2024 PCR london valves

Clinical Impact of Mid-Frame Underexpansion following TAVR using a Self-expanding Transcatheter Heart Valve

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Potential conflicts of interest

Speaker's name: Won-Keun Kim

☑ I have the following potential conflicts of interest to report

- Receipt of honoraria or consultation fees - Abbott
- Receipt of honoraria or consultation fees - Boston Scientific
- Receipt of honoraria or consultation fees - Edwards Lifesciences
- Receipt of honoraria or consultation fees - JenaValve Technology
- Receipt of honoraria or consultation fees - Meril
- Receipt of honoraria or consultation fees - P&F Products & Features
- Receipt of grants / research supports - Boston Scientific

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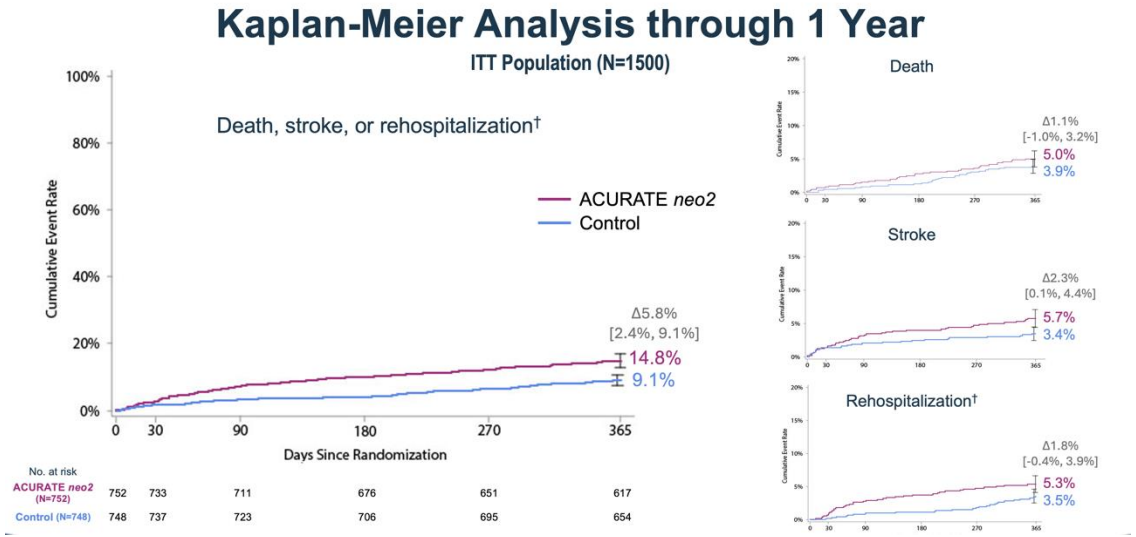
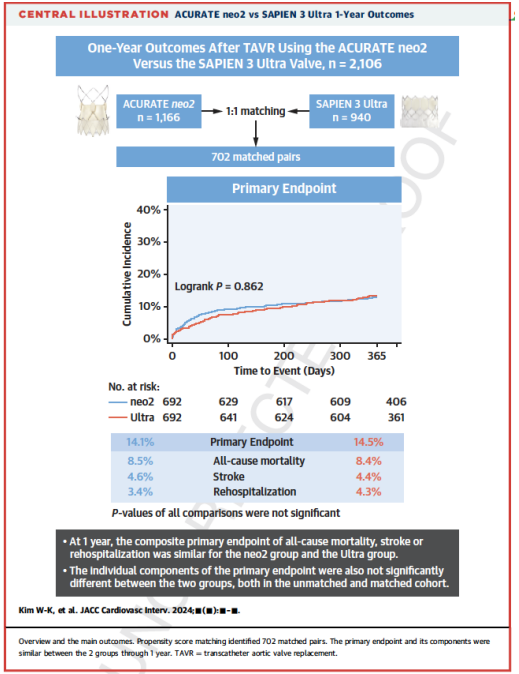
Why this study?

In the ACURATE IDE trial, non-inferiority of the ACURATE neo2 valve against the control group was not met for the primary endpoint.



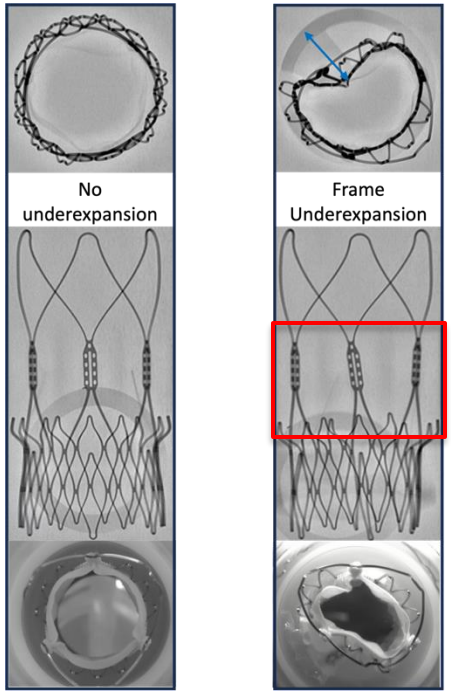


=> Discrepant to European real world data comparing ACURATE neo2 vs. SAPIEN 3

Reardon et al, Late breaking trial presentation at TCT 2024

Why this study?

Post-hoc analysis of the IDE trial:
Mid-frame underexpansion of the ACURATE neo2 occurred in 20% and was associated with adverse events at 1 year.



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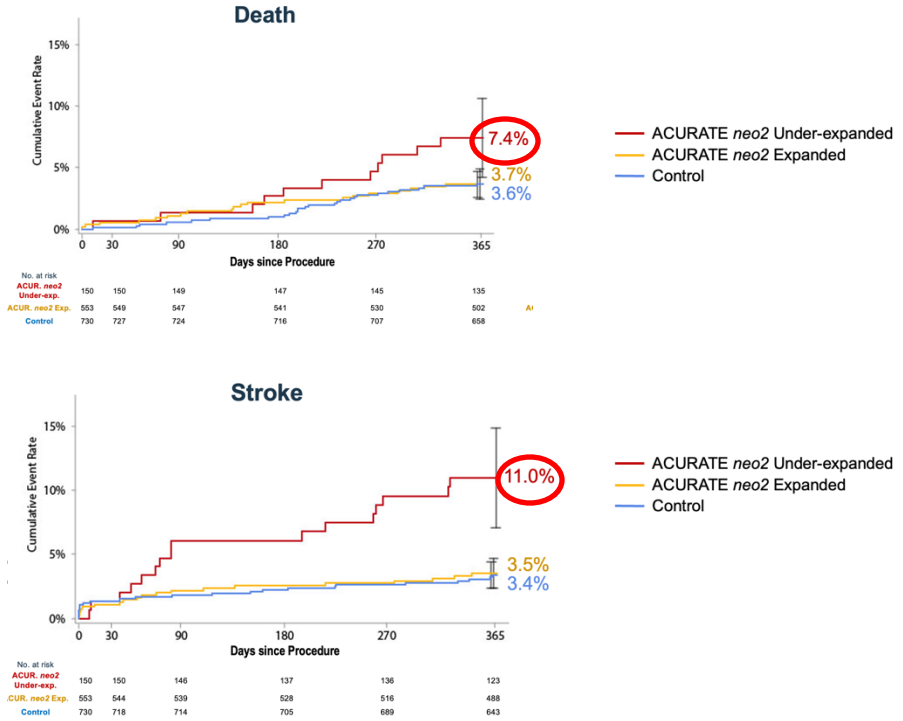
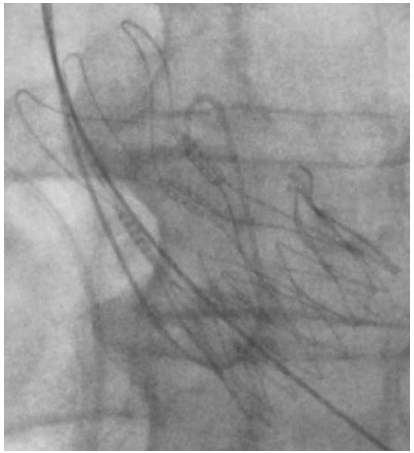


Reardon et al, Late breaking trial presentation at TCT 2024

What did we study?

Review of European ACURATE neo2 data from 2 experienced high volume centers.

Aims: To assess mid-frame underexpansion after TAVI using the ACURATE neo2 device and its impact on clinical outcomes.



Mid-frame underexpansion

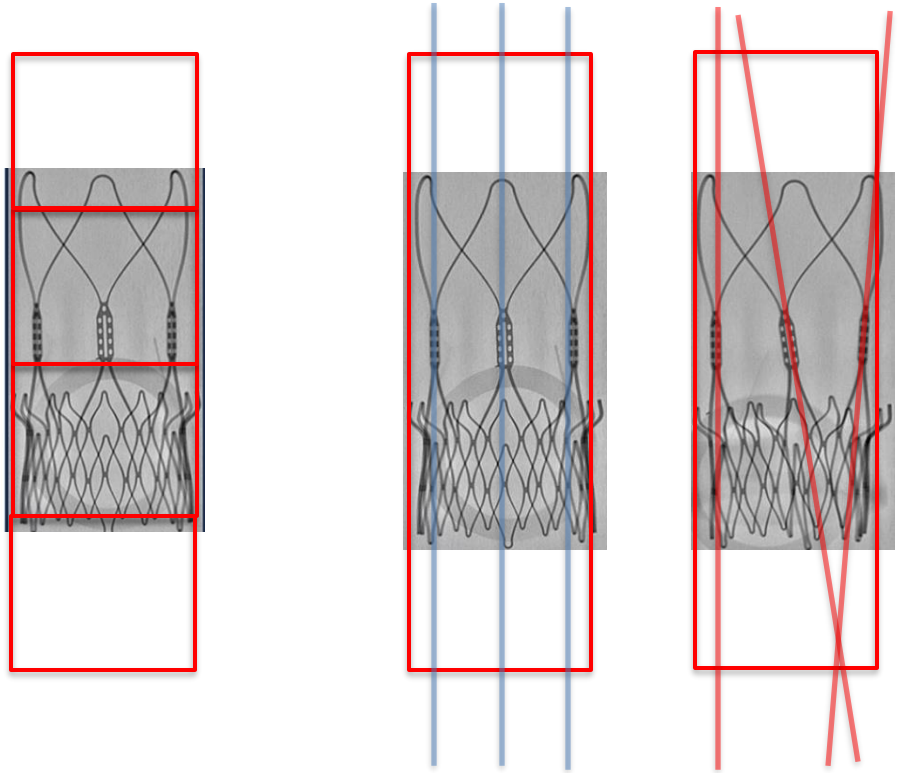
Primary endpoint at 1 year:
- All-cause mortality
- Stroke
- Rehospitalization

How was the study executed?

Definition of mid-frame underexpansion:

- On 3-cusp view, the frame with the most severe misalignment of commissure posts was selected.
- Non-parallelism indicating mid-frame underexpansion was defined as crossing of extended lines of the commissural posts within a prespecified frame

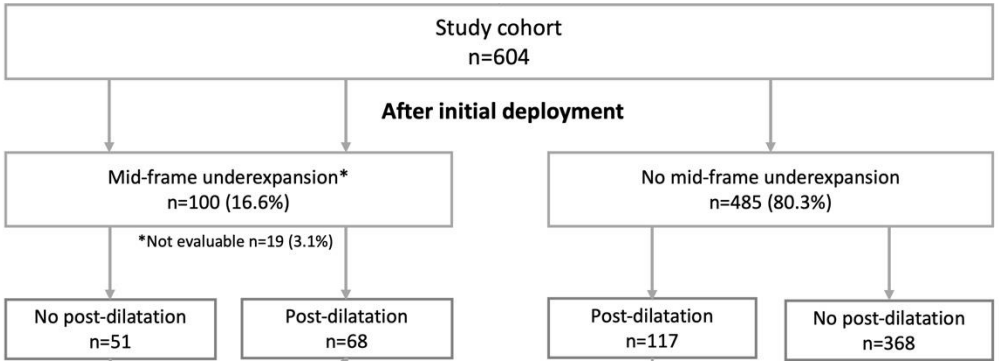
=> extension of the rectangle framing the stent-body of the prosthesis.



No underexpansion Underexpansion

Study flow chart

Transfemoral TAVR with ACURATE *neo2*
for native severe aortic stenosis Sep 2020 - Oct 2023



*Patients without evaluable angiographic images before post-dilatation

Study flow chart

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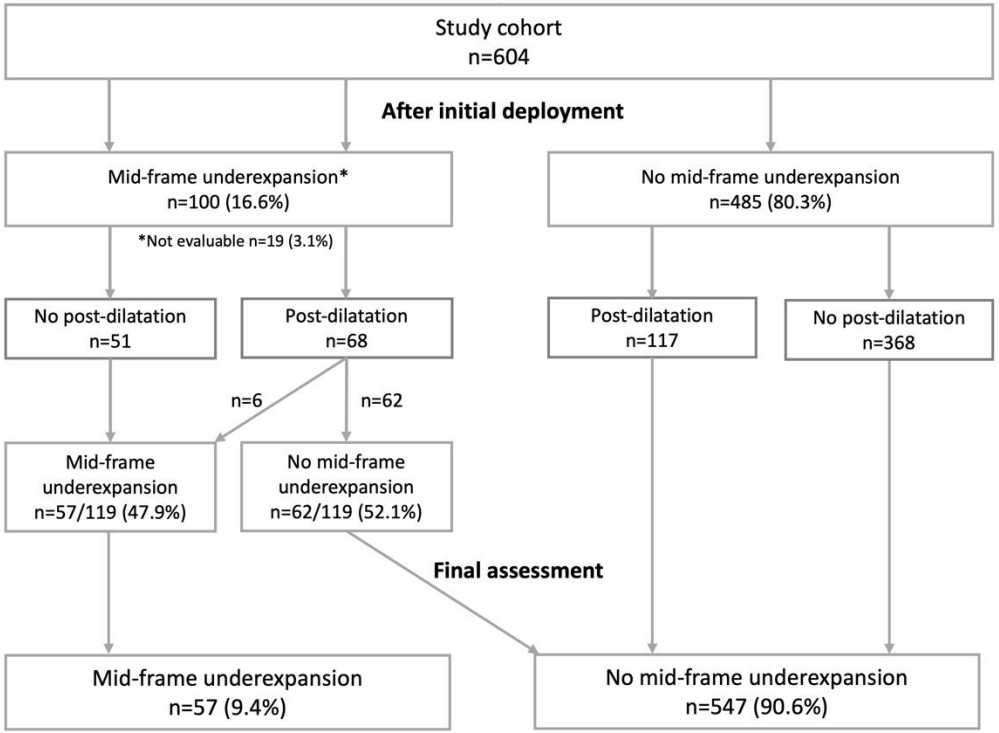

Mid-frame underexpansion was identified in 9.4%.

*Patients without evaluable angiographic images before post-dilatation

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Results: Baseline characteristics

Variable	Mid-frame underexpansion (n=57)	No mid-frame underexpansion (n=547)	P
Age, years	82 [78–85]	82 [79–86]	0.543
Female sex	35 (61.4%)	336 (61.4%)	0.997
Body mass index, kg/m^2	26.4 [24.2–28.9]	26.4 [23.6–30.4]	0.704
EuroSCORE II, %	3.1 [2.2–4.2]	2.9 [1.9–4.8]	0.845
eGFR, ml/min/1.73 m^2	65 [49–80]	67 [49–85]	0.451
Coronary artery disease	35 (61.4%)	309 (56.5%)	0.476
Atrial fibrillation	28 (49.1%)	213 (38.9%)	0.135
COPD	5 (8.8%)	94 (17.2%)	0.103
Ejection fraction, %	65 [60–65]	65 [60–65]	0.193
Mean gradient, mmHg	43 [37–49]	43 [32–51]	0.812
EOA, cm^2	0.7 [0.6–0.8]	0.7 [0.6–0.8]	0.436
Perimeter-derived annulus, mm	23.7 [22.7–24.9]	23.7 [22.5–25.0]	0.775
CI perimeter, %	6.7 [4.4–7.8]	6.1 [4.0–8.0]	0.425
LVOT, mm	22.2 [20.6–23.4]	22.5 [20.9–24.0]	0.091
SOV, mm	31.2 [29.4–33.4]	31.1 [28.9–33.3]	0.880
Calciumscore, AU	2213 [1701–2819]	2127 [1415–2895]	0.767

Results: Procedural data

Variable	Mid-frame underexpansion (n=57)	No mid-frame underexpansion (n=547)	p
Prosthesis size			0.451
S, 23 mm	10 (17.5%)	135 (24.7%)	
M, 25 mm	26 (45.6%)	216 (39.5%)	
L, 27 mm	21 (36.8%)	196 (35.8%)	
Pre-dilatation	48 (84.2%)	476 (87.0%)	0.552
Post-dilatation	6 (10.5%)	179 (32.7%)	<0.001
Commissural misalignment	23 (40.4%)	134 (24.5%)	0.009
Implantation depth NCC, mm	3.5 [2.0–5.8]	4.0 [2.3–5.8]	0.151
Procedural duration, min	40 [32–49]	41 [34–52]	0.443
Fluoroscopy time, min	9.1 [6.5–14.6]	9.2 [6.6–13.1]	0.863
Contrast agent, ml	20 [19–40]	30 [20–50]	0.018

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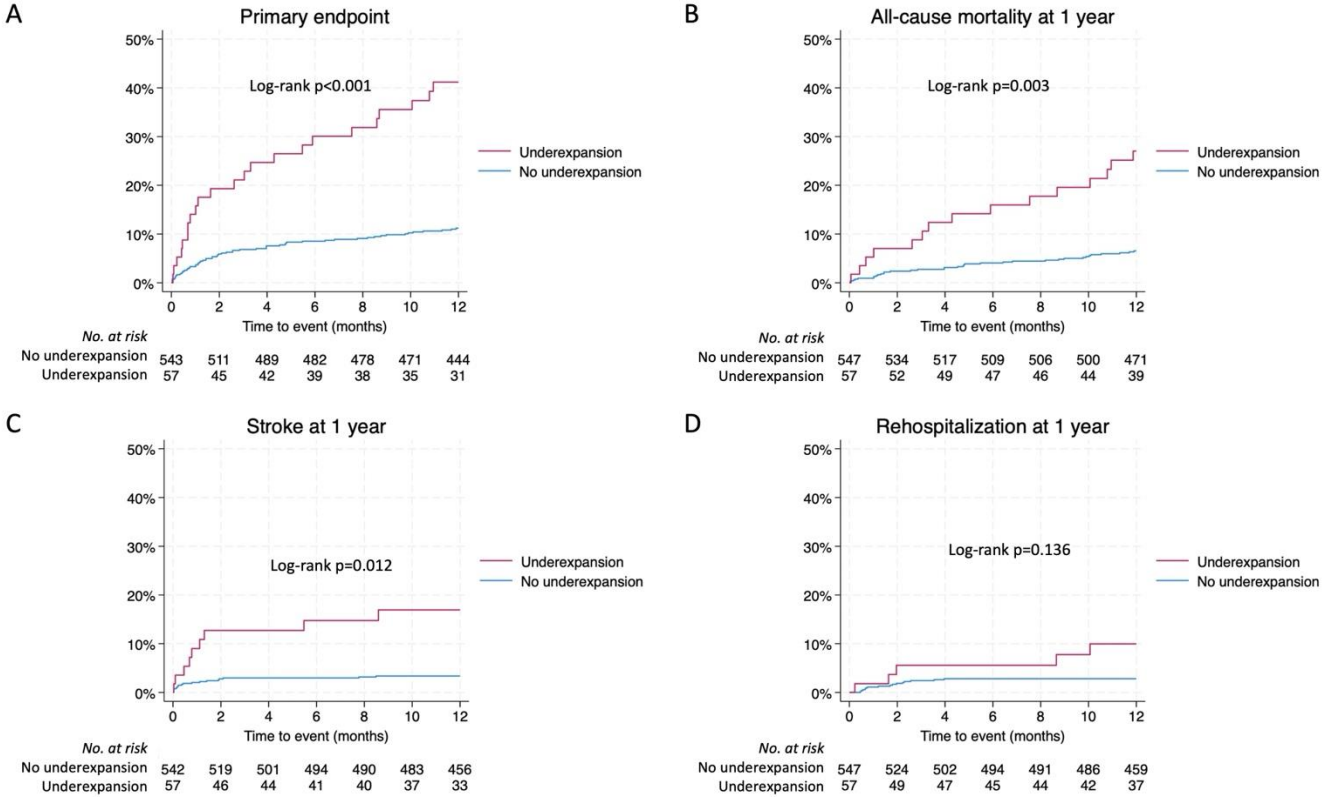
Results: In-hospital outcomes

Variable	Mid-frame underexpansion (n=57)	No mid-frame underexpansion (n=547)	p
Technical success (VARC-3)	56 (98.2%)	519 (94.9%)	0.258
Device success (VARC-3)	51 (89.5%)	500 (91.4%)	0.623
Ejection fraction post, %	65 [60–65]	65 [60–65]	0.190
Mean gradient post, mmHg	9 [7–11]	9 [7–12]	0.859
EOA post, cm^2	1.7 [1.4–2.0]	1.7 [1.5–1.9]	0.933
Severe PPM	5 (9.1%)	10 (1.9%)	0.001
PVR ≥moderate	1 (1.8%)	3 (0.6%)	0.288
Major cardiac structural complication	0 (0%)	4 (0.7%)	0.517
Conversion to sternotomy	0 (0%)	3 (0.6%)	0.575
Major vascular complication	2 (3.5%)	16 (2.9%)	0.805
Type 2-4 bleeding	4 (7.0%)	38 (6.9%)	0.984
Any stroke	2 (3.5%)	14 (2.6%)	0.671
Acute kidney injury St. 2-4	3 (5.3%)	42 (7.7%)	0.509
Pacemaker implantation	4 (7.0%)	43 (7.9%)	0.821

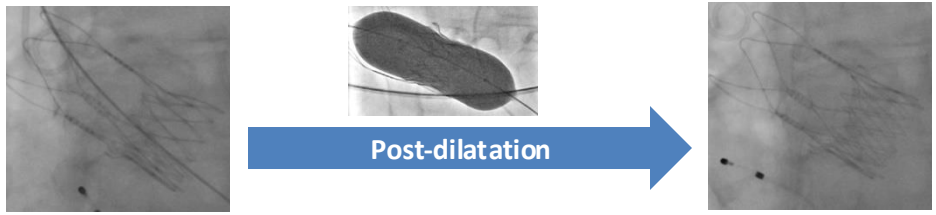
Results: Primary endpoint

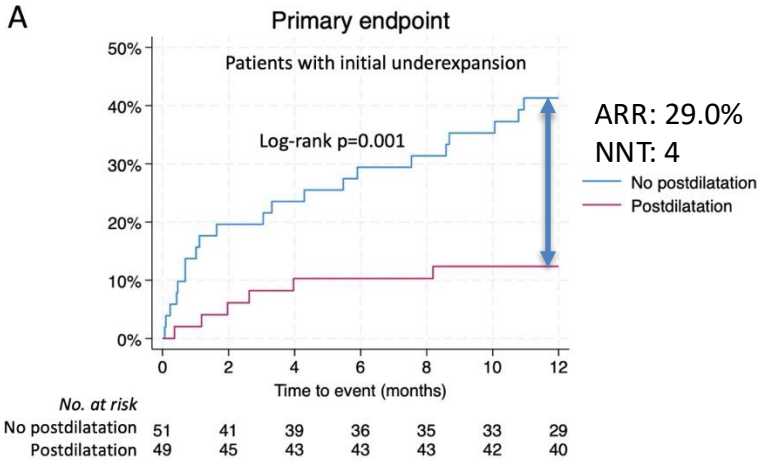


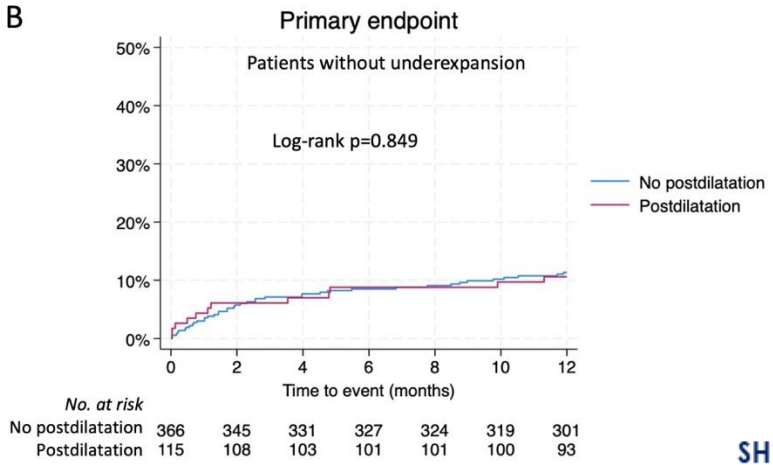
Mid-frame underexpansion only represented 9.4%, but drove a disproportionate number of events!

Why is this important?

Of 100 evaluable patients with initial mid-frame underexpansion, only 49 underwent post-dilatation. After post-dilatation, mid-frame underexpansion was mitigated in 45/49 (92%).







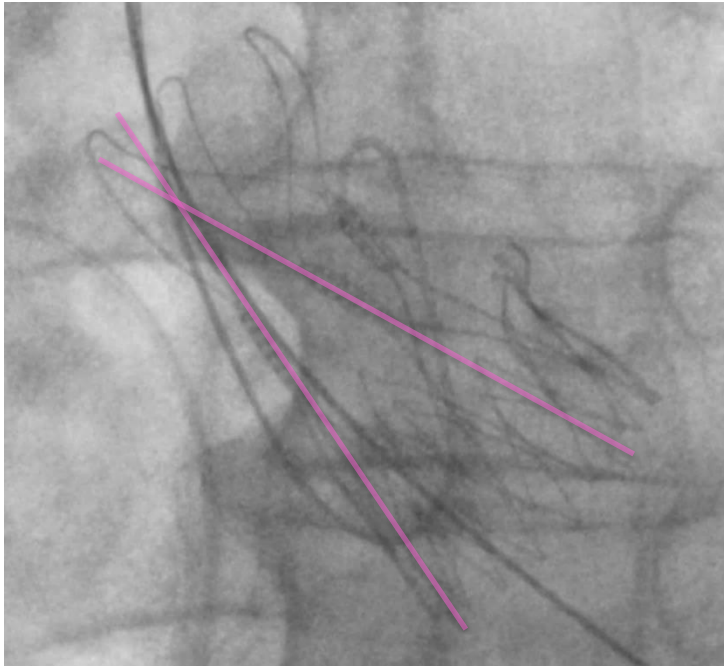
The essentials to remember

- **Why?** Valve underexpansion may be associated with adverse outcomes.
- **What?** We studied the incidence and clinical impact of mid-frame underexpansion of the ACURATE neo2 valve from two experienced European centers.
- **How?** Mid-frame underexpansion was assessed on post-TAVI angiograms in the 3-cusp view.
- **Results?** Mid-frame underexpansion occurred in <10% and was associated with adverse outcomes through one year.
- **Why is this important?**

  ⇒ If required, post-dilatation effectively mitigates mid-frame underexpansion and thereby may improve outcomes.

  ⇒ Post-dilatation should be considered in the presence of mid-frame underexpansion, irrespective of gradients or paravalvular leakage!

Never cross the beams!



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IDE trial vs. European data

Variable	IDE (n=752)	European data (n=604)
Age, years	78	82
Predilatation	99.6%	86.8%
Balloon size ≤ 1 mm of annulus diameter	19.0%	47.7%
Balloon size ≤ 2 mm of annulus diameter	63.0%	76.5%
Post-dilatation	26.1%	30.6%
Balloon size ≤ 1 mm of annulus diameter	49.0%	67.0%
Balloon size ≤ 2 mm of annulus diameter	84.0%	93.0%
Commissural alignment	NA	74.0%*
Mid-frame underexpansion	20.0%	9.4%
Implantation depth at NCC, mm	5.0	4.0
Primary endpoint	14.8%	14.4%
All-cause mortality	5.0%	8.3%
Stroke	5.7%	5.3%
Rehospitalization	5.3%	3.3%

Pre-dilatation was less common in the European cohort
=> Pre-dilatation may not be mandatory in all patients (e.g., very mild calcification), but if required, should be performed appropriately!

*Commissural alignment was attempted in 2/3 of the population

Predictors of mid-frame underexpansion

Variable	OR [95% CI]	p	Adjusted OR [95% CI]	p
Female sex	1.00 [0.57–1.75]	0.997		
AVCS, per AU	1.00 [0.99–1.00]	0.995		
DP mean, per mmHg	0.99 [0.98–1.02]	0.895		
NO pre-dilatation	1.25 [0.59–2.67]	0.552		
No post-dilatation	4.13 [1.74–9.81]	0.001	4.21 [1.77–10.03]	0.001
Commissural misalignment	2.08 [1.18–3.66]	0.011	2.14 [1.21–3.79]	0.009
Cover index perimeter, per %	0.99 [0.91–1.09]	0.989		
Implantation depth NCC, per mm	0.98 [0.88–1.08]	0.656		

Why is this important?