부산대학교병원
PUSAN NATIONAL UNIVERSITY HOSPITAL

Evolut Pro™ Features and Latest Clinical Datas

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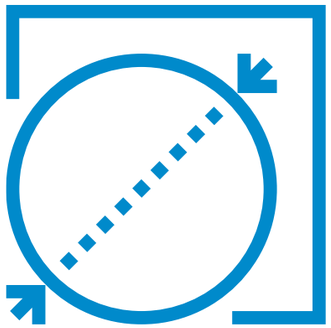
EVOLUT PRO+ SYSTEM

The Evolut™ PRO+ System builds on the Evolut platform's hemodynamic advantage by **Expanding Access to More Patients** with the lowest delivery profile for low risk of vascular complications. Additionally, it features the external tissue wrap on all valve sizes for **Advanced Sealing** across the broadest annular range.



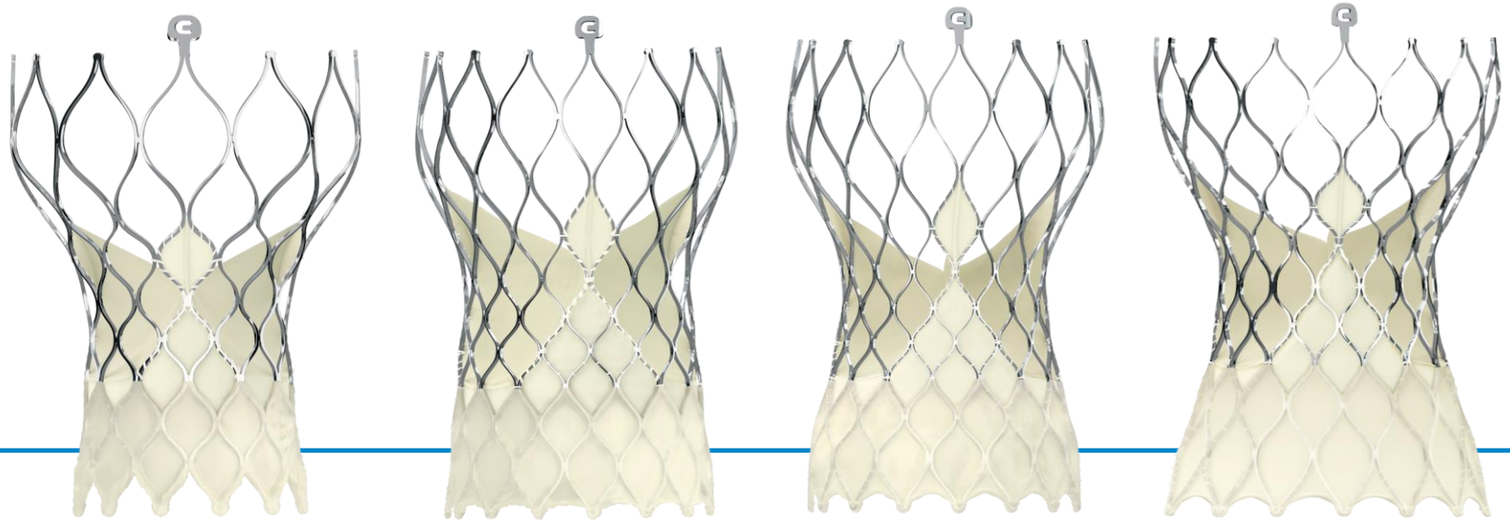
LOWEST DELIVERY PROFILE
for access down to 5.0mm vessels with the 23-29 mm valves

ADVANCED SEALING
for all valve sizes with the addition of the external tissue wrap to the 34 mm valve

MEDTRONIC EVOLUT™ PRO+ SYSTEM
INDICATED ANNULUS RANGE

Together, the Evolut PRO+ System treats the **widest annulus range** of any commercially available TAVR system.*

17/18**



30 mm

Evolut PRO+
23 mm Valve

Evolut PRO+
26 mm Valve

Evolut PRO+
29 mm Valve

Evolut PRO+
34 mm Valve

*Broadest annulus range based on CT derived diameters.
**Measurement for TAV-in-SAV only.

EVOLUT™ LOW RISK TRIAL HEMODYNAMICS TO 2 YEARS[1]

1. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. May 2, 2019;380(18):1706-1715

PATIENT CONSIDERATIONS VALVE PERFORMANCE

TAVR outperforms at all time points post procedure

The Evolut TAV's supra-annular design enables excellent hemodynamic performance.

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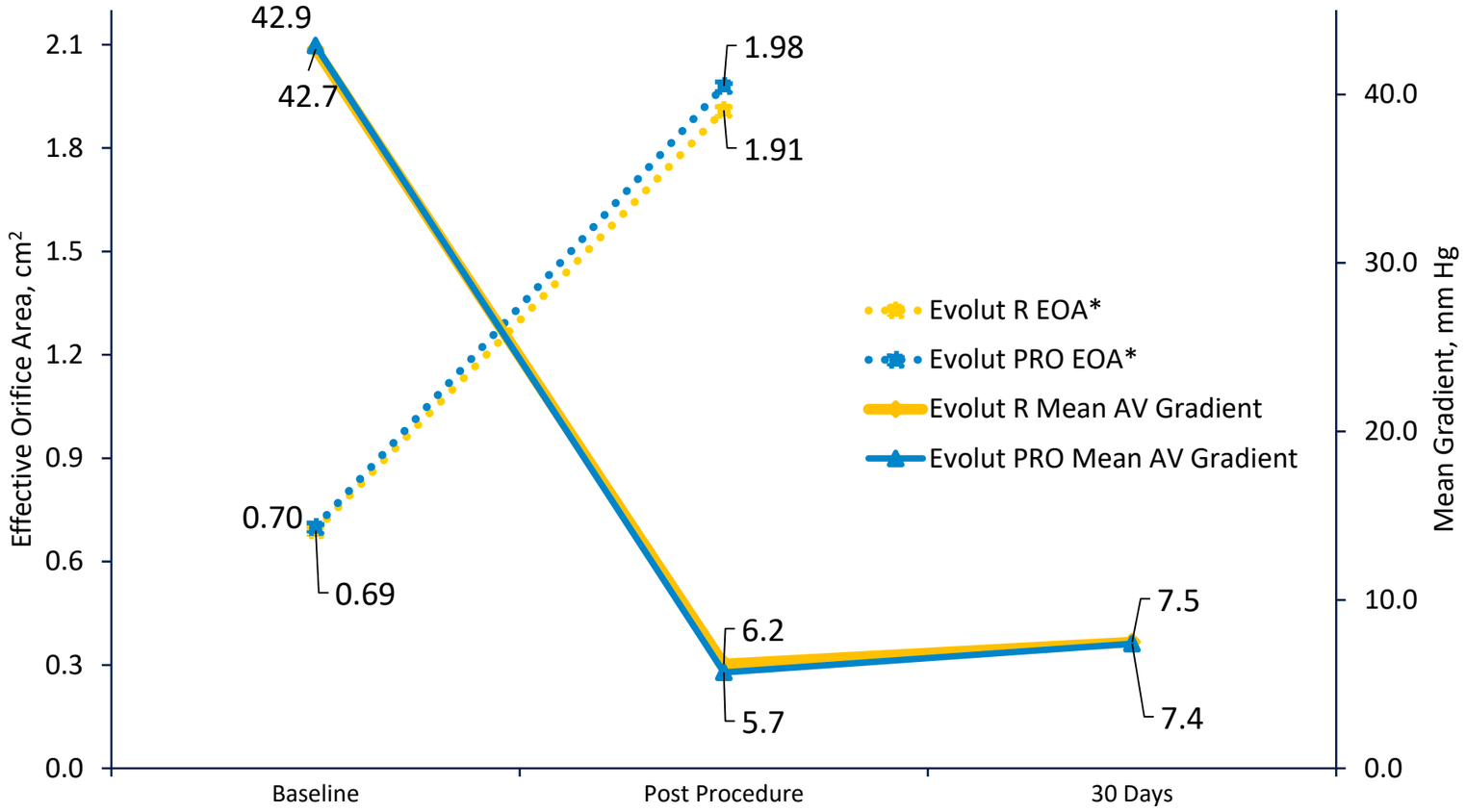
CONSISTENTLY EXCEPTIONAL HEMODYNAMICS MINIMIZES TRADEOFFS

No evidence of impact on the Evolut™ platform's industry-leading hemodynamics with the addition of the external tissue wrap.

Valve Hemodynamics



Baseline data from all attempted implants, post-procedural and 30-day data for implanted patients.

*EOA not collected at 30 days.

Forrest J, et al. 30-Day Outcomes Following Transcatheter Aortic Valve Replacement with the Evolut PRO Valve in Commercial Use: A Report from the STS/ACC TVT Registry™*. Presented at TCT 2018; September 21-25, 2018; San Diego, CA.

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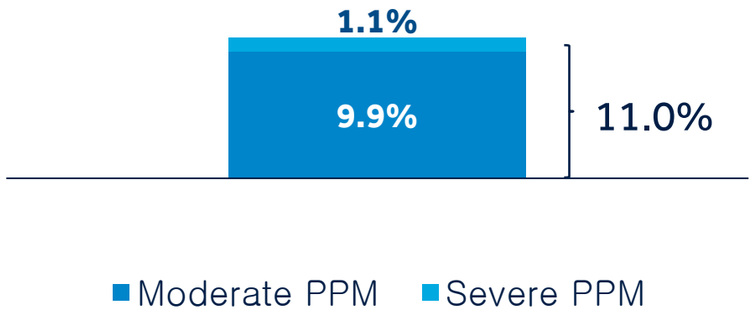
HEMODYNAMICS FOR THE LONG RUN

Evolut 30 Day Patient Prosthesis Mismatch in the MDT Low Risk Trial[1]



The Evolut System's low incidence of 30-Day Patient Prosthesis Mismatch suggests that its supra-annular valve design provides hemodynamic benefit for the younger, more active patient.

1. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. May 2, 2019;380(18):1706-1715

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EVOLUT PRO+ SYSTEM LOWEST DELIVERY PROFILE

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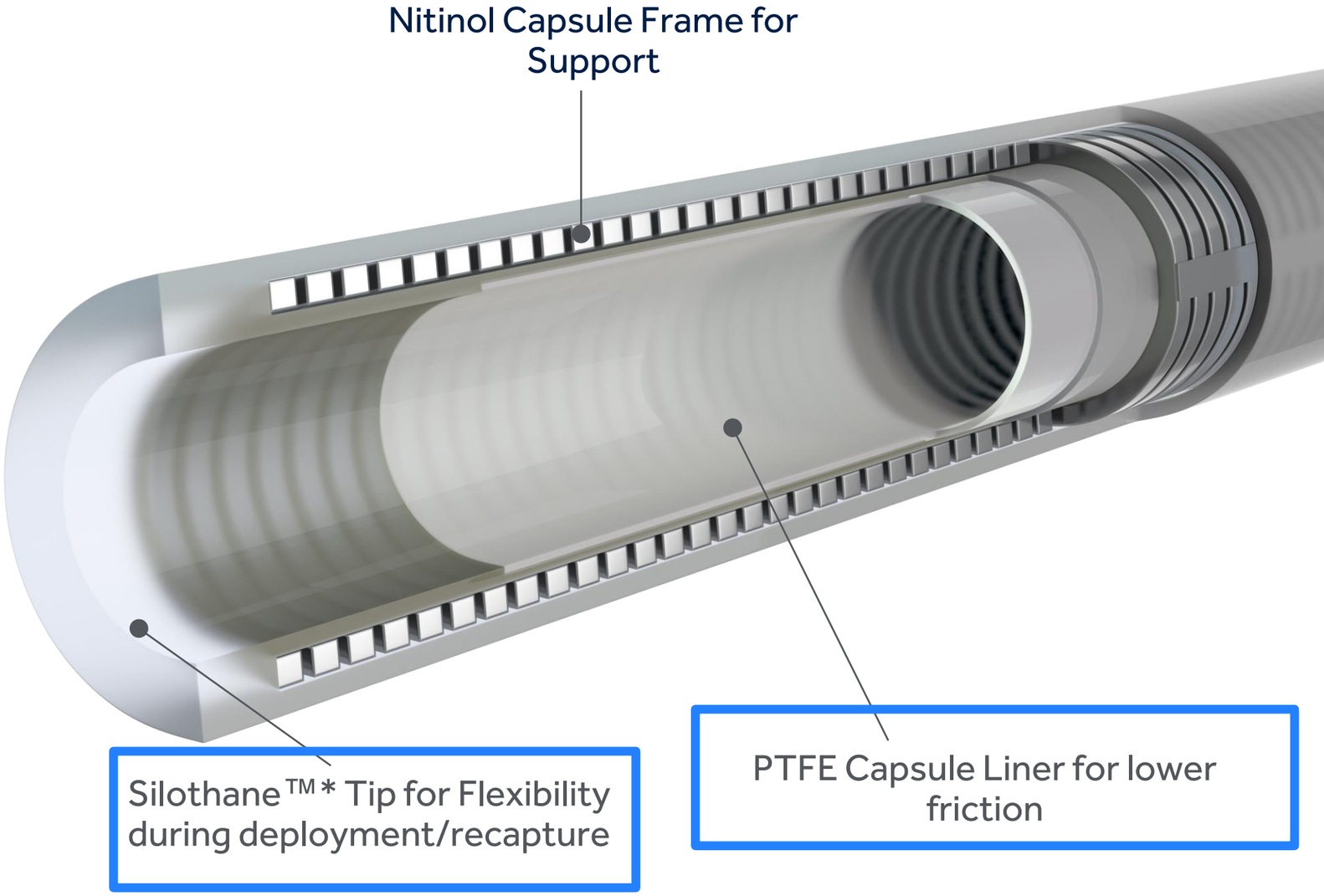
Further, Together

LOWEST DELIVERY PROFILE WITH HYBRID CAPSULE LINER

Hybrid Capsule Liner allows for a lower delivery profile, which may help reduce the risk of vascular complications.[1]



*Medtronic Data on File. Bench test data may not be indicative of clinical performance.

1. Borz, Bogden et al. "Expandable Sheath for Transfemoral Transcatheter Aortic Valve Replacement: Procedural Outcomes and Complications," Catheterization and Cardiovascular Interventions, 83:E227-E232 (2014)

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LOWER DELIVERY PROFILE
REDUCES RISK OF ACCESS COMPLICATIONS[1]

Lowest delivery profile across all valve sizes with InLine Sheath

Evolut PRO+ 23/26/29 mm TAV

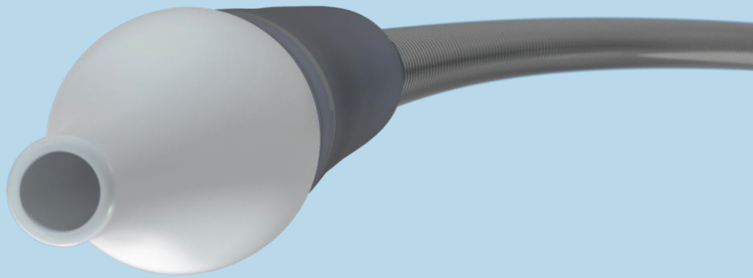
≥ 5.0 mm
Treatable Access Vessel Diameter

6.0 mm
Outer Diameter Capsule

Evolut PRO+ 34 mm TAV

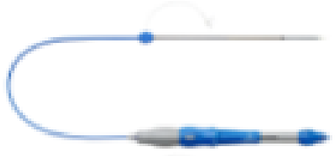
≥ 6.0 mm
Treatable Access Vessel Diameter

7.33 mm
Outer Diameter Capsule



Considering degree of angulation and calcification !

1. Barbanti M, et al. Impact of low-profile sheaths on vascular complications during transfemoral transcatheter aortic valve replacement. EuroIntervention 9.8 (2013): 929-935.

Evolut™ R 	**23-29 mm**		**14 Fr Equivalent**
			InLine Sheath - **14 Fr** Outer Sheath - **18 Fr**
	34 mm		**16 Fr Equivalent**
			InLine Sheath - **16 Fr** Outer Sheath - **20 Fr**
Evolut™ PRO 	**23-29 mm**		**16 Fr Equivalent**
			InLine Sheath - **16 Fr** Outer Sheath - **20 Fr**
Evolut™ PRO+ 	**23-29 mm**		**14 Fr Equivalent**
			InLine Sheath - **14 Fr** Outer Sheath - **18 Fr**
	34 mm		**18 Fr Equivalent**
			InLine Sheath - **18 Fr** Outer Sheath - **22 Fr**

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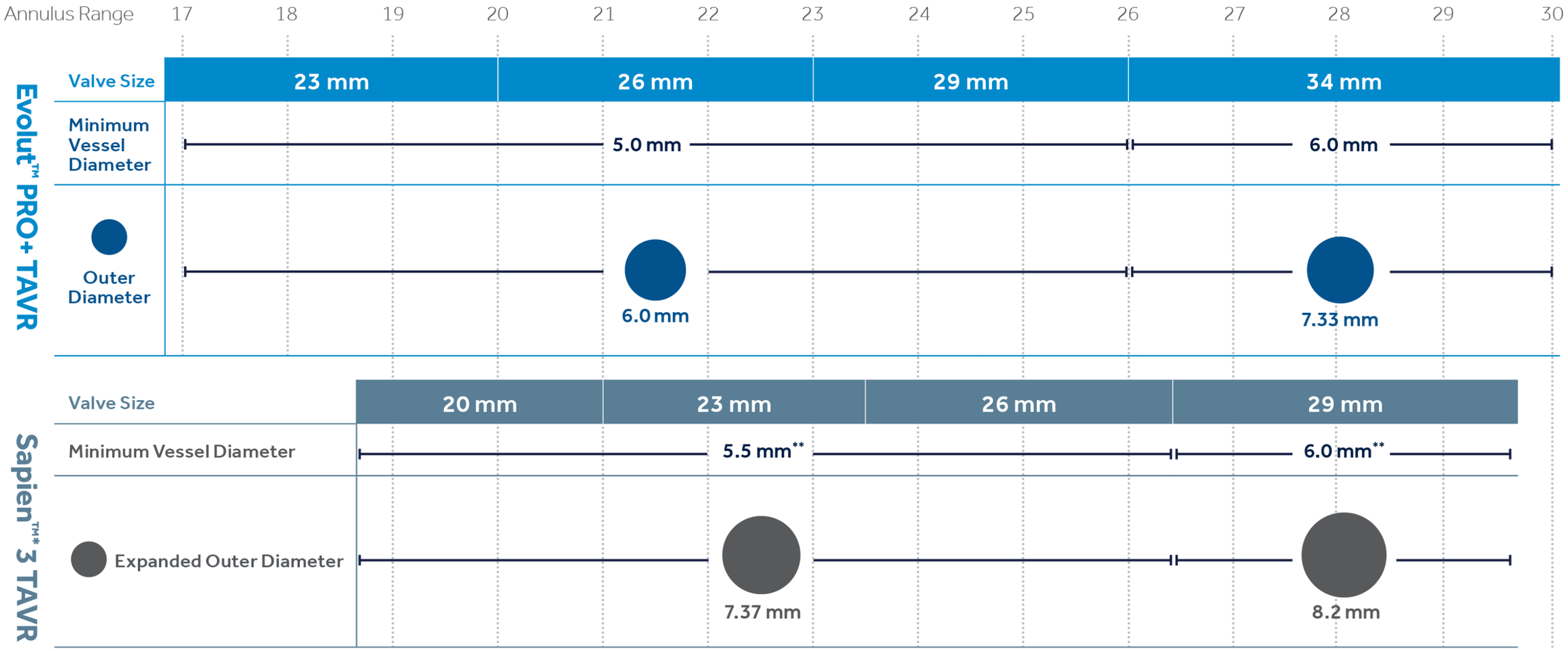
EVOLUT PRO+ SYSTEM HAS THE LOWEST DELIVERY PROFILE

EVOLUT PRO+ SYSTEM VS. SAPIEN™* 3 SYSTEM



Sheath circular cross section images are not to scale, but are intended to demonstrate the relative sizes of the devices. The labeled sizes are accurate based on the references noted and the Evolut PRO+ System Labeling.

Parma, Variations in Outer Diameters of Femoral Sheaths Used in Transcatheter Aortic Valve Replacement, Presented at TVT2017.

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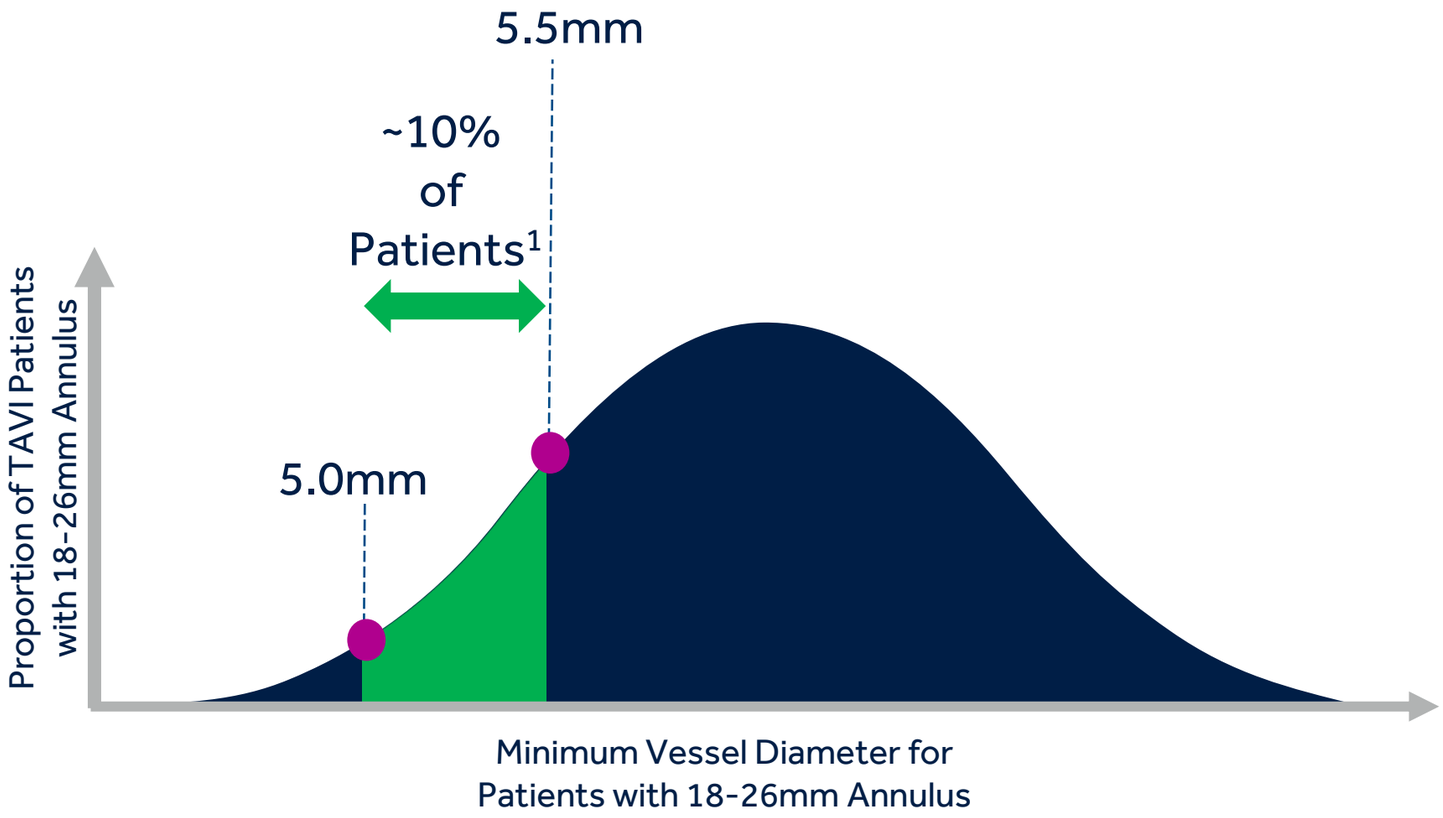
WITH THE LOWEST DELIVERY PROFILE YOU CAN TREAT MORE PATIENTS WITH THE EVOLUT PRO+ SYSTEM



Only Medtronic TAVR is indicated to treat patients with access vessels as small as 5.0 mm.

~10%

Of patients have access vessels between 5.0 and 5.5mm[1]

1. Medtronic Data on File

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EVOLUT PRO+ SYSTEM ADVANCED SEALING

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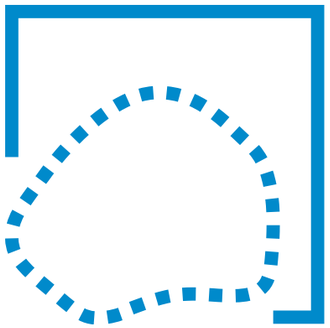
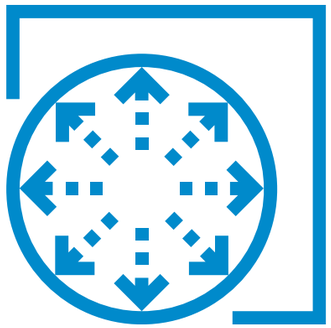
SEALING **MECHANISMS**

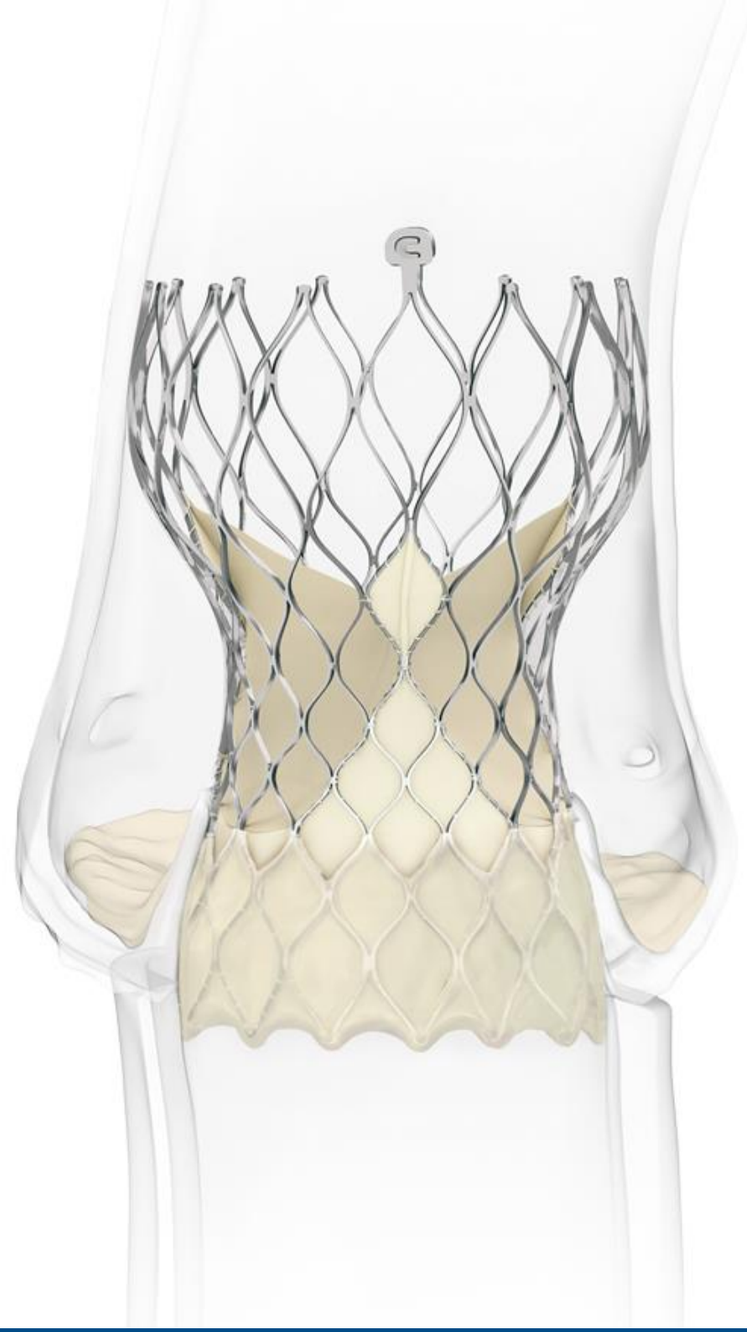


Conformable Frame
Self-expanding nitinol frame conforms to annulus



Consistent Radial Force
Frame oversizing and cell geometry provide consistent radial force across treatable annulus range

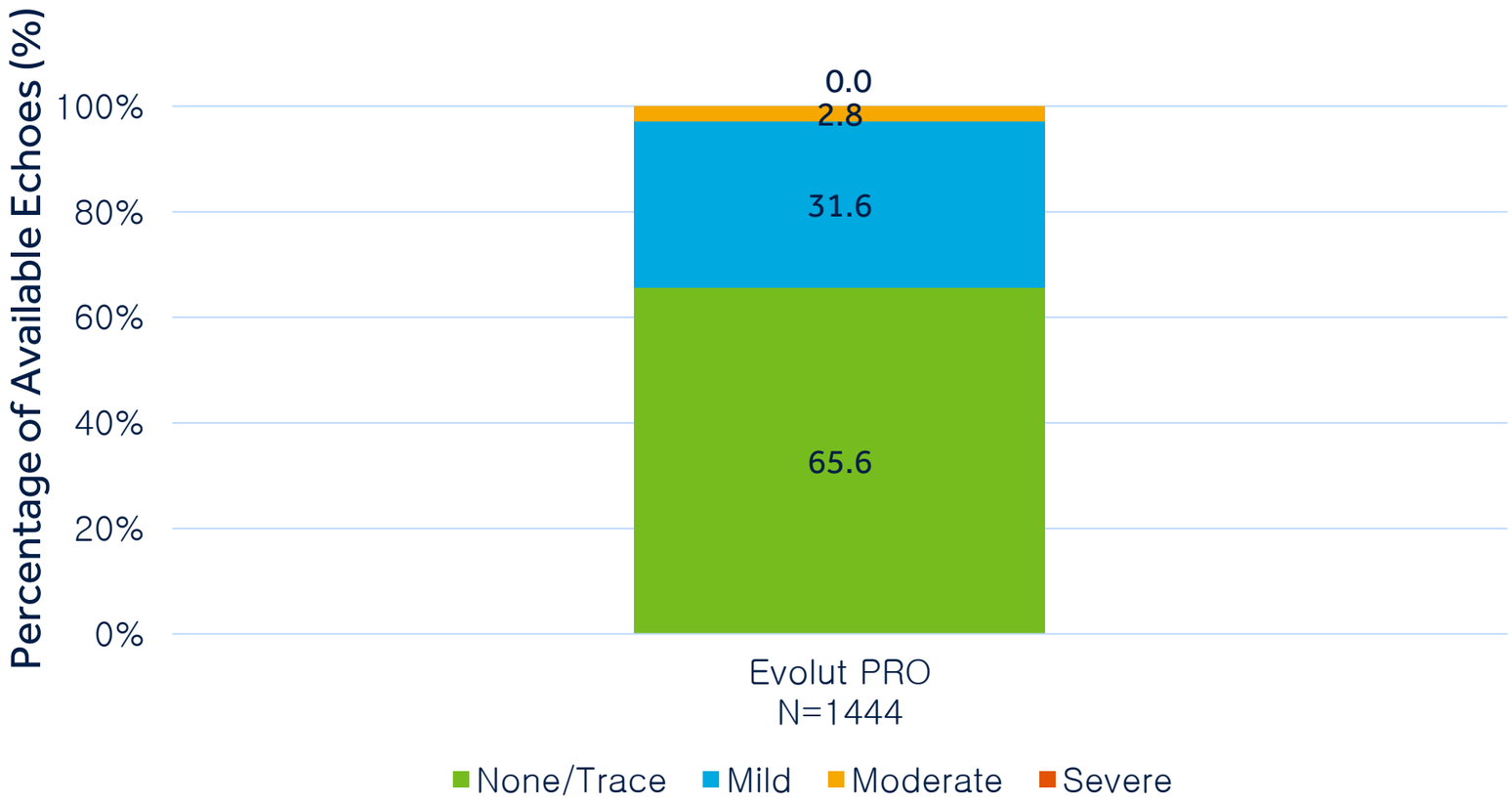
External Wrap
External tissue wrap increases surface contact with native anatomy



ADVANCED SEALING
REAL WORLD RESULTS

The external wrap on the Evolut PRO valve has shown advanced sealing with real world results and similar results can be expected from the 34mm Evolut PRO+ valve.

TOTAL AORTIC REGURGITATION AT 30-DAYS (TVT-R)



Forrest J, et al. 30-Day Outcomes Following Transcatheter Aortic Valve Replacement with the Evolut PRO Valve in Commercial Use: A Report from the STS/ACC TVT Registry™*. Presented at TCT 2018; September 21-25, 2018; San Diego, CA.

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CONFIRM
PRODUCT COMPATIBILITY

IMPORTANT: System failure could occur if an incorrect combination of devices is used.

Bioprosthesis

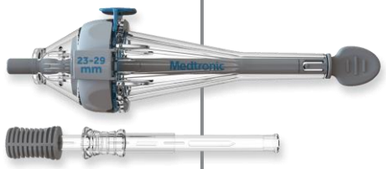

EVPROPLUS-23US


EVPROPLUS-26US

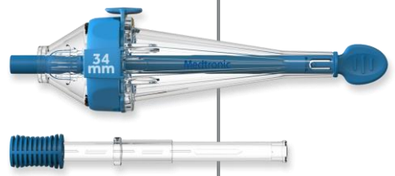

EVPROPLUS-29US


EVPROPLUS-34US

Loading System



L-EVPROP2329US



L-EVPROP34US

Catheter


D-EVPROP2329US


D-EVPROP34US

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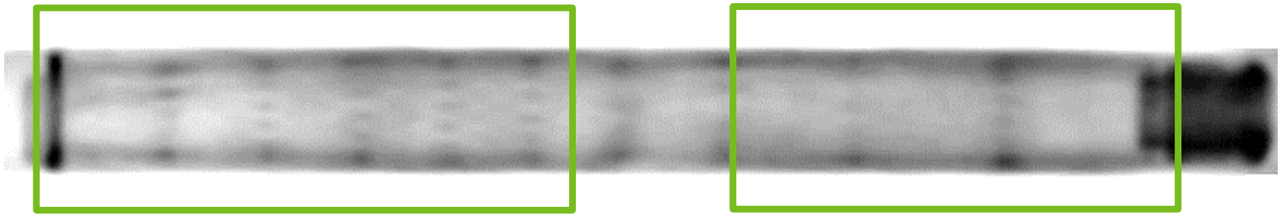
UPDATED FLOURO LOAD INSPECTION



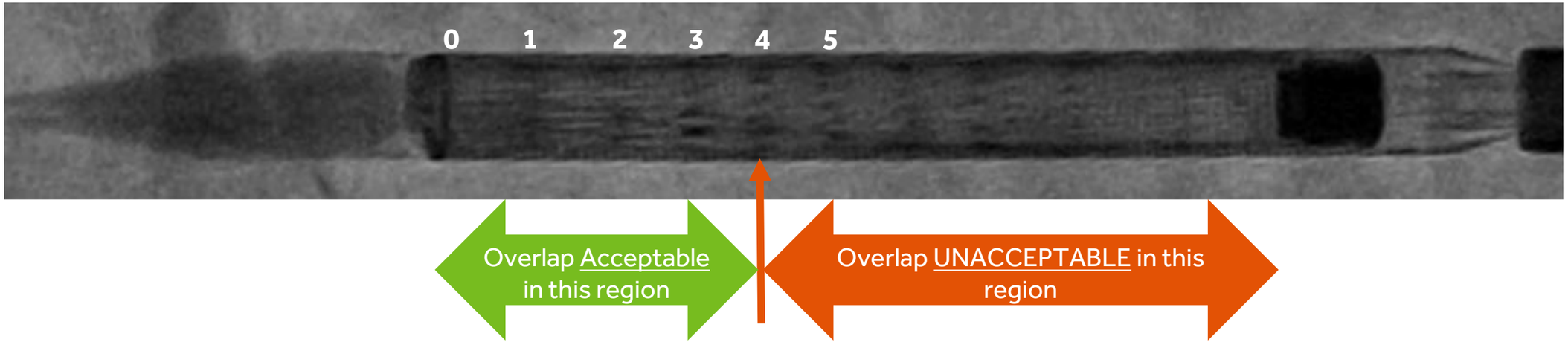
- Use the inspection to check for bent outflow crowns and severe inflow crown overlap.
  - Outflow crowns should be parallel to the distal end of the paddle attachment.
  - Inflow crown overlap should be **less than node 4**.
- Slowly **rotate the capsule 360°** when performing the fluoro check.

Note:

- It is no longer necessary to check for paddle out of pocket conditions during the fluoro load inspection.
- Tactile inspection is used to check that the capsule is straight and free of bends or curves.
- **The best image is an AP, high res, cine run.**

FLUORO LOAD CHECK
COUNTING NODES

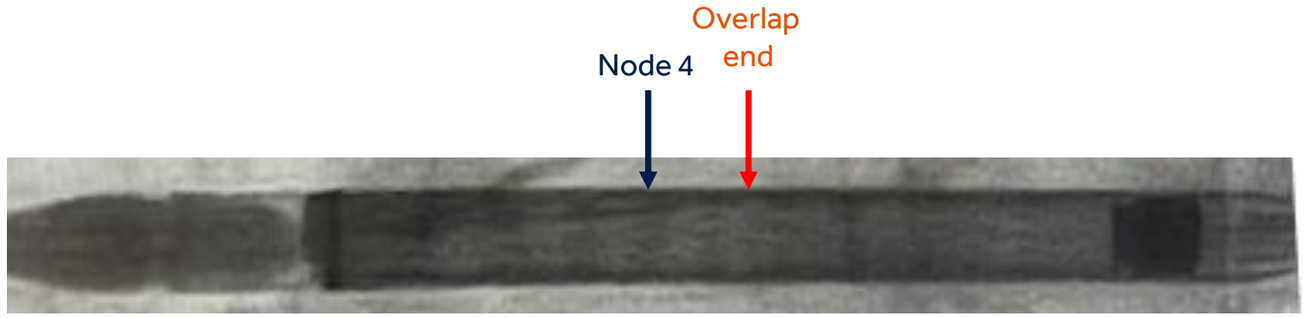
Under fluoro, nodes appears as bands around the capsule.



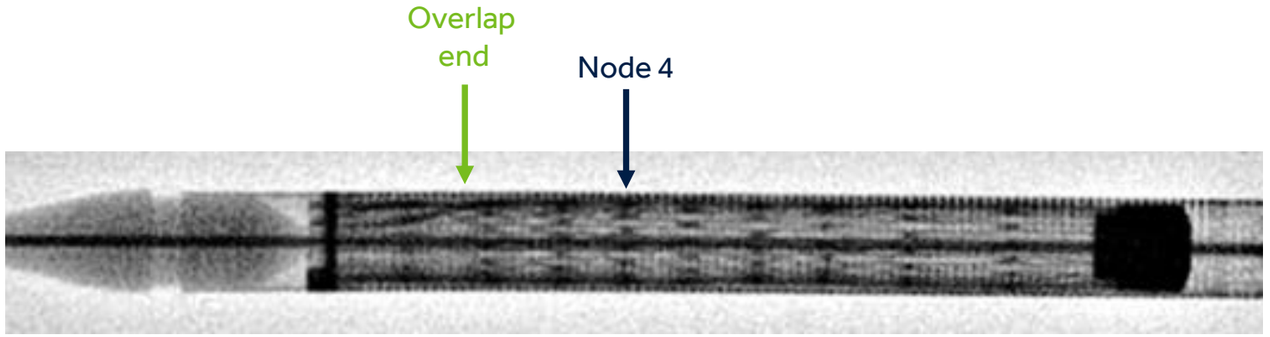
Inflow crown overlap appears as a non-uniform shadow starting at the inflow edge (node 0) and extending up the valve. Where the shadow ends or disappears is where the overlap ends.

FLUORO LOAD INSPECTION

INFLOW CROWN OVERLAP



Inflow crown overlap past node 4:
Unacceptable



Inflow crown overlap less than node 4:
Acceptable

- Crown overlap in the inflow region may be observed during the fluoro load inspection.
- Inflow crown overlap is **unacceptable if up to or past node 4**; this is a misload and the entire system (valve, loading system, and delivery system) must be replaced.

- Inflow crown overlap **less than node 4 is acceptable.**
- Inflow crown overlap up to or past node 4 can lead to infolding upon deployment.

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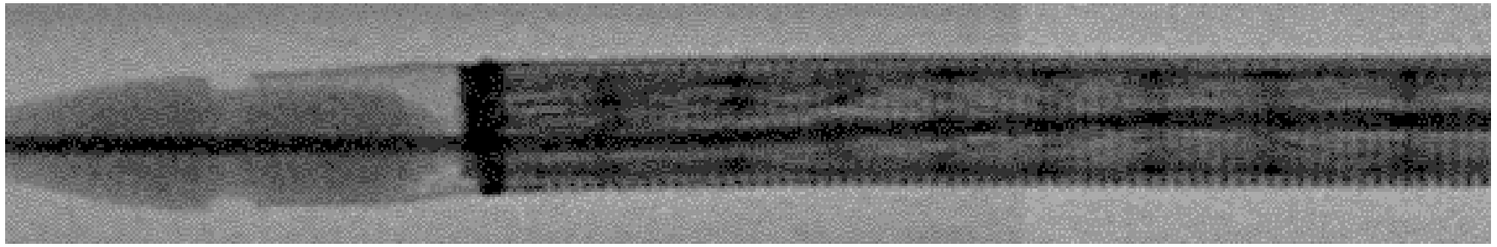
FLUORO LOAD INSPECTION
INFLOW CROWN OVERLAP CONSIDERATIONS

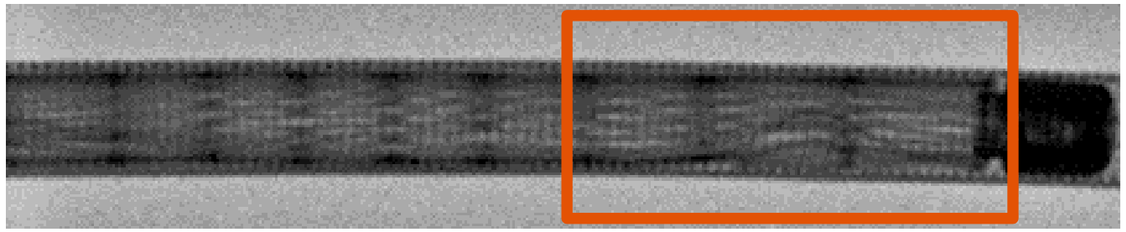


This fluoro image shows inflow crown overlap just short of node 4, which is acceptable.

Inflow crown overlap less than node 4 is acceptable and unlikely to result in infolding on initial deployment.

- Inflow crown overlap past node 4 is **rare** when the valve is loaded correctly.
- When improperly loaded, inflow crown overlap past node 4 is more likely to occur with the 34 mm Evolut PRO+ valve.
- Inflow crown overlap past node 3 and close to node 4 occurs more commonly with the 29 mm Evolut PRO+ valve, even when the valve has been loaded correctly.

FLUORO LOAD INSPECTION
OUTFLOW CROWNS



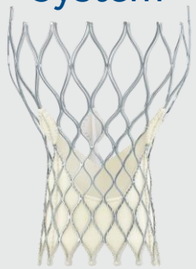
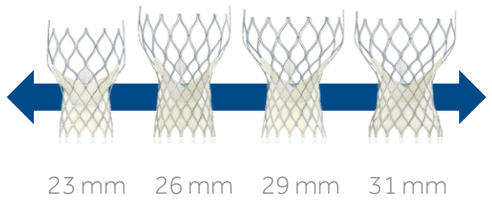
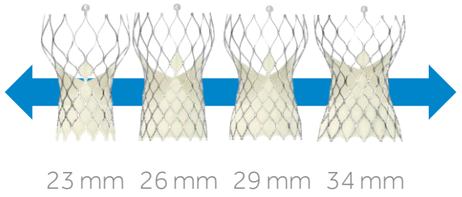
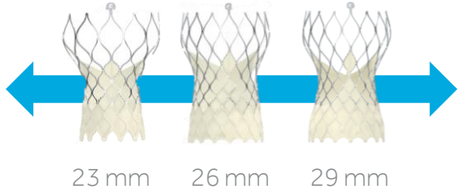
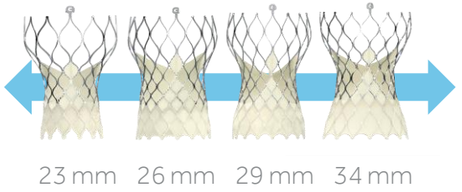
- Outflow crowns not aligned and/or not parallel to the paddle attachment indicate a misload.
- Shadow or outline present indicating a bent outflow strut

If any indication of a misload is identified, the valve, delivery system, and loading system must all be discarded and replaced.

TECHNOLOGY EVOLUTION

WITHOUT EXTERNAL TISSUE WRAP

WITH EXTERNAL TISSUE WRAP

	CoreValve™ System	Evolut™ R System	Evolut™ PRO System	Evolut™ PRO+ System
Valve				
Device Profile (Indication)	6.0 mm + 18 Fr Sheath (≥ 6.0 mm) 	6.0-6.7 mm (5.0-5.5 mm) 	6.7 mm (≥ 5.5 mm) 	6.0-7.33 mm (5.0-6.0 mm) 
Annulus Range Covered	18-29 mm  23 mm 26 mm 29 mm 31 mm	17*-30 mm  23 mm 26 mm 29 mm 34 mm	17*-26 mm  23 mm 26 mm 29 mm	17*-30 mm  23 mm 26 mm 29 mm 34 mm

*Measurement is for TAV-in-SAV only.

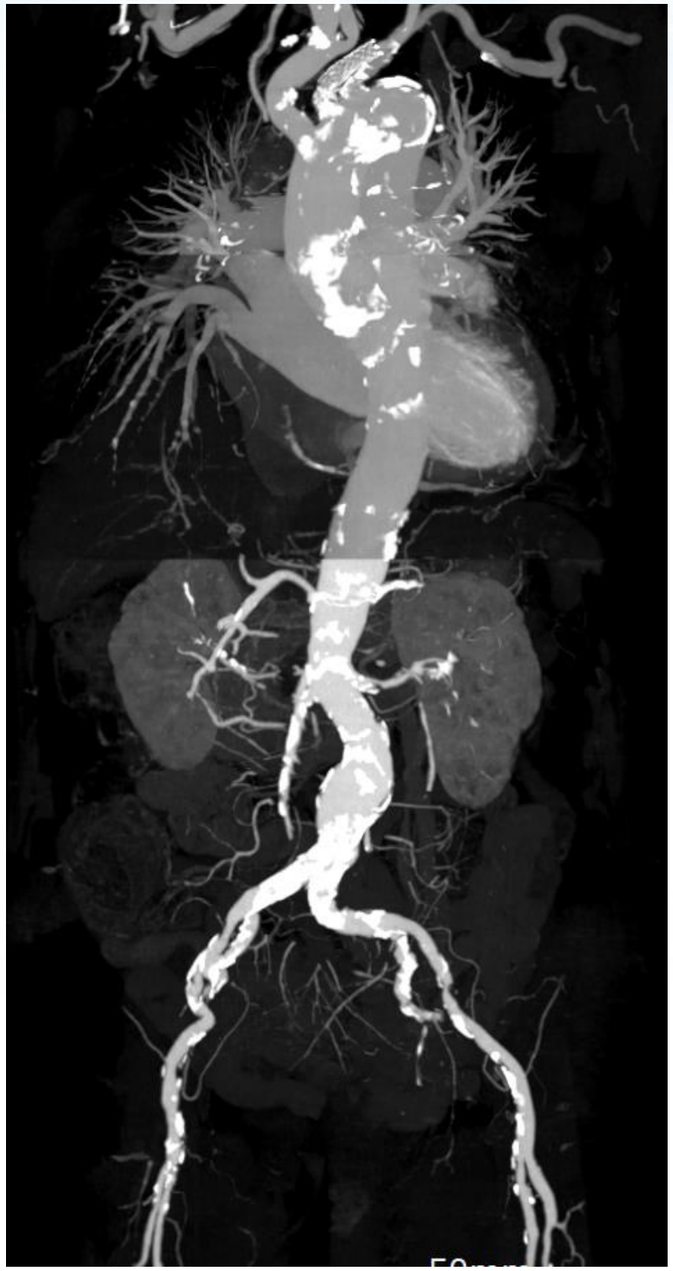
CASE
Hostile iliac artery

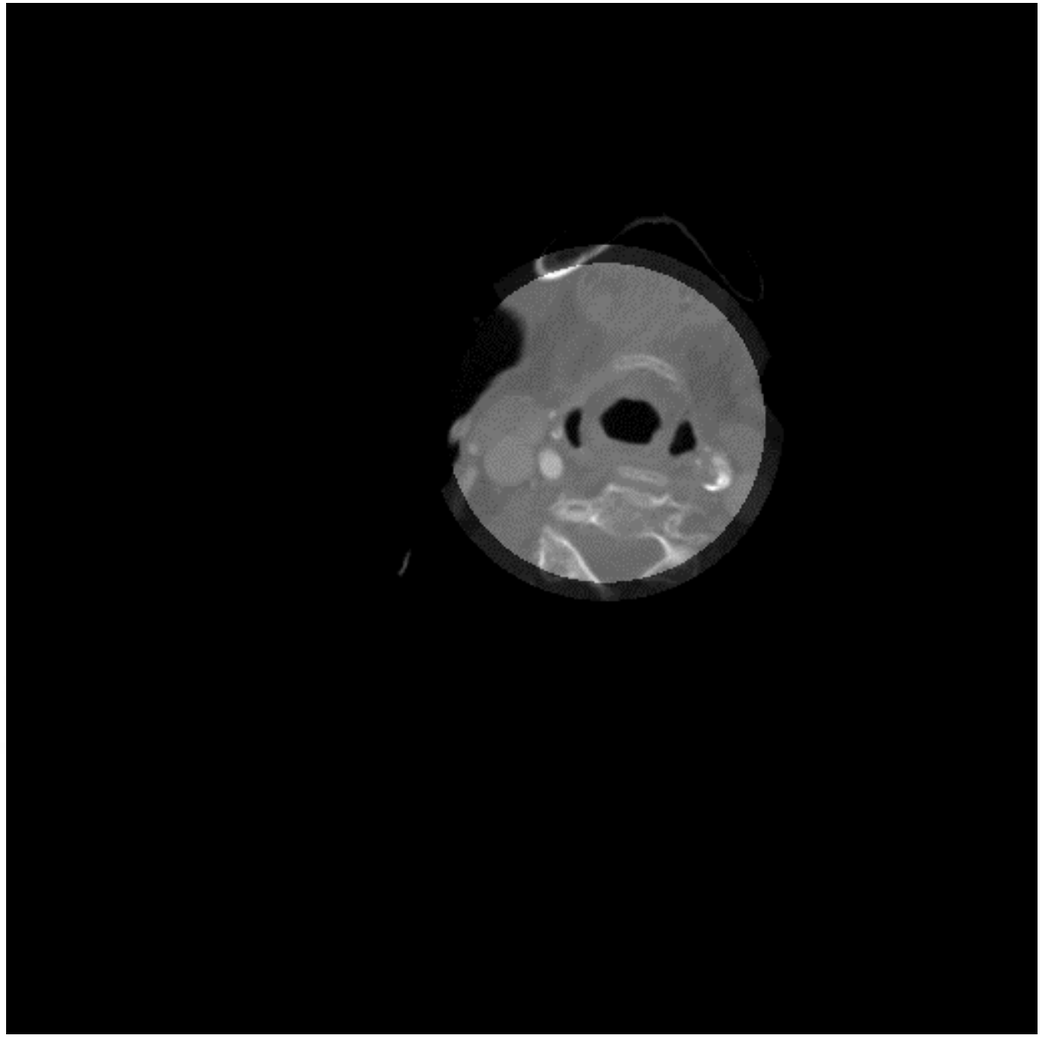
박O F/84

- Chief Complaint : Dsypnea, Severe AS

- Past History : HT(+), DM(+)
  Hyperlipidemia(+), Carotid a stent
  AAA(+)

C T





Which approach do you prefer?

1. Right femoral artery

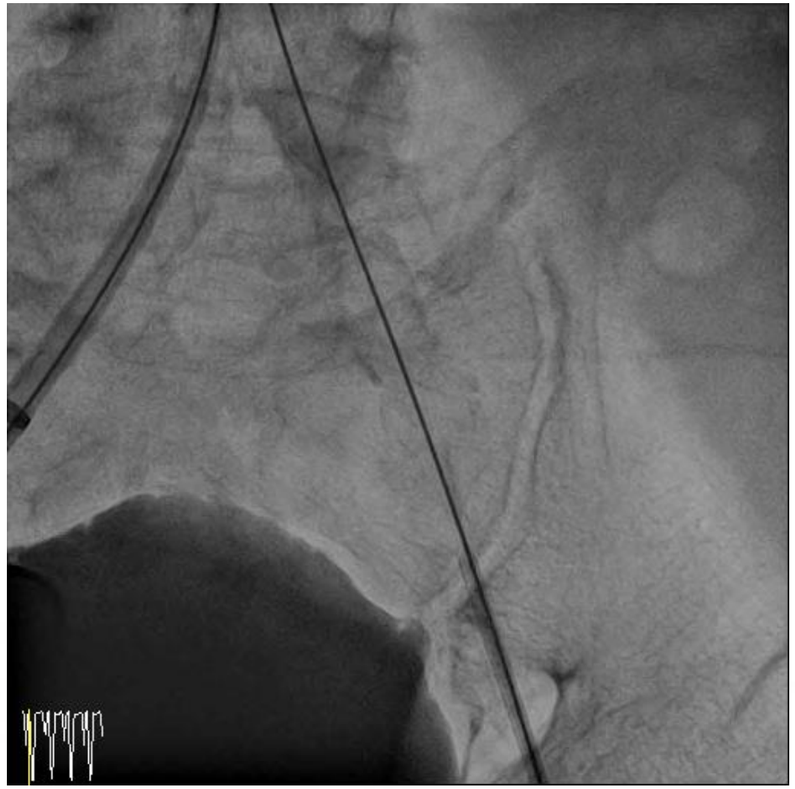
2. Left Femoral artery

3. Iliac conduit via retroperitoneal approach

4. Left SCA approach

5. Direct ascending aorta approach

Techniques according to trouble



1. Small Vessel Size

: Iliac conduit

2. Calcification

: Aseptic lubricant

Balloon dialtation : **rupture risk!!**

3. Angulation

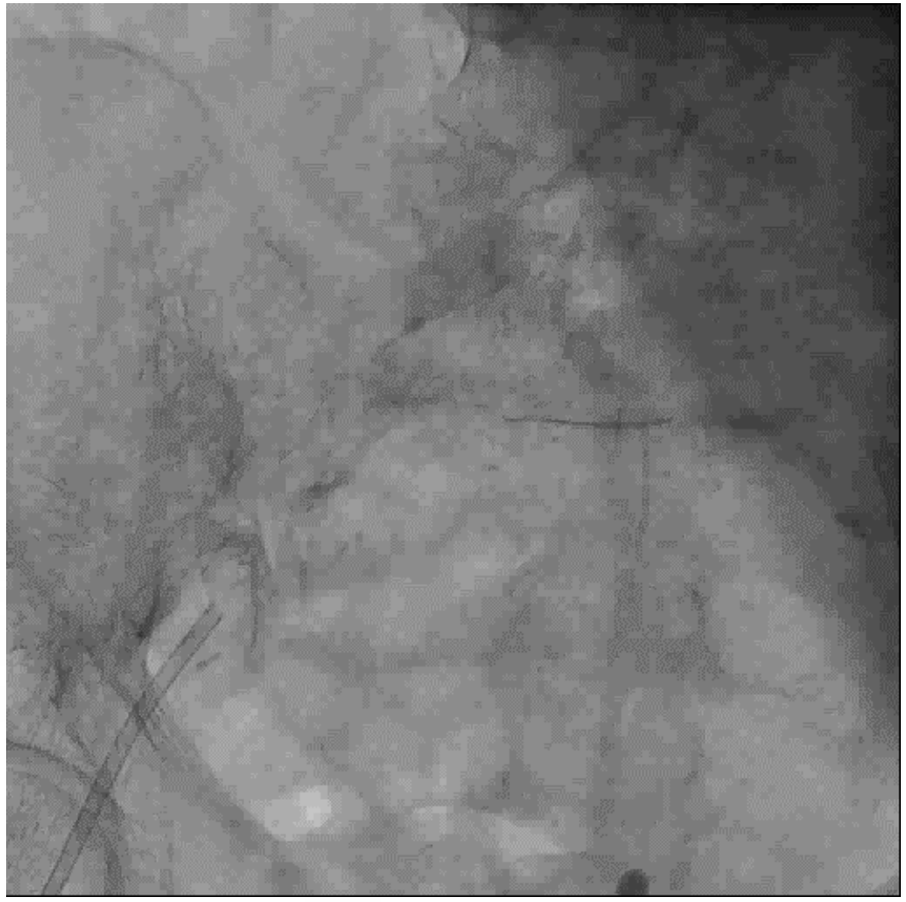
:Two extrastiff wire

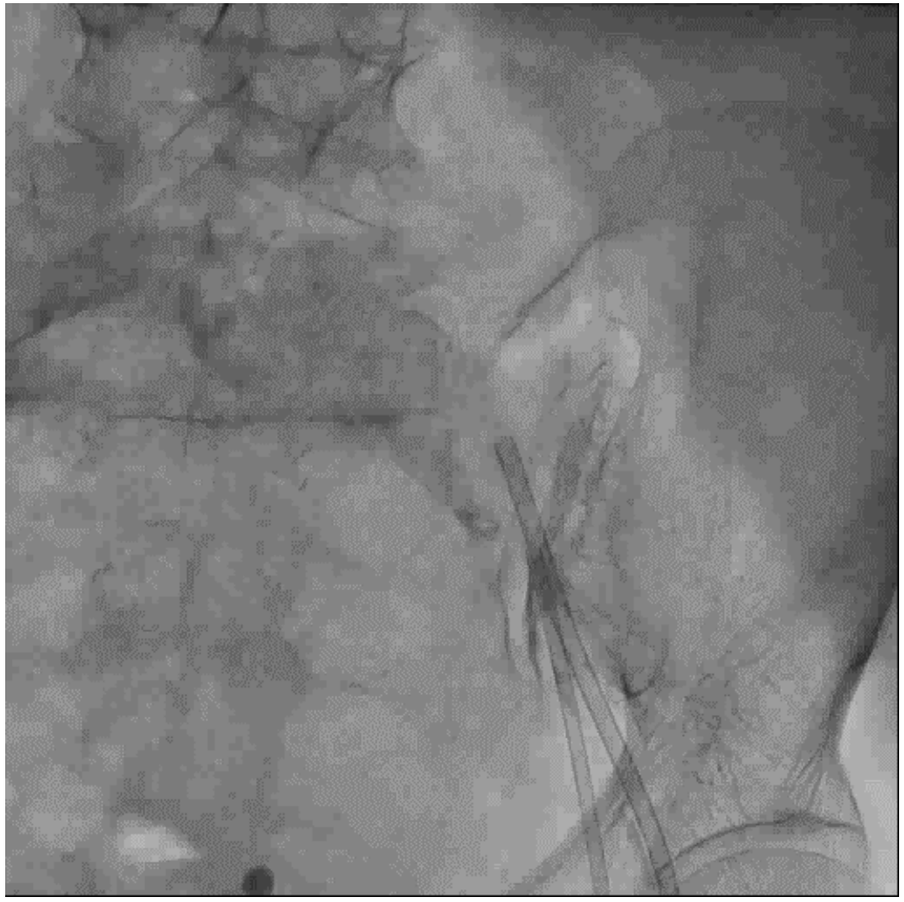
Sheath exchange

4. Stenosis

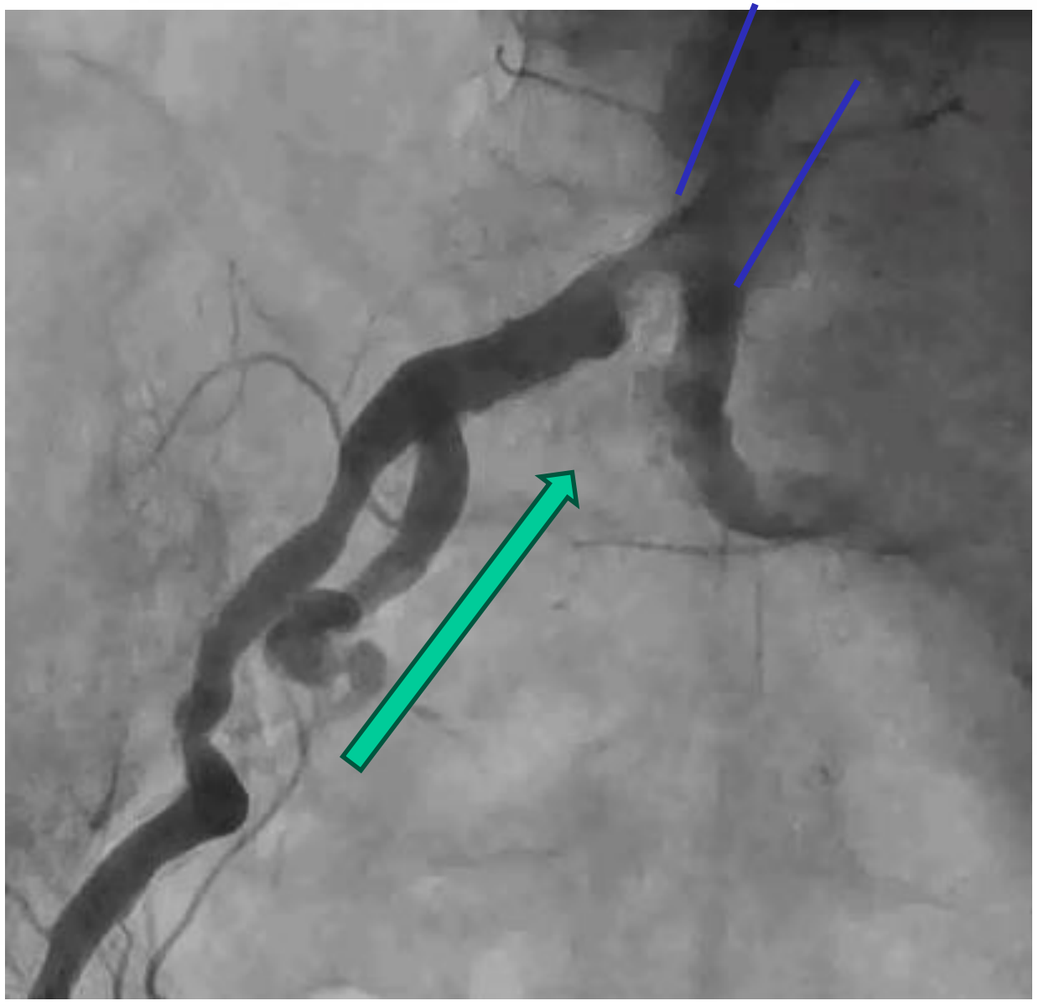
: Balloon dilatation

Which side is better to do TAVI ?

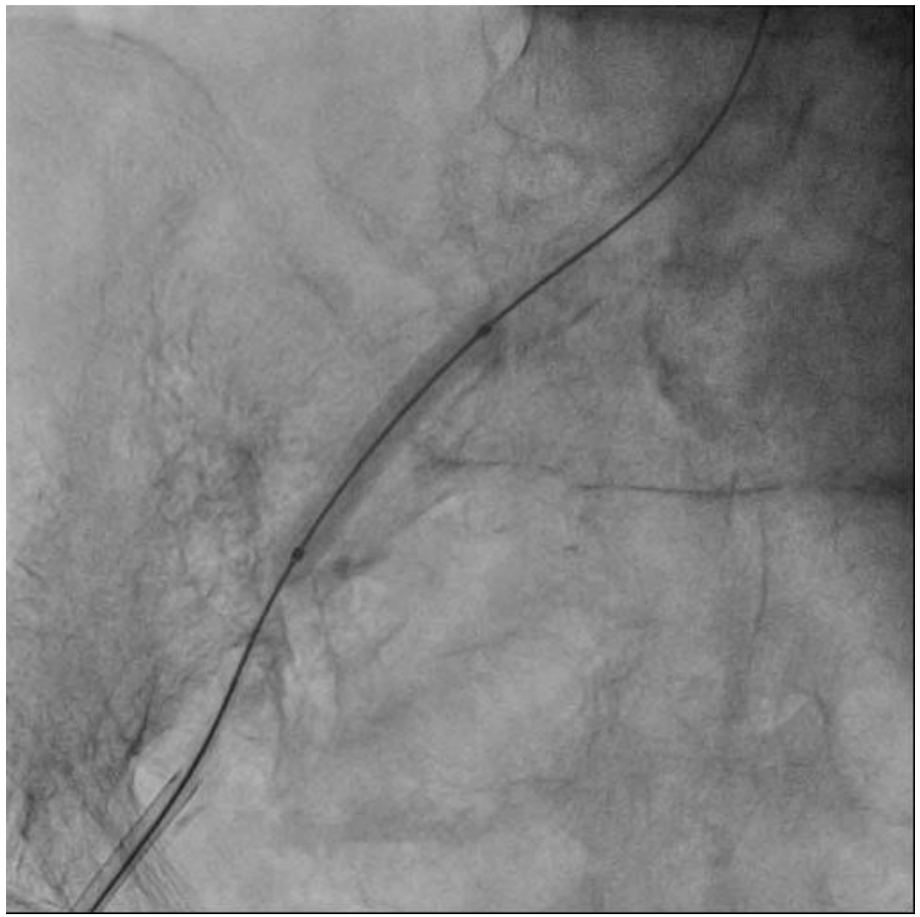


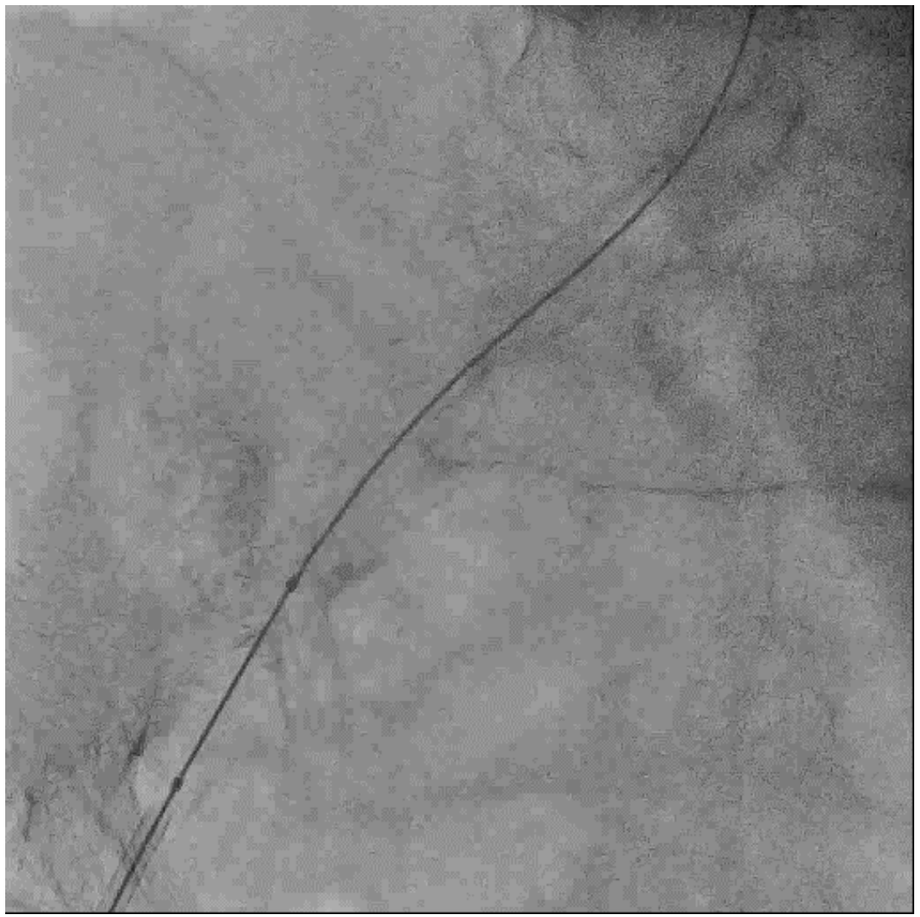


Distal Aorta Calcification + Angulation

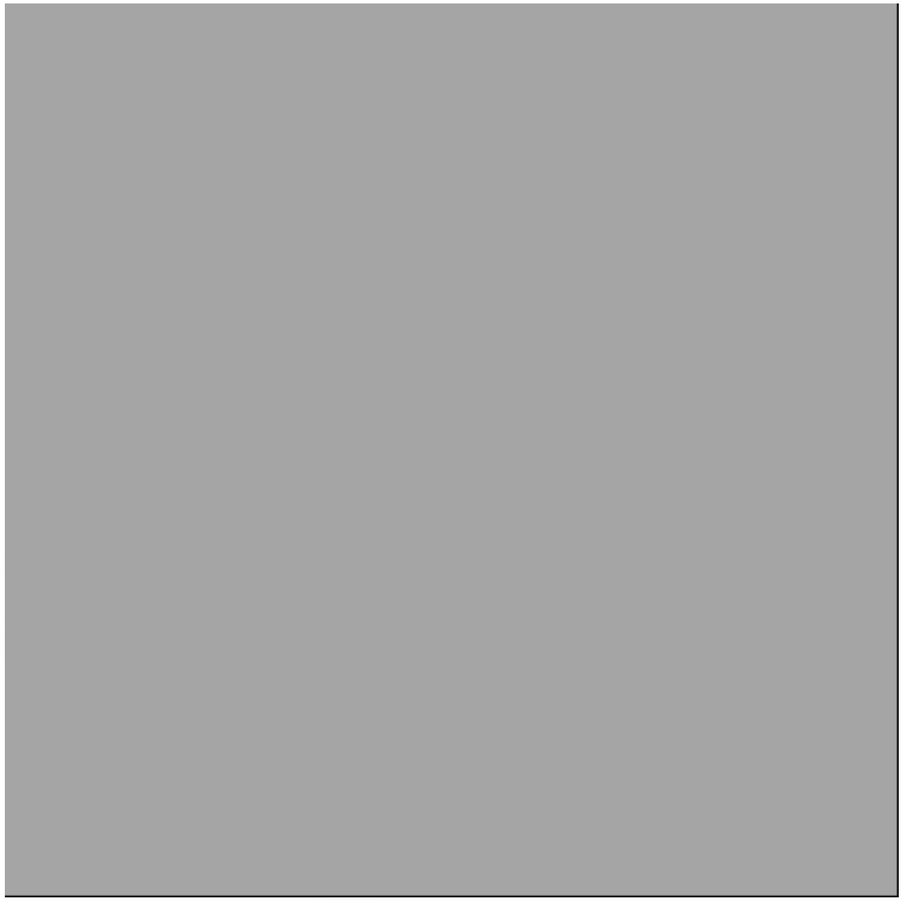


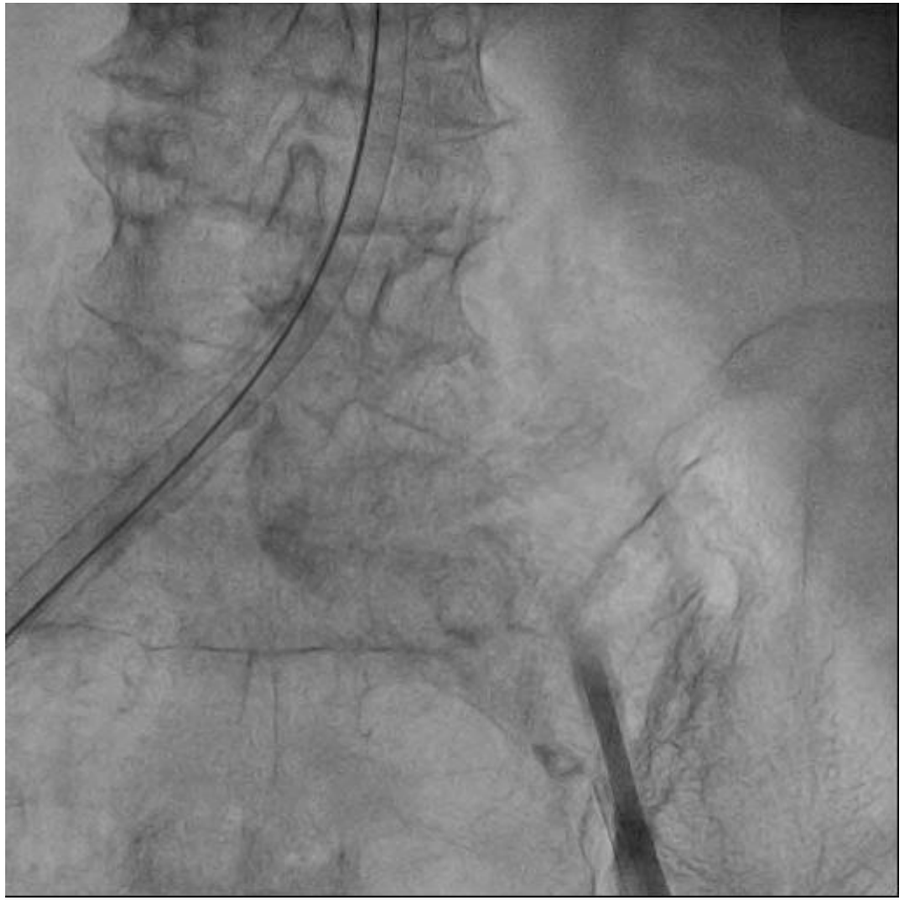
TAVI with Evolut R



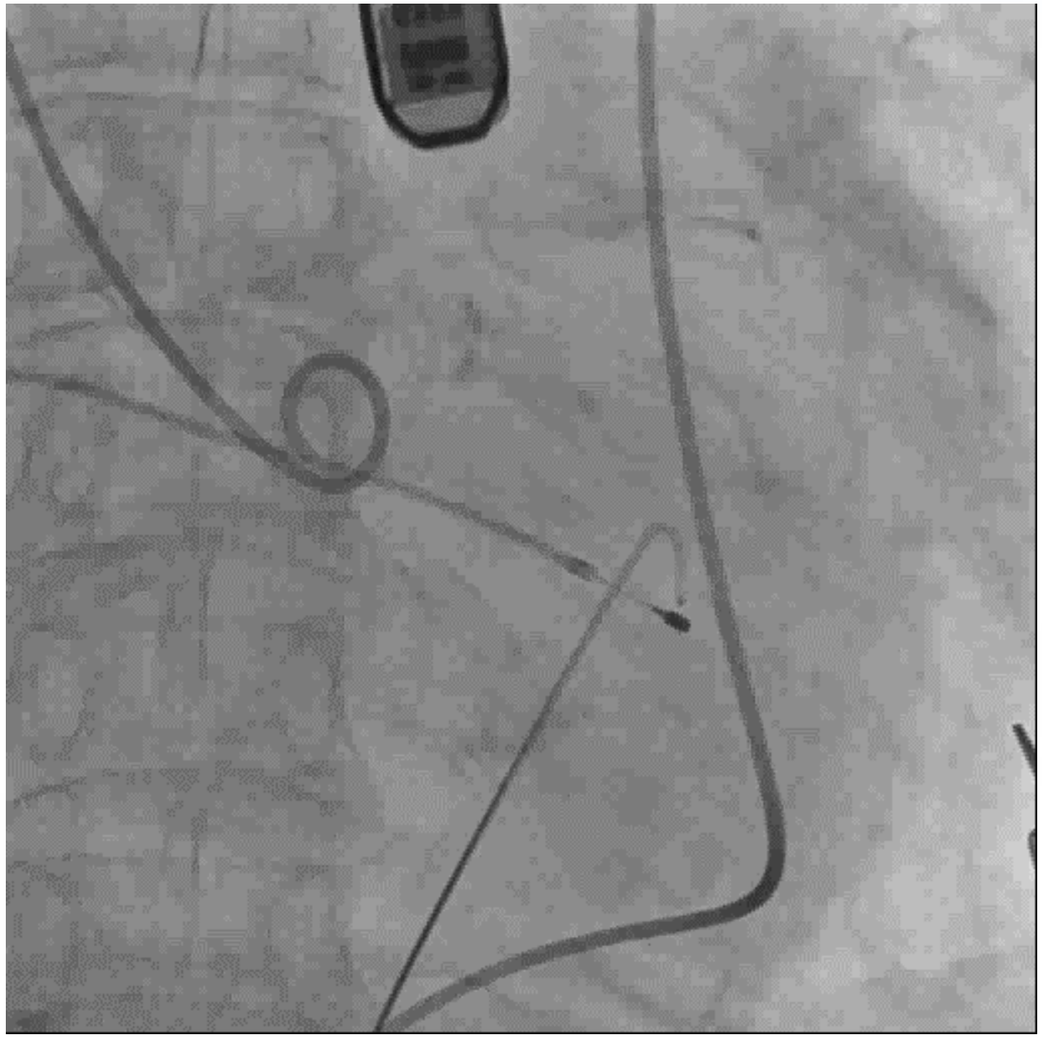


TAVI with Evolut R

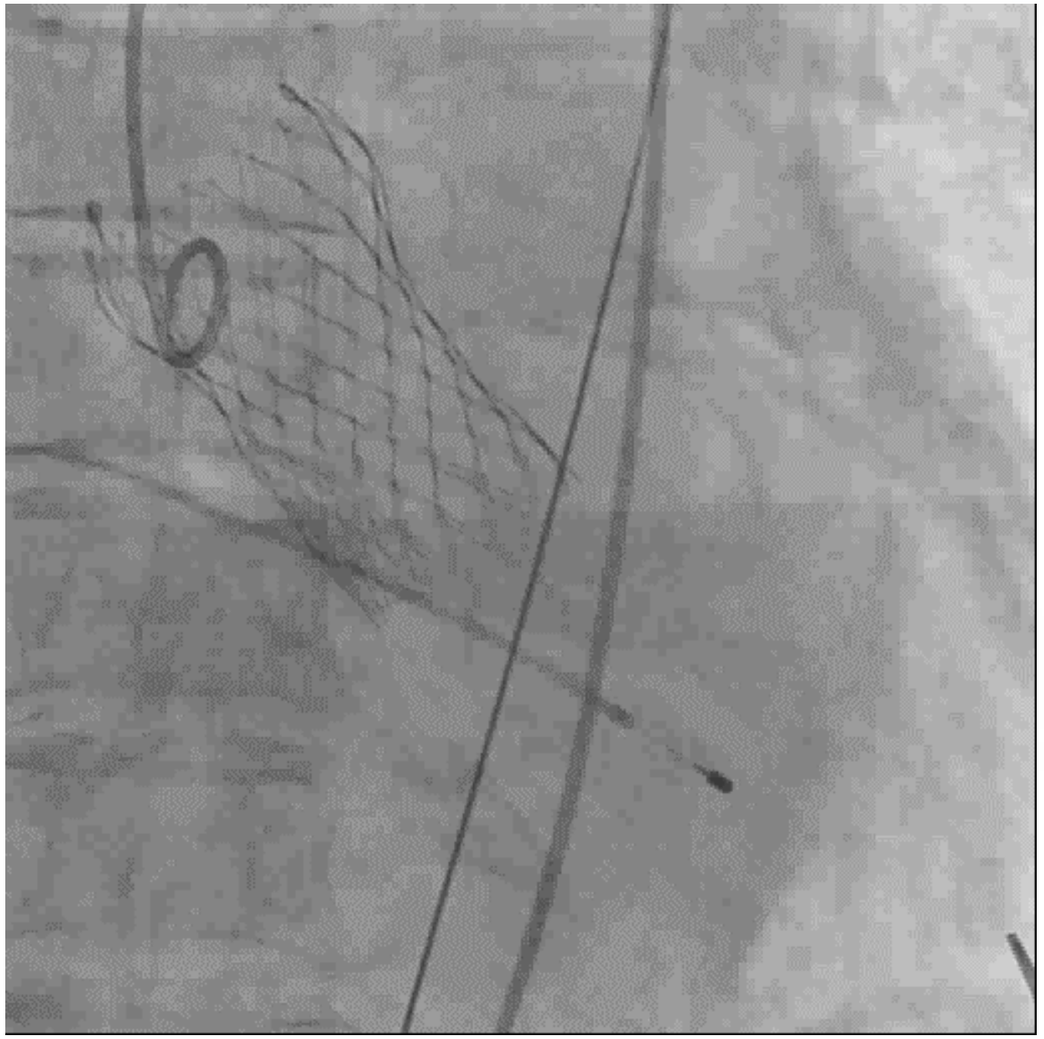




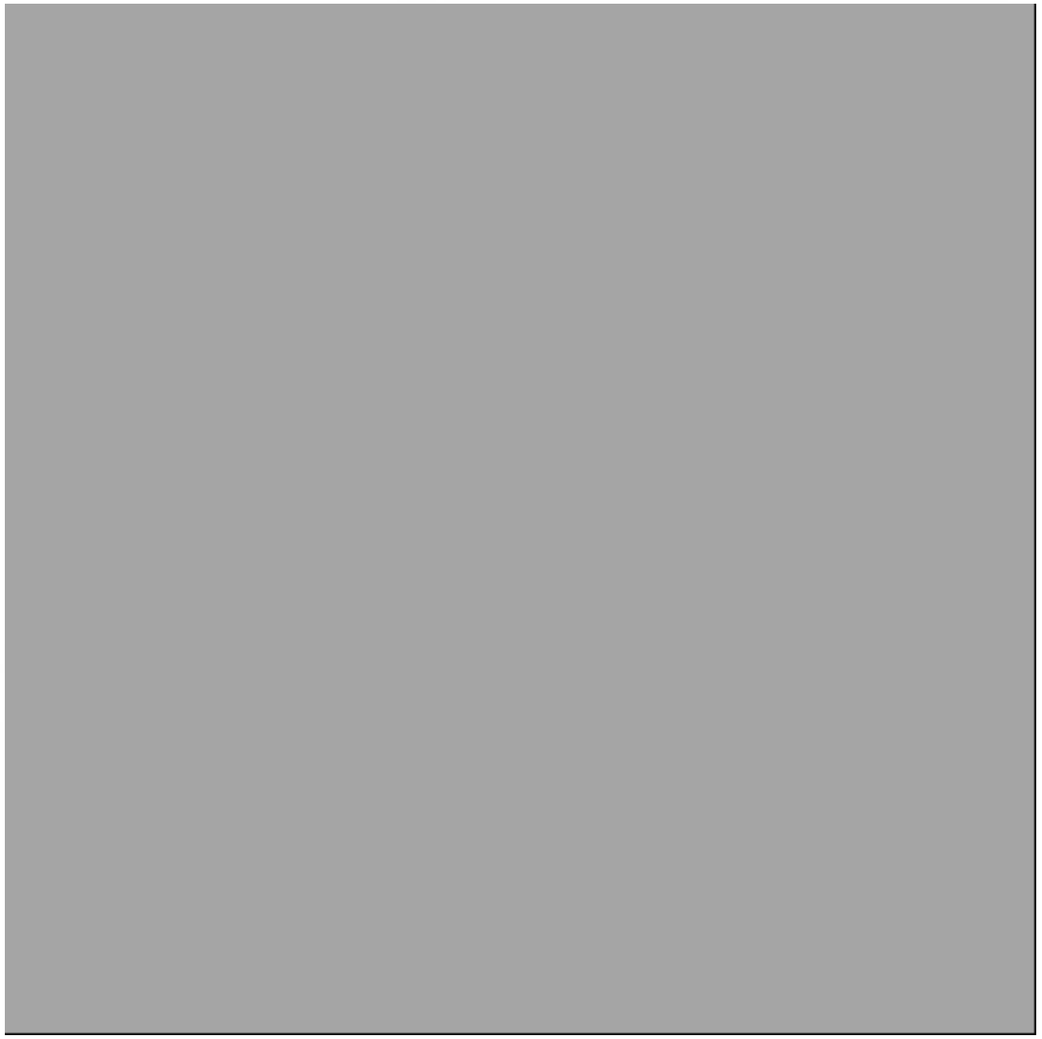
TAVI with Evolut R



TAVI with Evolut R



TAVI with Evolut R



- **Delayed DSA check !**

Which TAVI device is better to overcome hostile artery ?

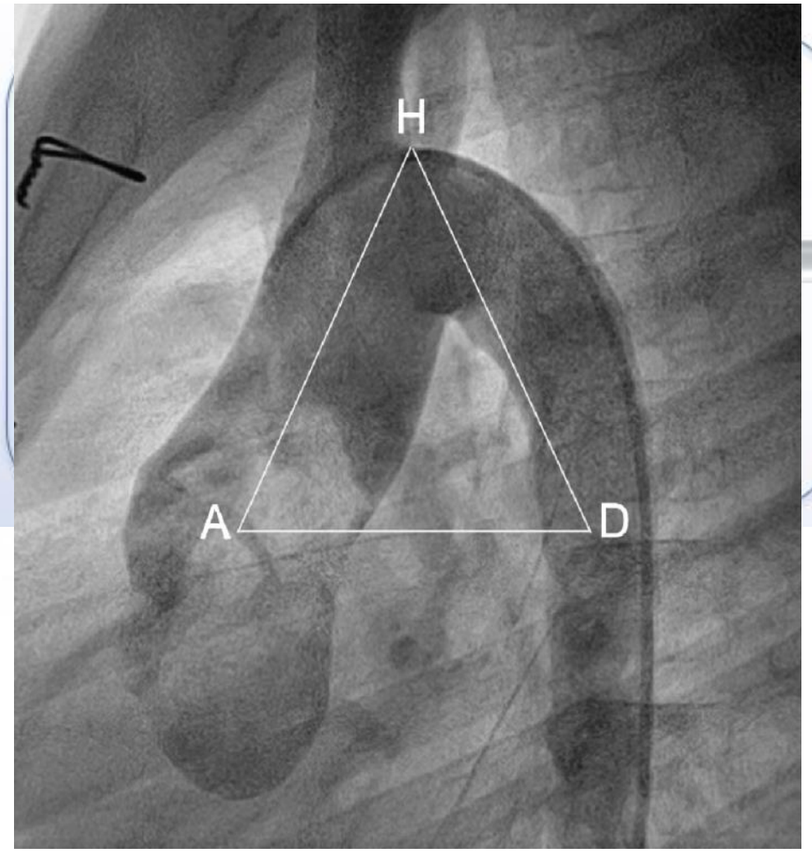
- Evolut Pro Plus
- Edward

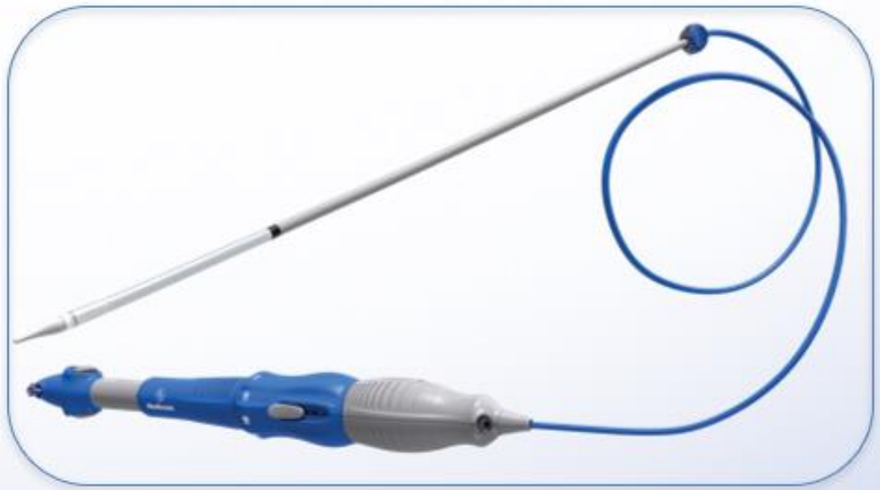
Evolut Device

- Retrieval system
- Non-steerable delivery system
- Sheathless procedure : severe angulated aorta

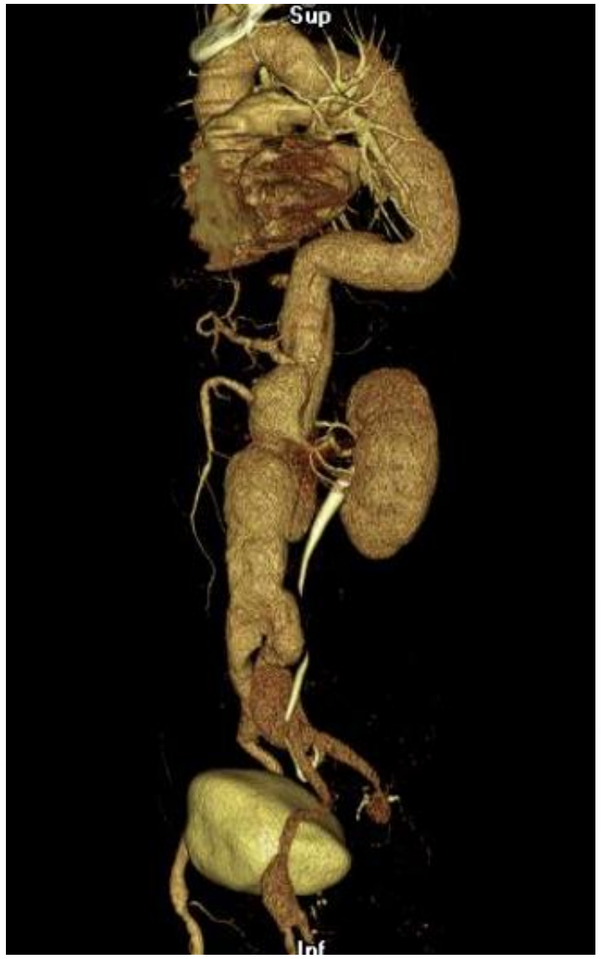
Evolut Pro Device

- Non-steerable delivery system





Evolut Pro Device



- Sheathless procedure : severe angulated aorta
- Need **Sheath** to make a strong support

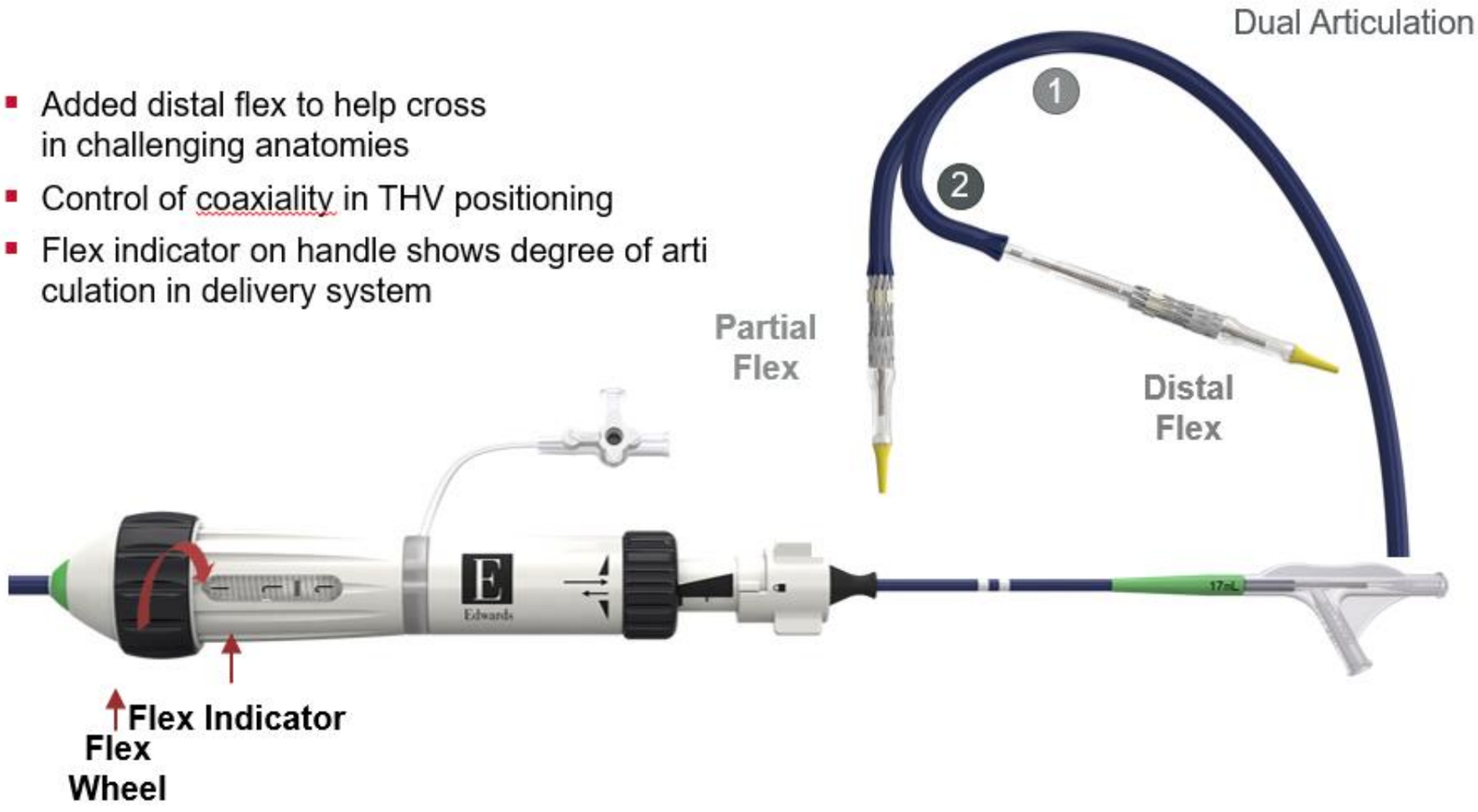
Edward Device

- Expandable sheath with silicone
- Non-retrieval system
- Steerable delivery system

Edward Device

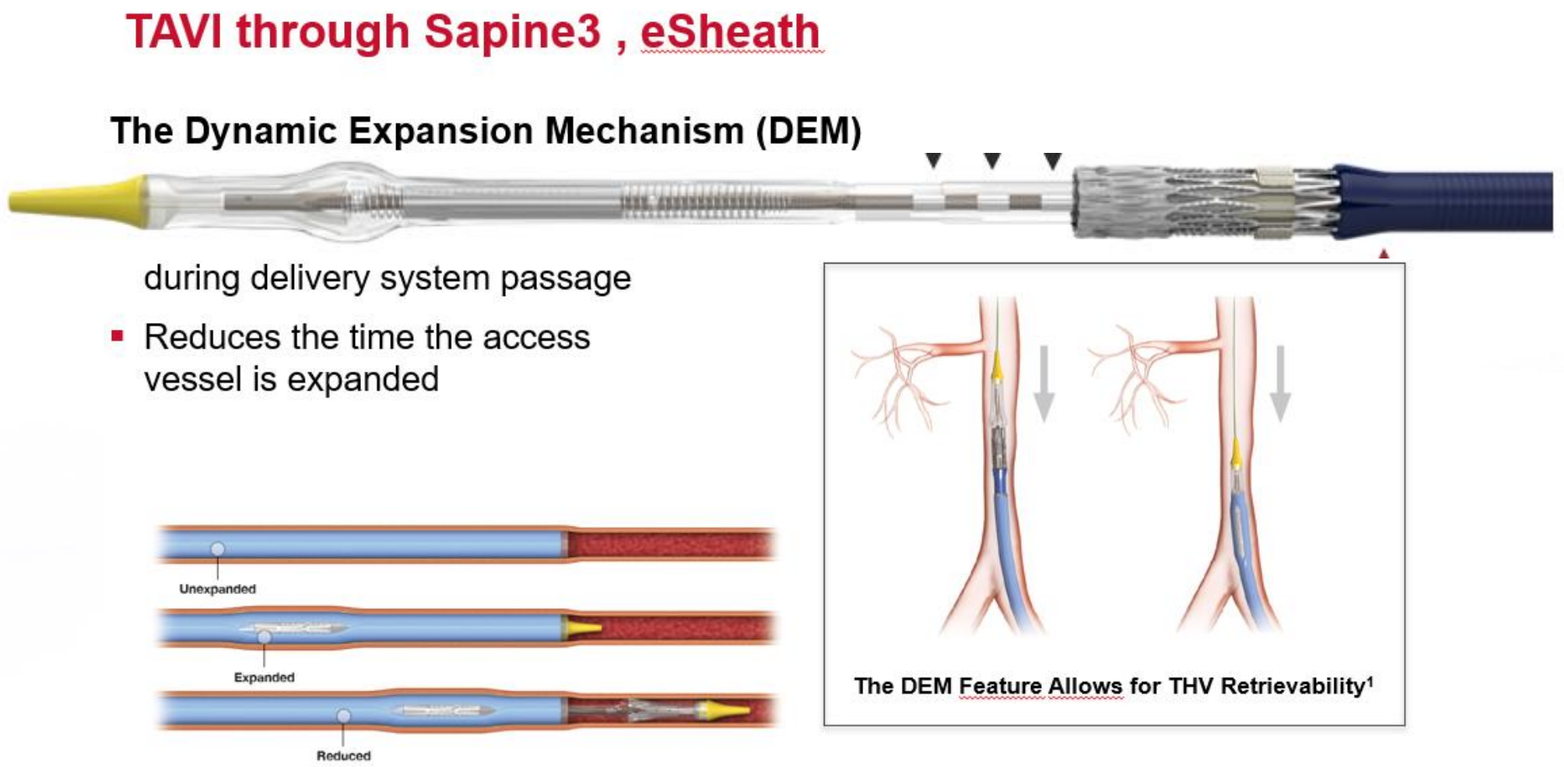
➢ Steerable delivery system

- Added distal flex to help cross in challenging anatomies
- Control of coaxiality in THV positioning
- Flex indicator on handle shows degree of arti culation in delivery system



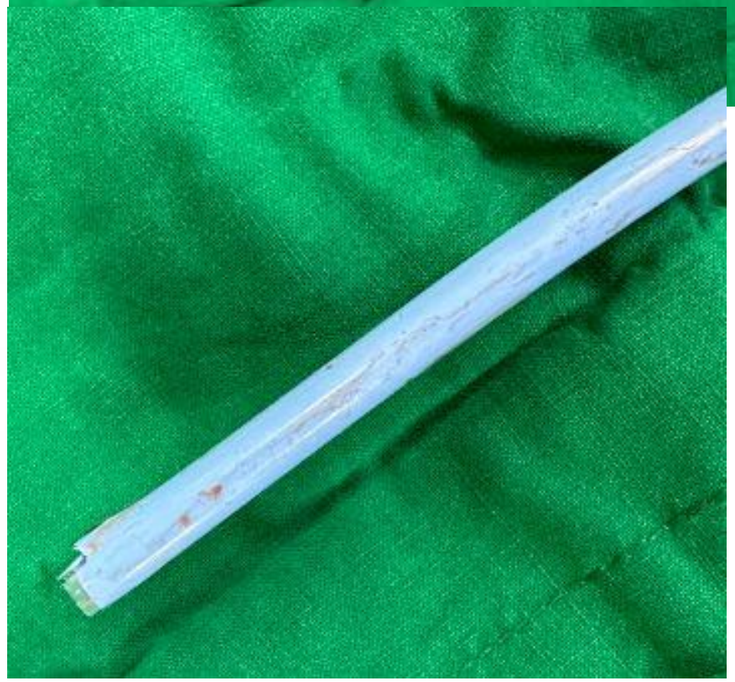
Edward Device

- Expandable sheath with silicone
- Non-retrieval system



Edward Device

- Expandable sheath with silicone

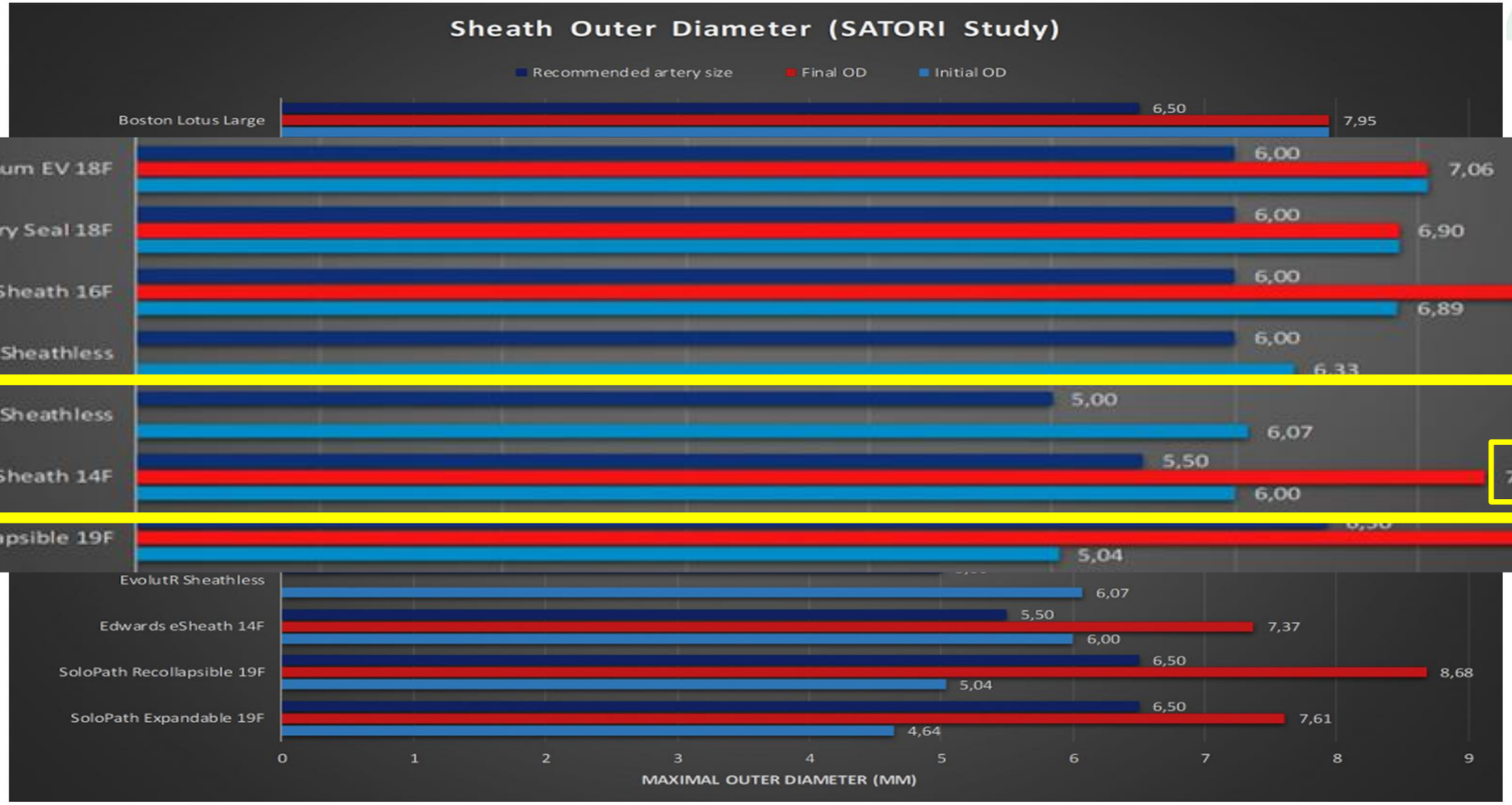


Edward Device

- Expandable sheath with silicone

- **Final diameter of sheath is different from initial diameter**

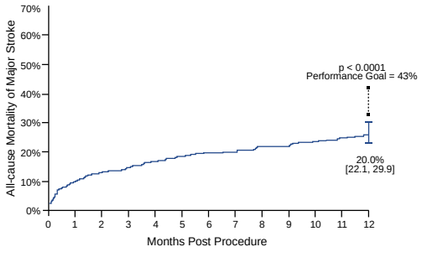
Sheath Outer Diameter (SATORI Study)



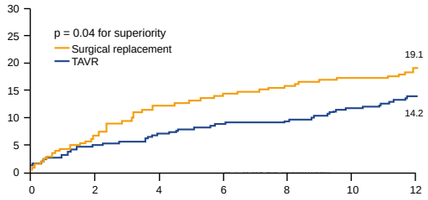
RANDOMIZED CLINICAL TRIAL AND SINGLE ARM STUDIES

FROM EXTREME RISK TO LOW-RISK

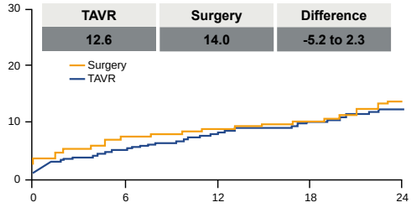
2011



Extreme Risk[1]

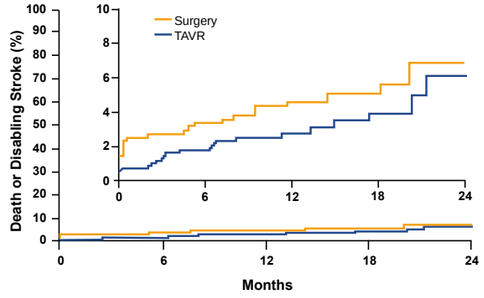


High Risk[2]

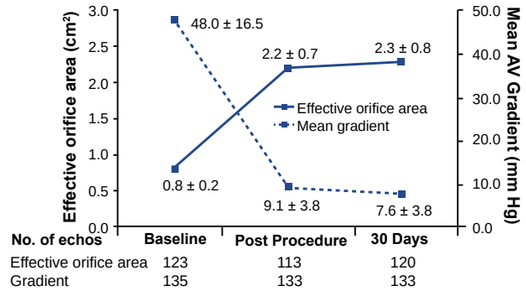


Intermediate Risk[3]

2020



Low-Risk[4]



LR Bicuspid[5]

TAVI DESIGN CHANGES EMBEDDED INTO CLINICAL TRIALS

CoreValve™

Evolut™ R

Evolut™ PRO

Evolut™ PRO+

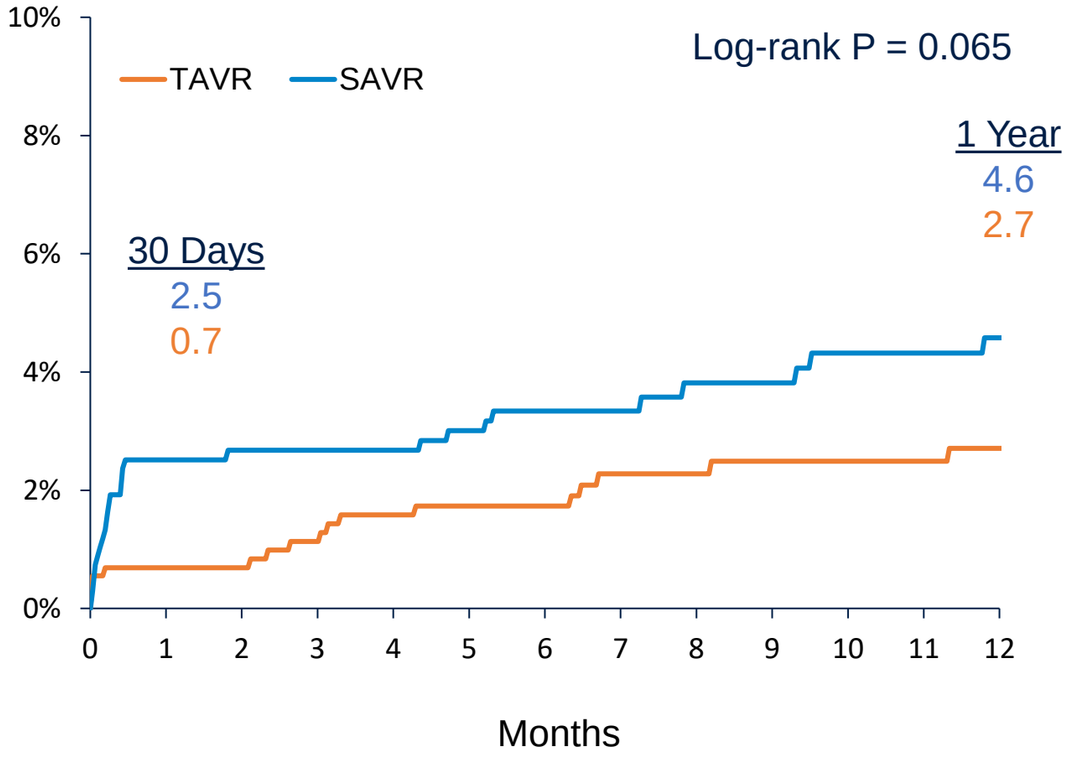
Annular Size 18–30 mm
Pericardial Wrap
14/18 Fr Sheath Equivalent

1. Popma JJ, et al., *JACC.* 2014;63:1972-1981.
2. Adams DH, et al., *NEJM.* 2014;370:1790-1798.
3. Reardon MJ, *NEJM*. 2017;376:1321-1331.
4. Popma JJ, et al., *NEJM.* 2019;380:1706-1715.
5. Forrest J, et al., *JAMA Cardiol* 2020 October 7, 2020.

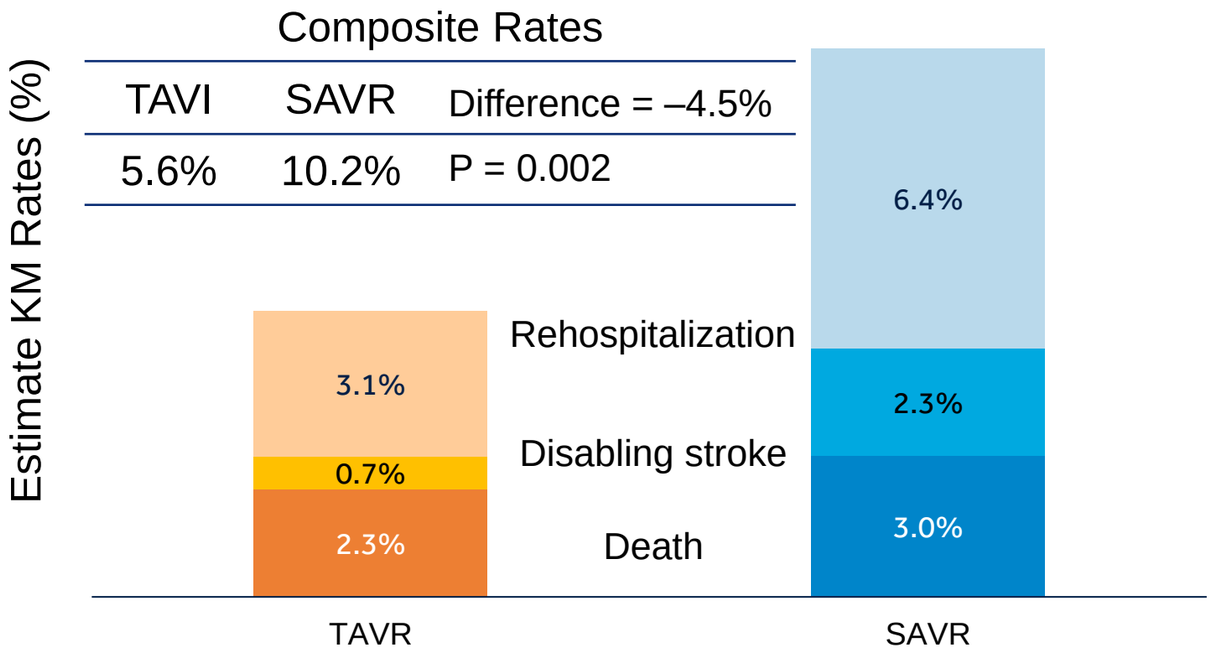
EVOLUT LOW RISK RANDOMIZED TRIAL

EVOLUT LOW RISK TRIAL ENDPOINTS AT ONE YEAR

1 Year All-Cause Mortality and Disabling Stroke[1,2]



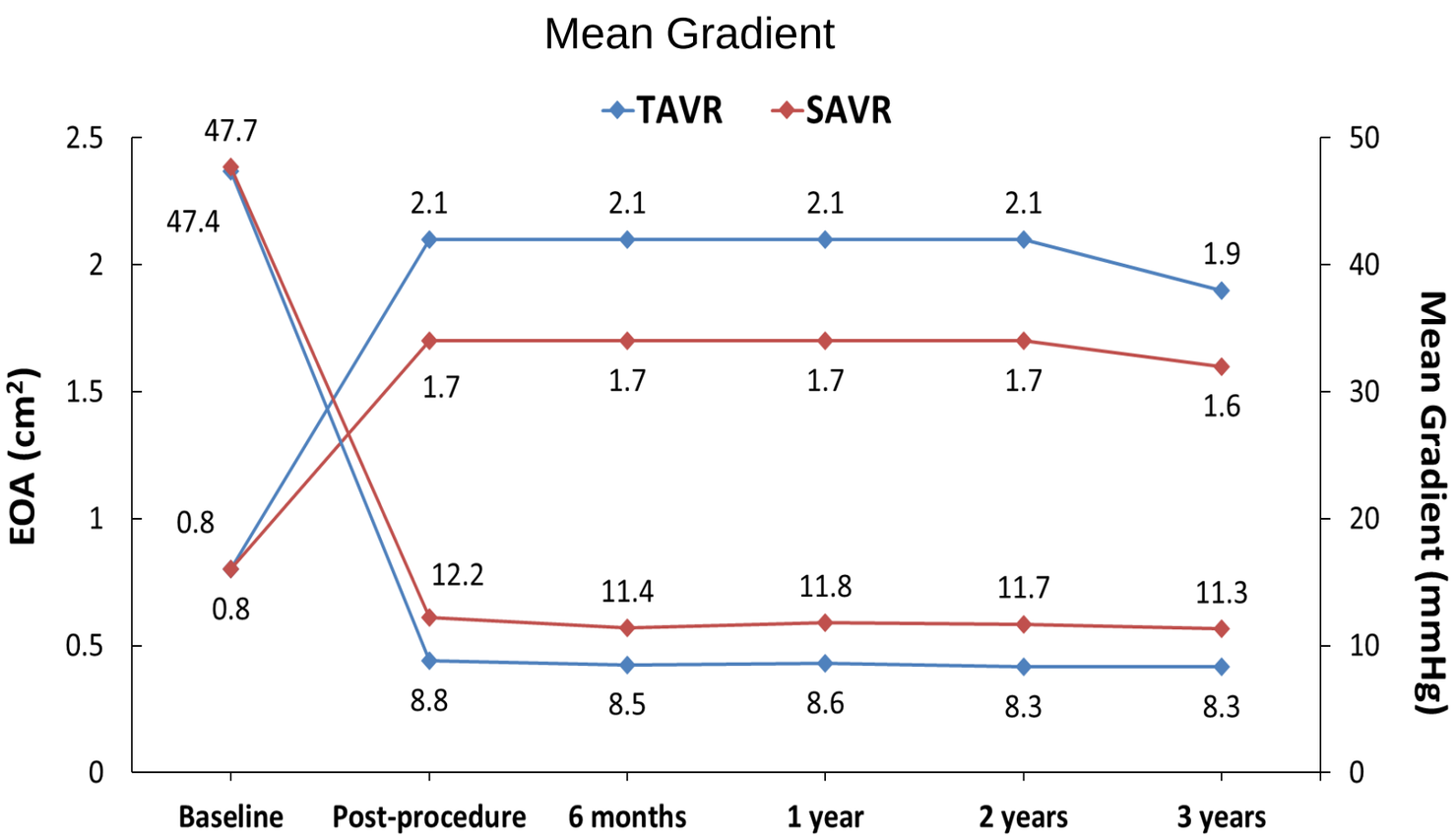
1 Year Death, Disabling Stroke, and Rehospitalization[2]

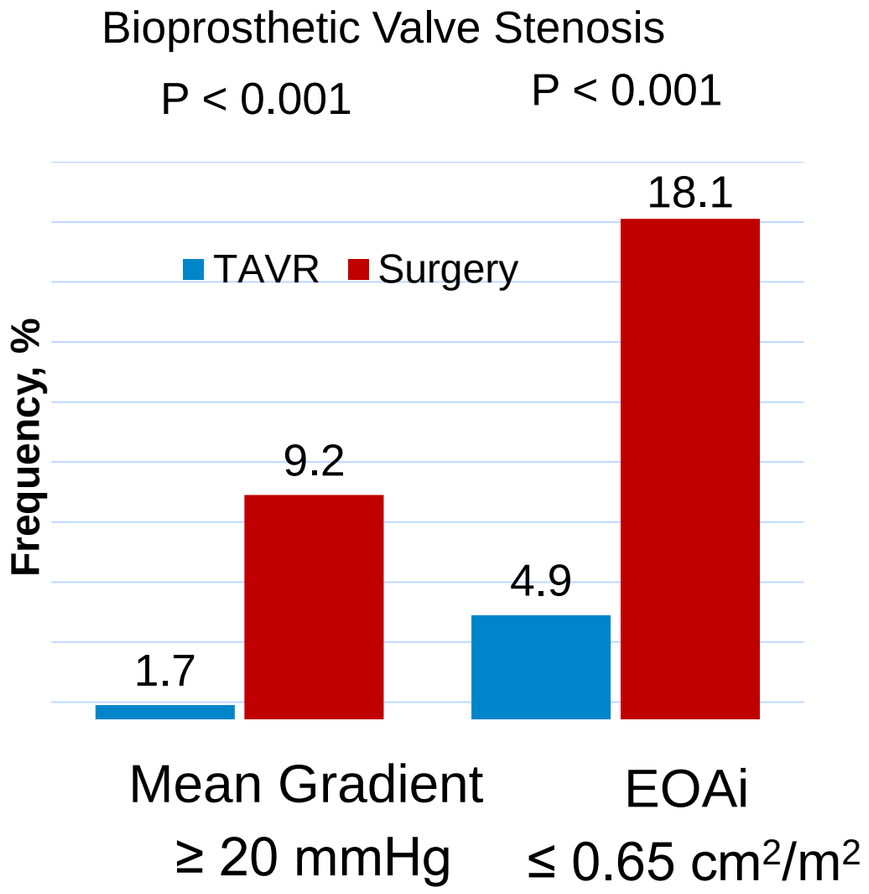


[1]Popma J, et al., *NEJM*. 2019; 380:1706-1715; [2]Reardon M et al ACC2019 LBCT

MEAN GRADIENT AND PROSTHETIC VALVE STENOSIS

SMALL DIFFERENCES IN MEAN GRADIENT TRANSLATE INTO LARGER DIFFERENCE IN BVS





Source: Rovin Abstract Presentation CRT2021

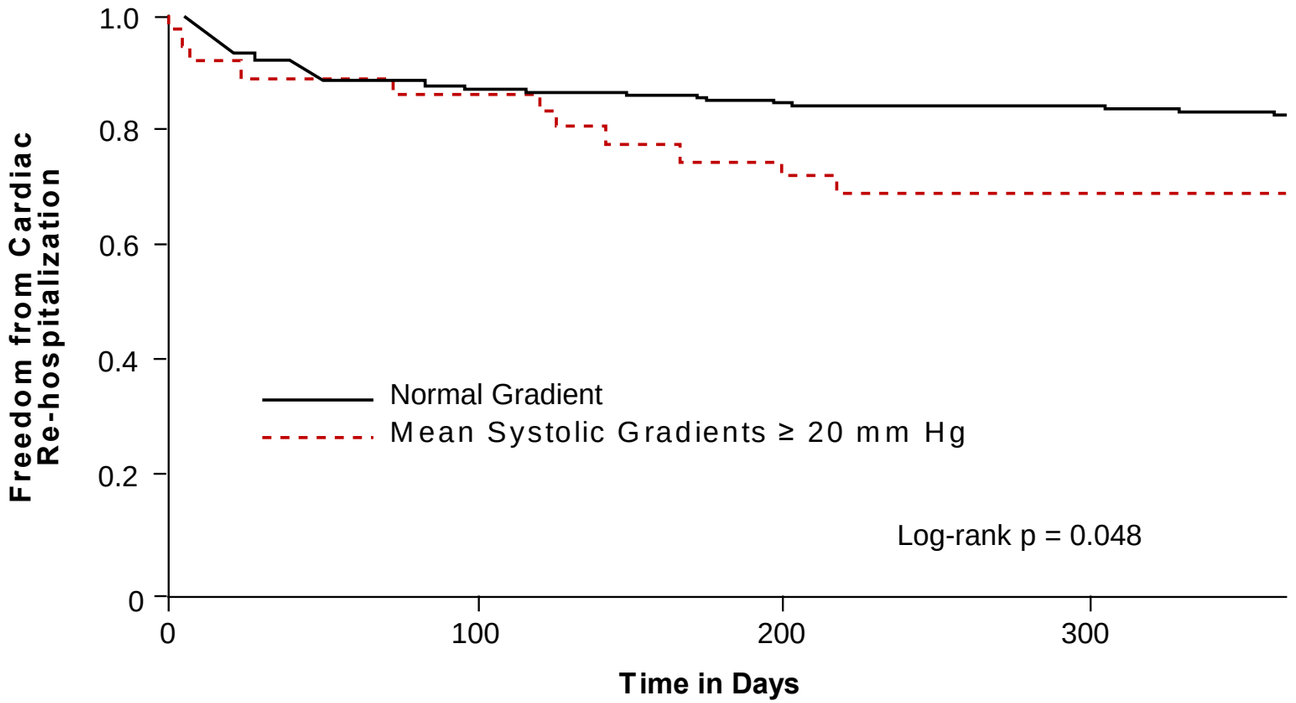
ELEVATED GRADIENTS > 20 MM HG – REHOSPITALIZATION

MAYO CLINIC SERIES (N=424 PATIENTS)

Baseline Characteristics

	Mean Systolic Gradient ≥ 20 mm Hg (n = 36)	Normal Gradient (n = 388)	p-value
Age, mean ± SD (years)	77.8 ± 7.8	81.0 ± 8.2	0.02
Women	19 (53%)	158 (41%)	0.16
BMI, mean ± SD (kg/m^2)	33.2 ± 9.2	29.6 ± 6.6	0.03
Hypertensive	32 (89%)	348 (90%)	0.88
Valve Size			
20 mm	2 (5%)	1 (0.3%)	< 0.0001
23 mm	16 (46%)	91 (24%)	
26 mm	16 (46%)	190 (50%)	
29 mm	0 (0%)	59 (16%)	
31 mm	1 (3%)	36 (10%)	

One Year Cardiac Rehospitalization Rate in Patients with High (≥ 20 mmHg) Gradients



Source: Anand V, et al., *Am J Cardiol.* 2020;125:941-947.

WOMEN'S INTERNATIONAL TAVI (WIN-TAVI) REGISTRY

PREDICTORS OF PPM IN WOMEN

- 250 women with symptomatic AS
- Incidence of VARC 3 PPM = 32.8%
- The peak and mean aortic gradients were higher in women with PPM.
- CT annulus perimeter was not significantly different in the two groups.
- Patients with PPM were more likely to have received a balloon expandable valve.

Multivariable regression model identifying independent predictors for patient-prosthesis mismatch

Model including interaction between valve type and valve sizes ≤ 23 mm				
	OR	**95% confidence interval**		**p-value**
BMI	1.075	1.02	1.14	0.011
Valve Type				
Balloon expandable	Ref			
Self-expanding	0.498	0.18	1.40	0.185
Others	1.994	0.62	6.40	0.246
Valve Size ≤ 23 mm	3.003	1.14	7.94	0.027
Valve type * valve ≤ 23 mm				0.203 (interaction test)

One Year Echocardiographic Parameters

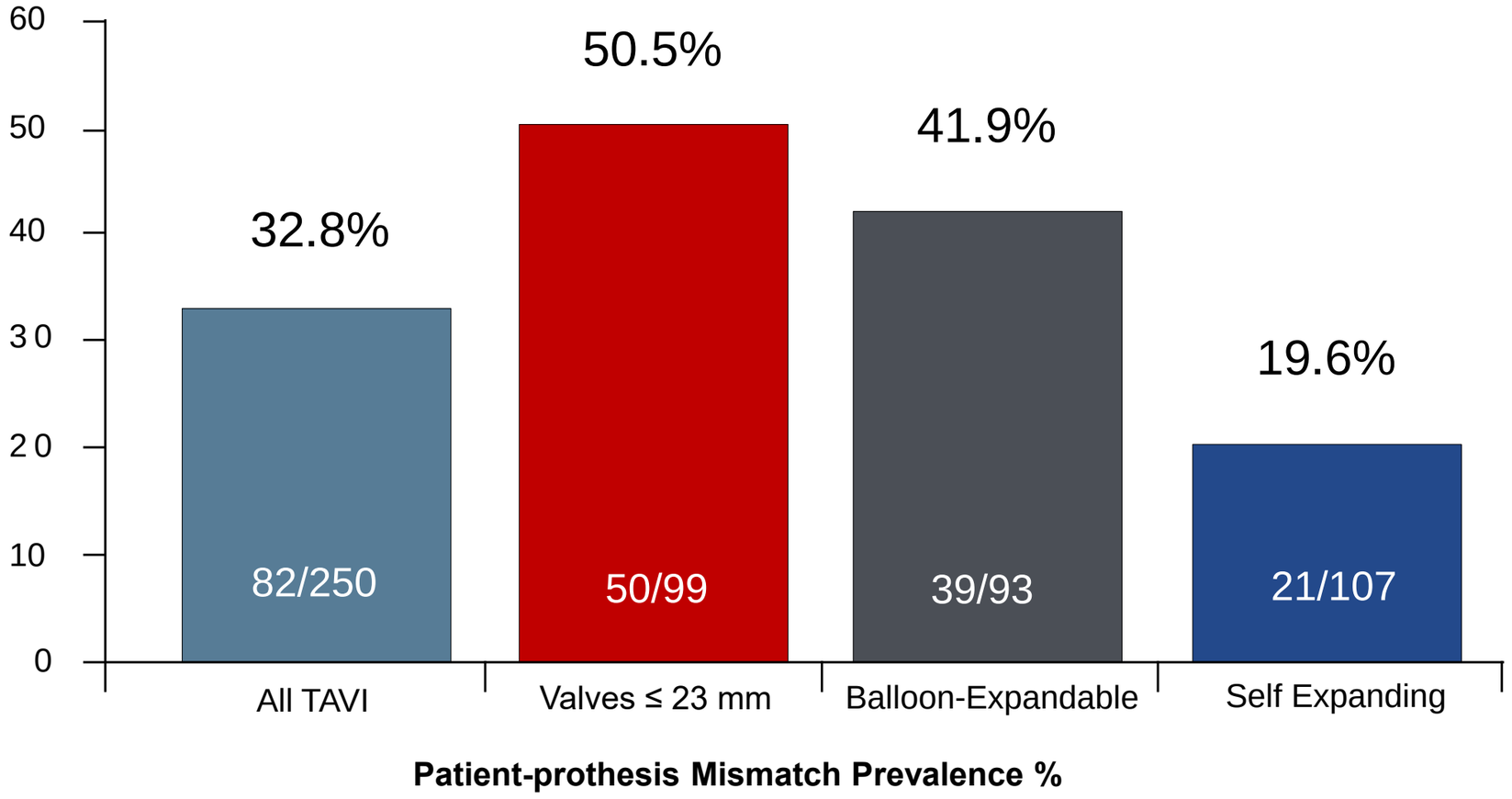
	PPM = 1; n = 82 (32.8%)	**PPM = 0; n = 168 (67.2%)**	**p-value**
LVEF	57.8 ± 9.1	58.5 ± 8.6	0.650
Peak AV gradient (mm Hg)	24.5 ± 13.0	19.8 ± 10.5	0.040
Mean AV gradient (mm Hg)	14.0 ± 5.9	10.7 ± 5.4	0.001
Aortic paravalvular regurgitation			0.898
None	29 (55.8%)	37 (51.4%)	
Mild	21 (40.4%)	32 (44.4%)	
Moderate	2 (3.8%)	3 (4.2%)	

Source: Panoulas VF, et al., *Catheter Cardiovasc Interv*. 2021;97:516-526.

WOMEN'S INTERNATIONAL TAVI (WIN-TAVI) REGISTRY

PREDICTORS OF PPM IN WOMEN

Balloon-expandable transcatheter heart valves (THV) include all the Edwards valves (S3, XT) and self-expanding THV all the Medtronic iterations (CoreValve and Evolut R).

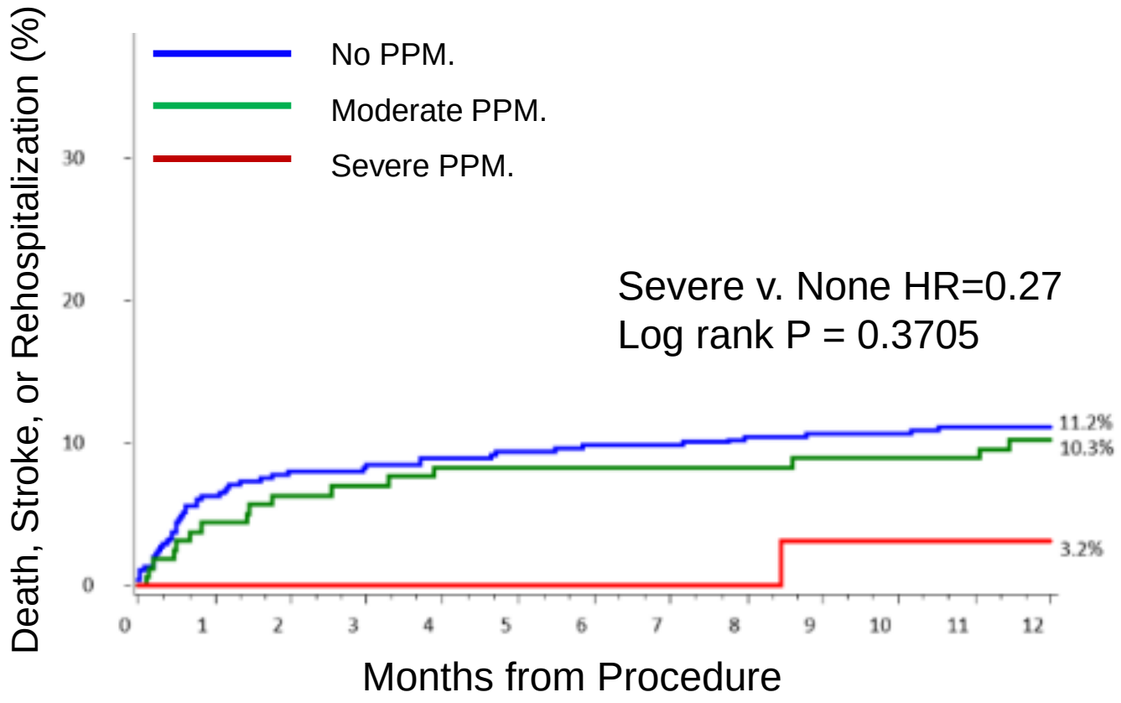


Source: Panoulas VF, et al., *Catheter Cardiovasc Interv.* 2021;97:516-526.

PROSTHESIS PATIENT MISMATCH IN PARTNER III LOW RISK PARTNER

CLINICAL OUTCOME IN WOMEN WITH SEVERE PPM AFTER SAPIEN™* 3 TAVI

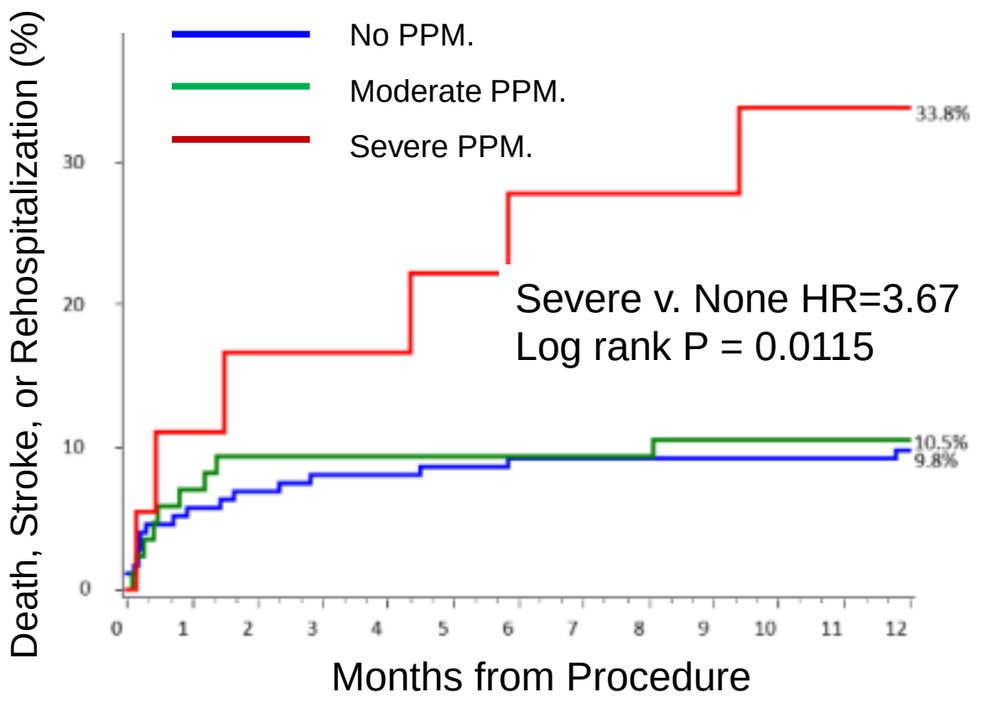
Outcomes with Severe PPM in Men



Number at risk:

None	446	418	393
Moderate	157	149	136
Severe	31	31	30

Outcomes with Severe PPM in Women



Number at risk:

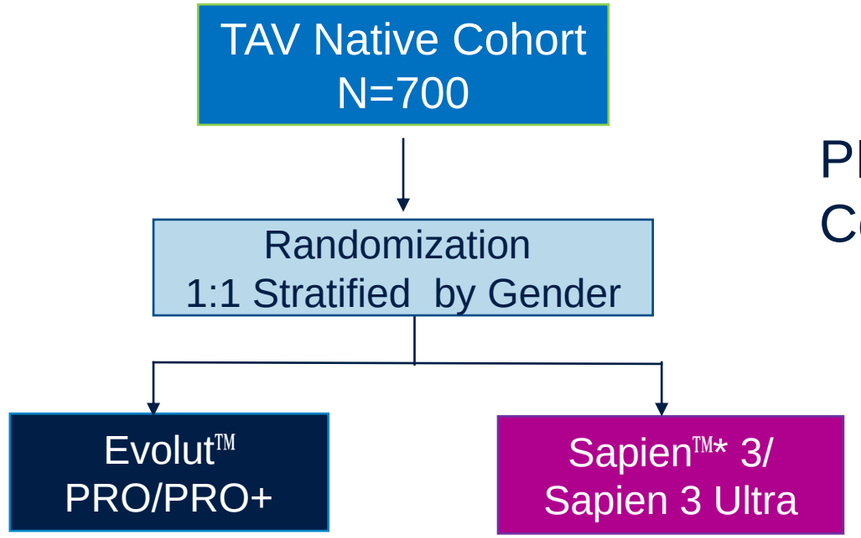
None	174	163	155
Moderate	86	79	76
Severe	18	16	11

Source: Pibarot P, et al., *Circulation*. 2020;141:1527-1537.

THE SMART TRIAL (ENROLLING)

HEAD-TO-HEAD RCT IN ANNULAR AREA < 430 MM^2

Severe aortic valve stenosis with a small annulus



Approximately 700 subjects
90 sites in the US, Canada and EMEA

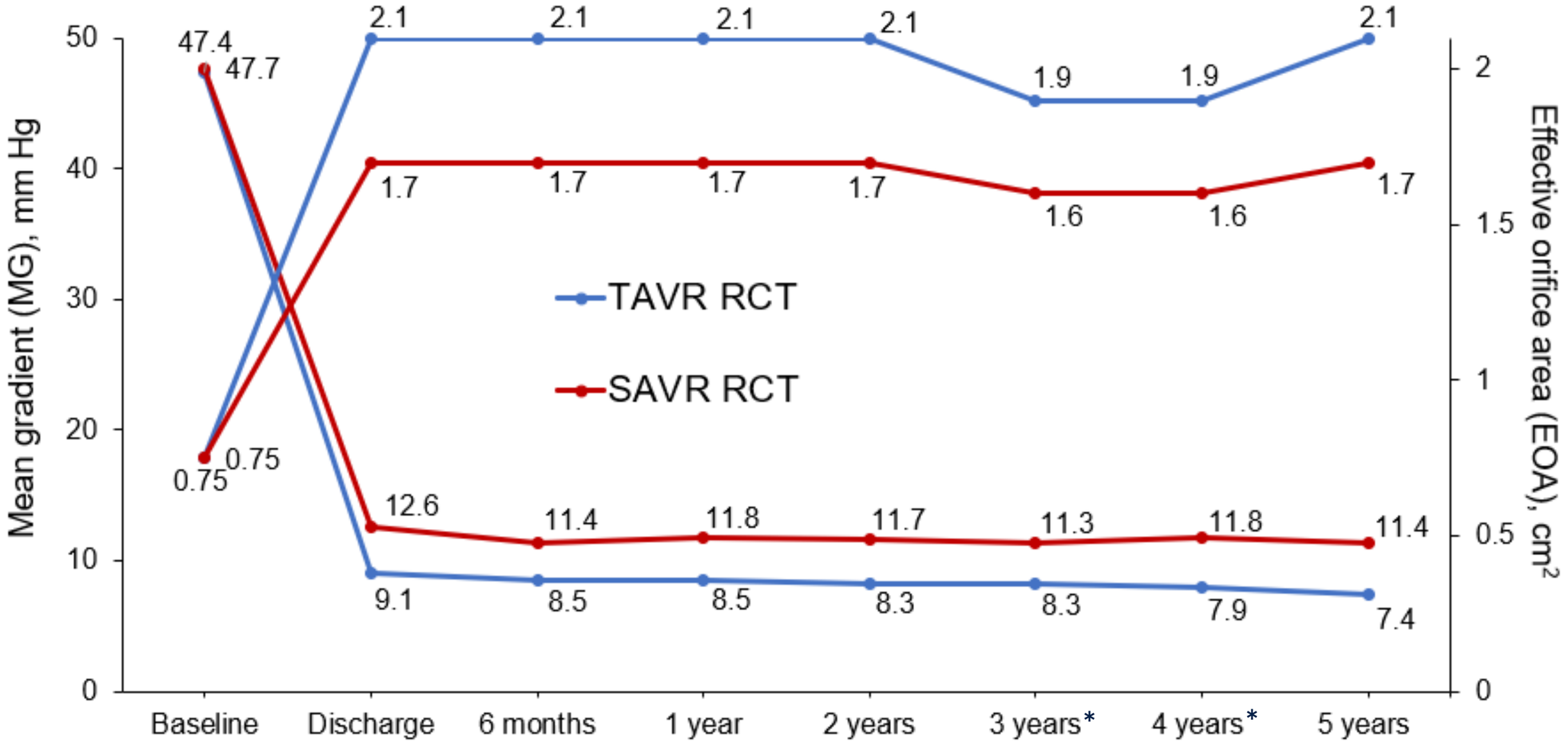
PI: Howard Herrmann, MD
Co-PIs: Didier Tchetche, MD
Roxana Mehran, MD

Co-Primary Endpoints (12 months):
- Mortality, disabling stroke, or rehospitalization
- Bioprosthetic valve dysfunction (BVD)

5-Year Follow-Up for all patients

HEMODYNAMIC VALVE DETERIORATION (HVD)

VALVE PERFORMANCE TO FIVE YEARS



O'Hair D, et al., Presented at ACC2021

***** Core lab to site-reported echo data

HEMODYNAMIC VALVE DETERIORATION (HVD)

CORRELATION WITH HVD AND 5 YEAR MORTALITY

Time-dependent covariate: HVD	HR (95% CI)	P value
All TAVI and SAVR RCT		
All-cause mortality	2.122 (1.533, 2.938)	<0.001
Cardiovascular mortality	2.148 (1.422, 3.245)	<0.001
AV-related hospitalization	3.074 (1.902, 4.971)	<0.001
Composite	2.506 (1.818, 3.454)	<0.001
All TAVI		
All-cause mortality	3.224 (2.188, 4.751)	<0.001
Cardiovascular mortality	3.182 (1.941, 5.216)	<0.001
AV-related hospitalization	3.834 (2.112, 6.960)	<0.001
Composite	3.227 (2.190, 4.755)	<0.001
SAVR RCT		
All-cause mortality	1.853 (1.011, 3.394)	0.046
Cardiovascular mortality	2.026 (0.946, 4.337)	0.069
AV-related hospitalization	2.973 (1.308, 6.758)	0.009
Composite	2.483 (1.392, 4.428)	0.002

O'Hair D, et al., Presented at ACC2021

HEMODYNAMIC VALVE DETERIORATION (HVD)

Multivariable Predictors of HVD – 5 years (TAVI Only)

All TAVI	HR (95% CI)	P value
Model 1		
Age, years	0.951 (0.921, 0.982)	0.002
Mean Gradient*	**1.107 (1.072, 1.144)**	**<0.001**
Model 2		
Age, years	0.941 (0.915, 0.968)	<0.001
History of Hypertension	0.452 (0.199, 1.023)	0.057
DVI*	0.272 (0.018, 4.107)	0.347
Model 3		
Age, years	0.945 (0.917, 0.974)	<0.001
Severe PPM (vs not severe)*	**2.873 (1.296, 6.371)**	**0.009**
Model 4		
Age, years	0.945 (0.917, 0.972)	<0.001
NYHA class III/IV (Yes vs No)	0.554 (0.285, 1.076)	0.081
EOA*	0.689 (0.349, 1.362)	0.284

O'Hair D, et al., Presented at ACC2021

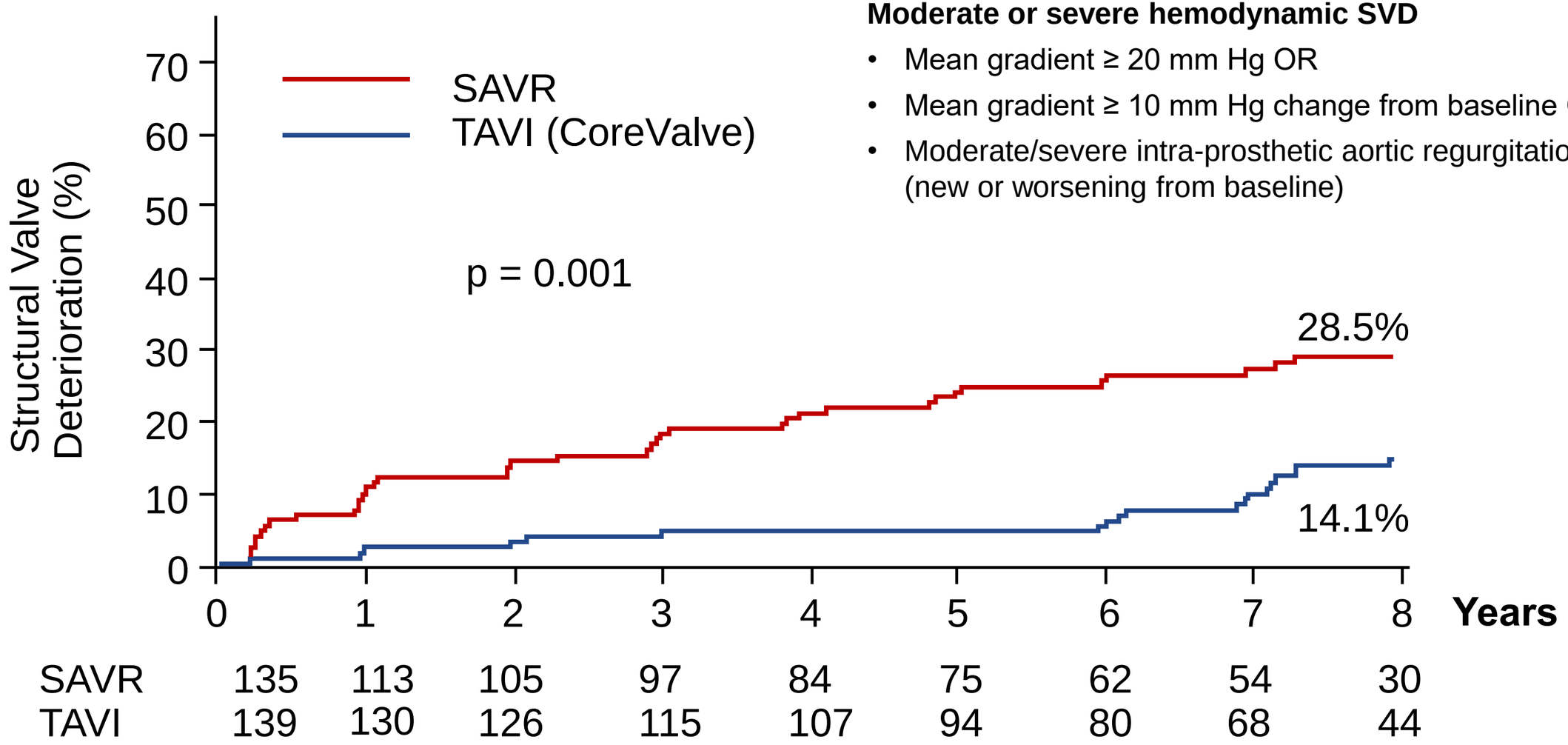
***** Evaluated at first post-procedure (discharge or 30-days)

NOTION 8-YEAR FOLLOW-UP

Structural Valve Deterioration

Moderate or severe hemodynamic SVD

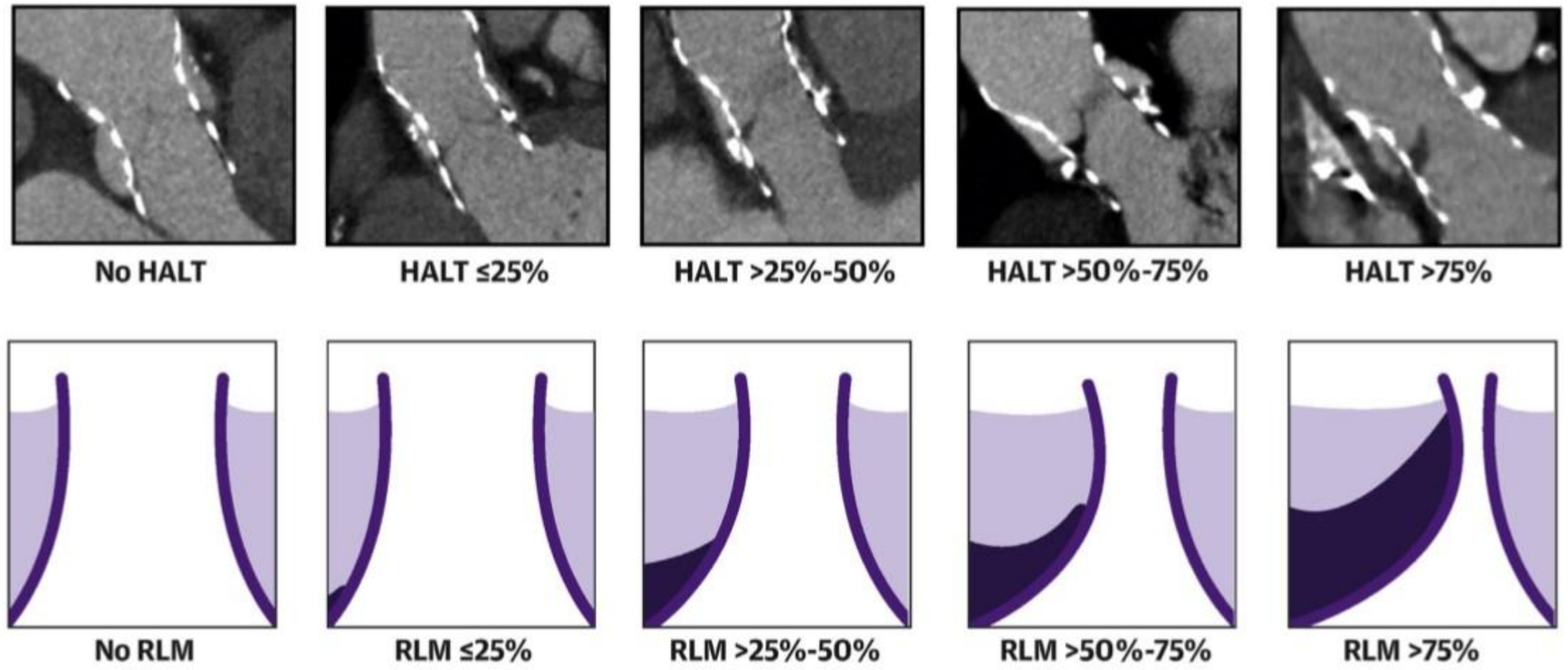
- Mean gradient ≥ 20 mm Hg OR
- Mean gradient ≥ 10 mm Hg change from baseline OR
- Moderate/severe intra-prosthetic aortic regurgitation (new or worsening from baseline)



Source: Søndergaard L, et al., Presented at PCR Valves Conference 2020.

EVOLUT™ LOW RISK LEAFLET THROMBOSIS/IMMOBILITY STUDY

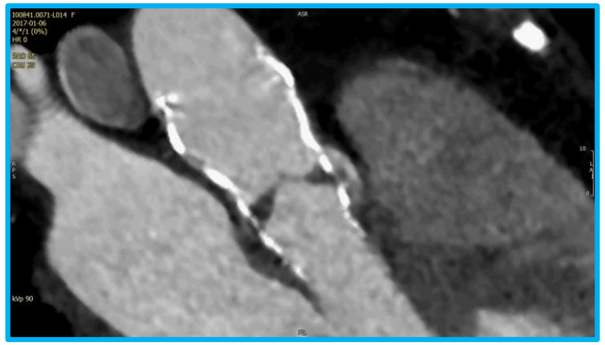
CT Core Laboratory Classification System



Hypoattenuated Leaflet Thickening (HALT)

Restricted Leaflet Mobility (RLM)

Figure: RLM > 75% RLM 1 leaflet; 50–75% 2nd leaflet



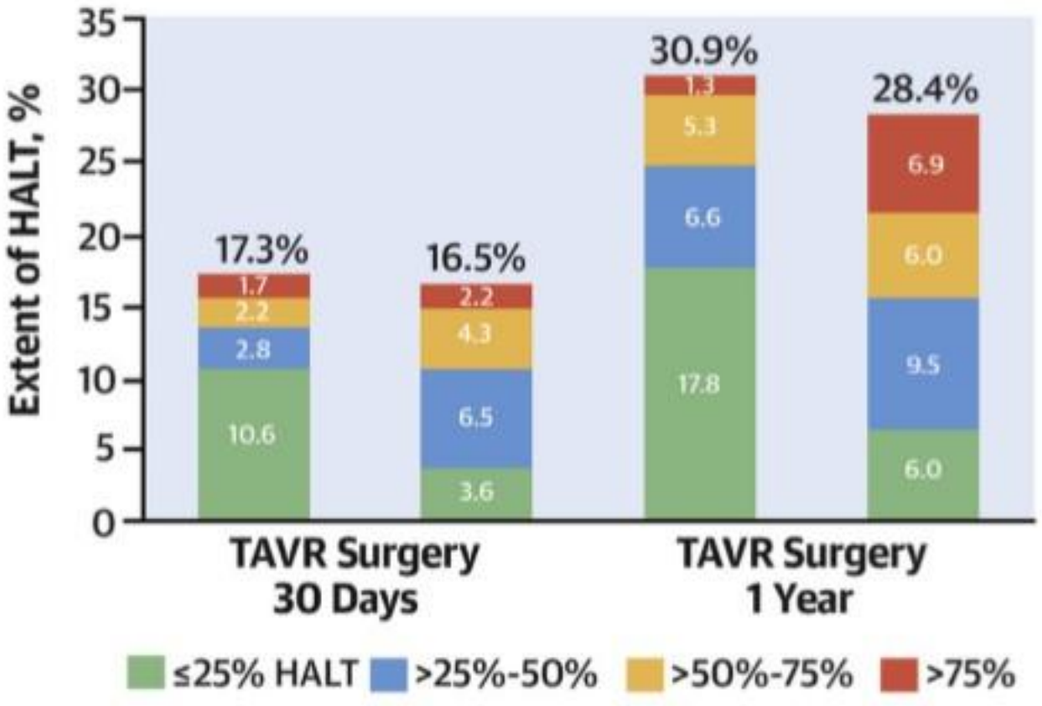
Source: Blanke P, et al., *JACC*. 2020;75:2430-2442.

Popma J et al., ACC2020 abstract

EVOLUT™ LOW RISK LEAFLET THROMBOSIS AND IMMOBILITY STUDY

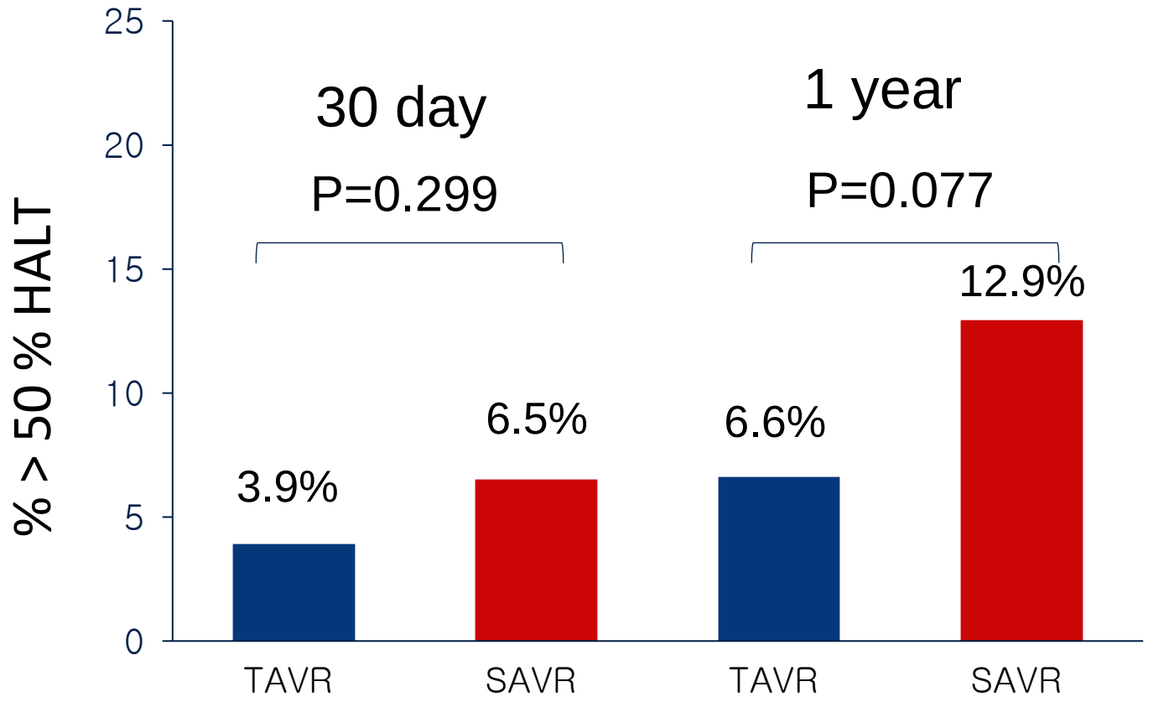
315 PATIENTS WITH 30-DAY CTA

All HALT Classification



Blanke, P. et al., J Am Coll Cardiol. 2020;75(19):2430–42

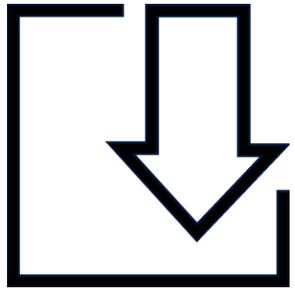
Severe HALT > 50%



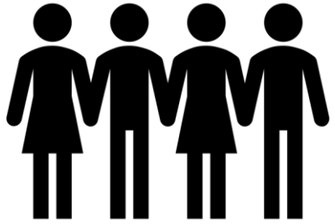
Popma ACC 2020 Abstract

Result of Evolut Pro and Pro plus™

The Optimize PRO Study



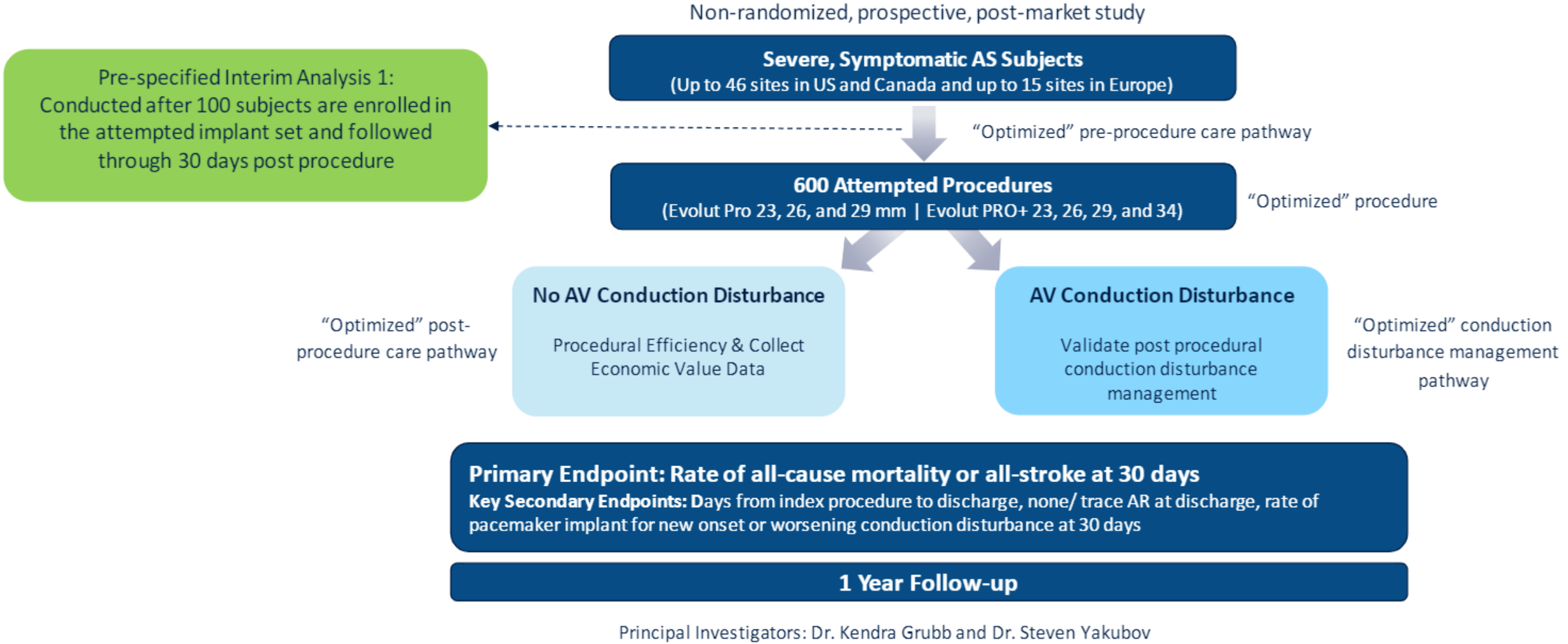
Single and Multicenter Reports



TVT Registry

OPTIMIZE PRO CLINICAL TRIAL

STUDY DESIGN SYNOPSIS



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OPTIMIZE PRO INTERIM ANALYSIS

BASELINE CHARACTERISTICS

Variables	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
Age (years)	**77.4 ± 8.1**	**79.3 ± 6.5**	**78.5 ± 7.3**
Body mass index (kg/m^2)	29.7 ± 5.9	29.5 ± 5.6	29.6 ± 5.7
Male (%)	56.3	54.0	55.0
NYHA III/IV	40.8	33.0	36.3
STS-PROM (%)	**2.9 ± 1.9**	**2.9 ± 2.1**	**2.9 ± 2.0**
Diabetes mellitus	23.9	34.0	29.8
Hypertension	90.1	82.0	85.4
Peripheral arterial disease	8.6	9.0	8.8
Previous percutaneous coronary intervention	23.9	26.0	25.1
Arrhythmia history	22.5	30.0	26.9
Pre-existing RBBB (baseline ECG core lab)	**5.7**	**6.1**	**6.0**
Pre-existing PPI/ICD	**0**	**0**	**0**

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OPTIMIZE PRO INTERIM ANALYSIS

PROCEDURAL CHARACTERISTICS

	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
Total time in procedure room (minutes)	114 [91, 144]	117 [93, 143]	115 [92, 144]
Femoral access site, %	100	100	100
Lunderquist extra-stiff guide wire, %	**54.9**	**72.7**	**65.3**
Anesthesia type			
Conscious sedation, %	84.5	83.0	83.6
General anesthesia, %	15.5	17.0	16.4
Bioprosthesis used			
Evolut PRO , %	9.9	15.0	12.9
Evolut PRO+, %	90.1	85.0	87.1
Pre-balloon valvuloplasty, %	**46.5**	**46.0**	**46.2**
Post-dilatation, %	**12.7**	**17.0**	**15.2**
Embolic protection device used, %	38.0	42.0	40.4
Implant depth, NCC (mm), core lab, %	**3.3 ± 3.0**	**3.3 ± 2.9**	**3.3 ± 2.9**

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OPTIMIZE PRO INTERIM ANALYSIS

30 Day Outcomes

Kaplan-Meier rates as n (%)	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
All-cause mortality or all stroke, %	0 (0)	5 (5.0)	5 (2.9)
All-cause mortality, %	**0 (0)**	**0 (0)**	**0 (0)**
All stroke, %	**0 (0)**	**5 (5.0)**	**5 (2.9)**
Disabling stroke, %	**0 (0)**	**0 (0)**	**0 (0)**
Non-disabling stroke, %	0 (0)	5 (5.0)	5 (2.9)
Life threatening or disabling bleed, %	1 (1.4)	1 (1.0)	2 (1.2)
Major vascular complications, %	1 (1.4)	0 (0)	1 (0.6)
Reintervention, %	0 (0)	0 (0)	0 (0)
Permanent pacemaker implant, %	**5 (7.0)**	**10 (10.0)**	**15 (8.8)**
Myocardial infarction, %	0 (0)	2 (2.0)	2 (1.2)
New-onset LBBB (site reported), %	**17 (23.9)**	**27 (27.0)**	**44 (25.7)**
Hospital readmission (site reported), %	3 (4.2)	8 (8.1)	11 (6.5)

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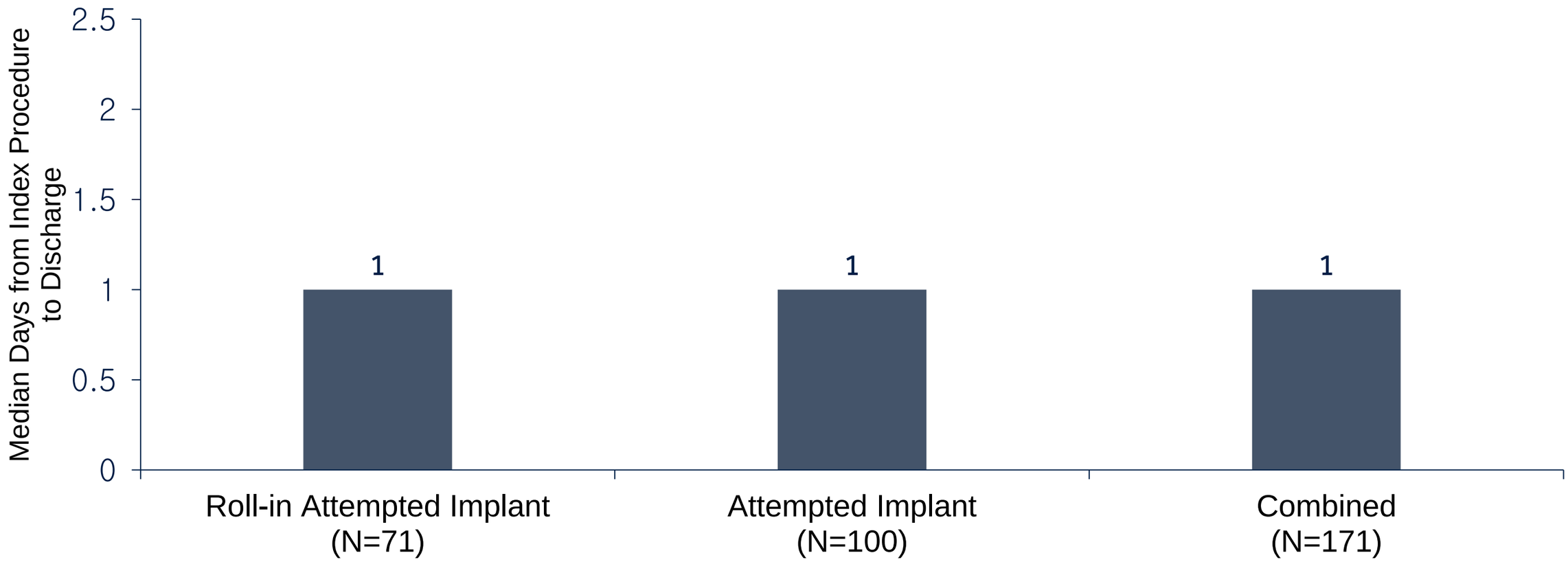
OPTIMIZE PRO INTERIM ANALYSIS

Median Days to Discharge



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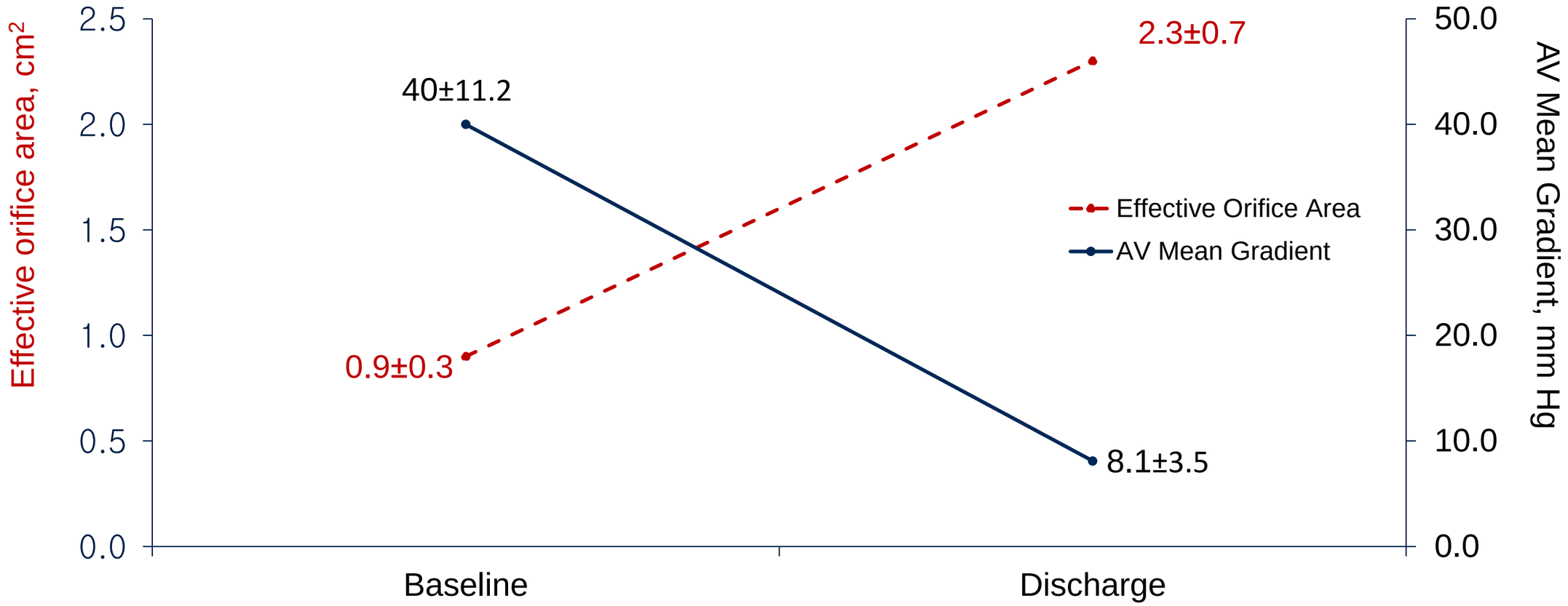
OPTIMIZE PRO INTERIM ANALYSIS

MEDIAN DAYS TO DISCHARGE



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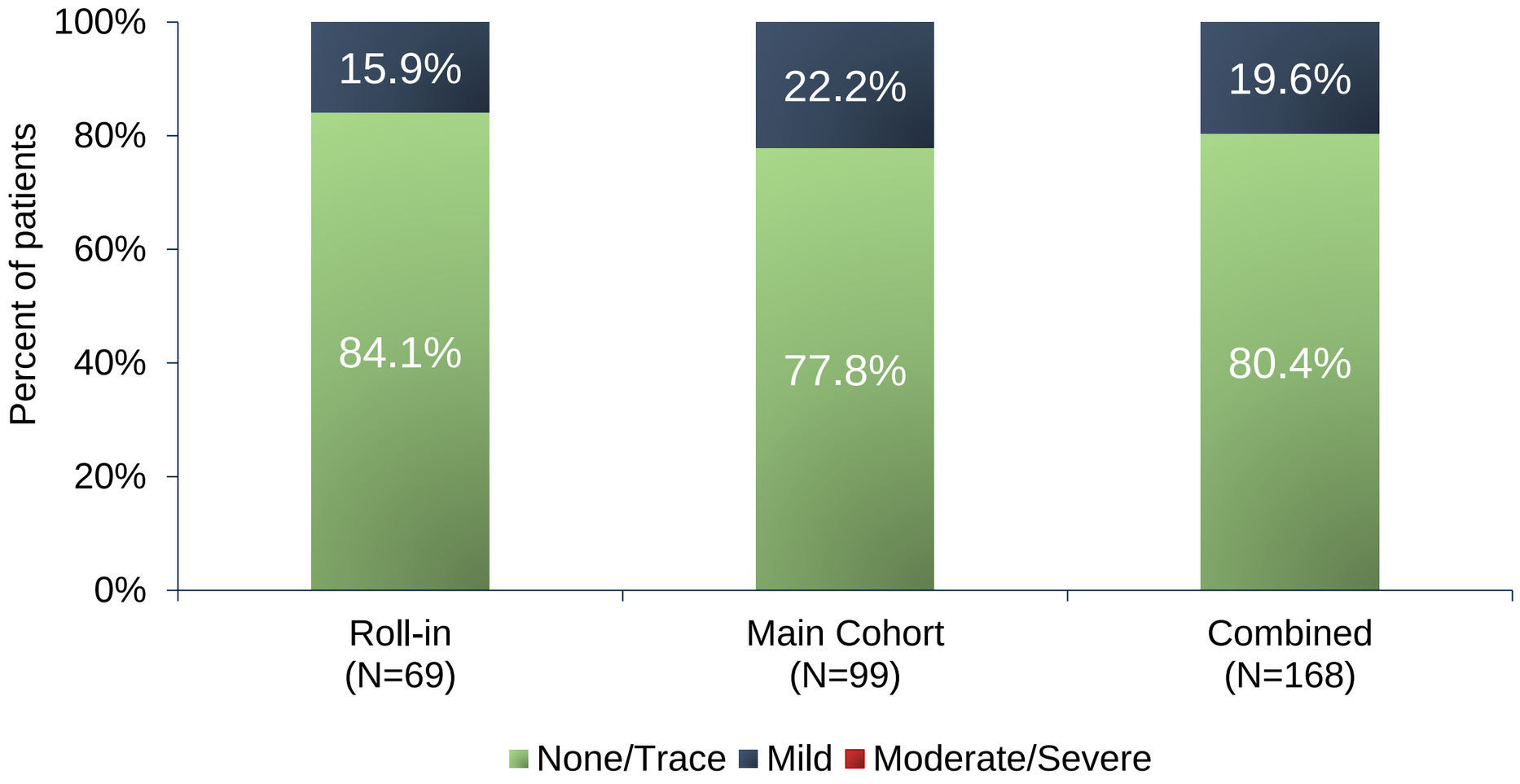
OPTIMIZE PRO INTERIM ANALYSIS

TOTAL AORTIC REGURGITATION



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OPTIMIZE PRO INTERIM RESULTS

SUMMARY

- Thirty-day outcomes from the Optimize PRO study interim analysis demonstrate excellent outcomes.
  - No deaths
  - No disabling strokes
  - Low pacemaker implantation rates (8.8% for combined cohorts)
- Extremely low rates of total AR.
  (80.4% none/trace; 19.6% mild, in combined cohorts)
- Excellent post-procedure hemodynamics (mean gradient 8.1 mmHg).
- 1 valve implanted in all patients.
- Median length of stay was 1 day.
- Outcomes expected to improve with Cusp Overlap experience and continued refinement of procedural technique and accessories (wire choice).
- Key steps in procedure technique to be confirmed with additional patients and longer follow-up (clinical study ongoing to 600 patients).

Evolut PRO+ Device

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EVOLUT CUSP OVERLAP

PRELIMINARY CLINICAL RESULTS

Author	Abstract	Centers	No. Pts	Valves	Standard View — PPI	Cusp Overlap — PPI
Pisaniello, et al[1]	PCR2019	Single	382	EV, S3	NR	< 5%
Mendiz, et al[2]	TCT2020	Two	443	EV, Neo, S3, Port, Jena	30.9%	6.6%
Gada, et al[3]	TCT2020	Single	134	EV 34 mm	NR	5.2%
Ajabbary, et al[4]	TCT2020	Single	520	EV	16.5%	7.2%
Giuliani, et al[5]	TCT2020	Two	65	EV	24.9%	0%
Gada, et al[6]	TCT2020	7 countries	105	EV	NR	5.7%

1. Pisaniello, et al. Abstract. Presented at PCR 2019.
2. Mendiz, et al. Presented at TCTConnect2020.
3. Gada, et al. Cusp Overlap. Presented at TCTConnect2020.
4. Aljabbary, et al. Abstract. Presented at Canadian CV Society 2020.
5. Guiliani, et al. TCT2020 Abstract.
6. Gada, et al. Presented at TCTConnect2020.

Summary

- **Easy to access small artery** with Evolut Pro plus™ that has **very low profile**.
- Evolut Pro plus™ including outskirt **reduce PVL** significantly
- Only remaining issue is **long term durability**.