

# How is SAPIEN 3 Valve Design Connected to Clinical Benefit?



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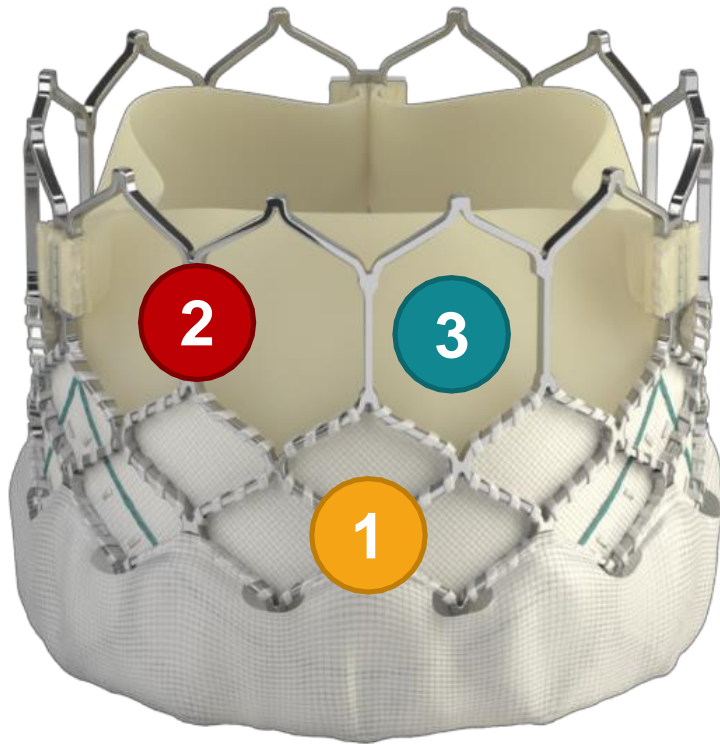
# Disclosures



- Working as a proctor for
  - *Edwards*
  - *Medtronic*



# Sapien 3 Valve Design



## Inner/outer Sealing Skirt

- Designed to minimize paravalvular leak



## Frame Design

- Cobalt-chromium frame for high radial strength
- Enhanced frame geometry for low delivery profile



## Proven Valve Tissue

- Same bovine pericardial tissue and processes as Edwards surgical valves

# Sapien 3 Design: Clinical Benefits

1. Reduced paravalvular leak

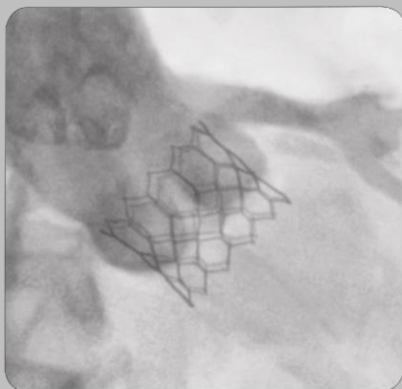


# Designed to Minimize Paravalvular Leak

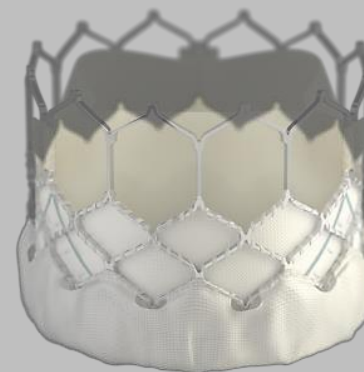


## 1 Inner/outer Sealing Skirt

### Polyethylene Terephthalate (PET) Inner and Outer Sealing Skirt



Outer Sealing Skirt Designed to Minimize PV Leak



Inner Skirt Covers ~1/2 of Valve  
Outer Skirt Covers ~1/3 of Valve

# Paravalvular Leak According to TAVI Valves



The 2<sup>nd</sup> Cohort of K-TAVI Registry



# Sapien 3 Ultra: PVL

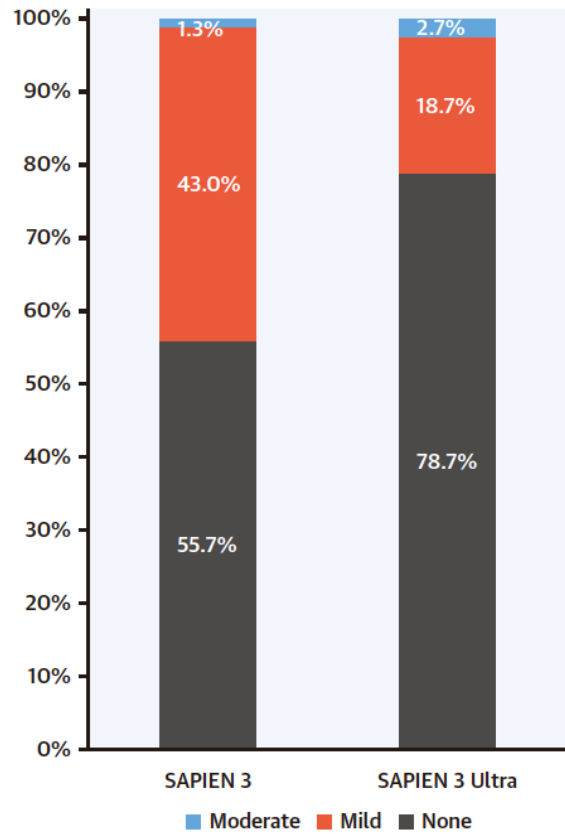


Rheude T. *JACC Interv.* 2020;13:2631

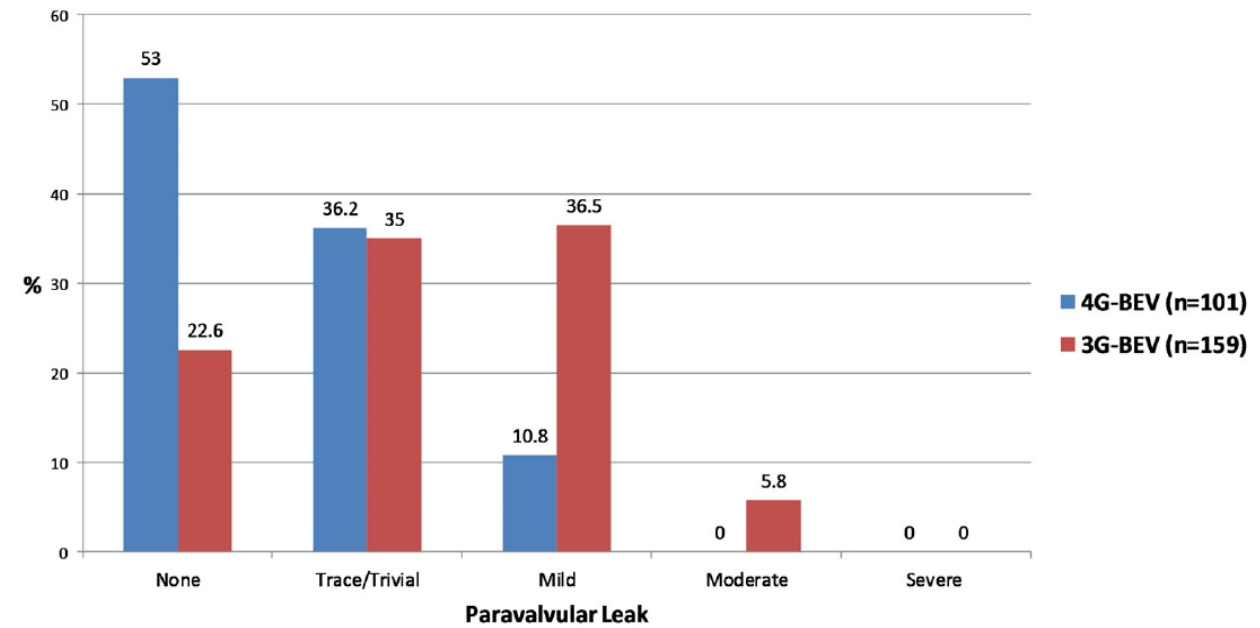
Welle GA. *Catheter Cardiovasc Interv.* 2021;97:895



SAPIEN 3



SAPIEN 3 Ultra



# Sapien 3 Design: Clinical Benefits

1. Reduced paravalvular leak
2. Provides better access to coronary arteries

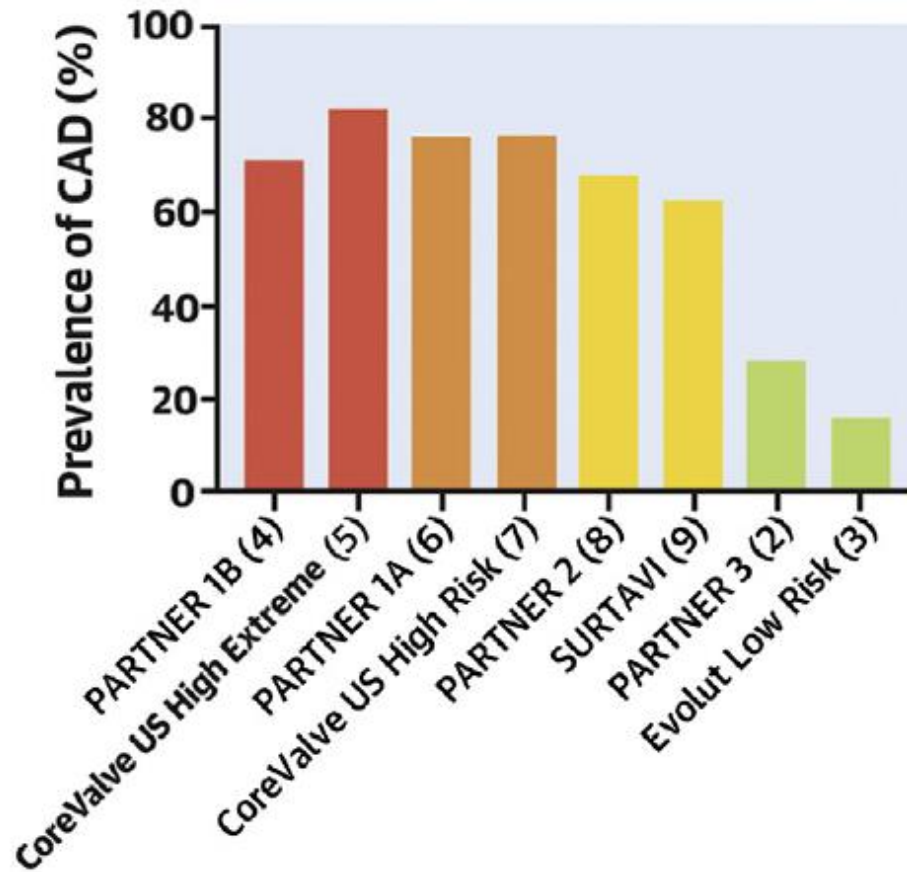




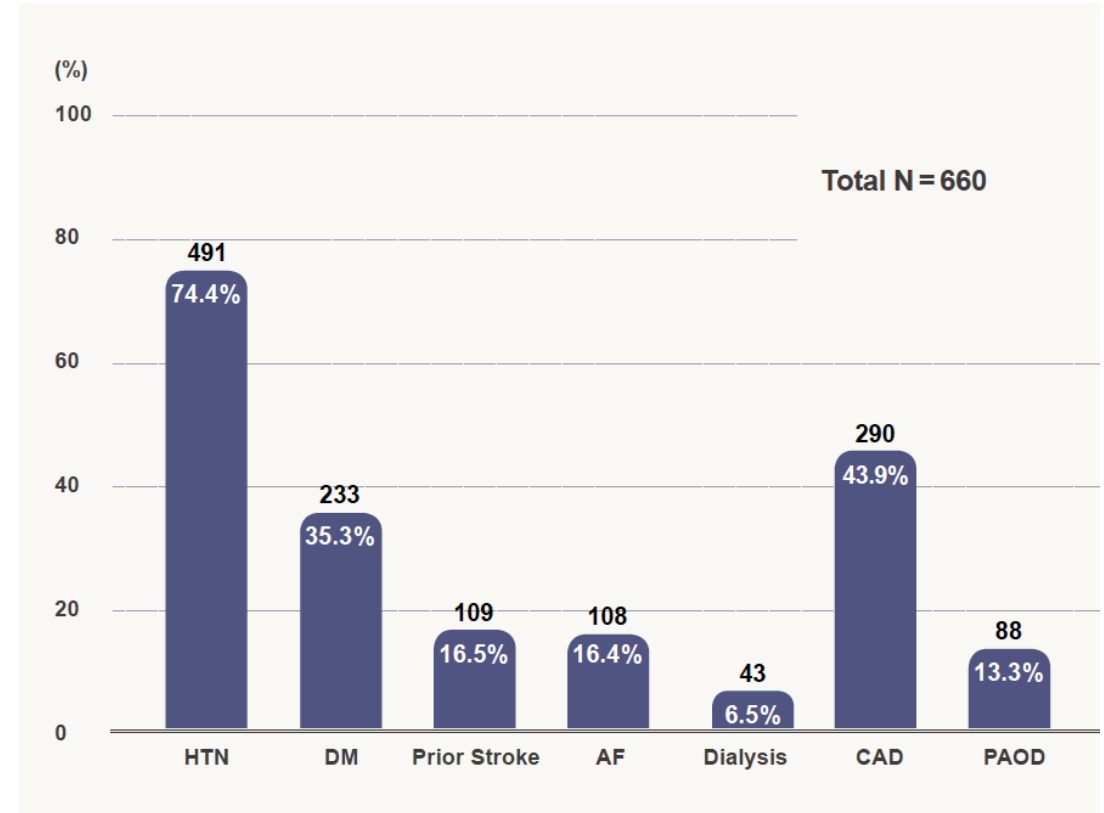
# Prevalence of CAD in TAVR Patients



## Clinical Trials



## K-TAVI



*Faroux L, JACC 2019;74:362*

Severance Cardiovascular Hospital, Yonsei University Health System

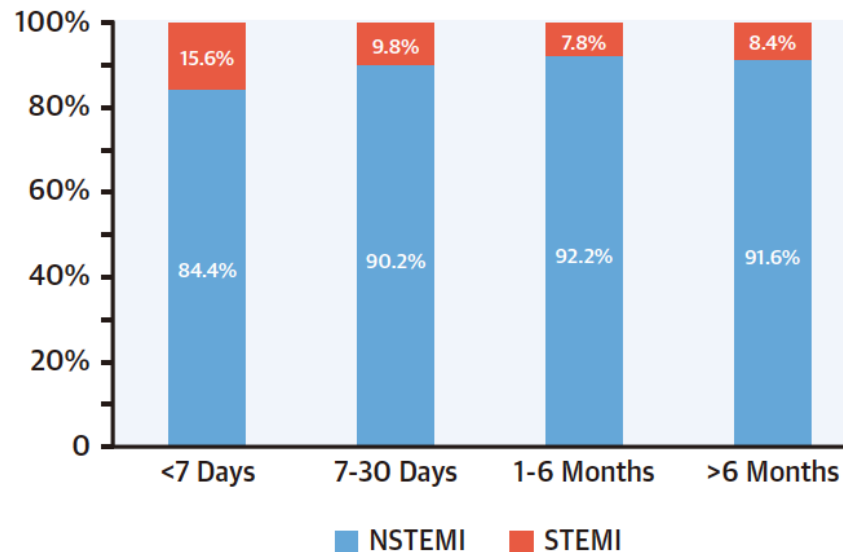


# US Medicare Data: Incidence of ACS after TAVR

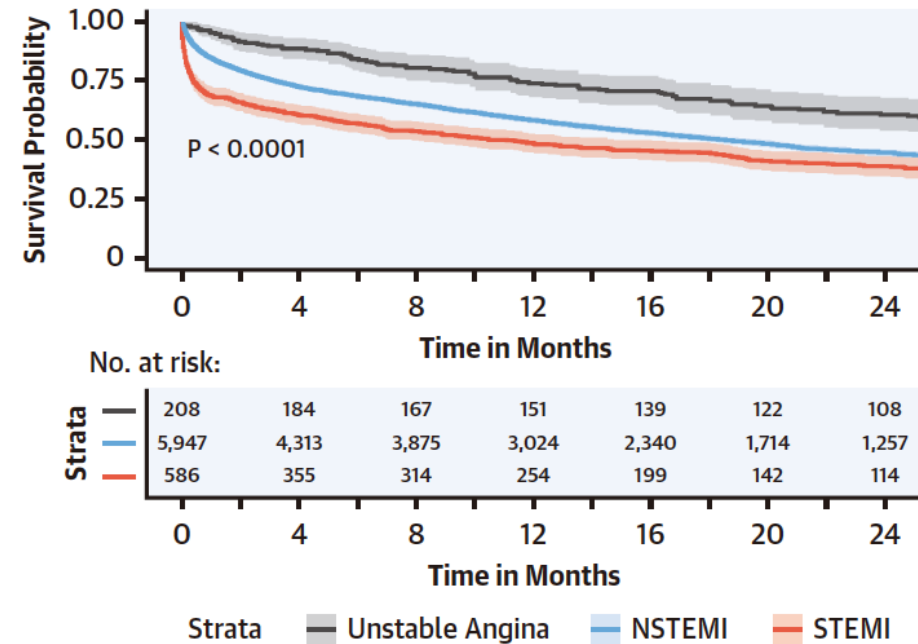


- 142,845 patients treated with TAVR between 2012 and 2017
- 4.7% admitted with ACS after a median time of 297 days

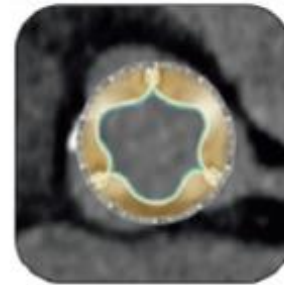
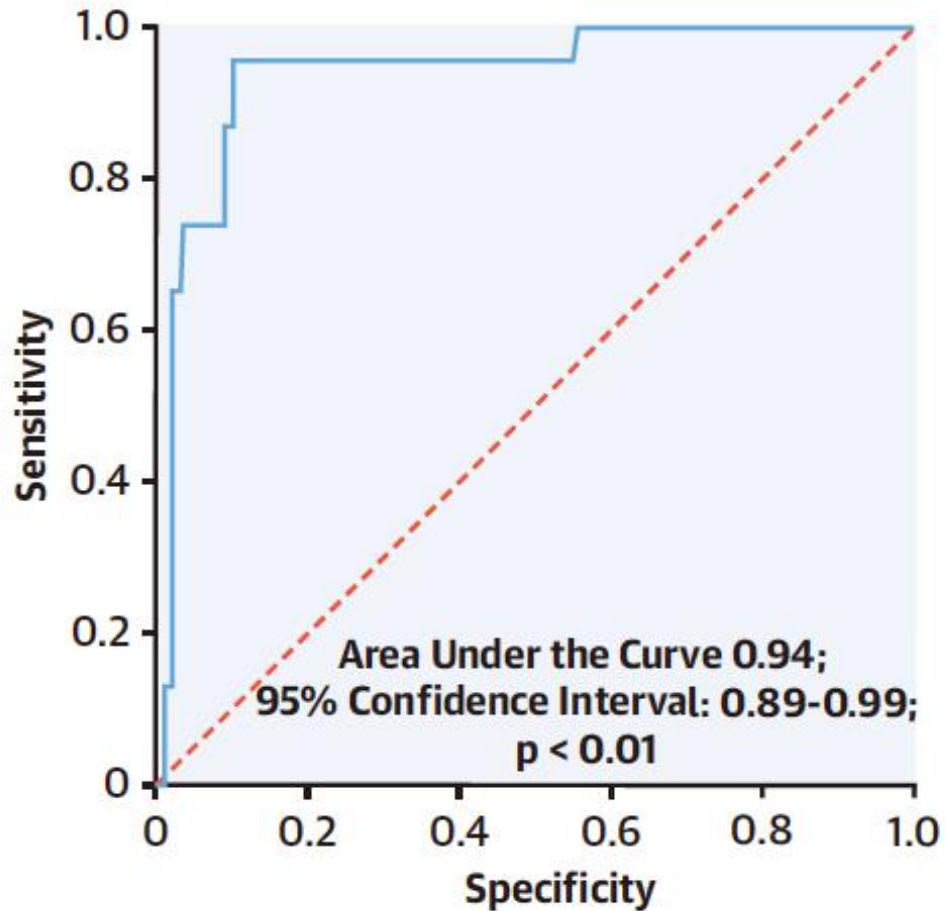
**A** Distribution of MI Type by Time of Presentation



**B** Survival by Type of Acute Coronary Syndrome



# Predictors of Unsuccessful Coronary Cannulation After TAVR



**Transcatheter Aortic Valve/  
Sinuses of Valsalva Relation**  
Odds Ratio 1.1;  
95% CI: 1.0-1.2; p < 0.01



**Transcatheter Aortic Valve Implant Depth**  
Odds Ratio 1.7;  
95% CI: 1.3-2.3; p < 0.01



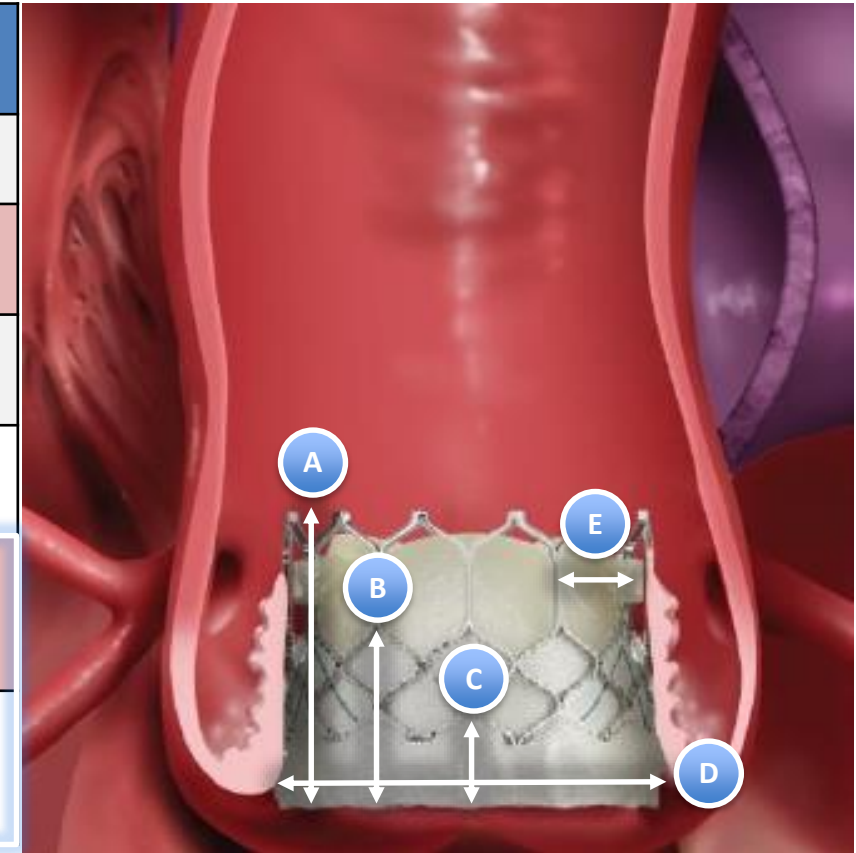
**Evolut Transcatheter Aortic Valve**  
Odds Ratio 29.6;  
95% CI: 2.6-335.0; p < 0.01

*Barbanti M, JACC Intv 2020;13:2542*



# Advantage in Future Coronary Access due to the Intra-annular, Low Frame, Large Cell Design

	20 mm	23 mm	26 mm	29 mm
<b>A</b> Frame Height	15.5	18	20	22.5
<b>B</b> Inner skirt height	7.9	9.3	10.2	11.6
<b>C</b> Outer skirt height	5.2	6.6	7.0	8.1
<b>D</b> Valve Diameter	20	23	26	29
<b>E</b> Cell adjacent to commissure size	4.4	5.1	5.7	6.5
Size catheter that can fit (Fr)*	13	15	17	19



\*The most common catheter size for intervention is 6 Fr

\*Yudi, et al. Coronary Angiography and Percutaneous Coronary Intervention After Transcatheter Aortic Valve Replacement. JACC VOL. 71 , NO.12, 2018

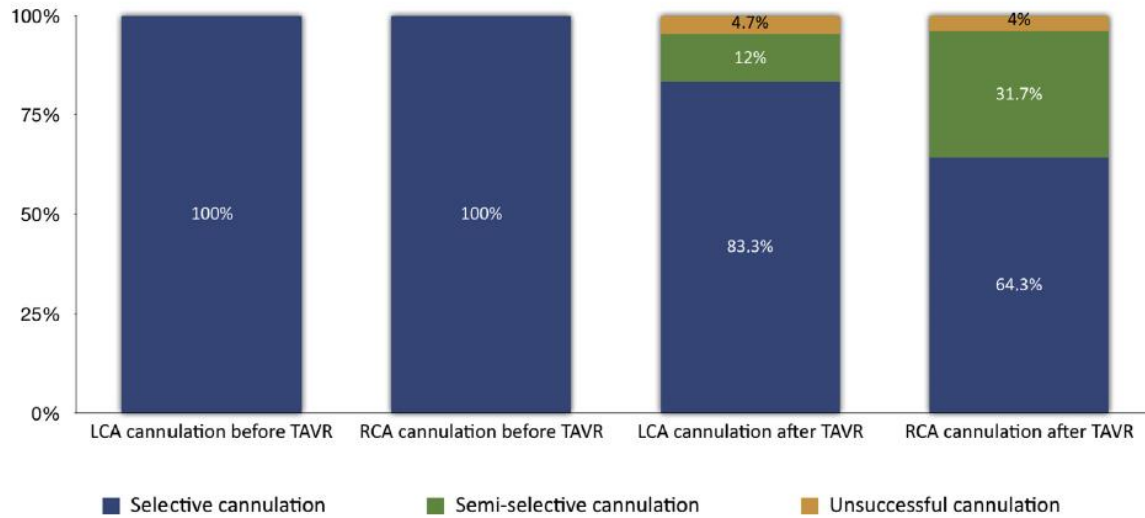


# Re-ACCESS Study

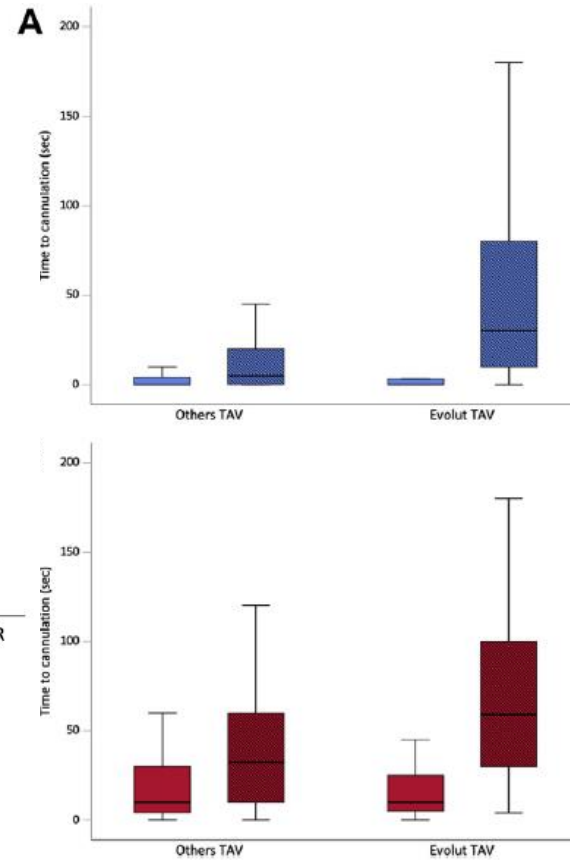


Single center prospective registry (n=300):

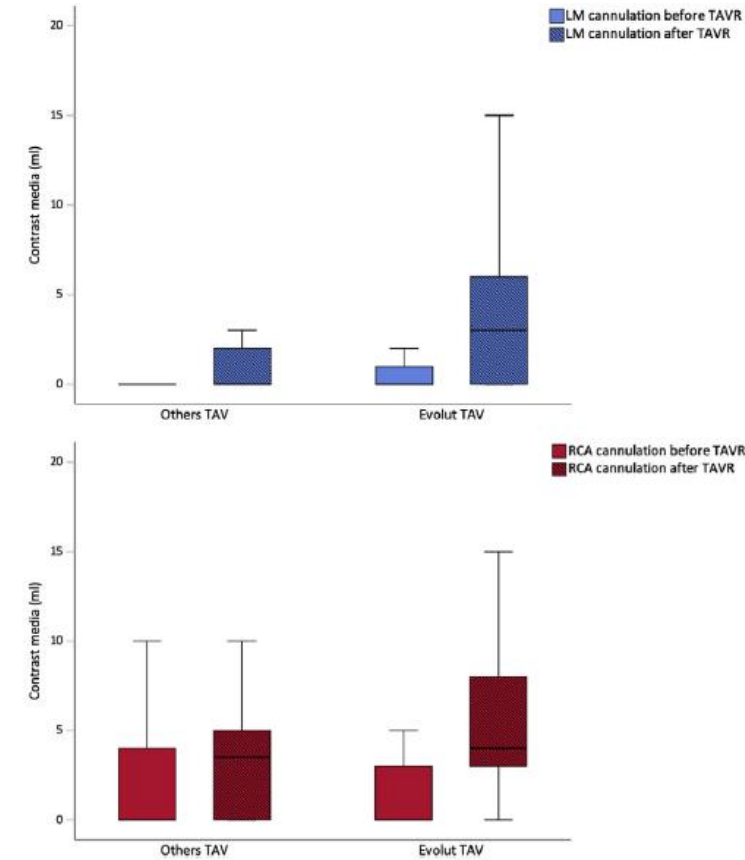
- 7.7% failed cannulation
- 22/23 failed cases used Evolut V



Time to cannulation



Volume of contrast media

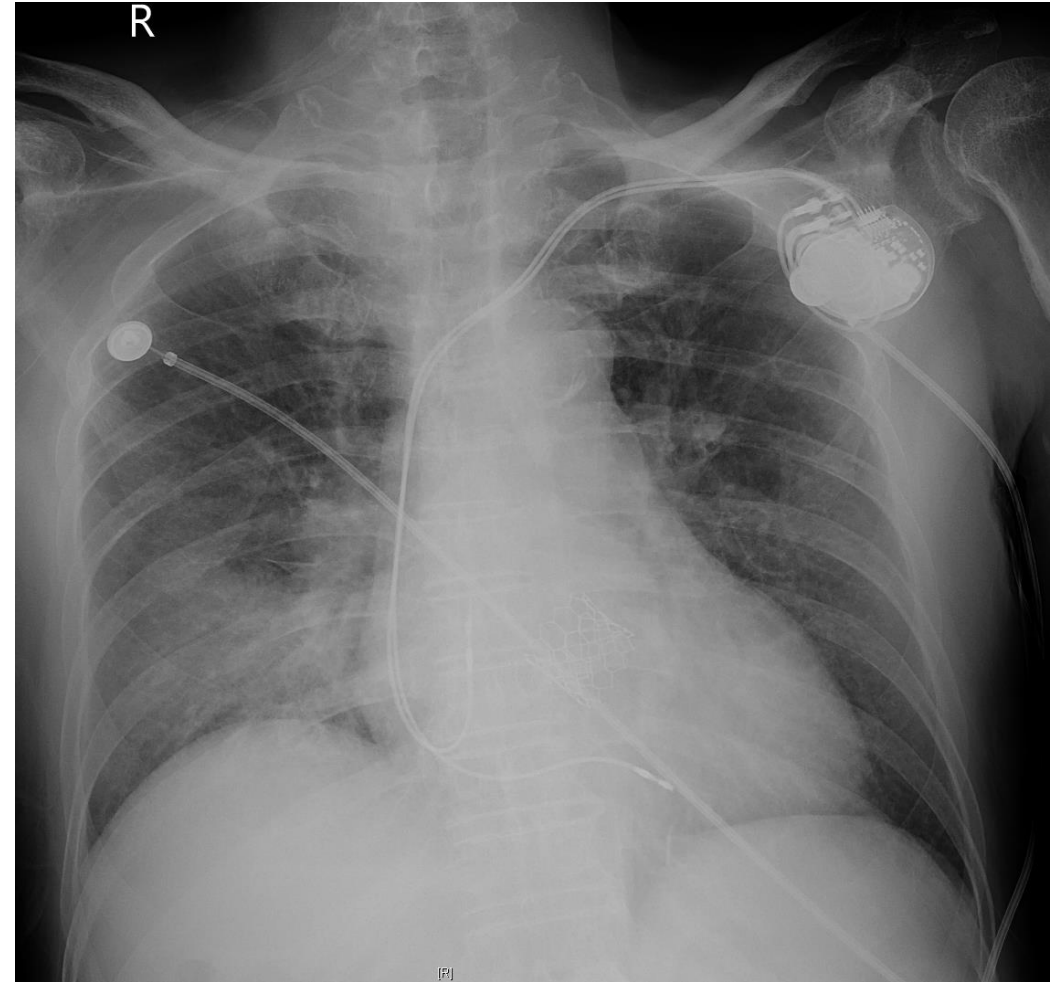


Barbanti M, JACC Intv 2020;13:2542

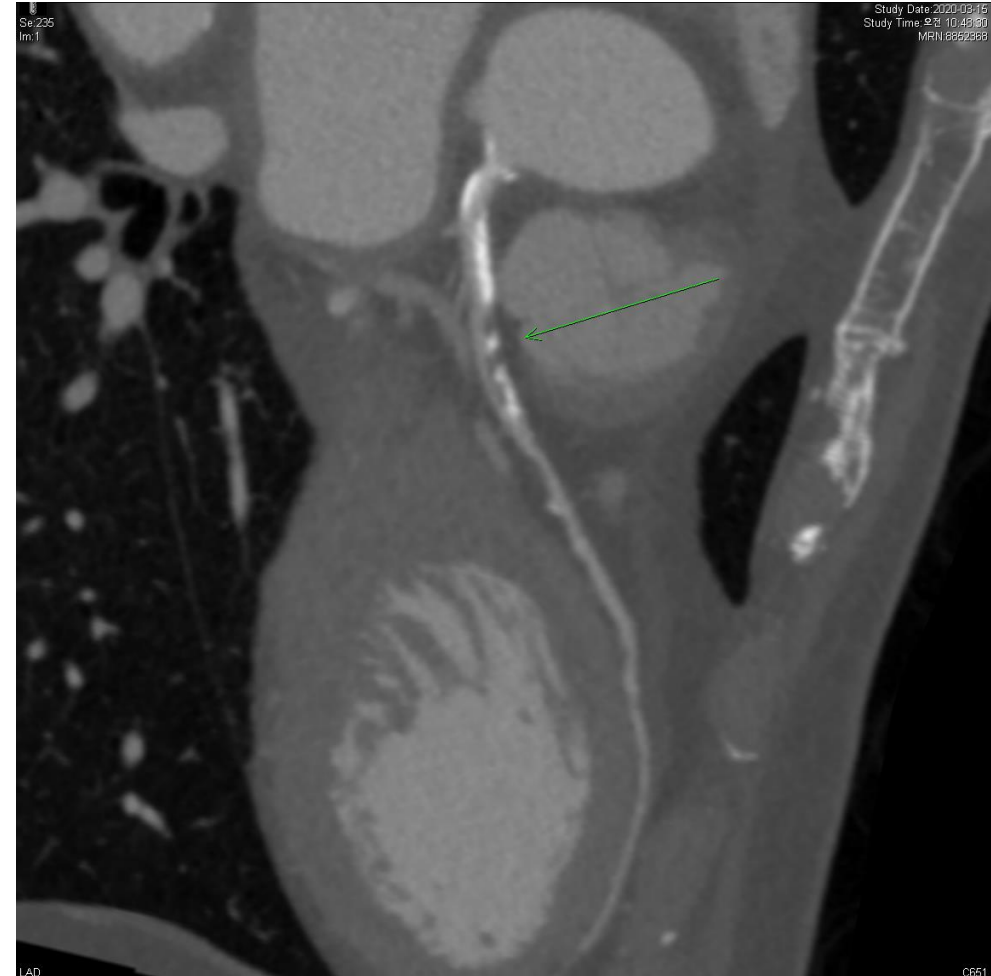
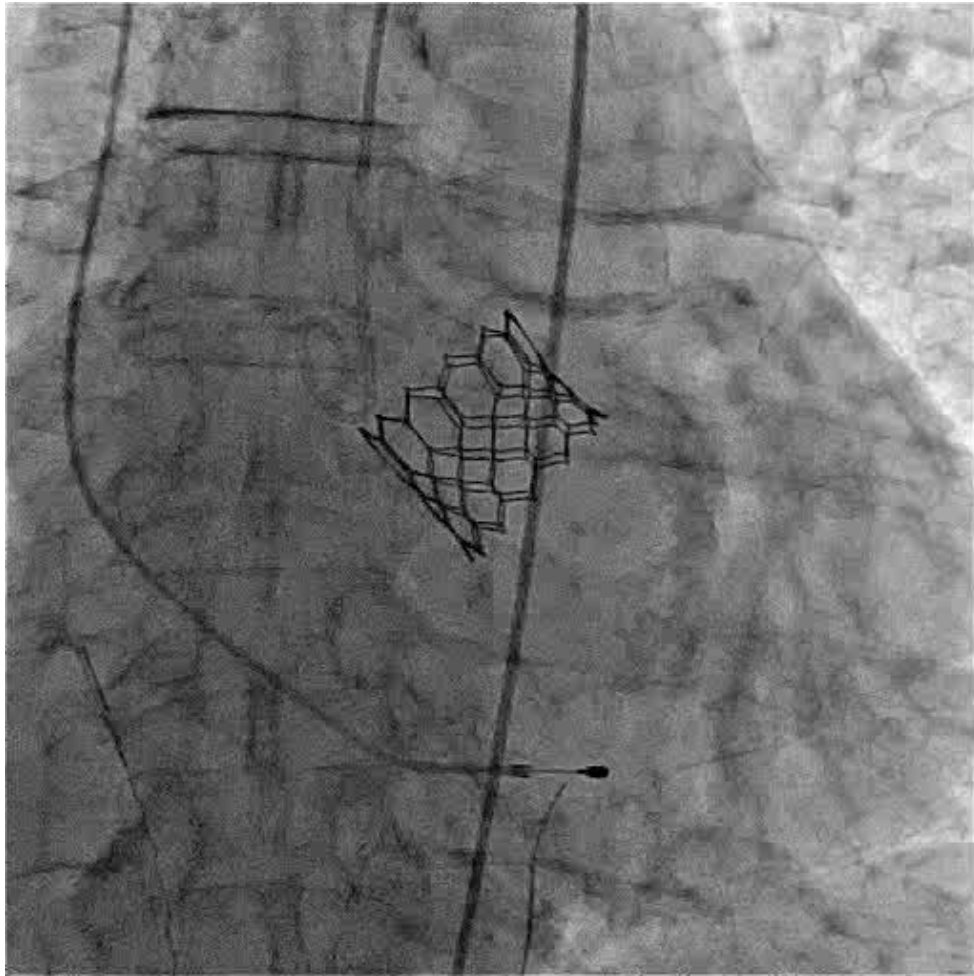




- Sx: Chest pain & dyspnea
- PHx:
  - S/P TAVR with Sapien 3 (17 months ago)
  - S/P Pacemaker
  - HTN, DM, CKD
- Lab:
  - Cr 1.86 mg/dL
  - CKMB 4.4 => 92.4 ng/mL
  - Troponin-T 82=> 917 pg/mL



# At the Time of TAVR (17 months ago)

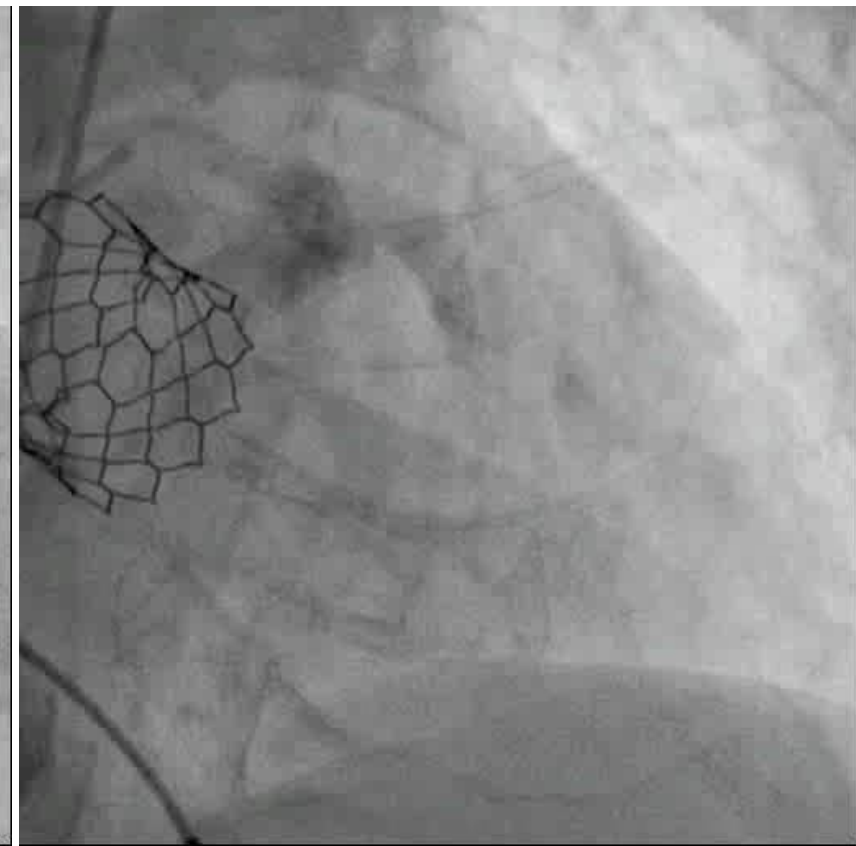
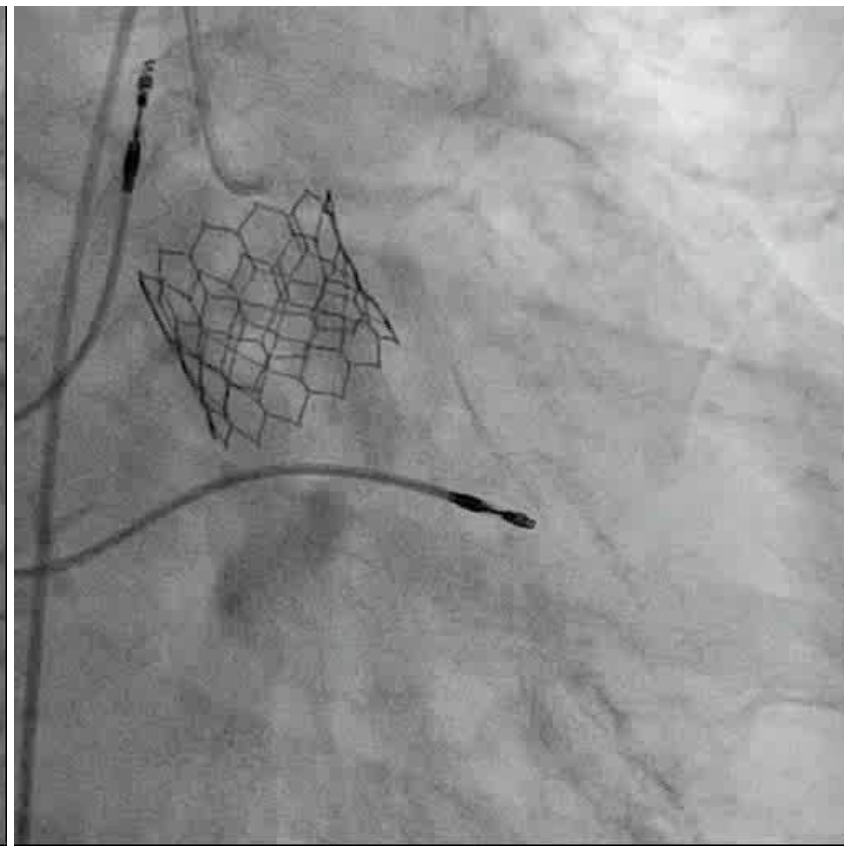
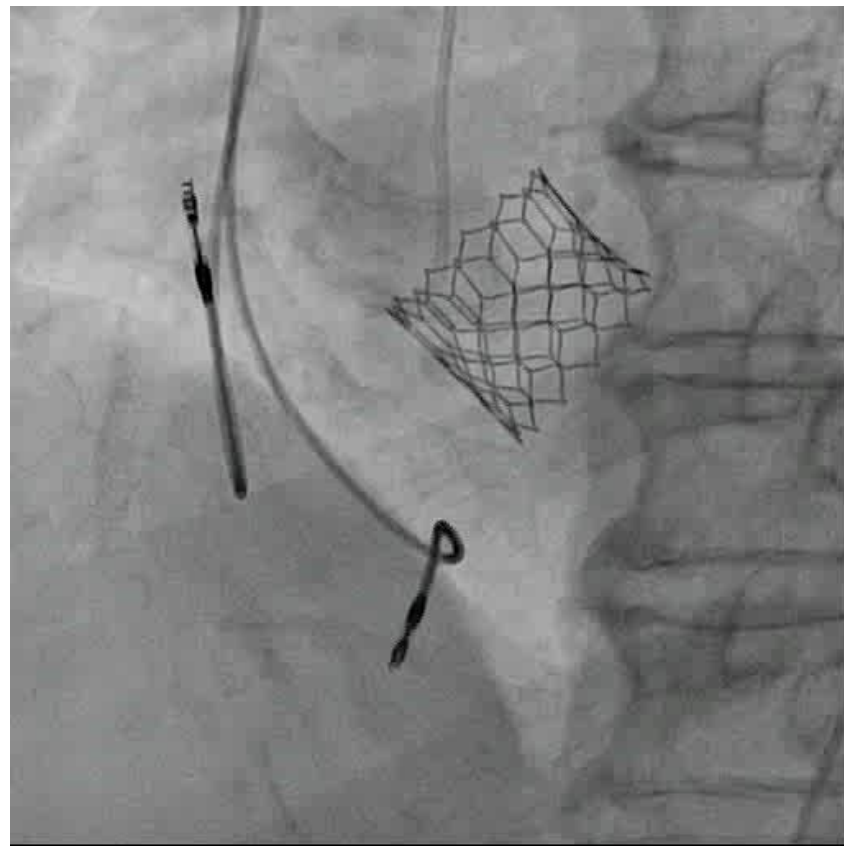


# Coronary Angiogram



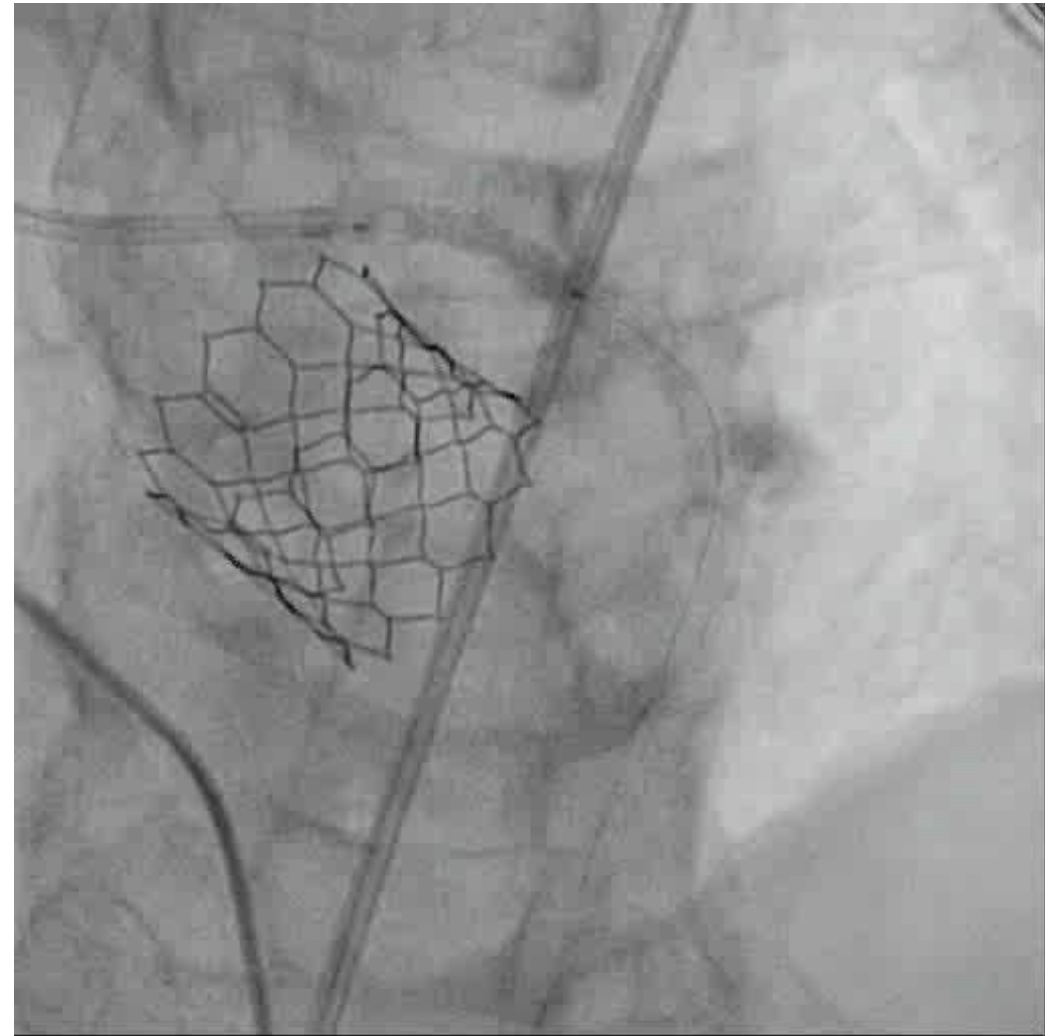
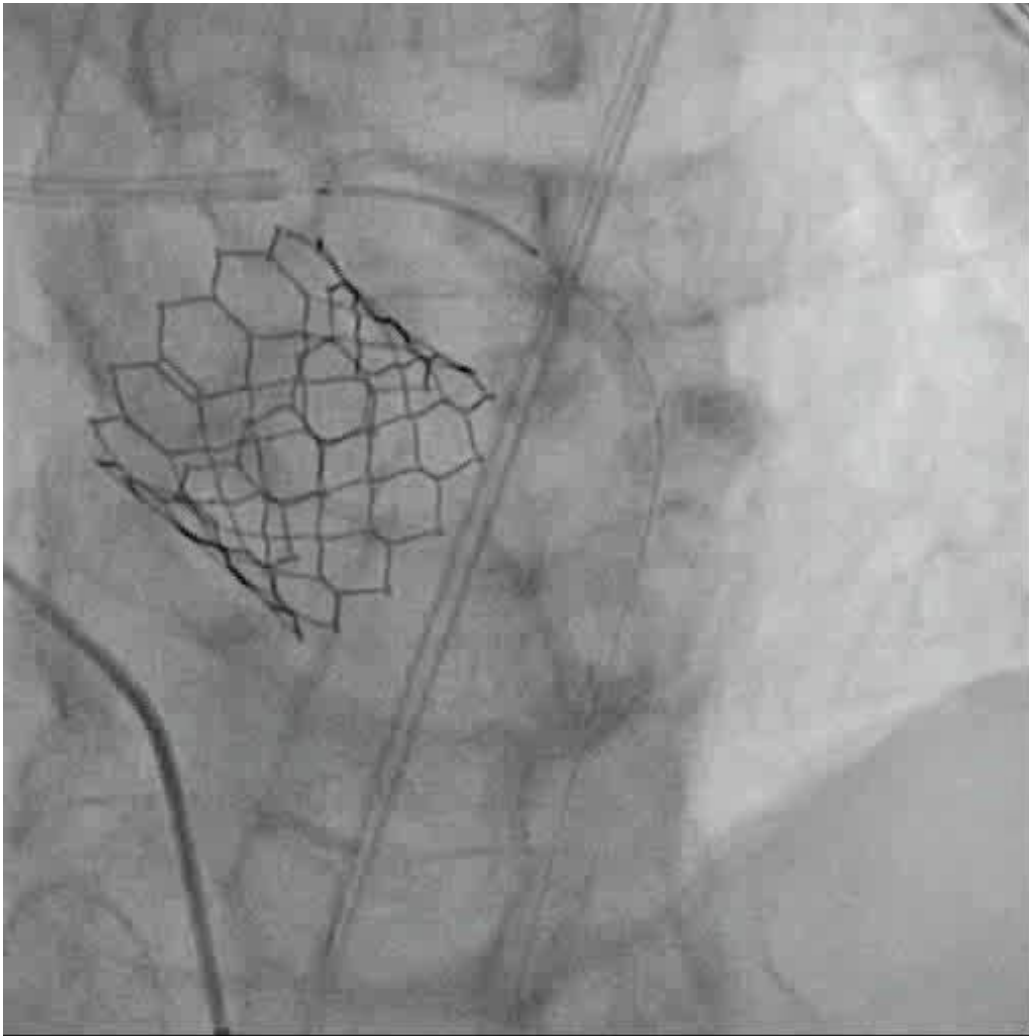
JR 5-4

JL 5-4

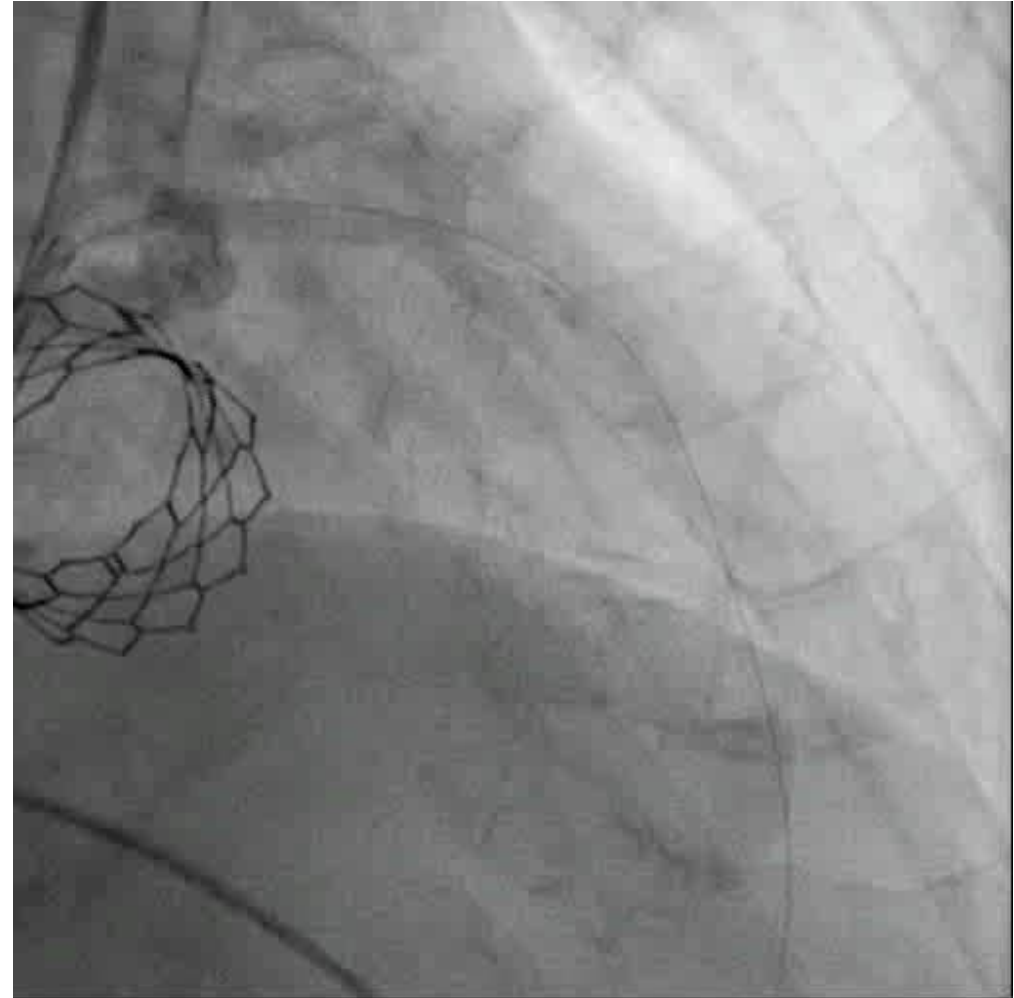
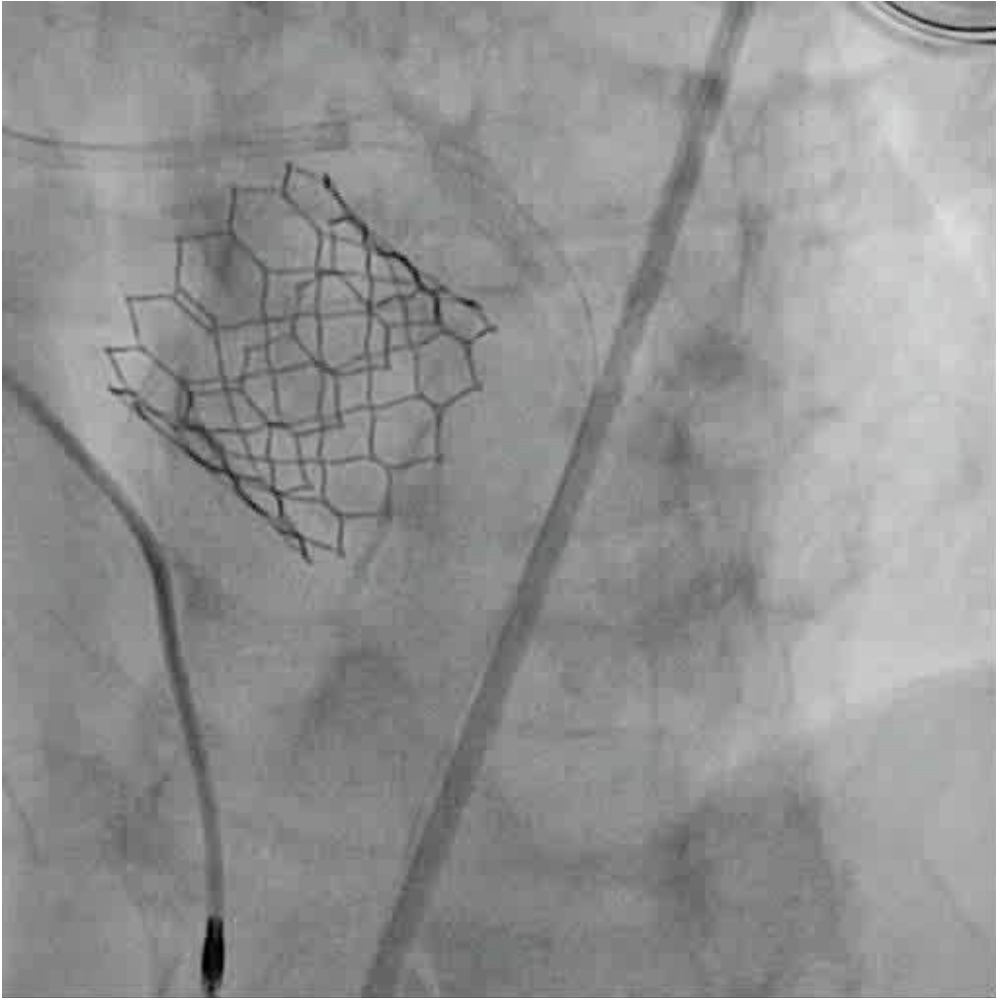




# Coronary Stenting



# Angio after PCI



# Sapien 3 Design: Clinical Benefits

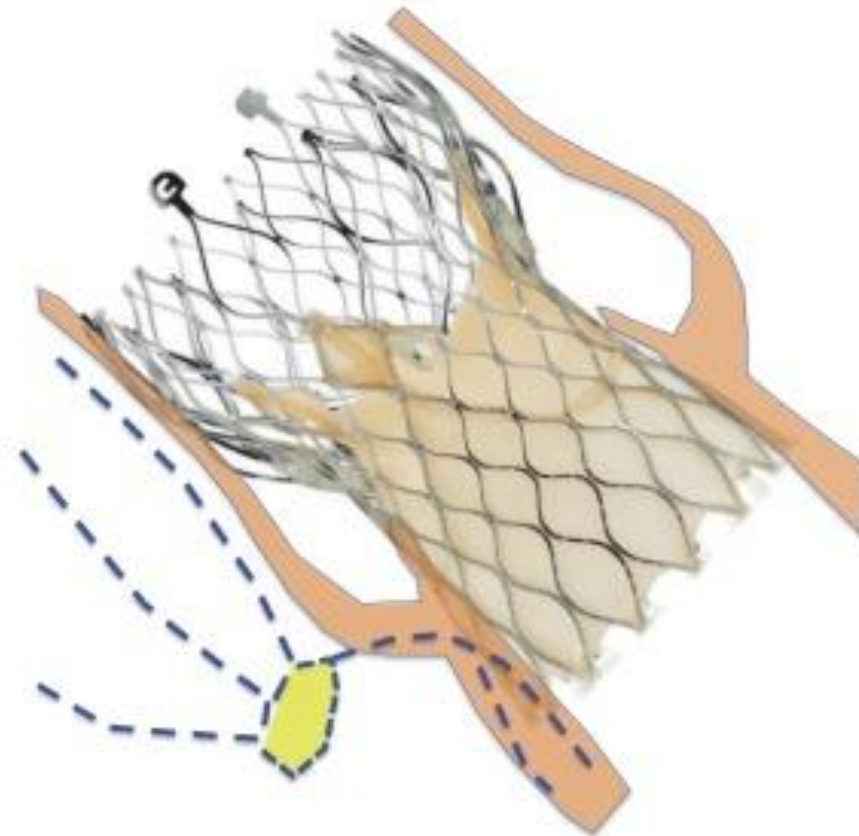
1. Reduced paravalvular leak
2. Better access to coronary arteries
3. Lower incidence of AV conduction disturbance



# Conduction Disturbances after TAVR



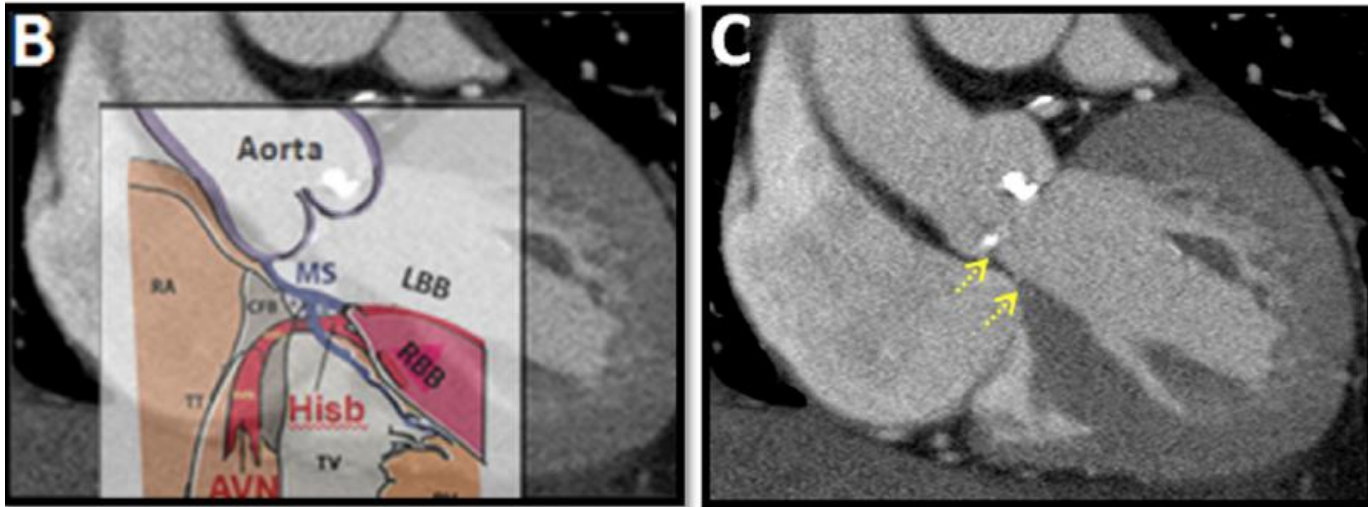
Patient related
Age > 75 years
Female sex
LVEF
Smaller LVOT
Pre-procedural conduction disturbances (pre RBBB, pre QRS duration)
Calcification: aortic valve and/or mitral annulus
Previous CABG or myocardial infarction
Diabetes Mellitus
Procedure related
Depth of valve implantation
Mismatch LVOT/Valve size (over-sizing)
Balloon pre-dilatation
CoreValve



# Membranous Septum Length



*Lower end of the MS = LV exit point of the His bundle*

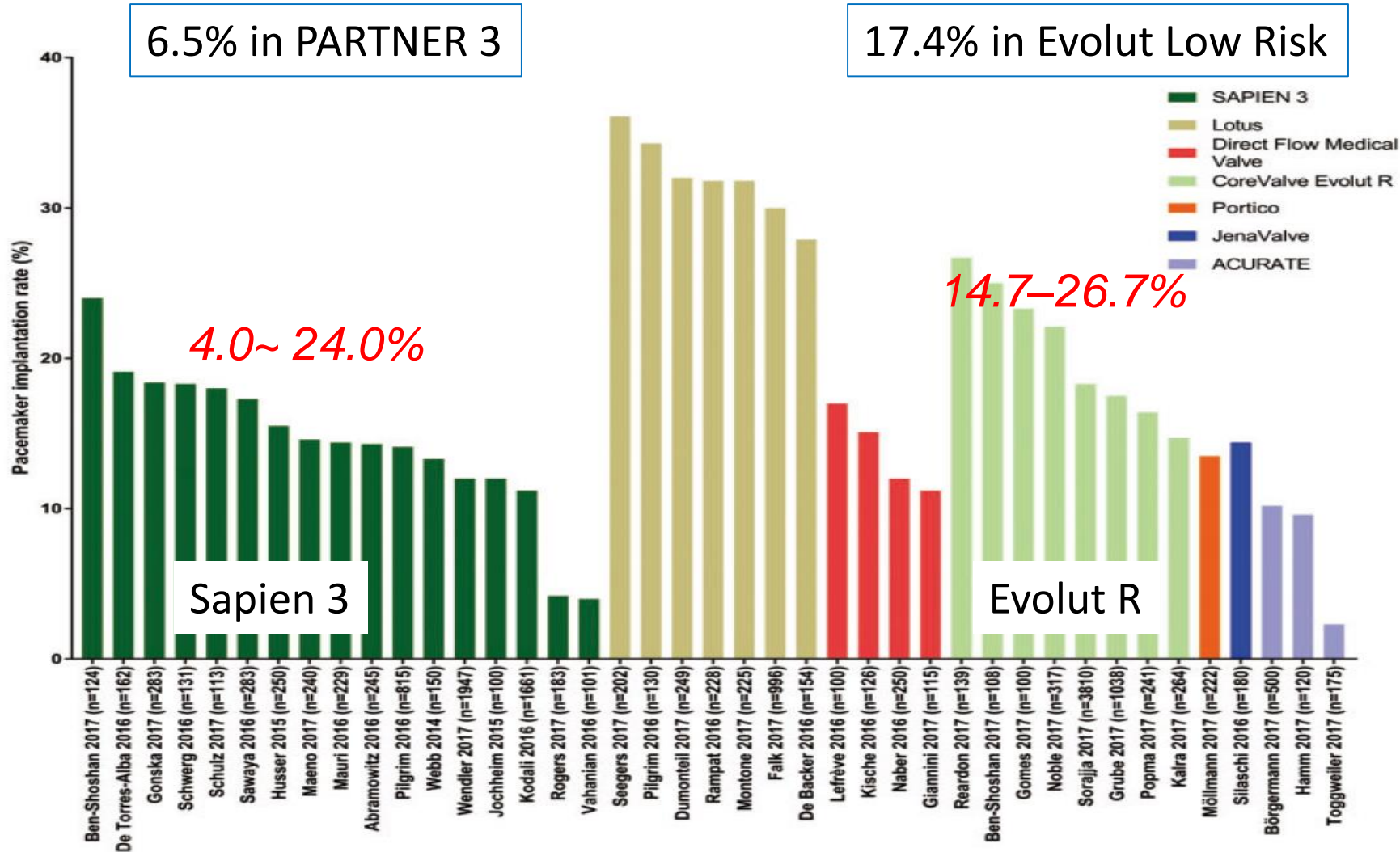


- Inverse relationship between MS length and the risk of AV block
- Difference between MS length and implantation depth is the most power predictor of PPM implantation

*JACC Intv 2015;8:1218*



# PPM Implantation Rate after TAVR Using Newer Generation Prosthesis



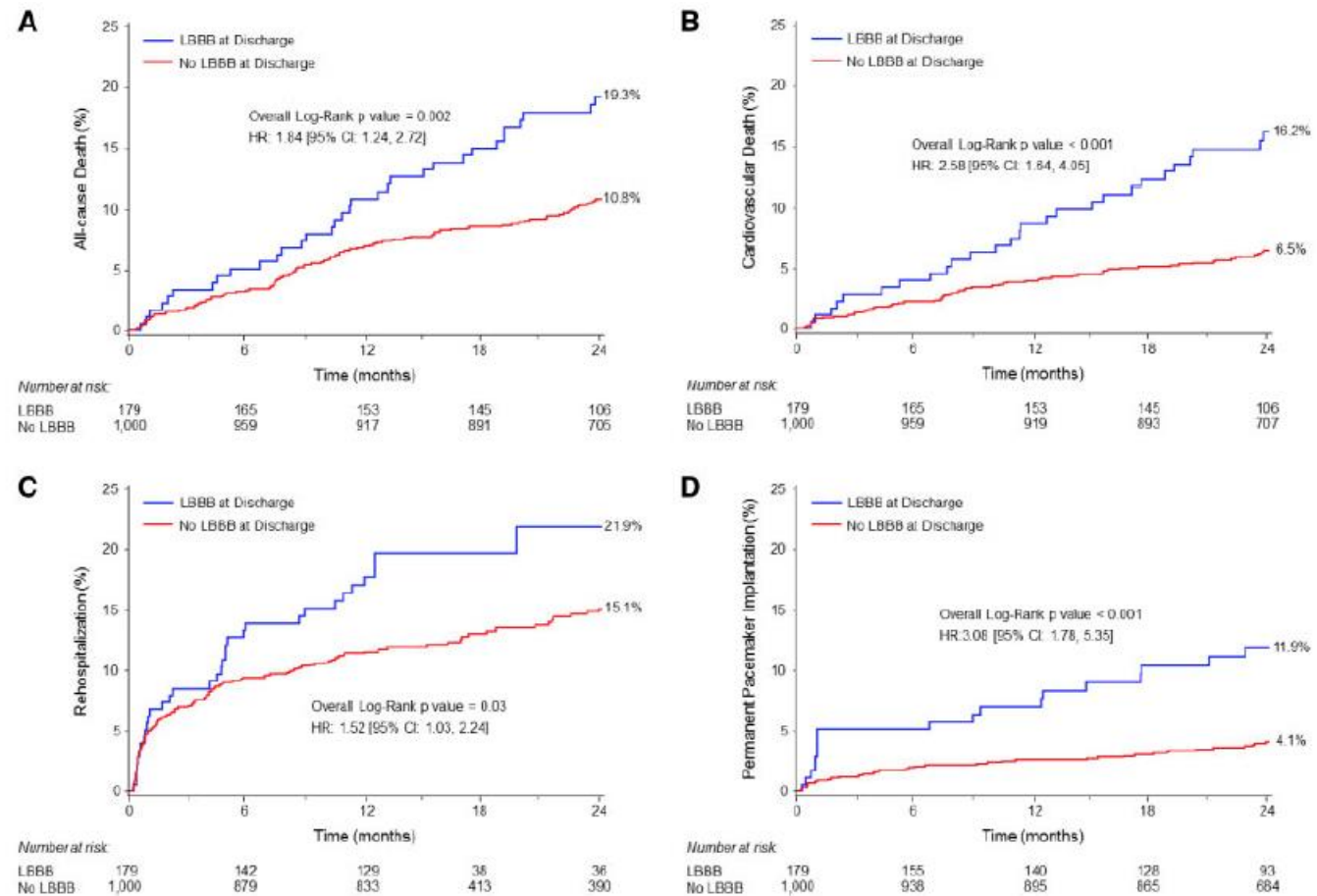
# New-onset LBBB after TAVR is not Benign



Incidence ranges 15-75% across valve types

The clinical impact of new LBBB after TAVR remains controversial.

## PARTNER II trial: new LBBB in 15.2%



Nazif TM, *Eur Heart J*, 2019;40:2218



# Sapien 3 Design: Clinical Benefits

1. Reduced paravalvular leak
2. Better access to coronary arteries
3. Lower incidence of AV conduction disturbance
4. **Safe delivery of the valve**  
(Prevention of major vascular complications)

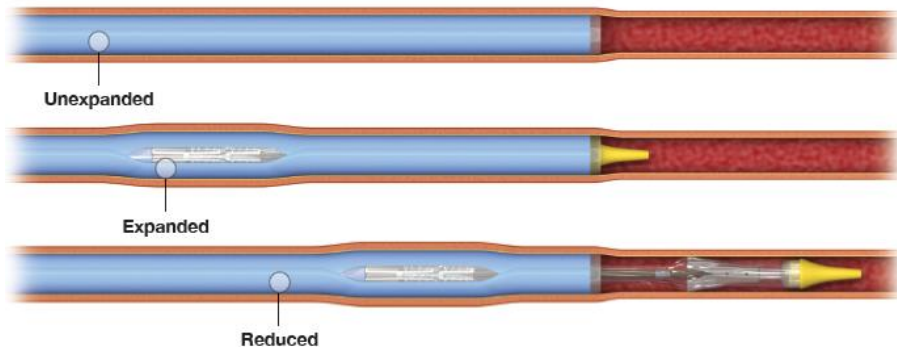




# Minimum Vessel Diameter Required for Sapine 3 Delivery



eSheath



THV	Sheath ID (unexpanded)	Sheath OD (unexpanded)	Minimum Vessel Diameter*
20 mm SAPIEN 3 valve	14F (4.6 mm)	6.0 mm	5.5 mm
23 mm SAPIEN 3 valve	14F (4.6 mm)	6.0 mm	5.5 mm
26 mm SAPIEN 3 valve	14F (4.6 mm)	6.0 mm	5.5 mm
29 mm SAPIEN 3 valve	16F (5.3 mm)	6.7 mm	6.0 mm

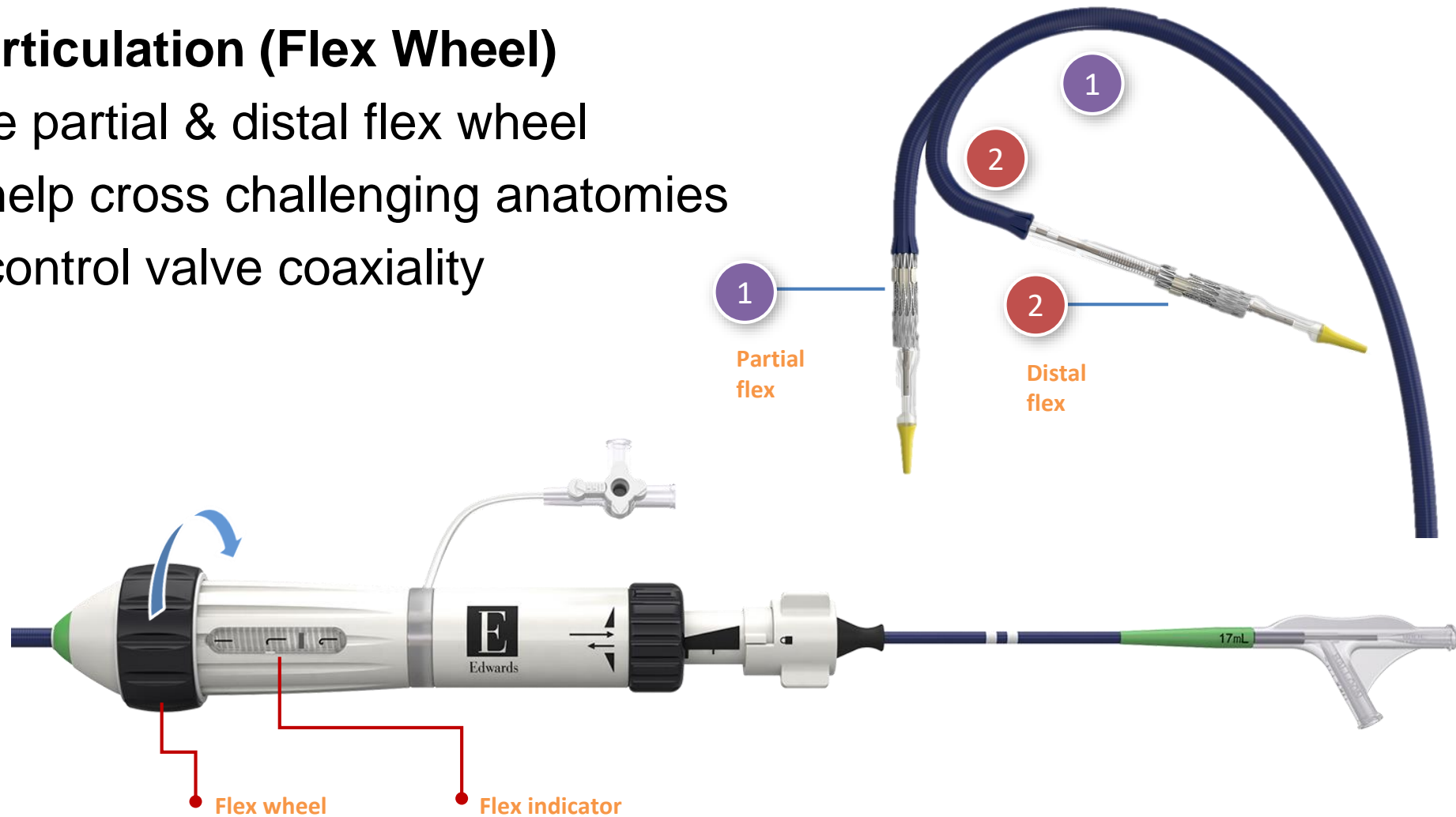
\*The Edwards eSheath Introducer Set is contraindicated for tortuous or calcified vessels that would prevent safe entry of the introducer and sheath



# Dual Articulation of Delivery Catheter

## Dual articulation (Flex Wheel)

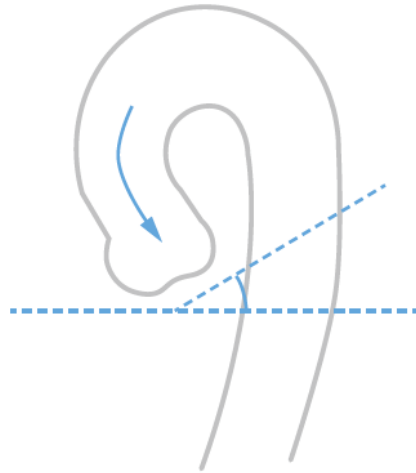
- Use partial & distal flex wheel
- To help cross challenging anatomies
- To control valve coaxiality



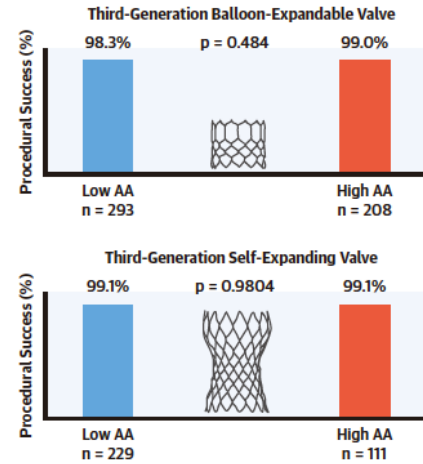
# Impact of Aortic Angulation on TAVR Outcomes



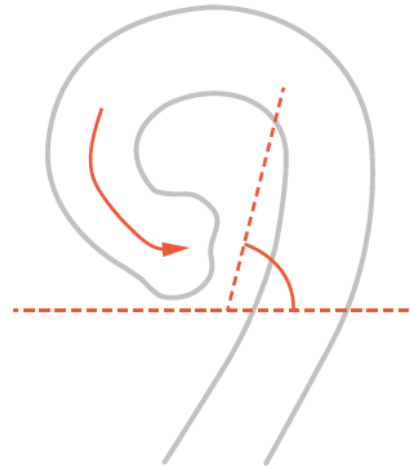
Low Aortic Angulation



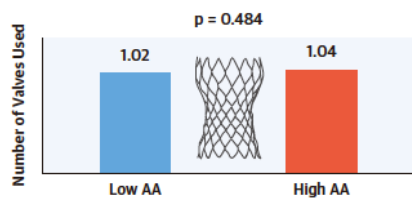
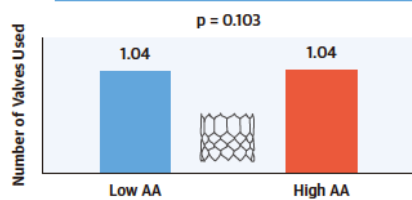
## A Transcatheter Aortic Valve Replacement Procedural Success



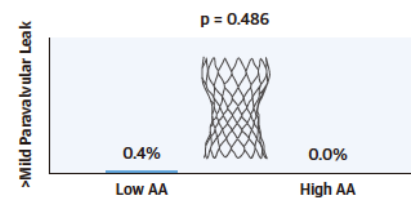
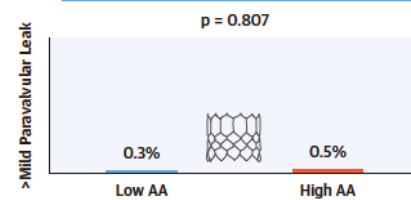
High Aortic Angulation



## B Number of Valves Used



## C >Mild Paravalvular Leak



Medranda GA. JACC Intv. 2021;14:1209



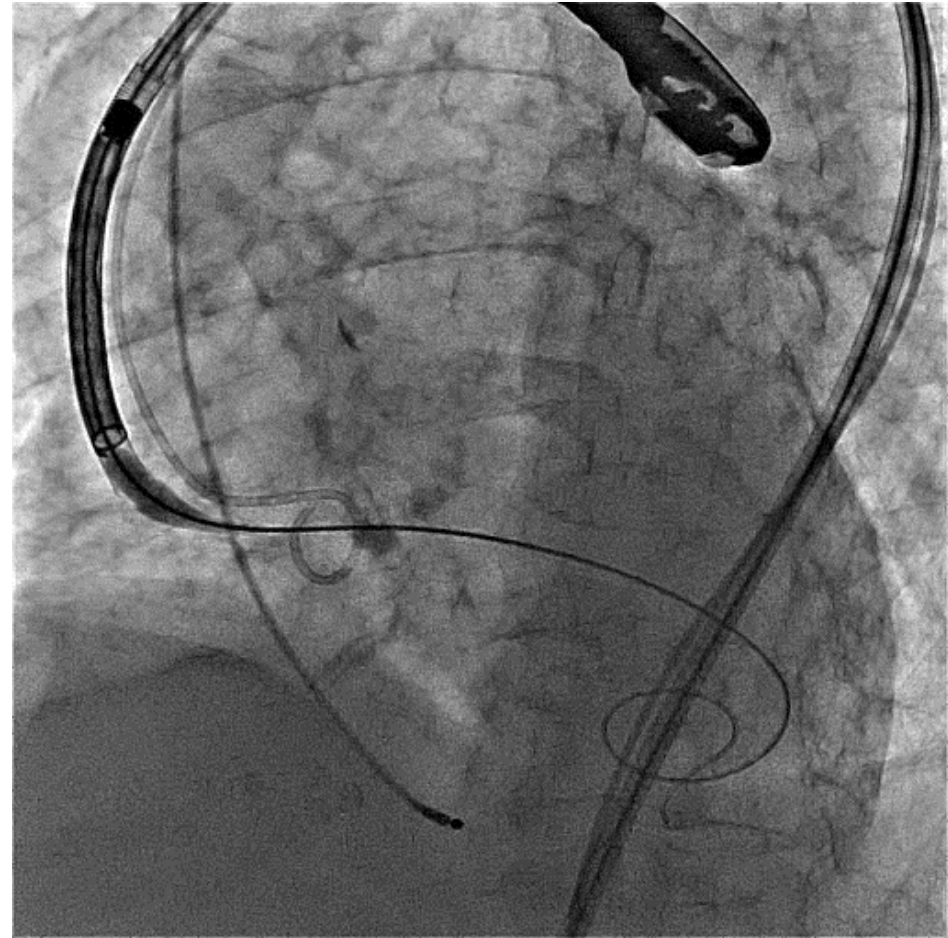
# F/80: Bicuspid AV



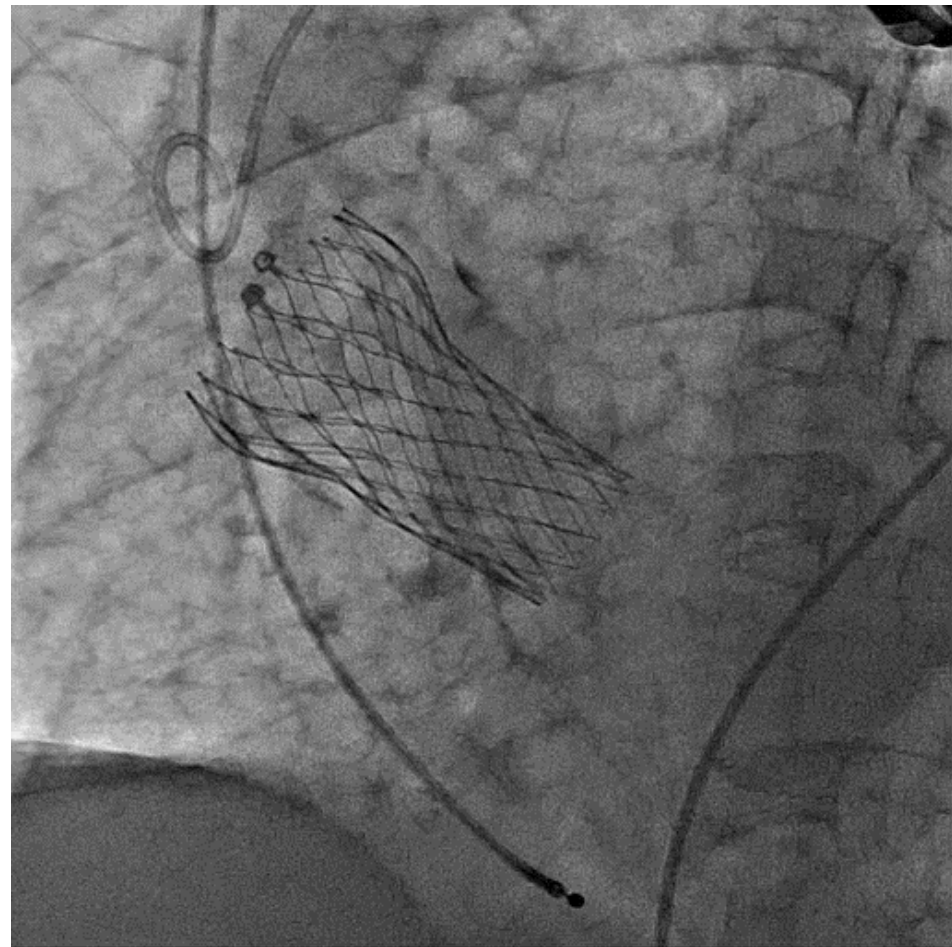
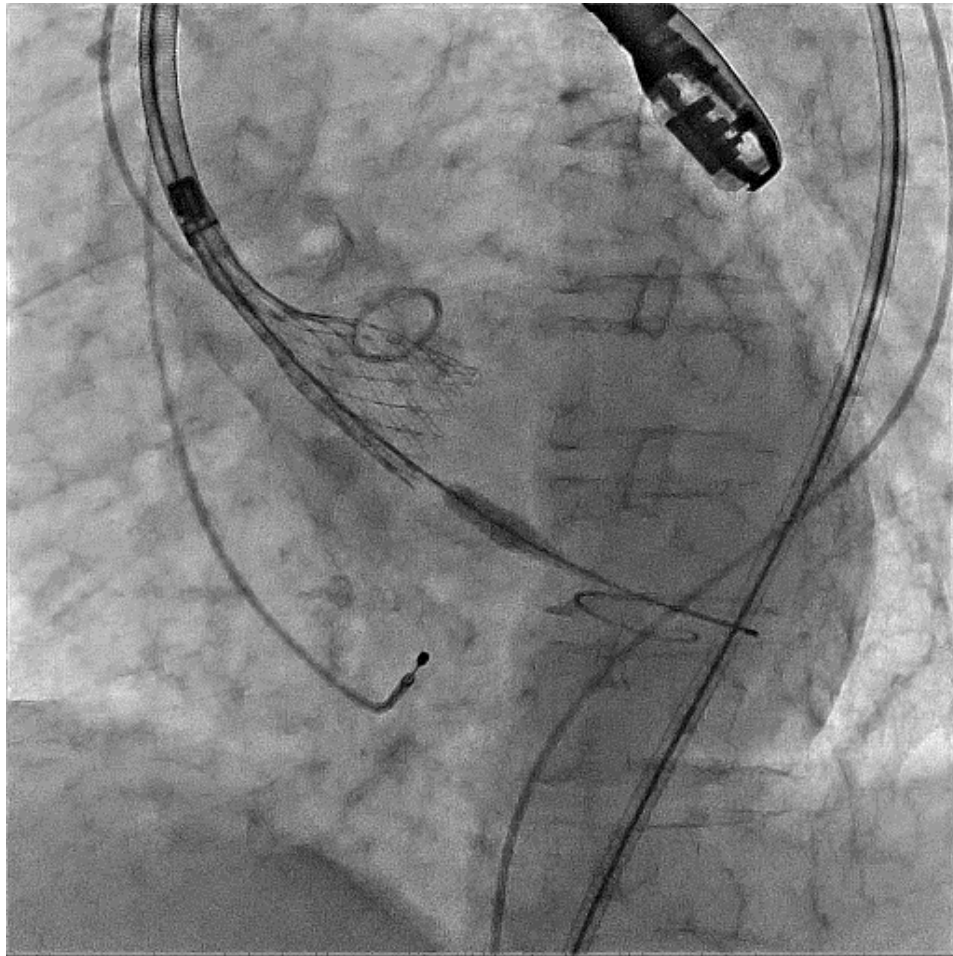
Ascending aorta: 45 mm



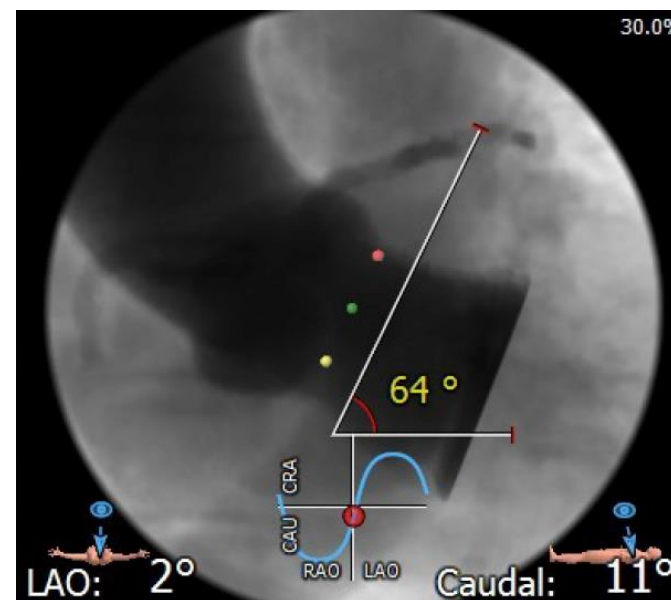
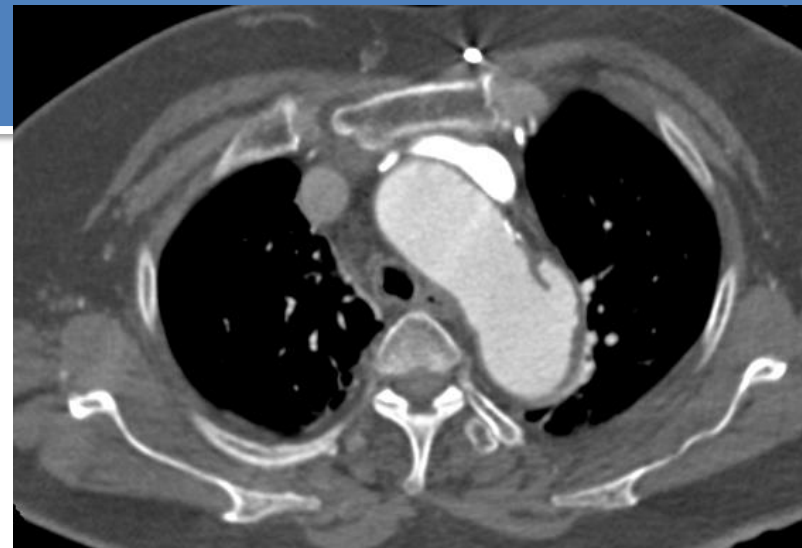
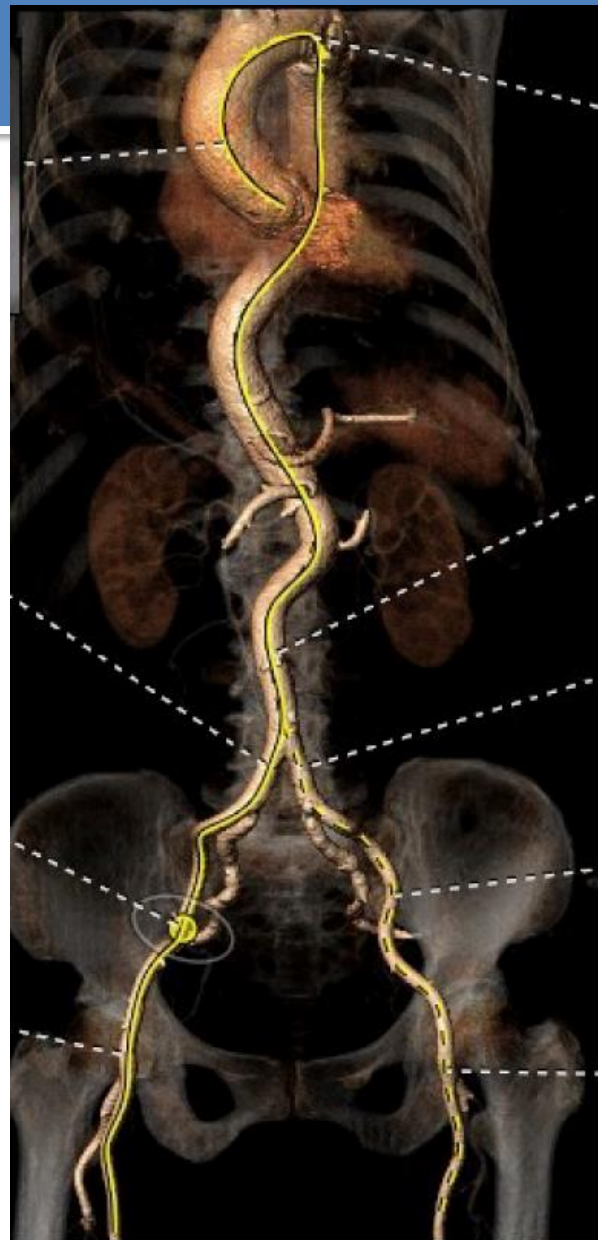
Evolut R 26 mm after predilation (18 mm B)



# Evolut R



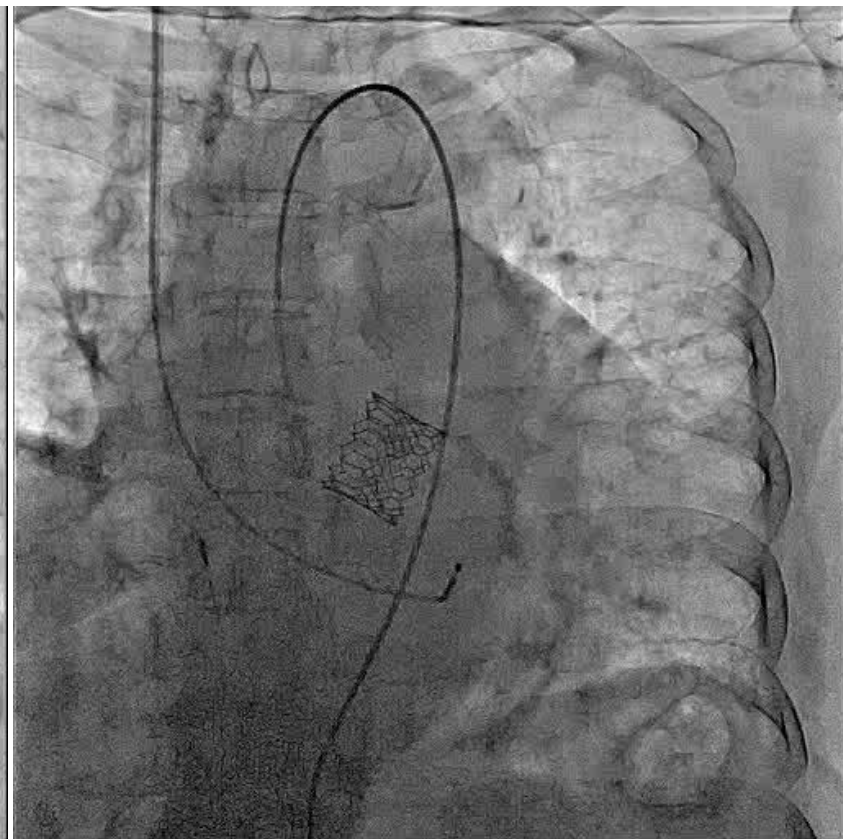
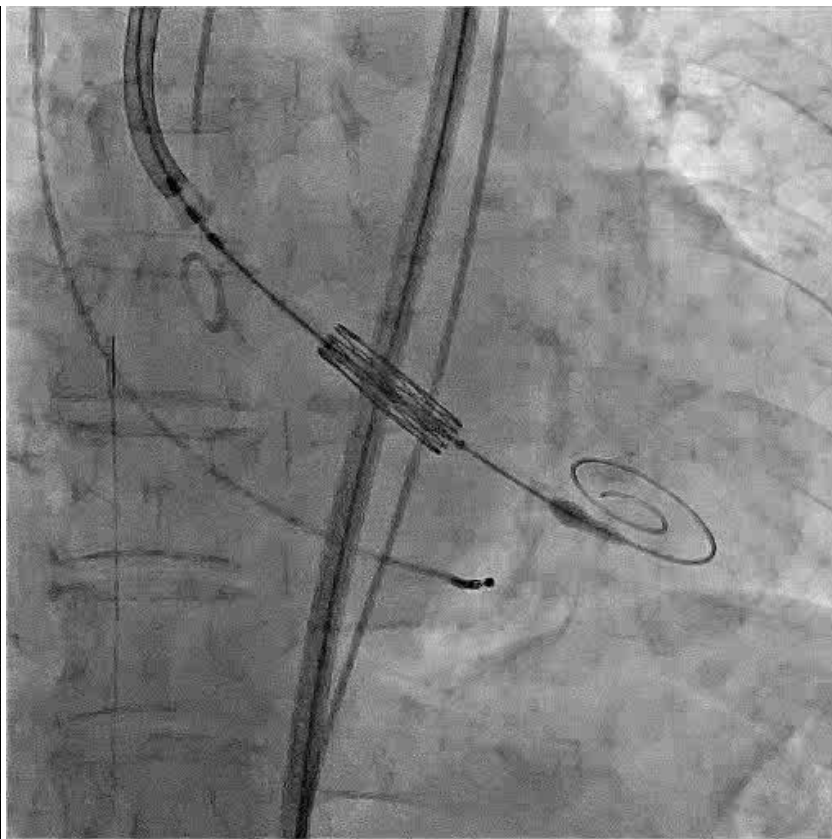
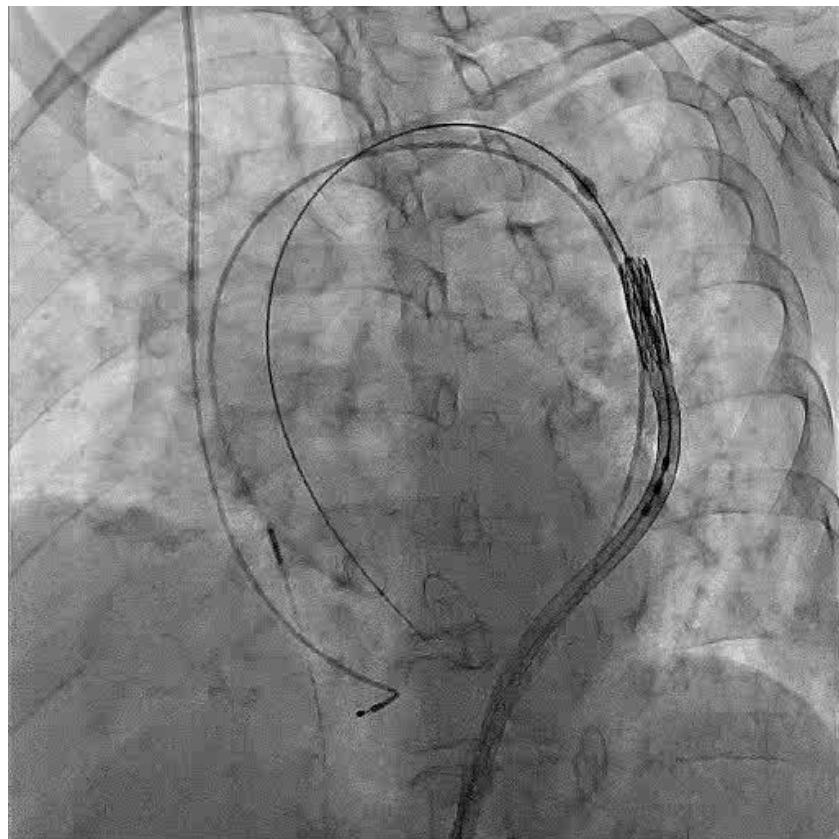
F/81



# F/81



Sapien 3, 26 mm



# Sapien 3 Design: Clinical Benefits

1. Reduced paravalvular leak
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3. Lower incidence of AV conduction disturbance
4. Safe delivery of the valve  
(Prevention of major vascular complications)
5. **Clinical evidence in low-risk patients**

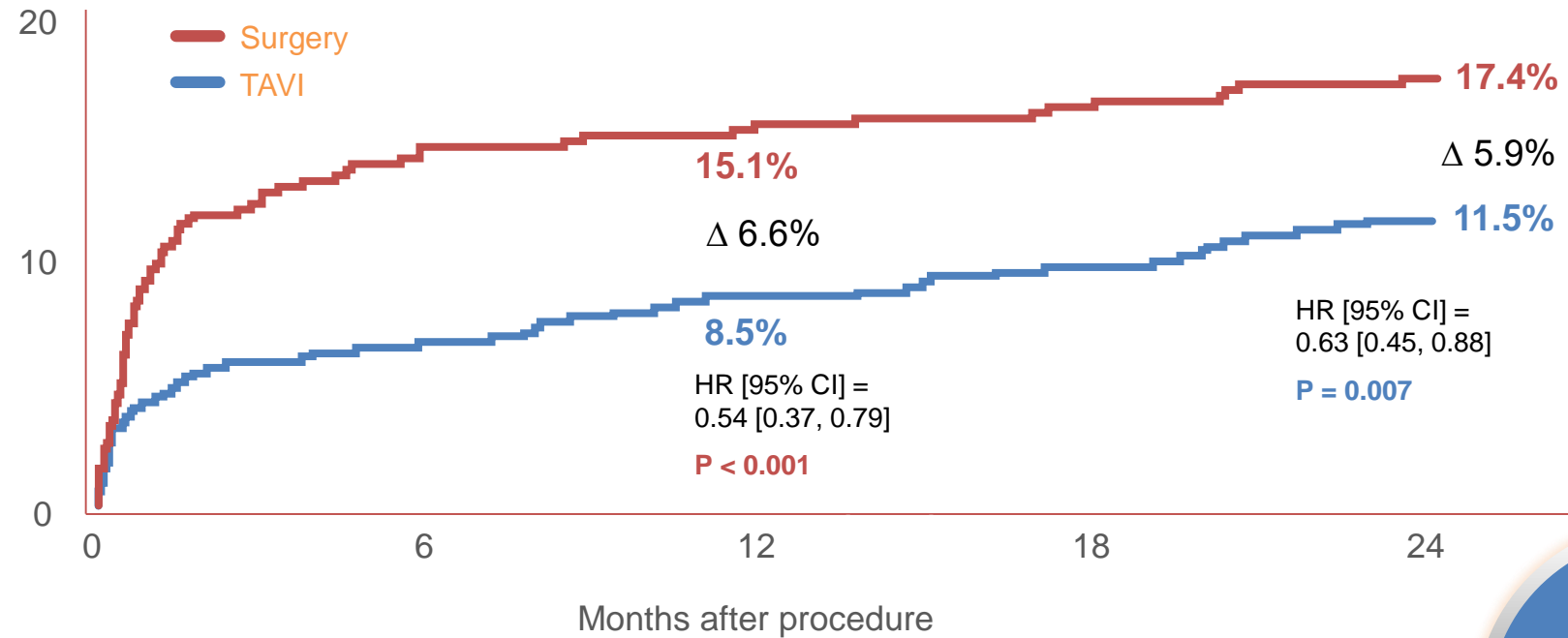




# PARTNER 3: SAPIEN 3 TAVI is Proven superior to Surgery in Low-risk Severe AS Patients

PARTNER 3  
Low Risk Trial:

Primary endpoint<sup>1</sup>  
Death, stroke, or  
rehospitalization



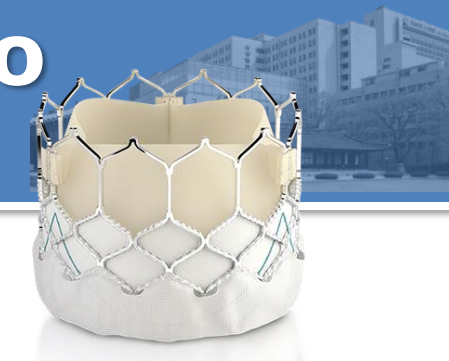
**Number at risk:**

Surgery	454	381	374	352	339
TAVI	496	462	451	436	422

Benefit  
of TAVI  
sustained at  
2 years<sup>2</sup>

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019.  
2. Mack, M. (2020). Two-year Clinical and Echocardiographic Outcomes from the PARTNER 3 Low-risk Randomized Trial. Presented at ACC 2020 March. Virtual ACC.

# PARTNER 3: SAPIEN 3 Proven Superior to Surgery in Various Secondary Endpoints



Subject to Multiplicity Adjustment

Order of Testing	Endpoint	SAPIEN 3 TAVI (N=496)	Surgery (N=454)	P-value
1	New onset atrial fibrillation at 30 days	5.0%	39.5%	<0.001
2	Length of index hospitalization (days)	3.0 (2.0, 3.0)	7.0 (6.0, 8.0)	<0.001
3	All-cause death, all stroke, or rehospitalizations at 1 year	8.5%	15.1%	0.001
4	Death, KCCQ < 45 or KCCQ decrease from baseline ≥ 10 points at 30 days	3.9%	30.6%	<0.001
5	Death or all stroke at 30 days	1.0%	3.3%	0.01
6	All stroke at 30 days	0.6%	2.4%	0.02

	30 Days		1 Year		P-Value
	TAVI	Surgery	TAVI	Surgery	
Life-threatening/Disabling or Major Bleeding	3.6%	24.5%	7.7%	25.9%	<0.001
New-onset Afib	5.0%	39.5%	7.0%	40.9%	<0.001
AKI – stage 2 or 3	0.4%	1.8%	0.4%	1.8%	0.05
Disabling Stroke	0.0%	0.4%	0.2%	0.9%	0.14

\* P-value is Log-Rank test for items 1, 3, 5 and 6; P-value is Wilcoxon Rank-Sum Test for item 2; P-value is Fisher's Exact test for item 4  
 Leon MB, Mack MJ. PARTNER 3: transcatheter or surgical aortic valve replacement in low risk patients with aortic stenosis. Presented at ACC 2019; March 2019; New Orleans, LA



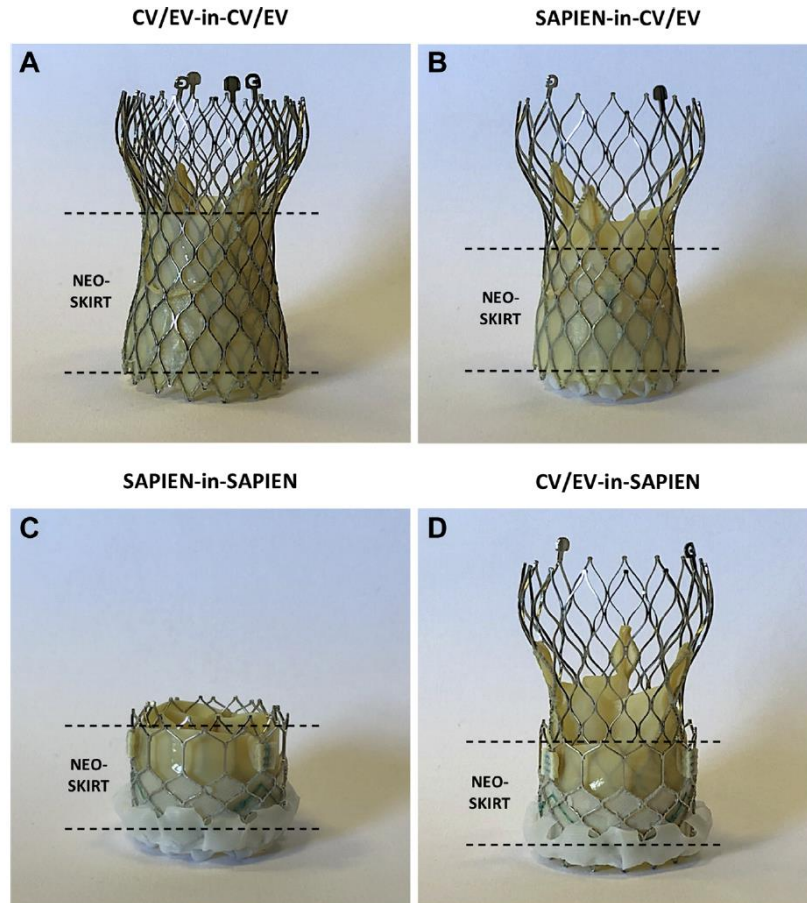
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5. Clinical evidence in low-risk patients
6. Advantage in future TAVR-in-TAVR

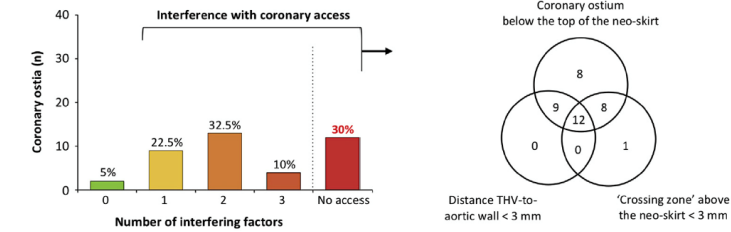


# The Risk for Loss of Coronary Access Is Higher in CoreValve/Evolut-first cases Than in SAPIEN-first cases

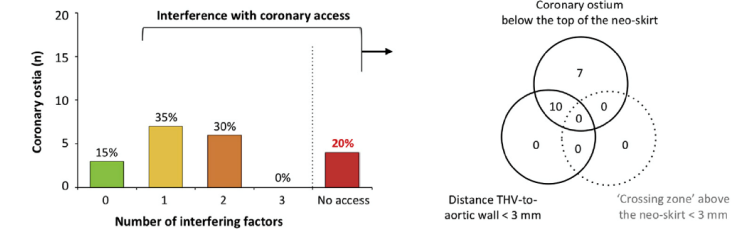
The leaflets of the initial THV will be jailed between the 2 stent frames, thereby establishing a "neo-skirt"



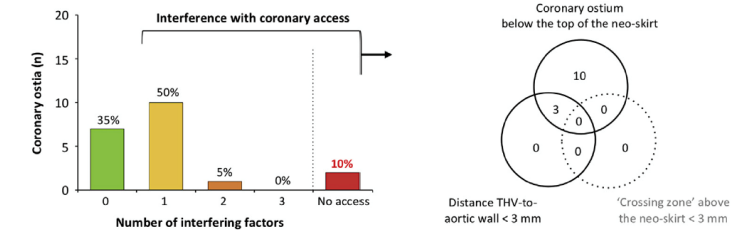
**A** CV/EV-in-CV/EV (n = 40)



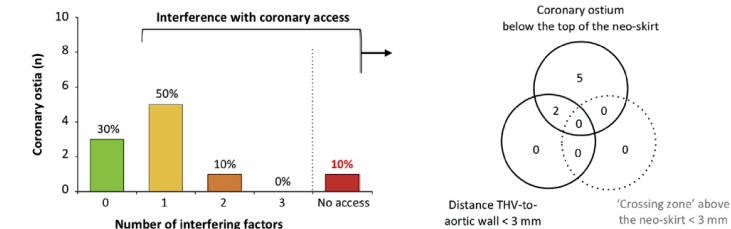
**B** SAPIEN-in-CV/EV (n = 20)



**C** SAPIEN-in-SAPIEN (n = 20)



**D** CV/EV-in-SAPIEN (n = 10)



Backer OD, JACC Intv 2020;13:2528

Severance Cardiovascular Hospital, Yonsei University Health



# Take Home Messages



- Sapien 3 was associated with lower incidences of paravalular leak and AV conduction disturbance which may have adverse impact on long-term clinical outcomes.
- The clinical benefits of Sapien 3 was well demonstrated in PARTNER 3 trial with low surgical risk patients.
- Sapien 3 enables future coronary access easier due to the low frame height and larger frame cell size.
- Especially, when consider coronary access after TAVR-in-TAVR, first BEV TAVR is more advantageous than first SEV TAVR.
- Thus, Sapien 3 should be preferred in younger and low-risk patients undergoing TAVR unless other factors favor other valve types.

