TAVR: the new frontier

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Rigshospitalet, Copenhagen, Denmark (July 2020 – June 2021)

- Hong Kong Heart Foundation Fellowship
- Dr. C O Pun and Dr. Mary B L Kwong Scholarship

Background

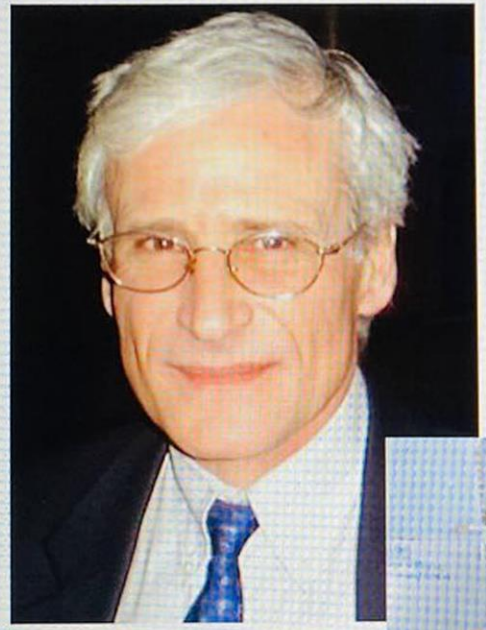
Evidence

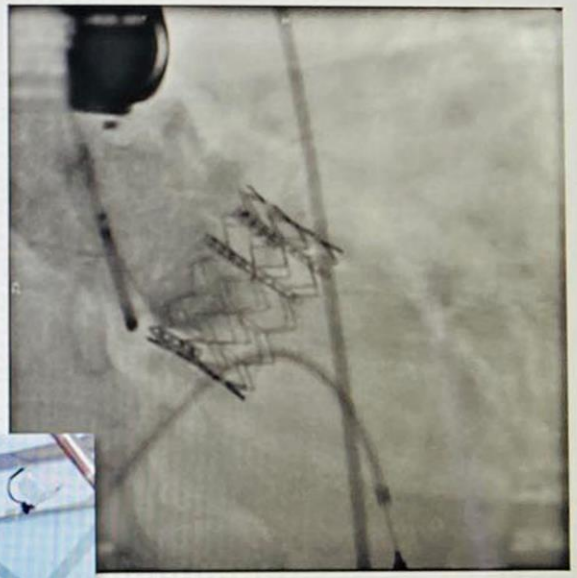
Case example

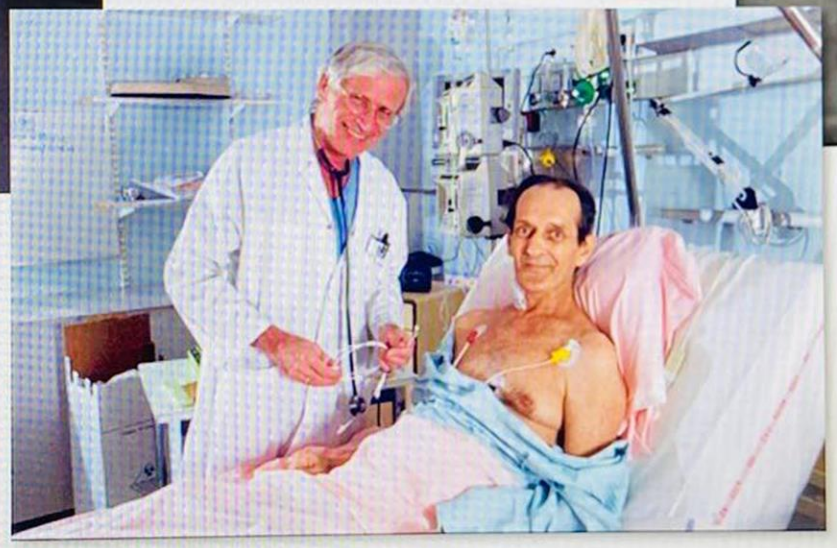
Conclusion

First Human Transcatheter Aortic Valve Replacement (TAVR)

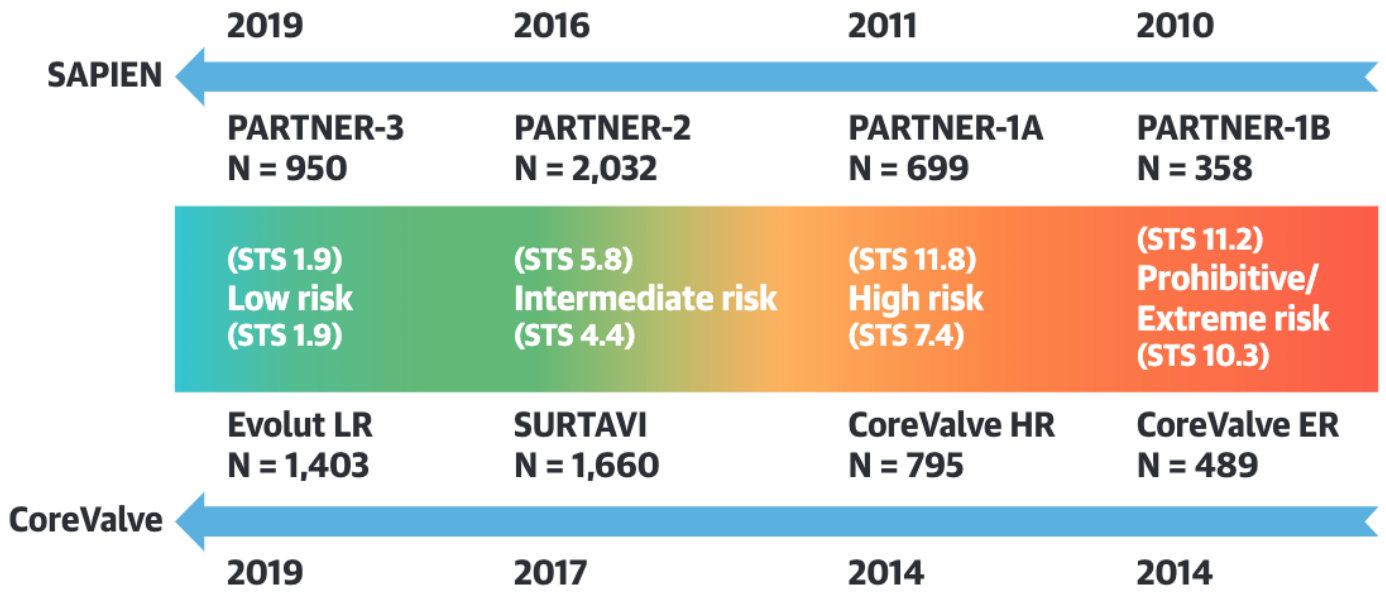
(Dr. Alain Cribier … in France … on April 16, 2002)







CENTRAL ILLUSTRATION Evolution of TAVR Over the Last Decade



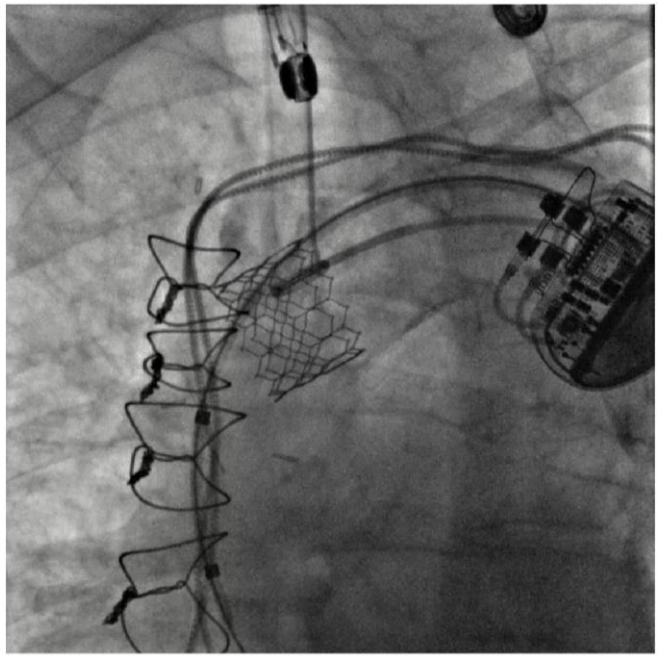
U.S. Food and Drug Administration approval				
- *SAPIEN*	8/2019	8/2016	10/2012	11/2011
- *CoreValve*	8/2019	7/2017	6/2014	1/2014
Center for Medicare and Medicaid Services National Coverage Determination (Coverage with Evidence Development)	6/2019	5/2012	5/2012	5/2012
2017 ACC/AHA guideline recommendations	No	Class IIa, Level of Evidence: B	Class I, Level of Evidence: A	Class I, Level of Evidence: A

Kaul, S. J Am Coll Cardiol. 2020;76(8):985-91.

Table 1: List of Challenges For Transcatheter Aortic Valve Implantation in Aortic Stenosis Versus Aortic Regurgitation

Key Differences	TAVI for Aortic Stenosis	TAVI for Pure Severe AR	Technical Challenges for TAVI in Pure Severe AR
Leaflets	Calcified	Non-calcified	Inadequate anchoring
Aortic root	Non-dilated	Dilated	Limited ability to oversize current devices
Stroke volume	Low to normal	High	Less precise positioning

AR = aortic regurgitation; TAVI = transcatheter aortic valve implantation.



Unmet Need is there!!

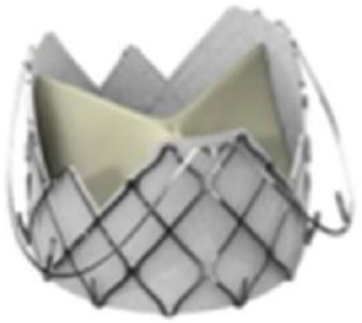
Background

Evidence

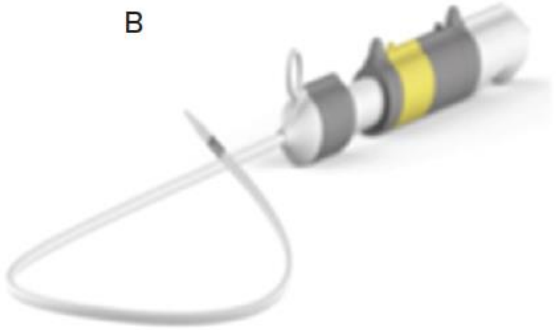
Case example

Conclusion

A

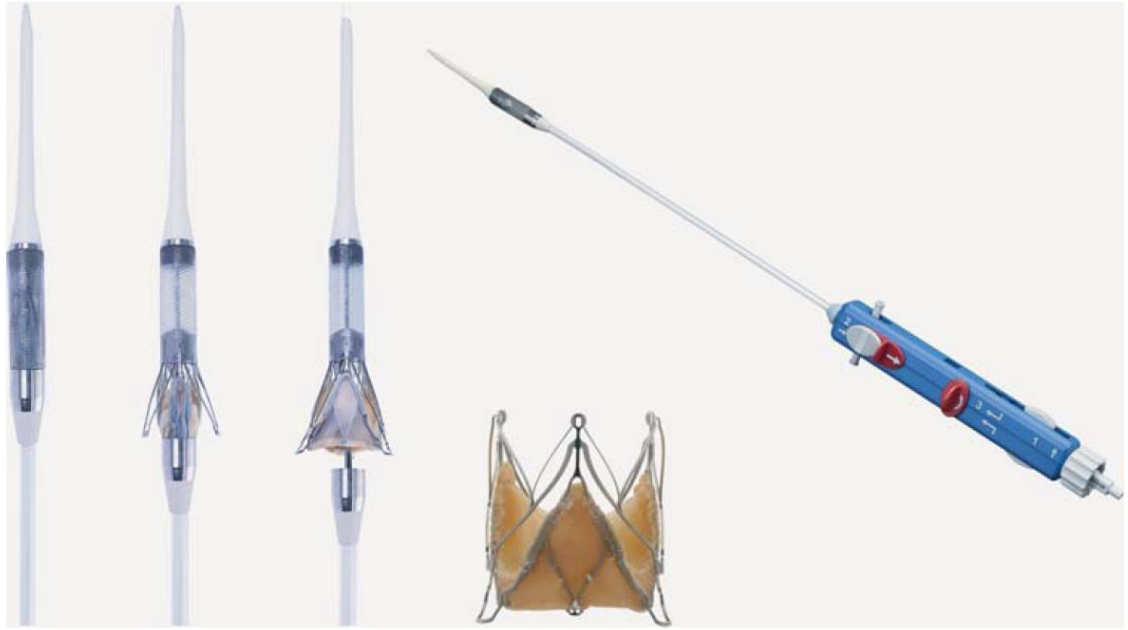


B

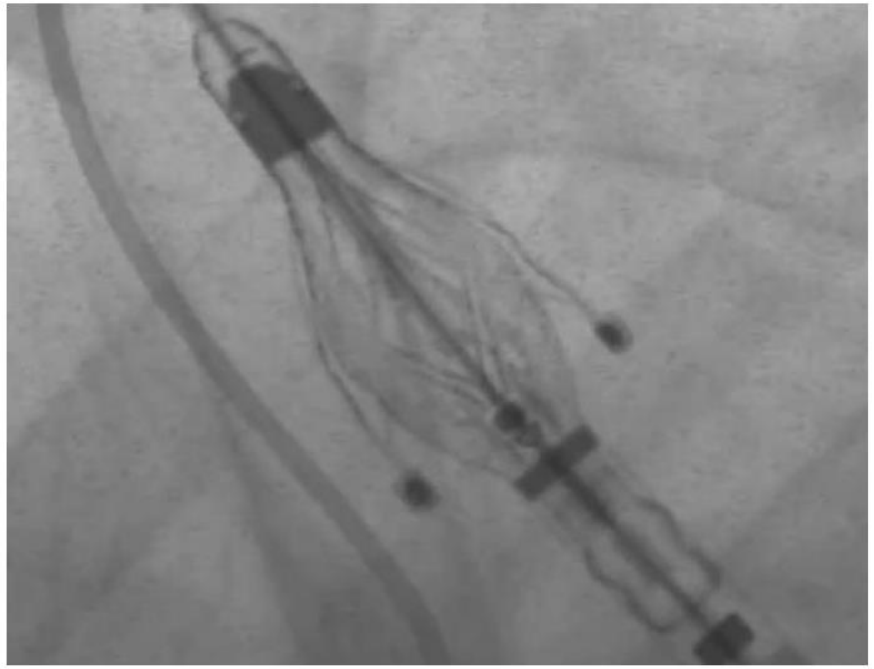


C

Valve size (mm)	Annulus diameter (mm)	Annulus perimeter (mm)	Annulus area (mm^2)
22	18–22	57–69	254–380
25	21–25	66–78	346–490
28	24–28	75–88	452–615
31	27–31	83–97	575–755
34	30–34	97–107	755–908



The JenaValve Trilogy Transcatheter Heart Valve System



- The Jenavalve Trilogy™ transfemoral TAVI system received **CE Mark for treatment of aortic regurgitation** and aortic stenosis (May 25th, 2021)

A new self-expanding TAVR system for Isolated Aortic Regurgitation
In hospital Outcome

Outcome characteristics	
Technical success	58 (100%)
Conversion to open surgery	0
Bleeding complication	
none	55 (95%)
Type 1	3 (5.2%)
Type 2	0
Type 3	0
Vascular complication	
none	54 (93%)
minor vascular complication	4 (6.9%)
major vascular complication	0 (0%)
Acute kidney Injury stage	
none	51 (88%)
Stage 1	6 (10%)
Stage 2	0
Stage 3	1 (1.7%)
New stroke	0
In-hospital mortality	0
Left ventricular ejection fraction discharge	22 (38%)
Mean aortic valve gradient, mmHg (discharge)	4.34 (1.58)
N (%); Mean (SD)	

A new self-expanding TAVR system for Isolated Aortic Regurgitation
30 day outcome

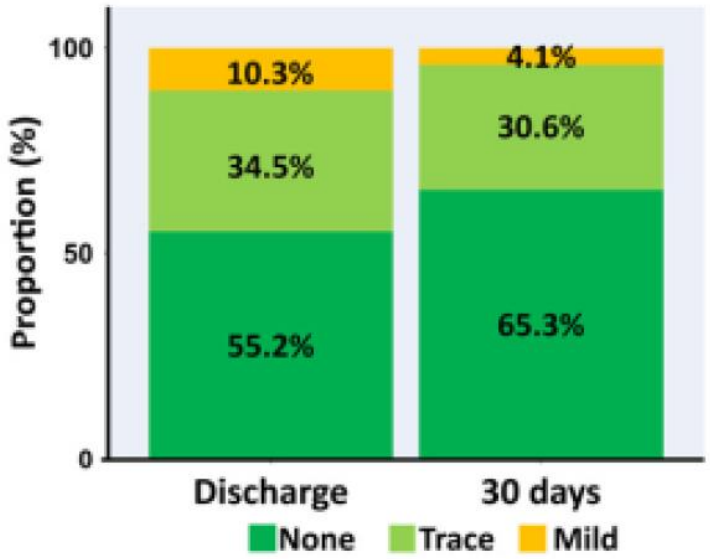
30day outcome characteristics

98%
Device success at 30 days (VARC-3)

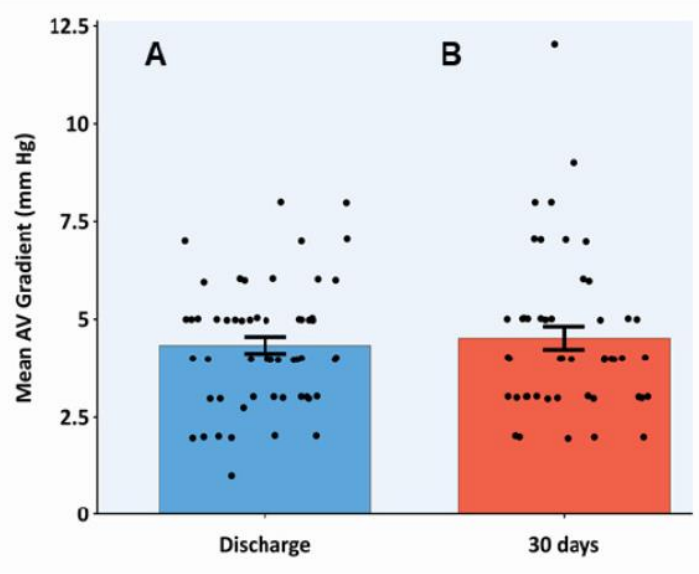
100%
Technical success

0%
PVL ≥ moderate

19.6%
PPI



Paravalvular regurgitation



Mean AV gradient

Background

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Conclusion

F/80

HT, ↑lipid

Admitted for APO with SOBOE and chest discomfort

ECG AF, QRS 70ms

TTE

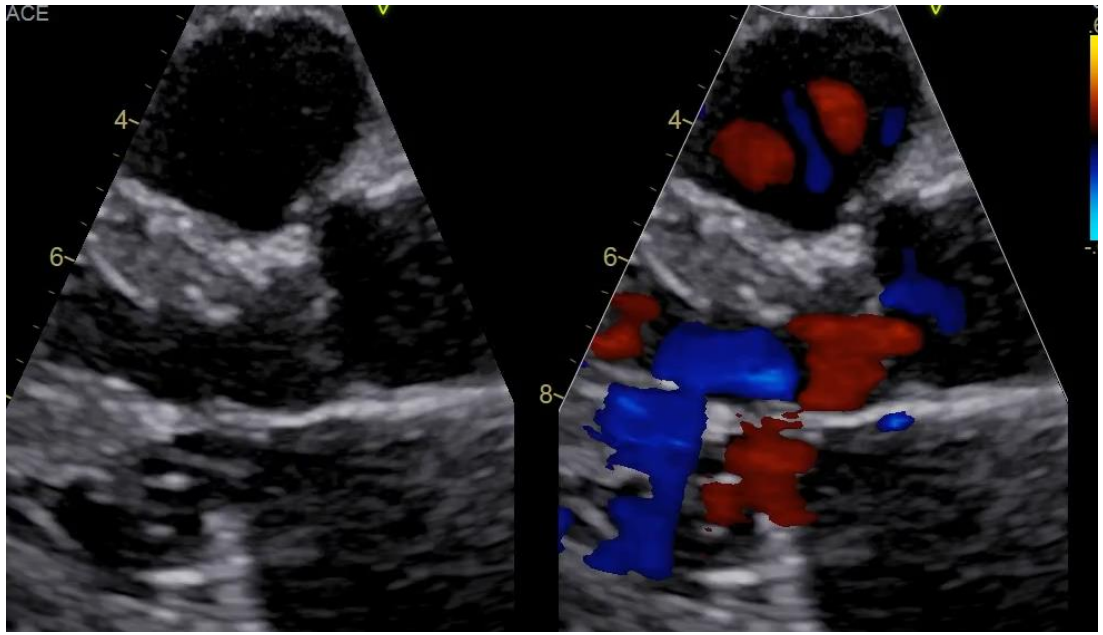
LVEF 60%

Severe AR, vena contracta 0.66cm

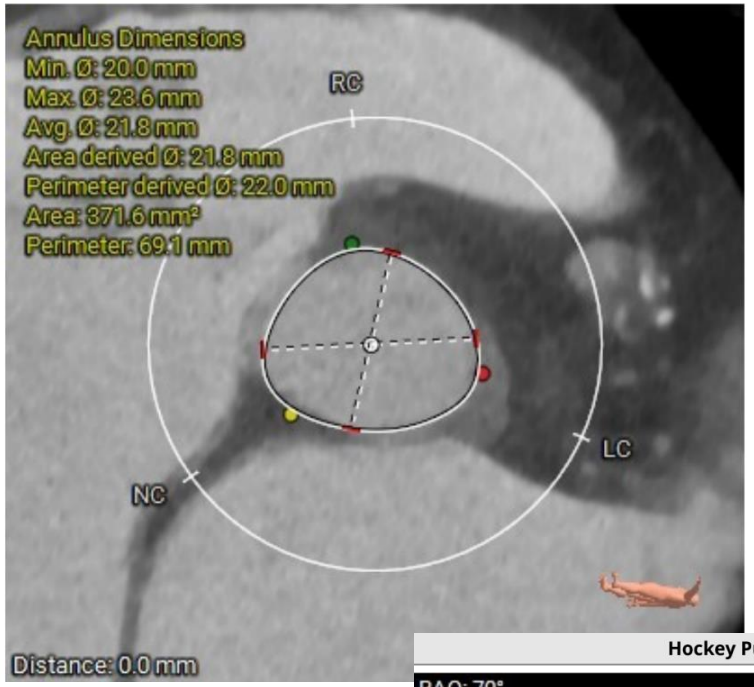
Presence of holodiastolic flow reversal in descending aorta

Moderate MR

Moderate TR, RVSP 32mmHg

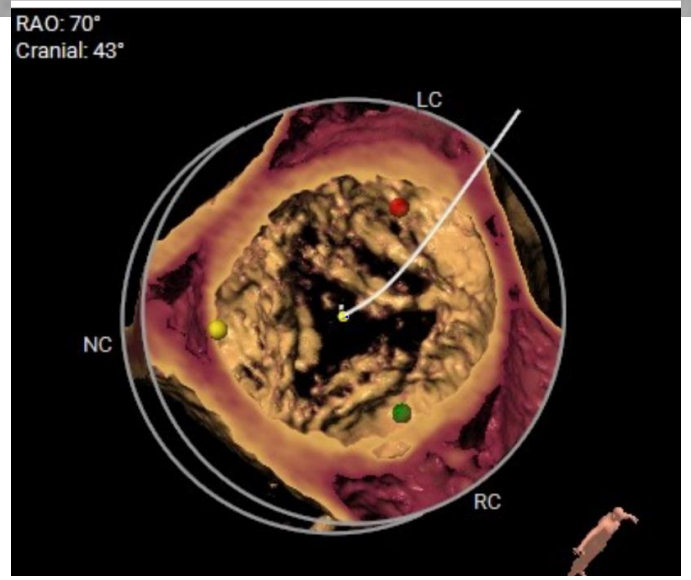


Annulus



SOV

Hockey Puck (VR)



CTS assessment

inoperable because of frailty

STS: 7%

Euro II: 5%

Logistic Euroscore: 24%

Frailty: 6

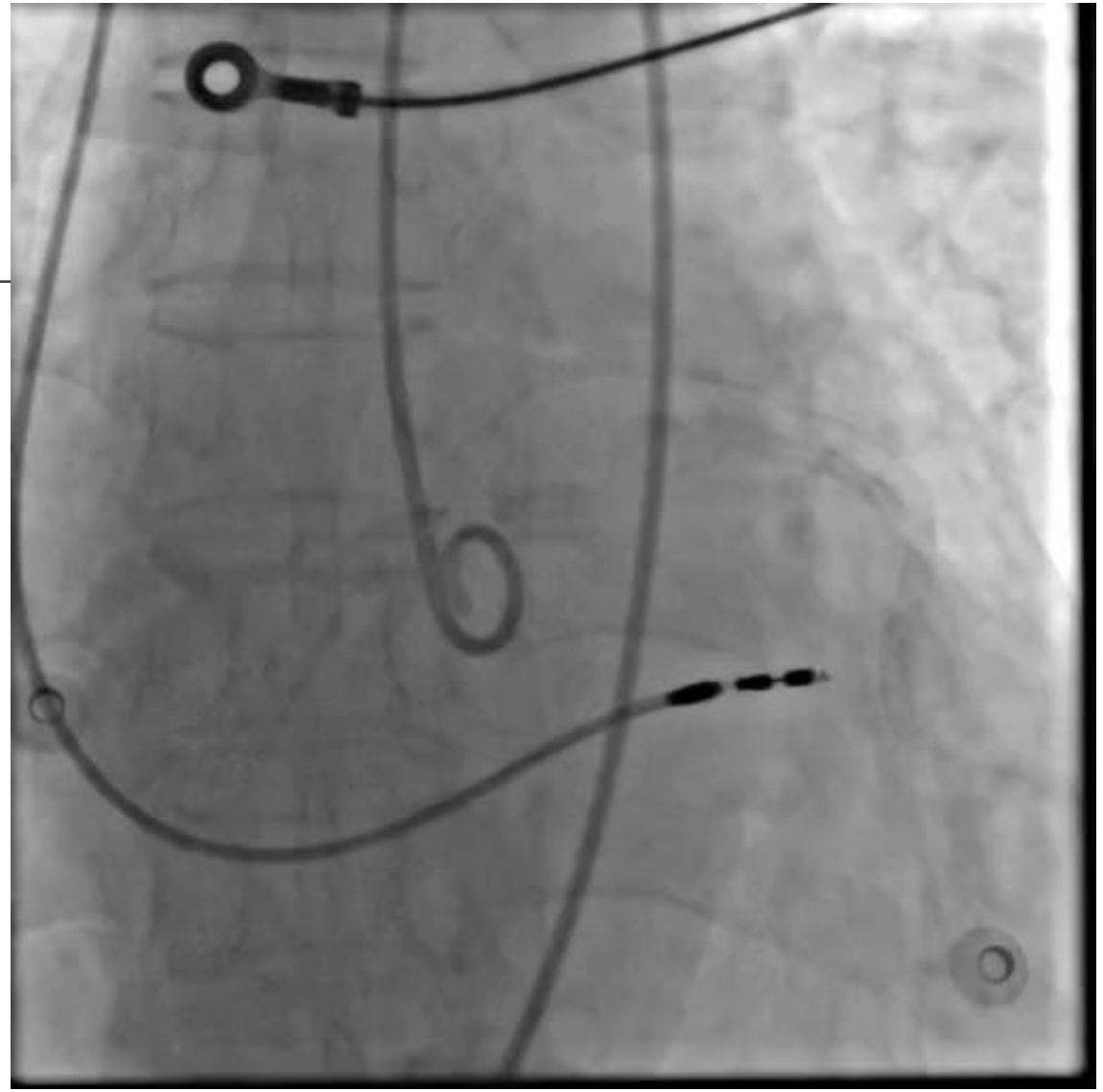
Plan

Transfemoral TAVR under local anesthesia

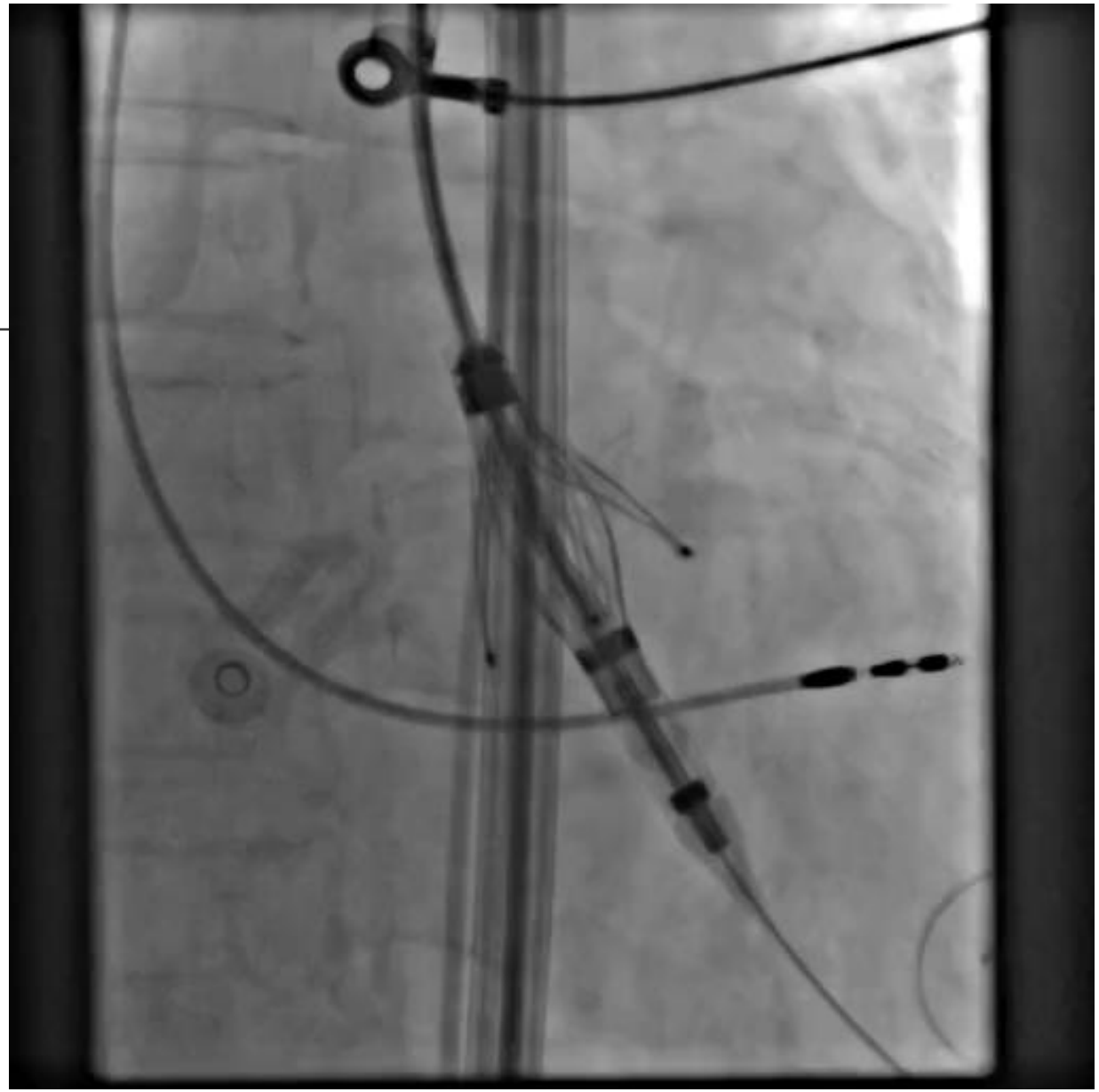
JenaValve trilogy 23mm

Screw-in pacing from right IJV

Baseline aortogram

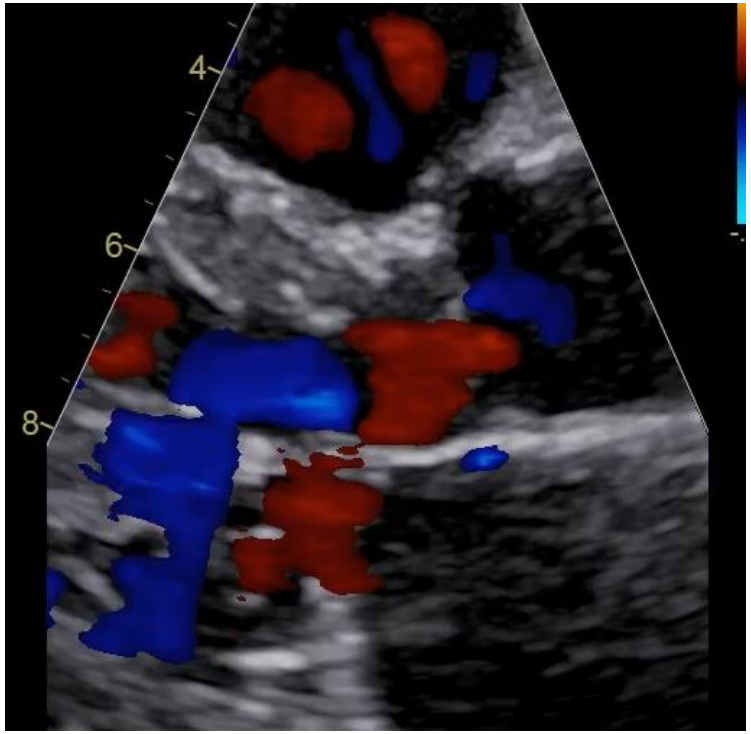


Deployment

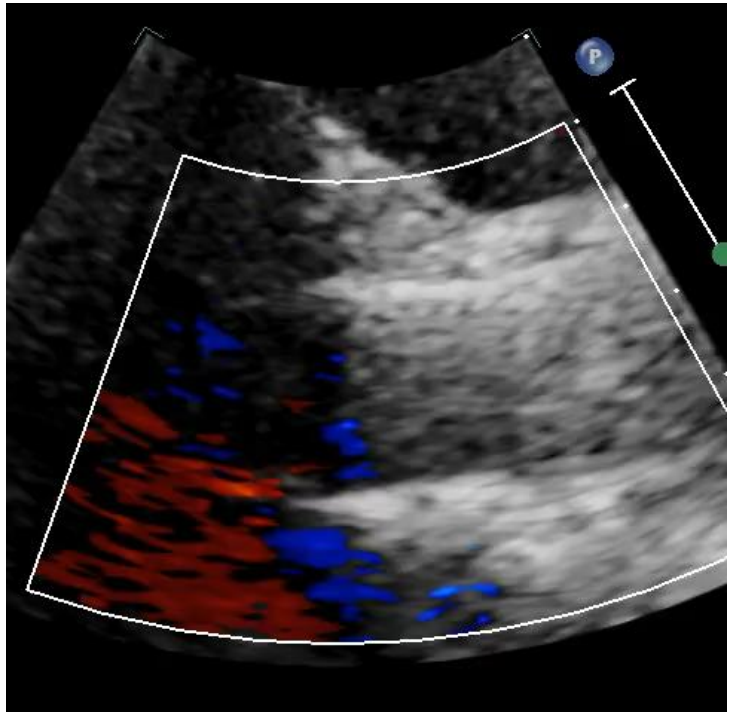


Final aortogram

BEFORE



AFTER



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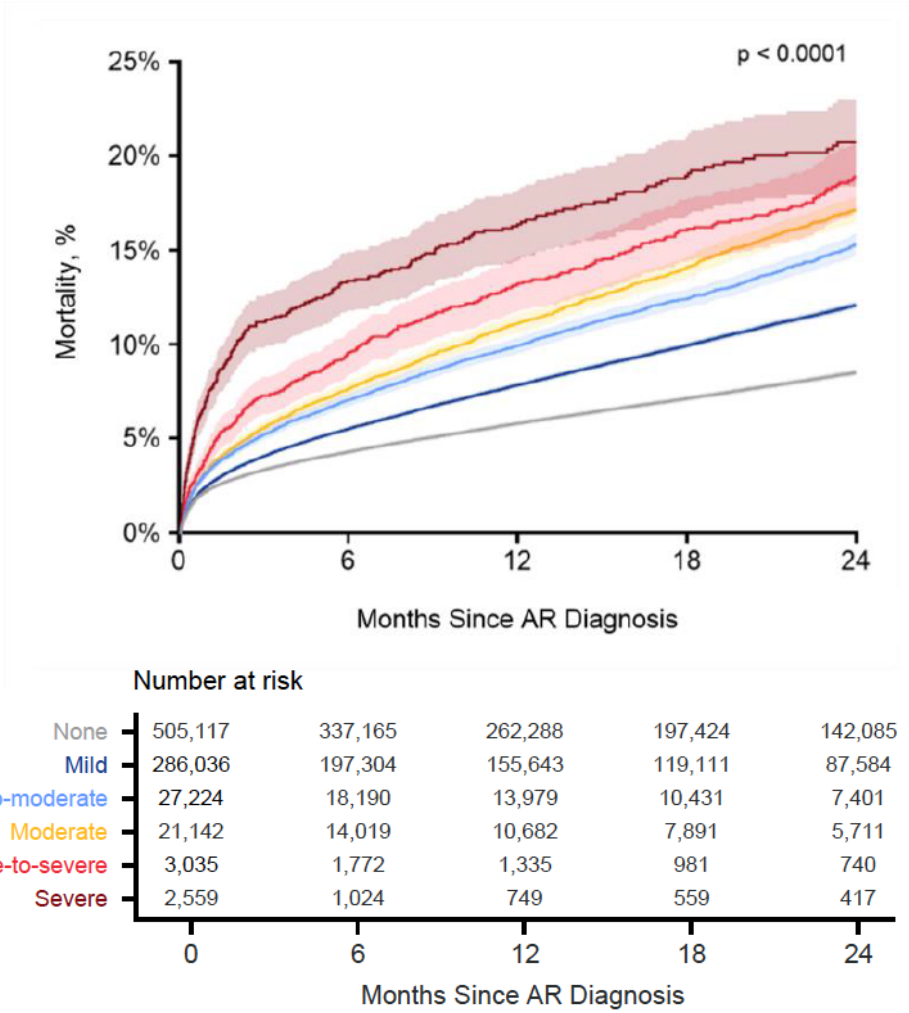
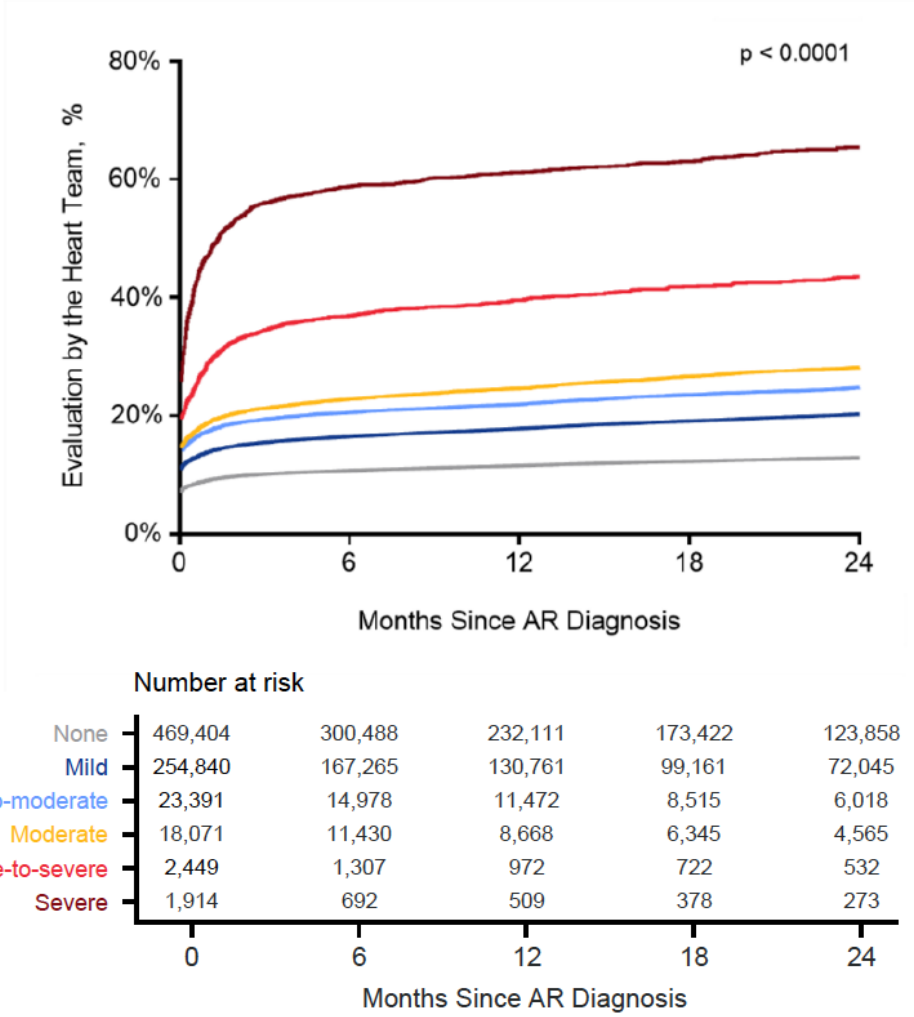
Mortality Among Patients Not Treated With AVR

- Mortality for patients not treated with AVR increased with greater AR severity
- At 2 years, mortality (95% CI) was 20.7% (18.4%-23.0%) for patients with severe AR



Evaluation by the Heart Team

- Rates of evaluation by the Heart Team (95% CI) at 2 years appeared low for patients with moderate-to-severe or severe AR
  - 65.4% (63.3%-67.4%) for patients diagnosed with severe AR
  - 43.5% (41.7%-45.3%) for patients diagnosed with moderate-to-severe AR



My personal viewpoints

Transfemoral TAVR in pure severe AR

- New frontier in the undertreated (but rapidly expanding!) population
- Follow the evolution of TAVR in severe AS

Thank you