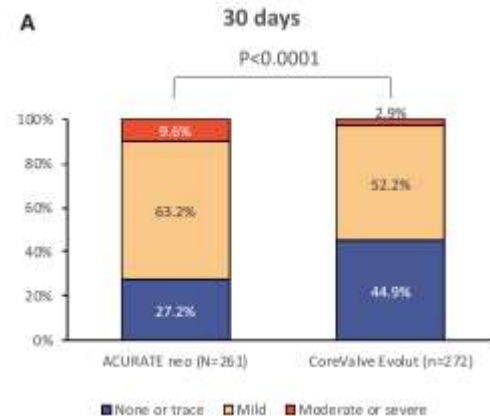
RCT (n=398, each group)
Primary endpoint: all-cause death or any stroke at 1 year
15.8% (ACURATE Neo) vs 13.9% (Evolut), p = 0.055 (non-inferiority)
Cardiac death 8% vs. 4%, p=0.01

Paravalvular Leak

B

|	ACURATE neo (N=398)	CoreValve (N=398)	Risk difference (95% CI)	p value
Primary analysis				
Primary endpoint	59 (16%)	52 (14%)	1.8 (NA to 6.1)	0.055
Key secondary endpoint				
New pacemaker at 30 days	41 (11%)	70 (18%)	-7.5 (-12.4 to -2.6)	0.0027
Components of primary endpoint				
All-cause death	46 (13%)	33 (9%)	3.5 (-1.0 to 8.0)	0.13
Stroke	18 (5%)	24 (6%)	-1.6 (-4.8 to 1.6)	0.33
Other secondary endpoints				
Life threatening or major bleeding	12 (3%)	12 (3%)	0.0 (-2.5 to 2.5)	1.00
Myocardial infarction	5 (1%)	4 (1%)	0.3 (-1.3 to 1.8)	0.76
New pacemaker at 1 year	43 (11%)	71 (18%)	-7.2 (-12.2 to -2.3)	0.0043
Hospitalisation for cardiac reasons	26 (7%)	15 (4%)	3.0 (-0.3 to 6.3)	0.079
New LBBB	53 (14%)	73 (19%)	-5.2 (-10.3 to -0.0)	0.048
Any tachyarrhythmia resulting in haemodynamic instability or requiring therapy	24 (6%)	17 (4%)	1.9 (-1.3 to 5.2)	0.24

Favours ACURATE   Favours CoreValve
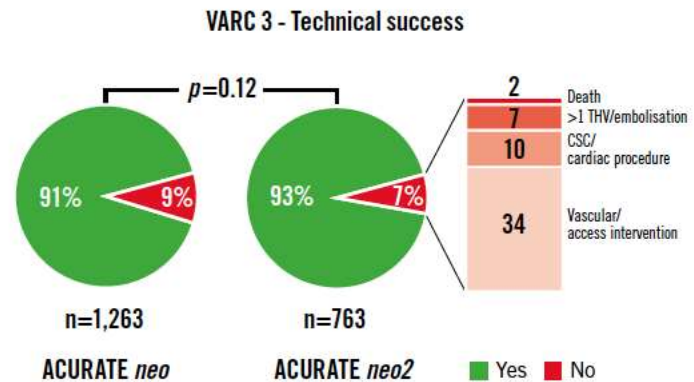
Acurate Neo vs. Acurate Neo2
Haemodynamic performance and clinical outcomes

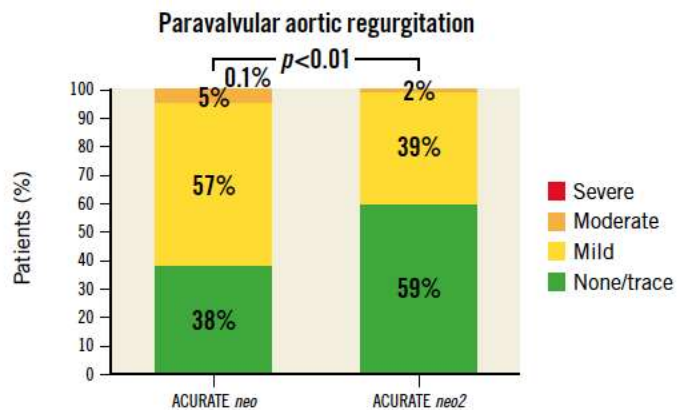*NEOPRO and NEOPRO-2 registries from European centers: Neo (n=1,263), Neo2 (n=763)*
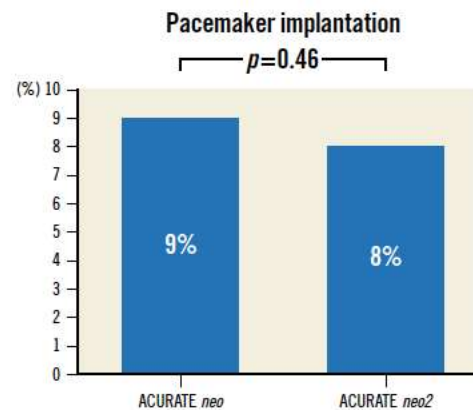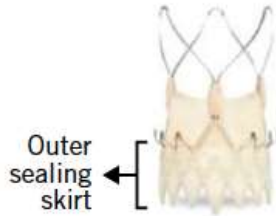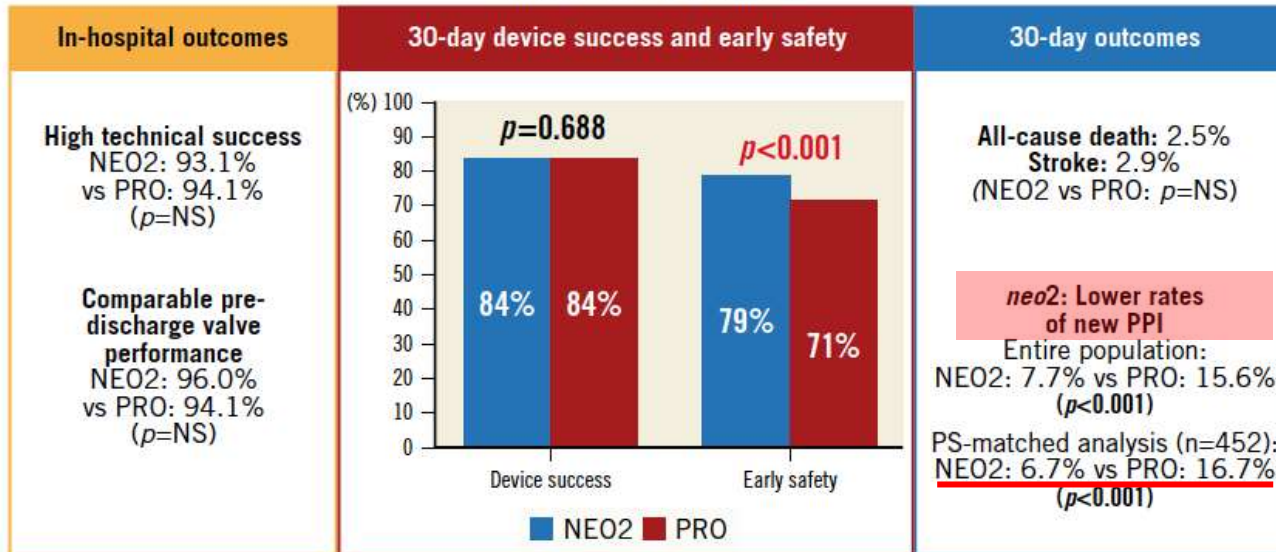

Scotti A, EuroIntervention 2022;18:804-811
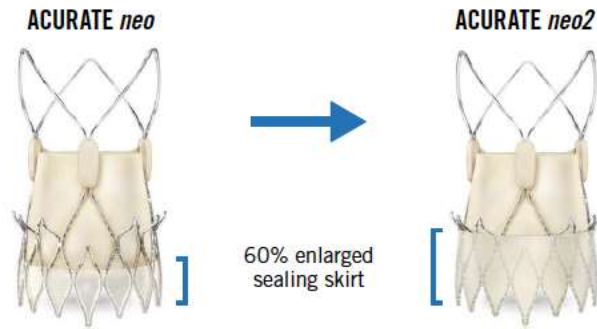
Acurate Neo2 vs. Evolut Pro/Pro+
NEOPRO-2 registry
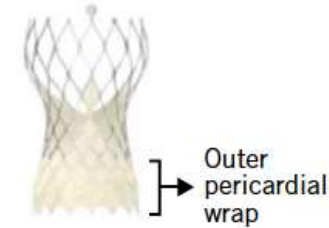
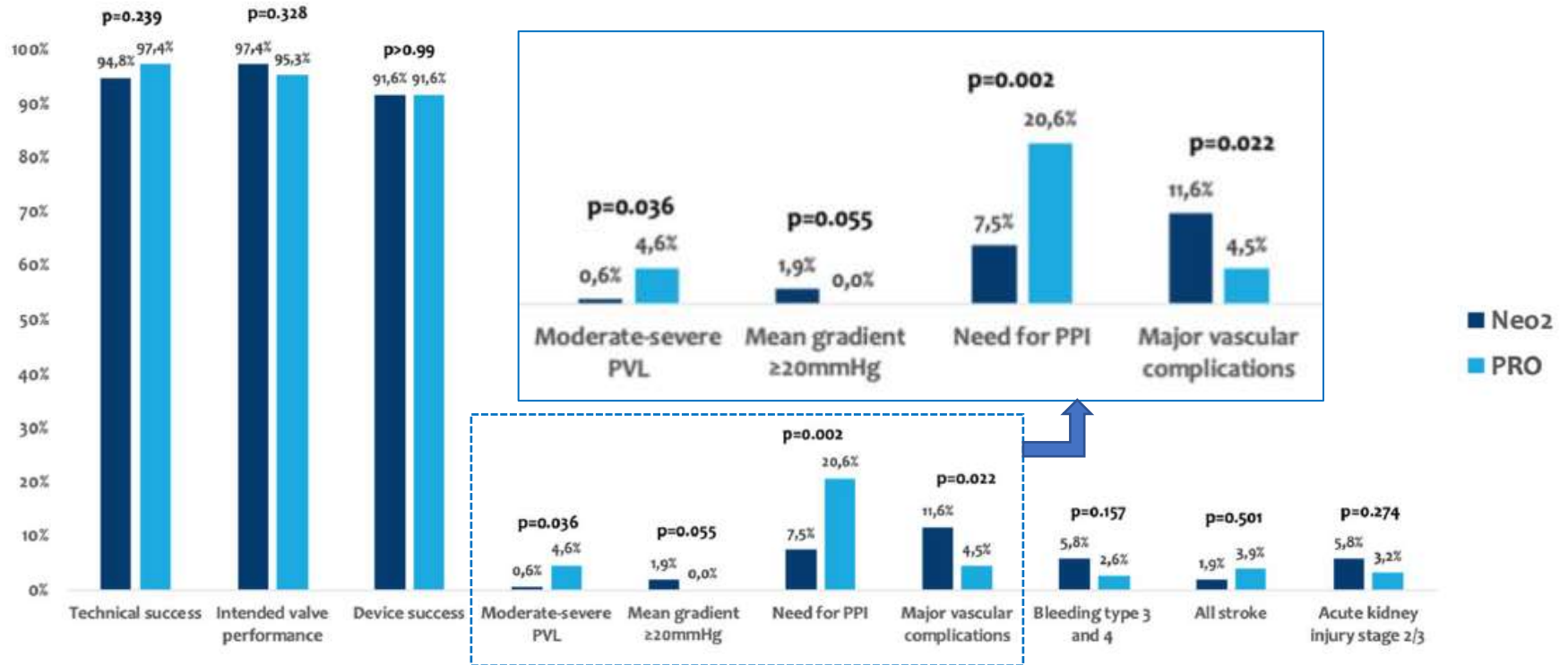# ACURATE NEO2 vs. EVOLUT PRO: Early Outcomes

PS Matched cohort from 7 German Centers
Neo2 (n = 496) or PRO (n = 213) => n=155 in each group

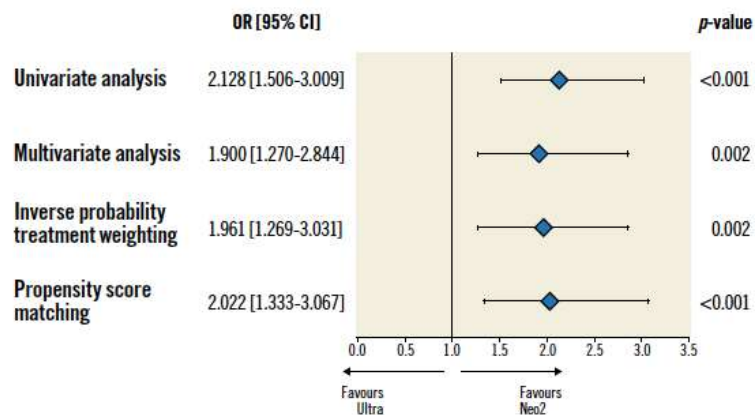*Rheude T, Clin Res Cardiol 2023 in press*

ACURATE NEO2 vs. SAPIEN ULTRA

Cohort from 4 German centers: n = 1356

	Entire population			Matched population		
	Neo2 n=608	Ultra n=748	*p*-value	Neo2 n=472	Ultra n=472	*p*-value
Post-procedural characteristics						
Moderate to severe PVL*	4 (0.7)	6 (0.8)	1.000	3 (0.6)	5 (1.1)	0.723
Mean gradient ≥20 mmHg	11 (1.8)	69 (9.3)	<0.001	11 (2.4)	36 (7.7)	<0.001
Indexed effective orifice area, cm²**	0.92 [0.79, 1.05] (n=453)	0.78 [0.68, 0.90] (n=261)	<0.001	0.92 [0.79, 1.05] (n=342)	0.78 [0.67, 0.91] (n=167)	<0.001
Severe PPM**	10 (2.2) (n=453)	39 (14.9) (n=261)	<0.001	10 (2.9) (n=342)	25 (15.0) (n=167)	<0.001
Annular rupture	1 (0.2)	2 (0.3)	1.000	1 (0.2)	0 (0.0)	0.999

VARC-3 defined device success

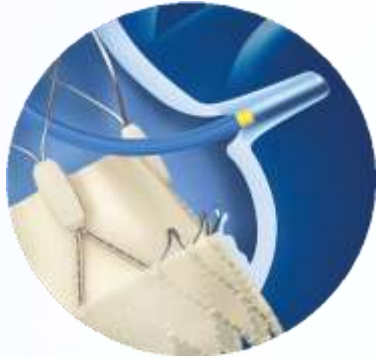|	OR [95% CI]		*p*-value
Univariate analysis	2.128 [1.506-3.009]		<0.001
Multivariate analysis	1.900 [1.270-2.844]		0.002
Inverse probability treatment weighting	1.961 [1.269-3.031]		0.002
Propensity score matching	2.022 [1.333-3.067]		<0.001

Favours Ultra ← → Favours Neo2

Device success was defined as technical success, freedom from mortality, freedom from surgery or intervention related to the device or to a major vascular, access-related or cardiac structural complication, and performance of the valve as intended (mean gradient <20 mmHg, peak velocity <3m/s, Doppler velocity index >0.25 and less than moderate AR)

28th TCTAP

ACURATE NEO2 vs. SAPIEN ULTRA

	Entire population			Matched population		
	Neo2 n=608	Ultra n=748	*p*-value	Neo2 n=348	Ultra n=348	*p*-value
In-hospital clinical outcomes						
All-stroke	17 (2.8)	24 (3.2)	0.778	16 (3.4)	11 (2.3)	0.435
New permanent pacemaker implantation*	40/553 (7.5)	66/677 (9.7)	0.170	33/415 (8.0)	42/426 (9.9)	0.332
Major vascular complication (VARC-3)	39 (6.4)	66 (8.8)	0.122	29 (6.1)	45 (9.5)	0.069
Bleeding type 3 and 4 (VARC-3)	26 (4.3)	33 (4.4)	0.999	18 (3.8)	17 (3.6)	0.999
Cardiac structural complication (VARC-3)	5 (0.8)	12 (1.6)	0.298	4 (0.8)	5 (1.1)	0.999
Myocardial infarction	0 (0.0)	3 (0.4)	0.326	0 (0.0)	2 (0.4)	0.479
Coronary obstruction requiring PCI	1 (0.2)	3 (0.4)	0.768	1 (0.2)	2 (0.4)	0.999
AKIN 2/3/4	18 (3.0)	23 (3.1)	0.999	15 (3.2)	15 (3.2)	0.999
In-hospital mortality	7 (1.2)	7 (0.9)	0.904	5 (1.1)	4 (0.8)	0.999
30-day clinical outcomes	Neo2 n=598**	Ultra n=734**	*p*-value	Neo2 n=464**	Ultra n=465**	*p*-value
All-cause mortality	11 (1.8)	18 (2.5)	0.566	8 (1.7)	11 (2.4)	0.646
All-stroke	18 (3.0)	23 (3.1)	0.999	16 (3.4)	11 (2.4)	0.435
Cardiovascular rehospitalisation	5 (0.8)	7 (1.0)	0.999	5 (1.1)	3 (0.6)	0.723
New pacemaker implantation*	40/522 (7.7)	70/664 (10.5)	0.090	33/406 (8.1)	43/419 (10.3)	0.289
Repeat procedure	0 (0.0)	1 (0.1)	0.999	0 (0.0)	0 (0.0)	–

Data are median [interquartile range] or n (%). *Excluding patients with pacemaker at baseline. **Patients with available follow-up at 30 days in the entire population 1,332/1,356 and in the matched population 929/944. AKIN: Acute Kidney Injury Network classifcation; CHF: congestive heart failure; PCI: percutaneous coronary intervention; THV: transcatheter heart valve

# Coronary Cannulation After TAVR: RE-ACCESS Study

	Overall (N = 300)	Coronary Artery Accessible (n = 277)	Coronary Artery Not Accessible (n = 23)	p Value
Mean TAV implantation depth, mm	−6.2 ± 2.9	−6.2 ± 3.0	−5.0 ± 1.2	<0.01
TAV/annular oversizing by area, %	22.4 ± 19.8	20.1 ± 18.7	36.9 ± 10.9	<0.01
TAV/annular oversizing by perimeter, %	12.3 ± 8.5	11.3 ± 8.1	23.5 ± 4.5	<0.01
TAV-SoV relation, %*	−12.6 ± 9.8	−13.6 ± 9.3	−0.7 ± 7.7	<0.01
TAV-SoV relation, %†	−19.6 ± 7.8	−19.9 ± 7.9	−16.8 ± 6.1	0.03
Medtronic Evolut R/PRO	123 (41.0)	101 (36.5)	22 (95.7)	<0.01
23 mm	0 (0.0)	0 (0.0)	0 (0.0)	
26 mm	78 (26.0)	62 (22.4)	16 (69.6)	
29 mm	36 (12.0)	30 (10.8)	6 (26.1)	
34 mm	9 (3.0)	9 (3.2)	0 (0.0)	
Edwards SAPIEN 3/ULTRA	96 (32.0)	95 (34.3)	1 (4.3)	<0.01
20 mm	0 (0.0)	0 (0.0)	0 (0.0)	
23 mm	24 (8.0)	23 (8.3)	1 (4.3)	
26 mm	45 (15.0)	45 (16.2)	0 (0.0)	
29 mm	27 (9.0)	27 (9.7)	0 (0.0)	
Boston Scientific Acurate neo	72 (24.0)	72 (26.0)	0 (0.0)	<0.01
Size S	21 (7.0)	21 (7.6)	0 (0.0)	
Size M	39 (13.0)	39 (14.1)	0 (0.0)	
Size L	12 (4.0)	12 (4.3)	0 (0.0)	
Abbott Portico	9 (3.0)	9 (3.2)	0 (0.0)	0.38
23 mm	0 (0.0)	0 (0.0)	0 (0.0)	
25 mm	6 (2.0)	6 (2.2)	0 (0.0)	
27 mm	3 (1.0)	3 (1.1)	0 (0.0)	
29 mm	0 (0.0)	0 (0.0)	0 (0.0)	

100% successful coronary cannulation.

Barbanti M, JACC Intv 2020;13:2542

F/82

- Sx: Aggravated DOE
- PHx:
  - HTN
  - CAD (2-VD), S/P PCI at dLAD (2011)
  - old CVA
- Body Ht/Wt: 155 cm/57 kg
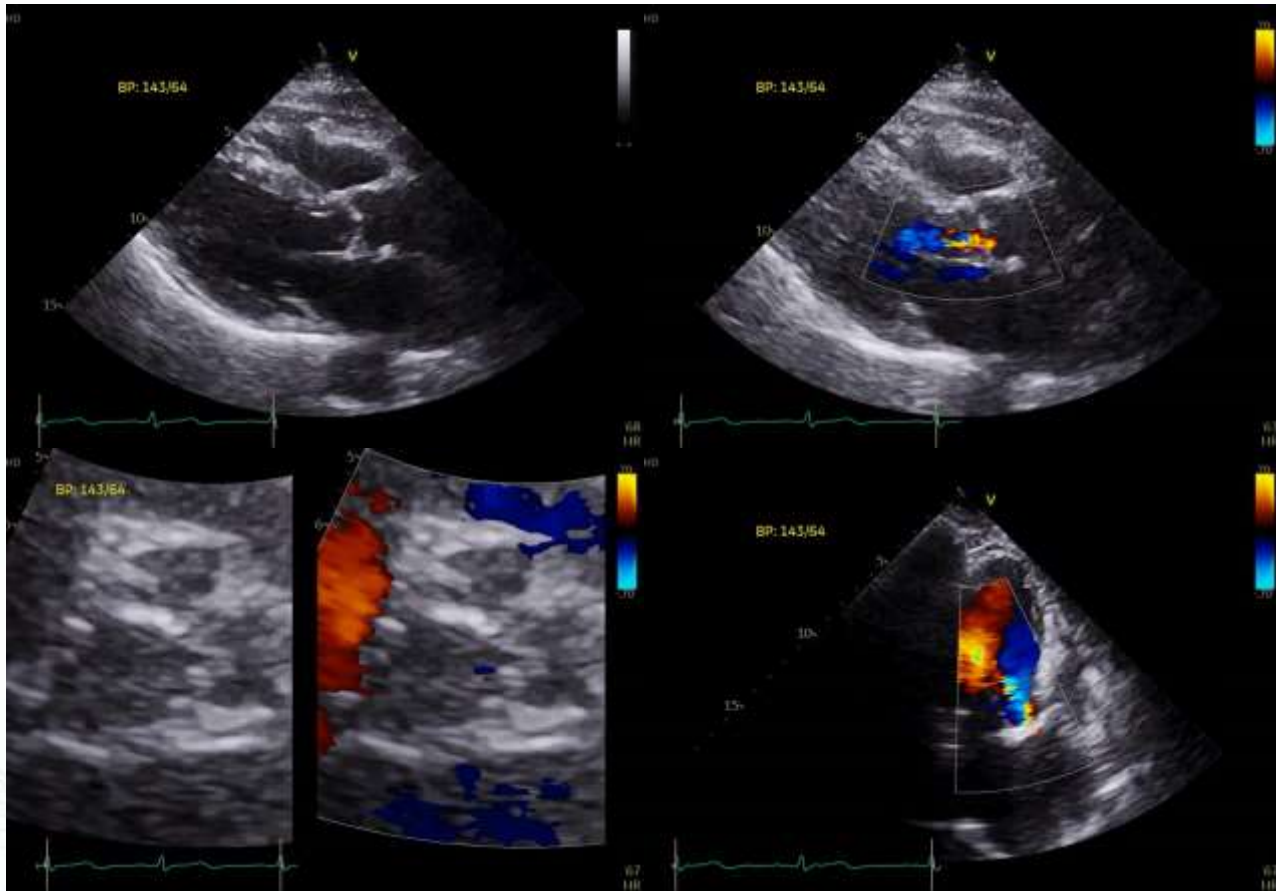- Lab: Cr 0.7 mg/dL,
  eGFR 80 mL/min/1.73
- STS: 3.90%

Baseline ECG
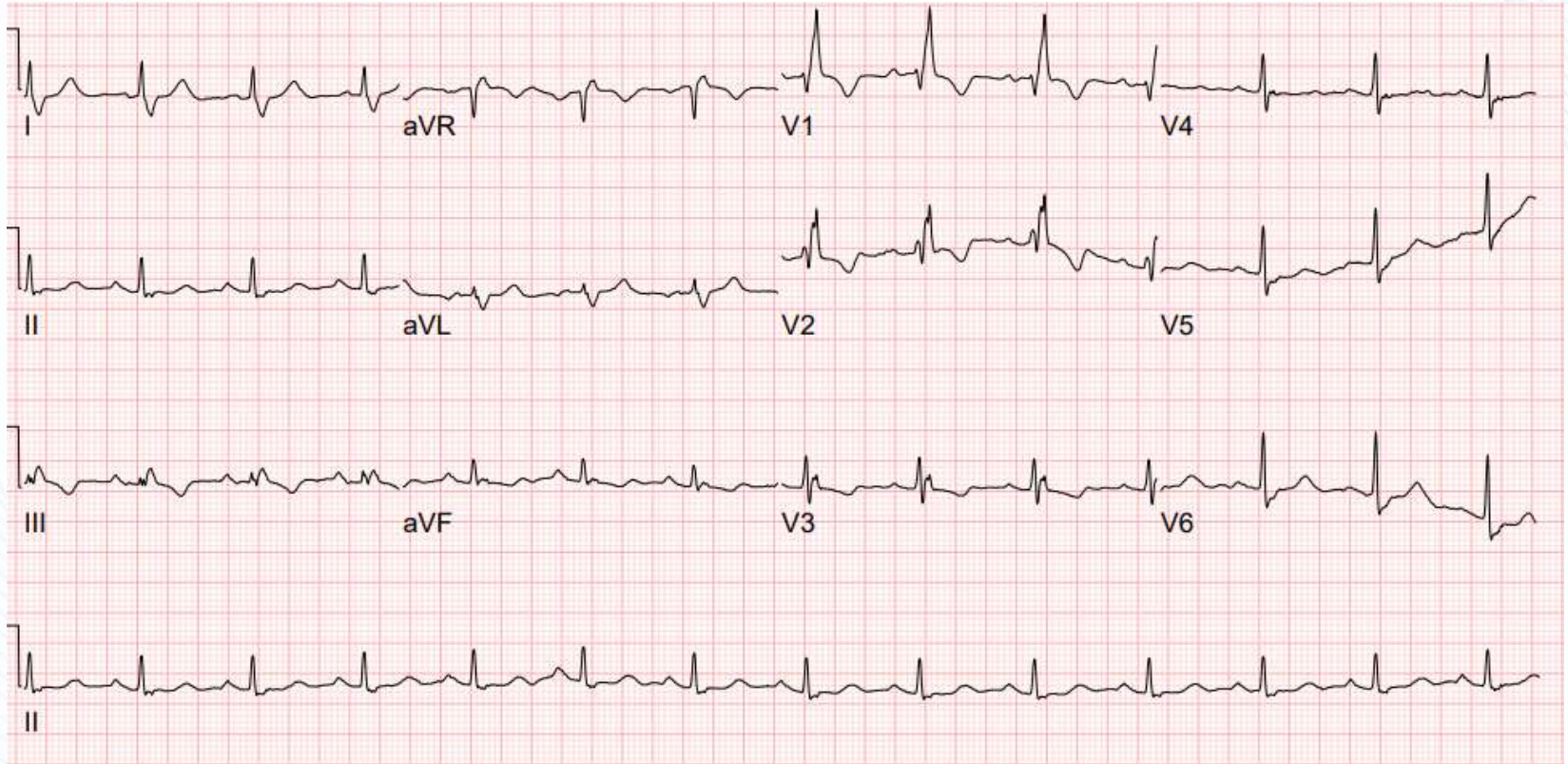
Baseline TTE

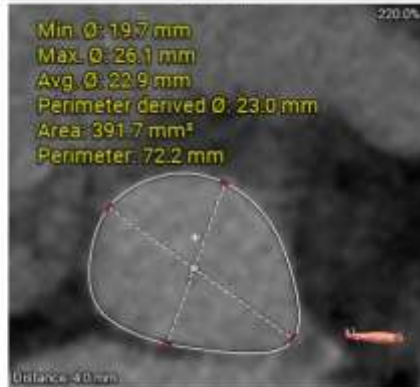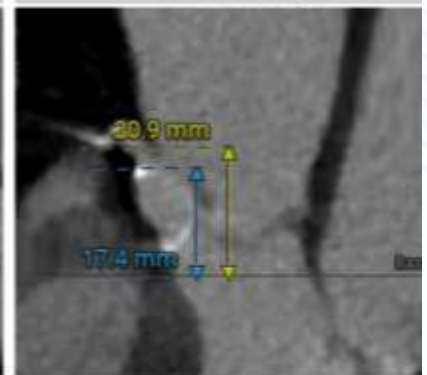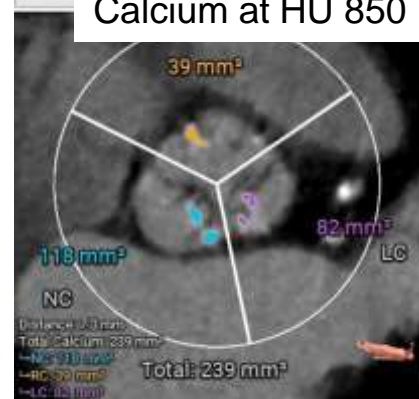Severe AS with mild AR, AVA 0.97cm^2, PSPG/MSPG 84/45mmHg, LVEF=68%

CT Analysis

Coronary Angiography

LAD: FFR = 0.83

Case Summary

- Elderly Korean female patient
- Relatively small body stature
- Small annulus & SOV
- Low LCA ostium
- Known CAD
- RBBB => High risk for PPI

We need a valve with
- Better hemodynamic performance
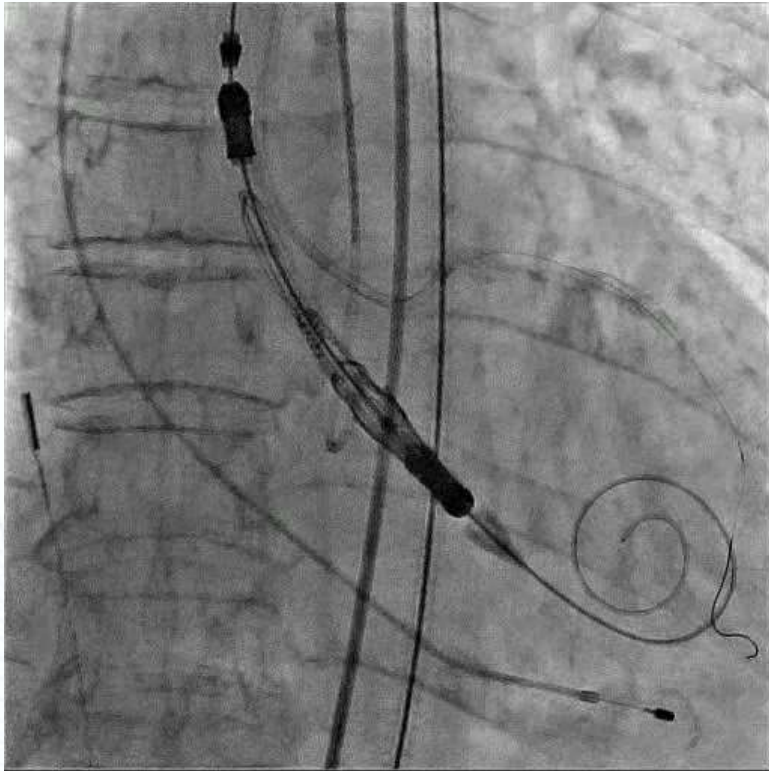- Easier coronary access
- Lower risk of PPI
- Coronary protection

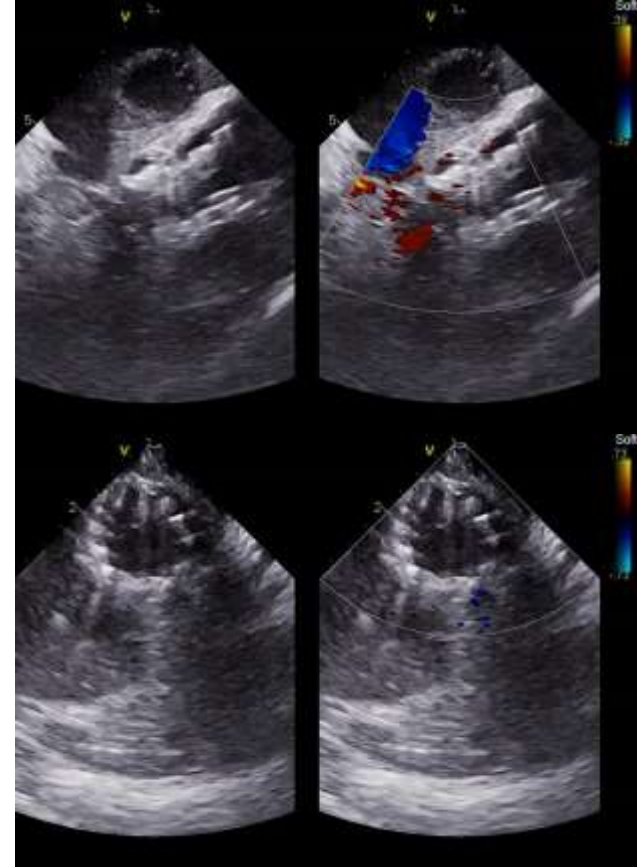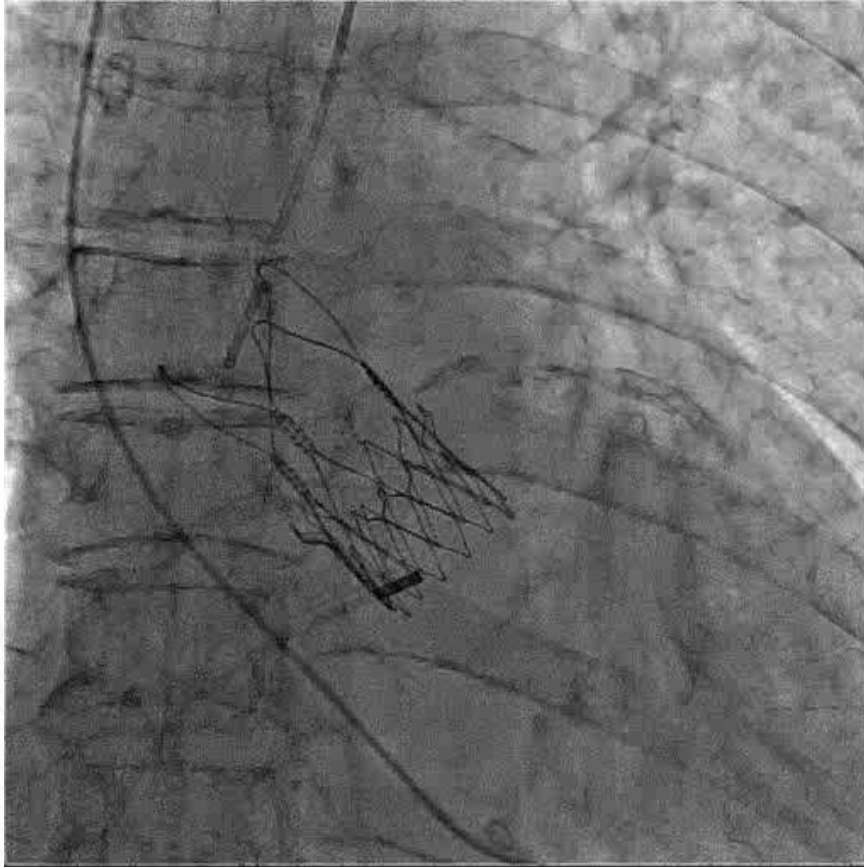# Coronary Protection & Predilation

Predilation (22 mm balloon)
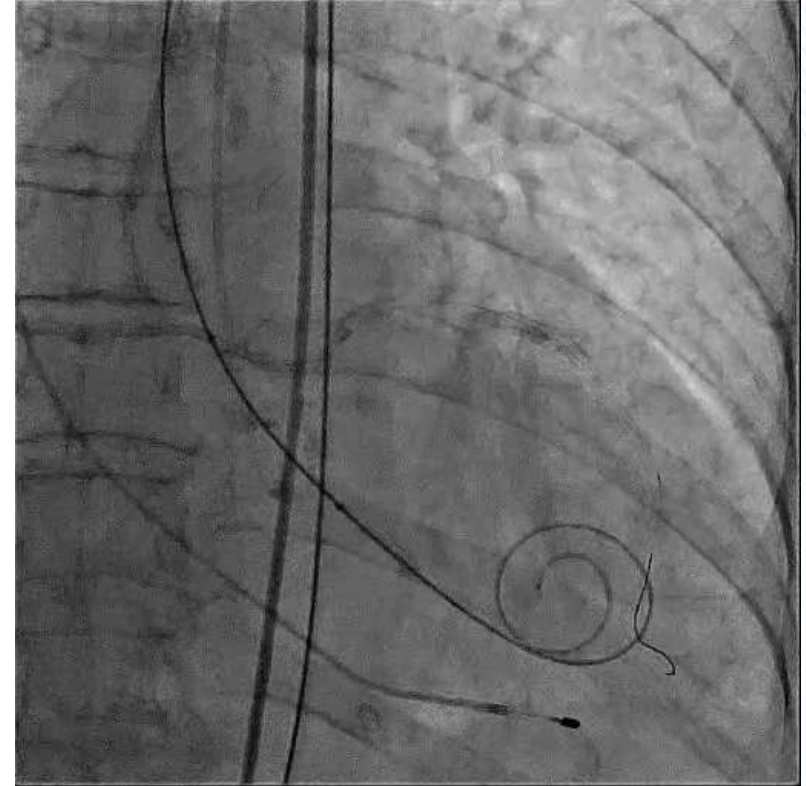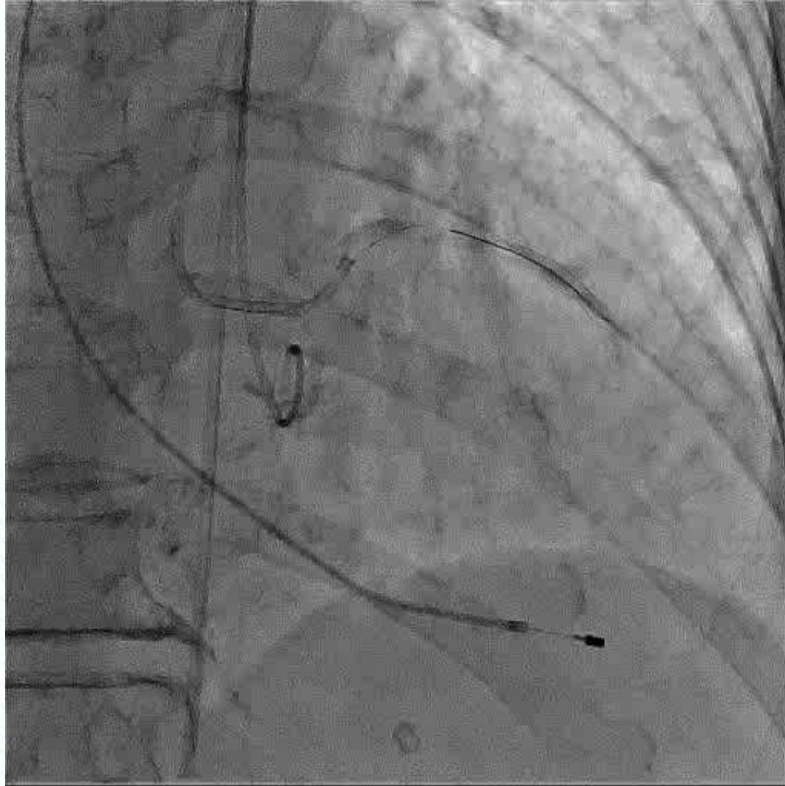
TAVR

ACURATE Neo2 25 mm
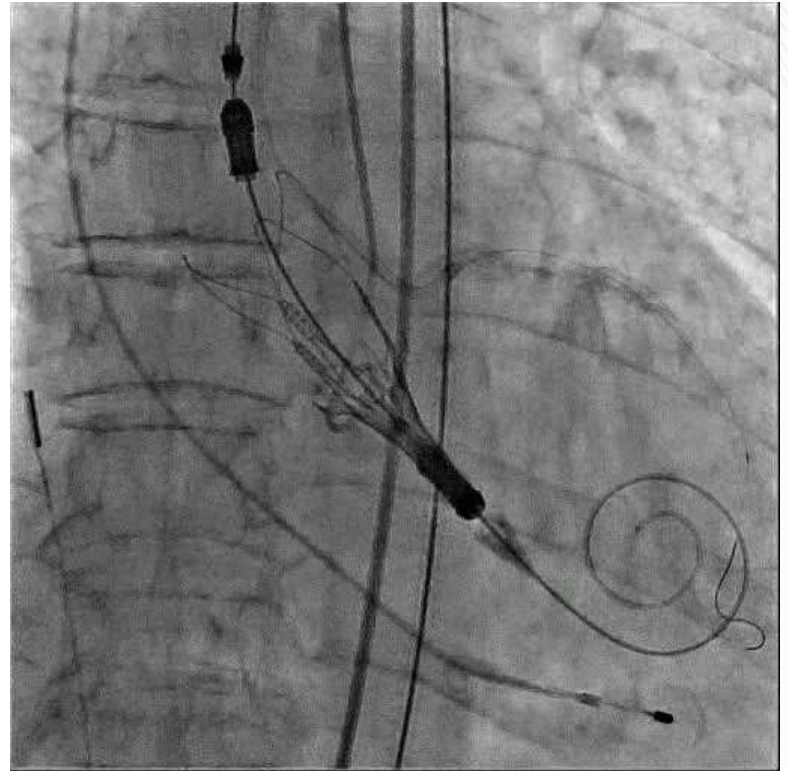
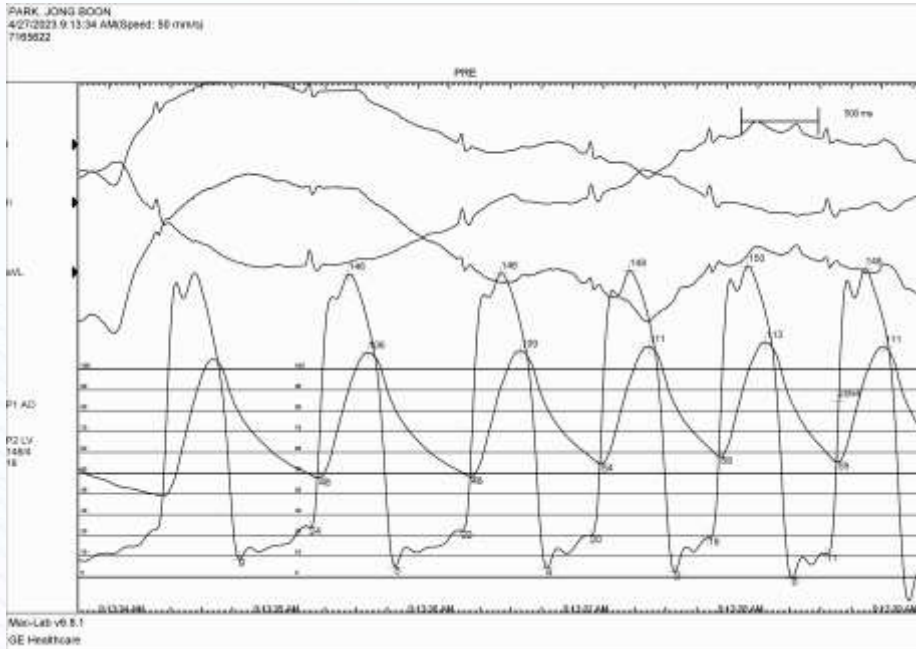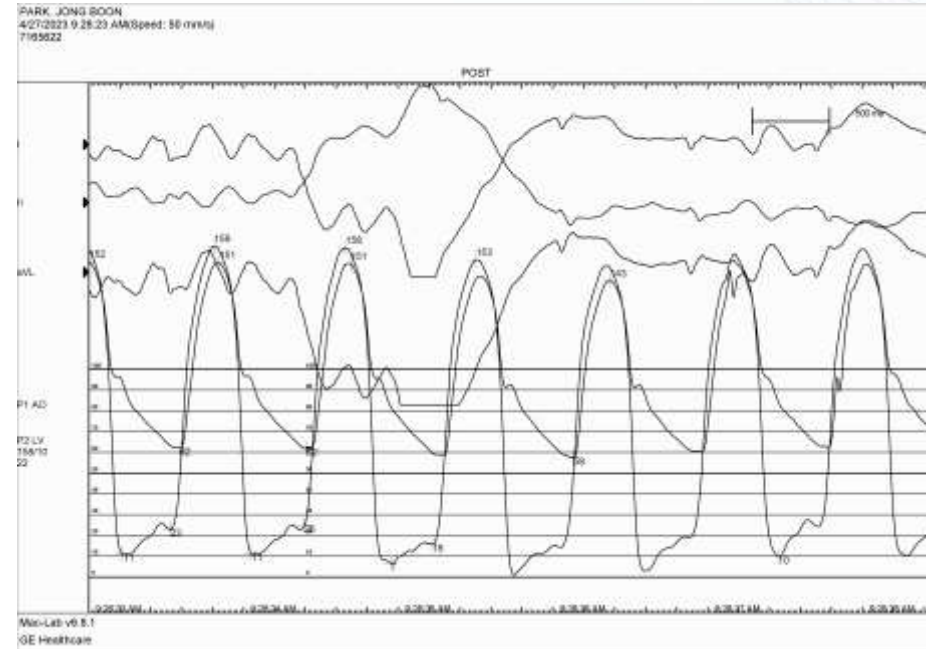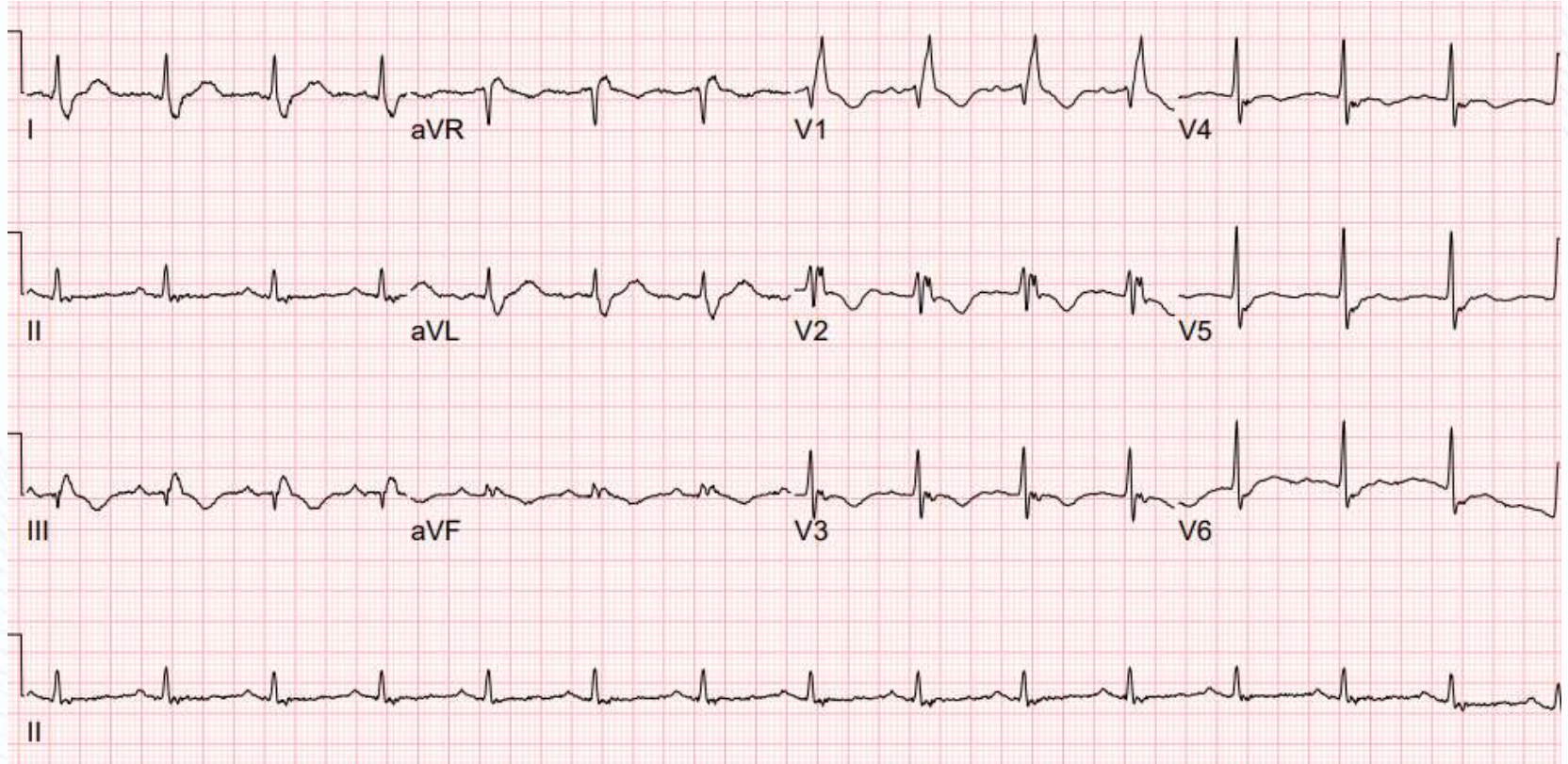# Final Aortogram & ICE

Hemodynamics Before and After TAVR

ECG after TAVR

Conclusions

- ACURATE Neo2 is a self-expanding valve with supra-annular design and augmented sealing skirt.

- ACURATE Neo2 shows significantly reduced rates of PVL than previous version. Its PVL rates are comparable with those of Evolut or Sapien systems.

- ACURATE Neo2 also demonstrates favorable hemodynamic performance due to its supra-annular valve design.

- ACURATE Neo2 shows a lower rate of PPI than Evolut, which is comaparable with that of Sapien.

- ACURATE Neo2 provides easier coronary access due its large cell size.

- The clinical benefit and safety of ACURATE Neo2 needs to be validated in RCTs.