# TAVR Remaining Unmet Needs: Valve in Valve

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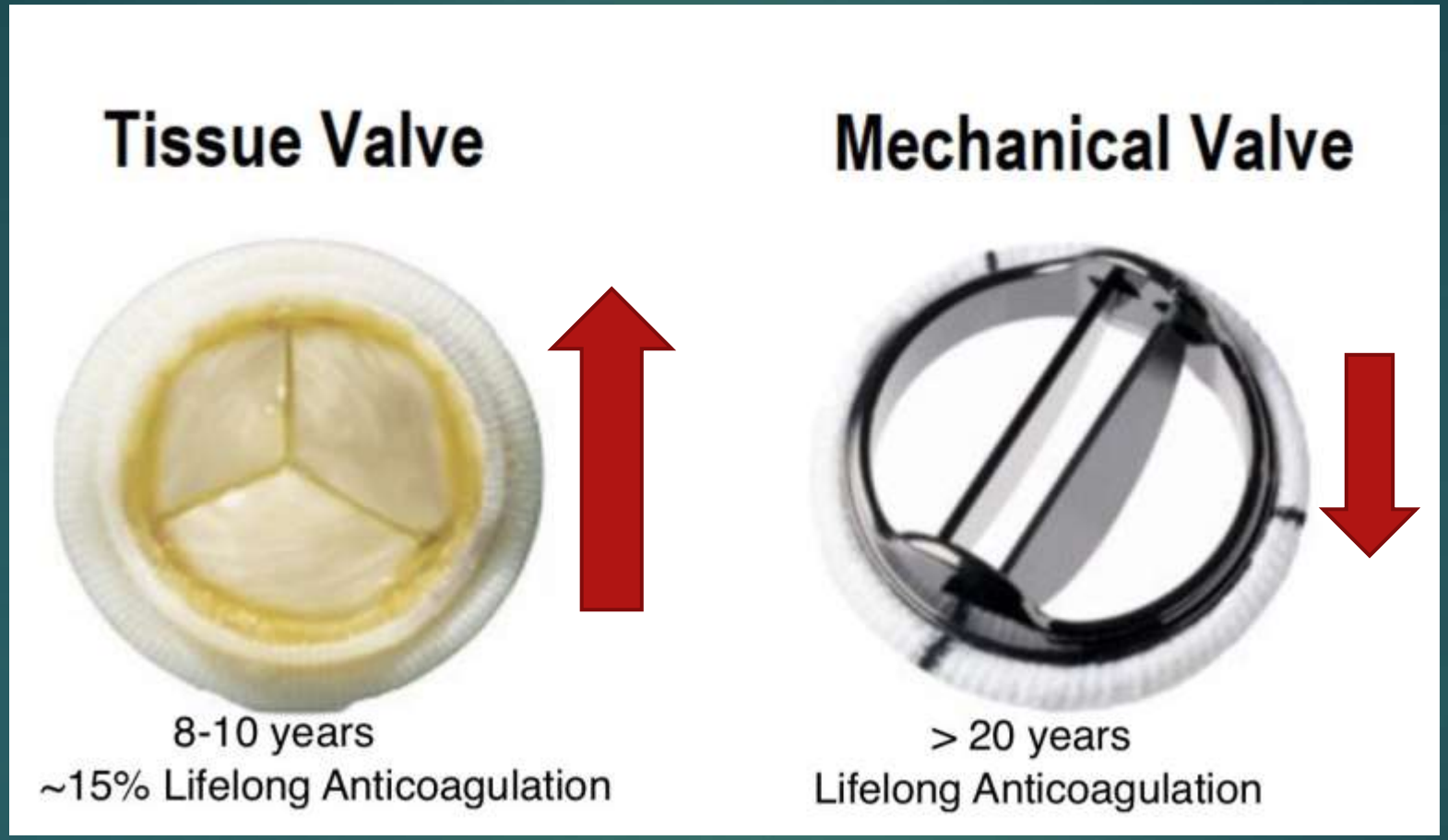
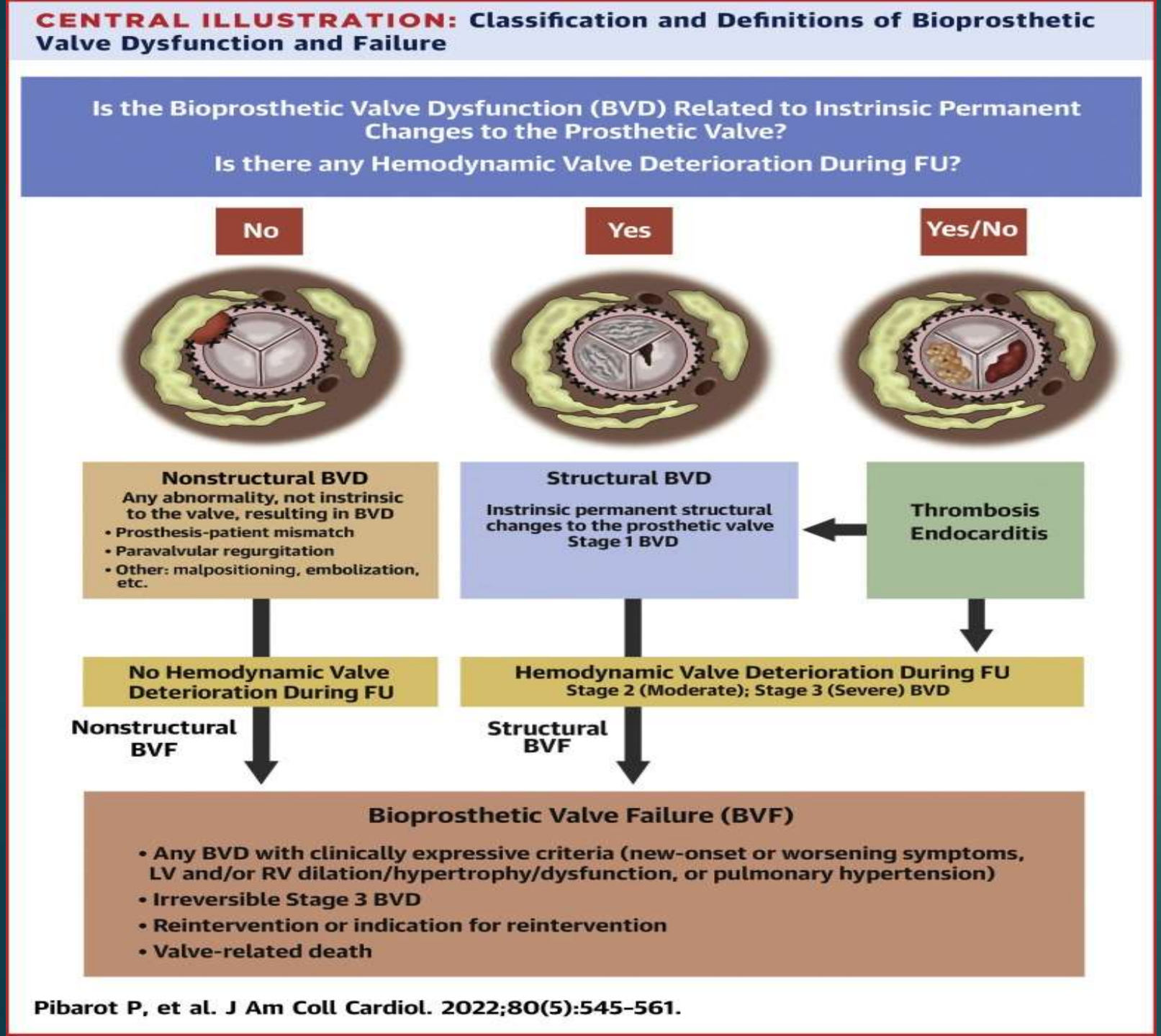
The use of bioprosthetic SAVR has been steadily increasing in people aged 50–70 years over the past decade.




driven by the desire to avoid long-term anticoagulation and the development of novel percutaneous treatment options.




- Current-generation bioprosthetic valves remain prone to structural valve deterioration and have finite durability.
- This has significant implications for the younger, low-risk populations whose life-expectancy may exceed that of the initial surgical valve

# The term “ViV TAVR”

- TAVR inside of a degenerated surgical valve (TAVR-in-SAVR),
- TAVR inside of a degenerated TAVR valve (TAVR-in-TAVR),
- TAVR inside of a TAVR valve, which was previously placed in degenerated SAVR valves (TAVR-in-TAVR-inSAVR)

# Transcatheter Aortic Valve-In-Valve Implantation for Severe Bioprosthetic Stenosis after Bentall Operation Using a Homograft in a Patient with Behçet's Disease

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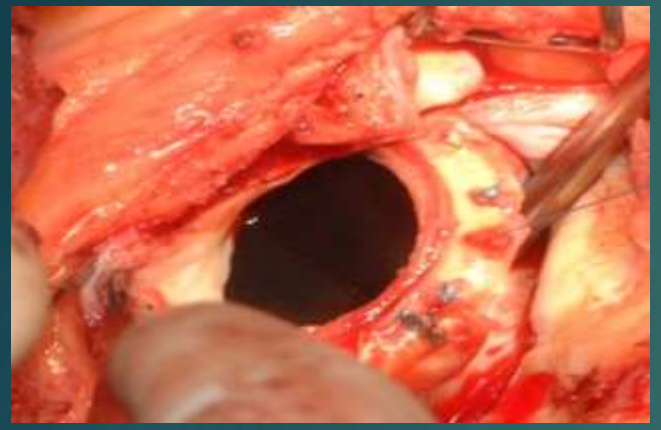

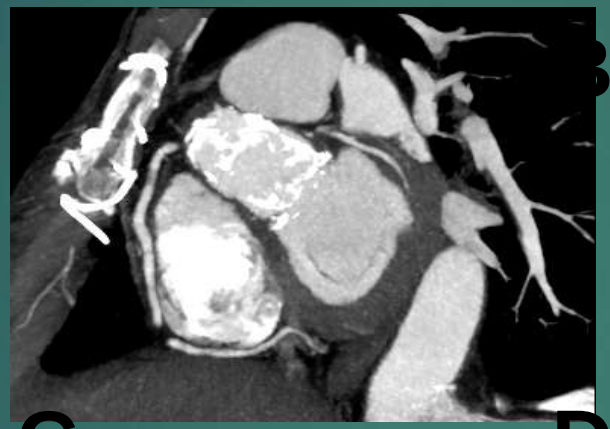

C

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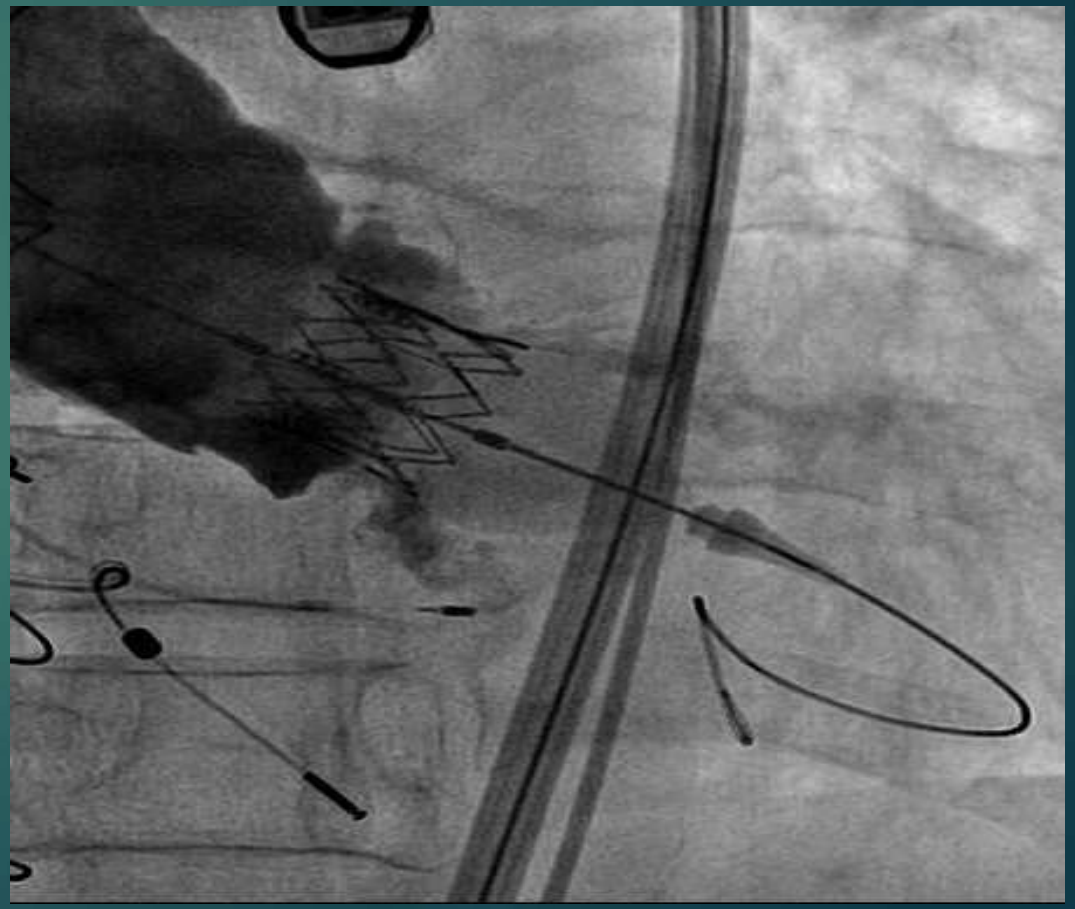
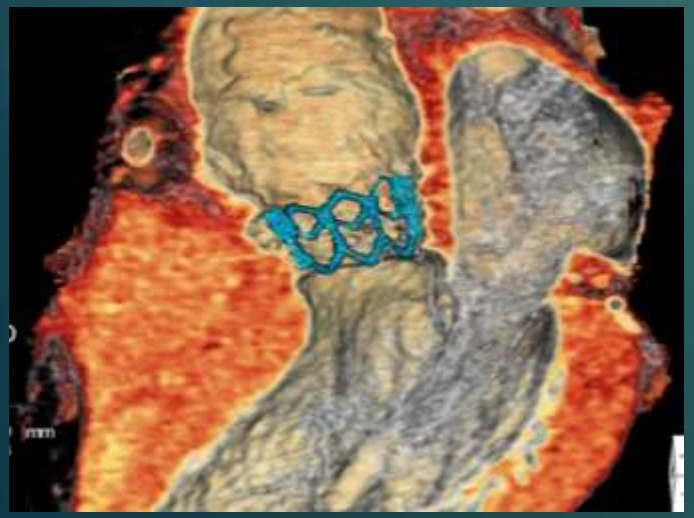
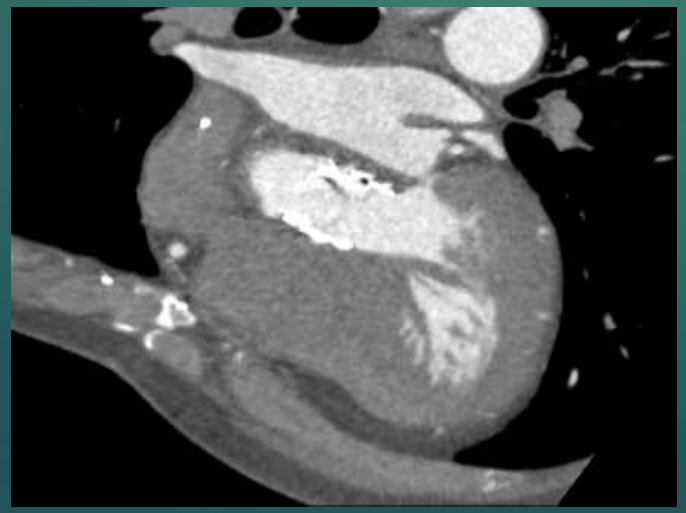
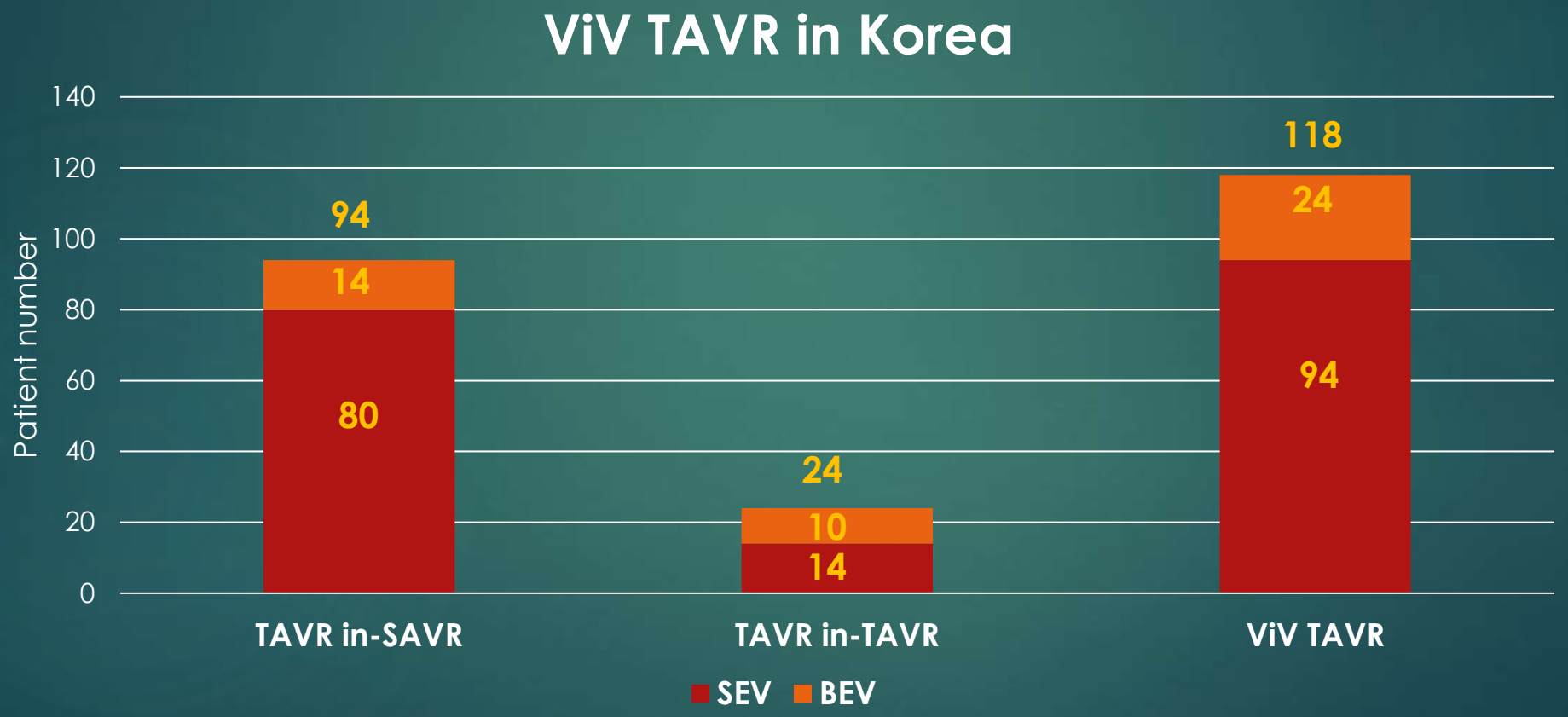









Unpublished data

# Type of failed bioprostheic valve type in Korea data (SEV)

| TAVR in-SAVR | |
|---|---|
| Failed Surgical valve | |
| Perimount | 19 |
| Magna | 20 |
| Hancock | 8 |
| Epic | 8 |
| Freestyle | 6 |
| Mitroflow | 7 |
| Mosaic | 4 |
| Perceval L | 1 |
| Prima | 5 |
| St.Jude Biocor | 1 |
| Trifecta | 1 |
| Grand Total | 80 |

| TAVI in TAVI | | | | | |
|---|---|---|---|---|---|
| Failed TAVI Valve | | | The 1st fialed Valve type | | |
| CoreValve | 1 | | Balloon Expendable type | 12 | 85.7% |
| Evolut Pro | 1 | | Self Expendable type | 2 | 14.3% |
| Sapien | 2 | | Grand Total | 14 | |
| Sapien XT | 6 | | | | |
| Sapien3 | 3 | | | | |
| SapienXT | 1 | | | | |
| Grand Total | 14 | | | | |

Unpublished data

# Valve-in-valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves

1. **ViV TAVR Outcomes**
2. **Preprocedural Planning for ViV TAVR**
3. **Choice of Transcatheter Heart Valve for ViV TAVR**
4. **Pitfalls of ViV TAVR**
    1. Coronary Obstruction Risk and Mitigation Strategies
5. **Patient–Prosthesis Mismatch**

# Valve-in-valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves and Adjunctive Therapies

## 1. ViV TAVR Outcomes

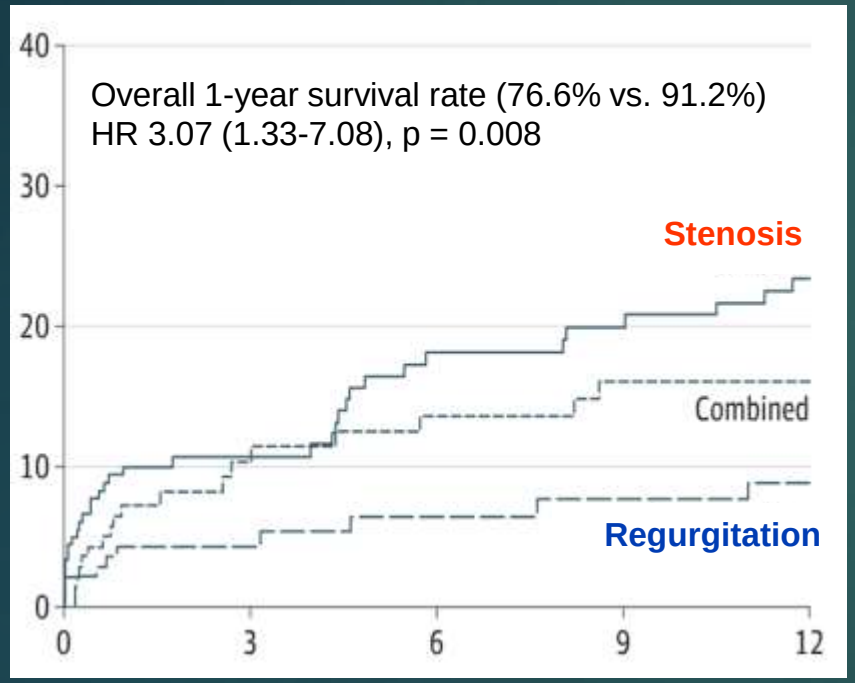
# TAVR for degenerative bioprosthetic surgical valves: Valve-in-Valve Registry

- **Treating a failed bioprosthesis via TAVR**
  Feasible and often effective but technically demanding
- **The Global Valve-in-Valve Registry**
  - 416 high-risk patients
  - 54 centers in Europe, North America, Australia, New Zealand, and the Middle East
  - 225 Sapien (Edwards) /190 CoreValve /1 Melody (Medtronic)
- **"Relatively high rates" of Complications**
  - initial device malapposition / attempted valve retrieval
  - implantation of a second device
  - post-implantation valvuloplasty
  - need for emergent surgery
  - clinically-evident coronary obstruction
- **Improvement of functional capacity at 30 days**
  **87.5% of patients classified as NYHA class I/IIs**

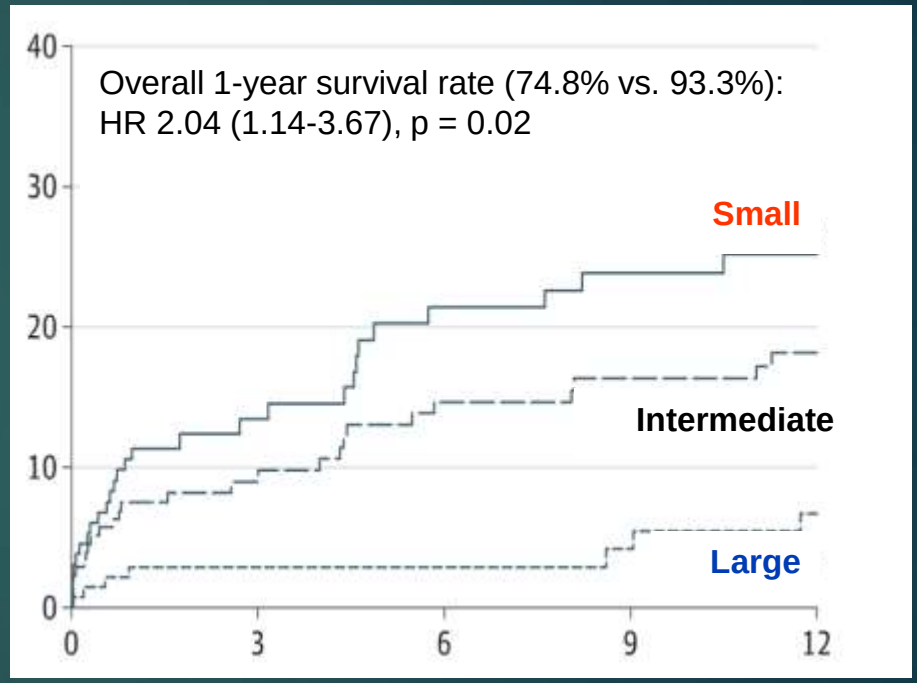
Danny Dvir, MD, Washington Heart Center

# Valve-In Valve TAVR in VIVID registry

Predominant Bioprostheses
Stenosis vs. Regurgitation




Size of Bioprostheses
Small vs. Large



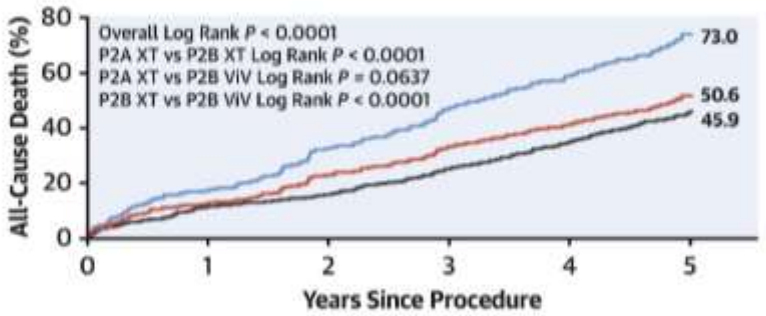

A total of 459 patients with degenerated bioprosthetic valves undergoing valve-in-valve were evaluated.

*Dvir D et al. JAMA. 2014;312(2):162-170*

# PARTNER 2 Valve-in-Valve Registry

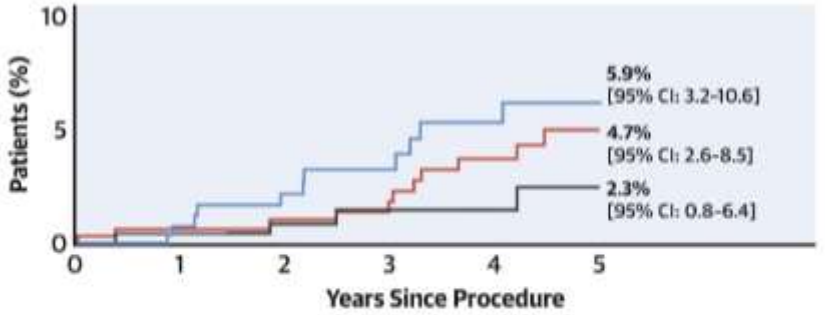
## Transcatheter Valve-in-Valve (ViV) 5-Year Outcomes in High Surgical Risk Patients

A




| No. at risk: | | | | | | |
|---|---|---|---|---|---|---|
| P2B XT (Inoperable) | 280 | 217 | 177 | 147 | 111 | 46 |
| P2B XT ViV (High Risk) | 365 | 320 | 274 | 234 | 190 | 141 |
| P2A XT (Intermediate Risk) | 974 | 854 | 800 | 696 | 592 | 311 |

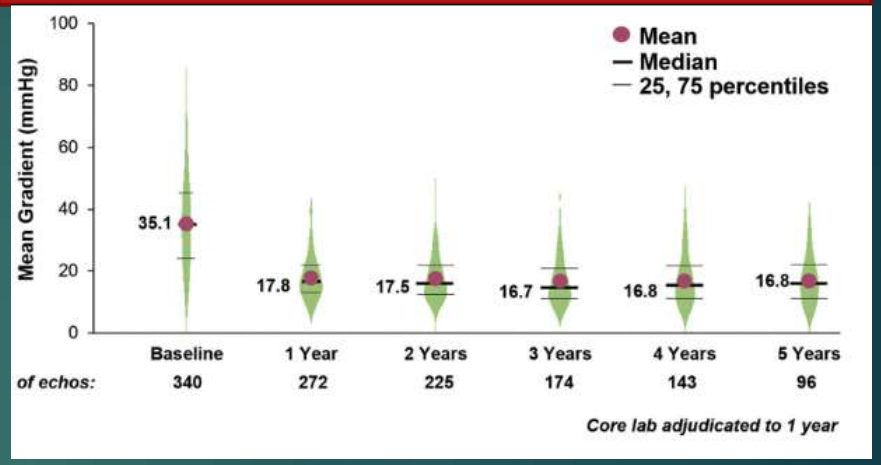
B



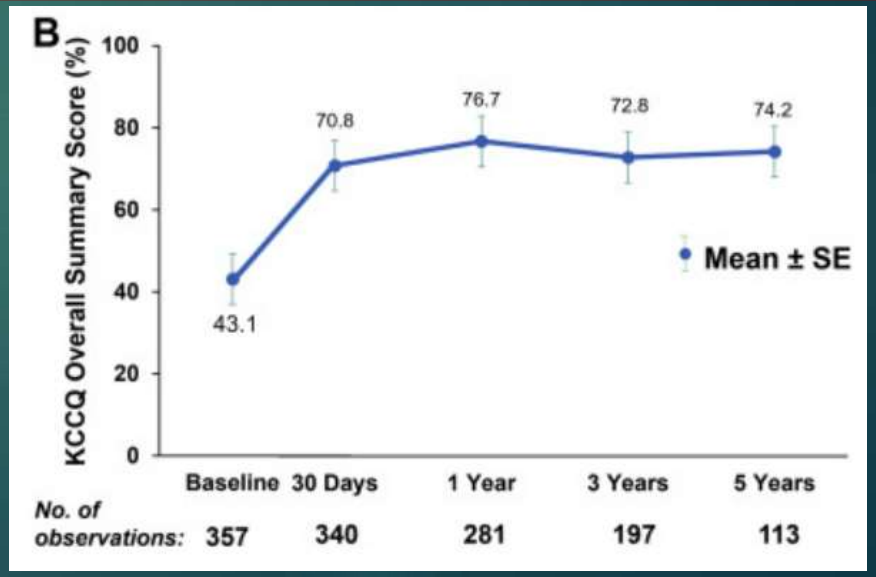

| No. at risk: | | | | | | |
|---|---|---|---|---|---|---|
| SVD-Related HVD | 273 | 251 | 201 | 158 | 125 | 86 |
| All BVF | 365 | 319 | 272 | 231 | 185 | 137 |
| SVD-Related BVF | 273 | 253 | 205 | 162 | 131 | 92 |

Hahn RT, et al. J Am Coll Cardiol Intv. 2022;15(7):698-708.

## A. Changes in hemodynamics




## B. Changes in function and quality of life

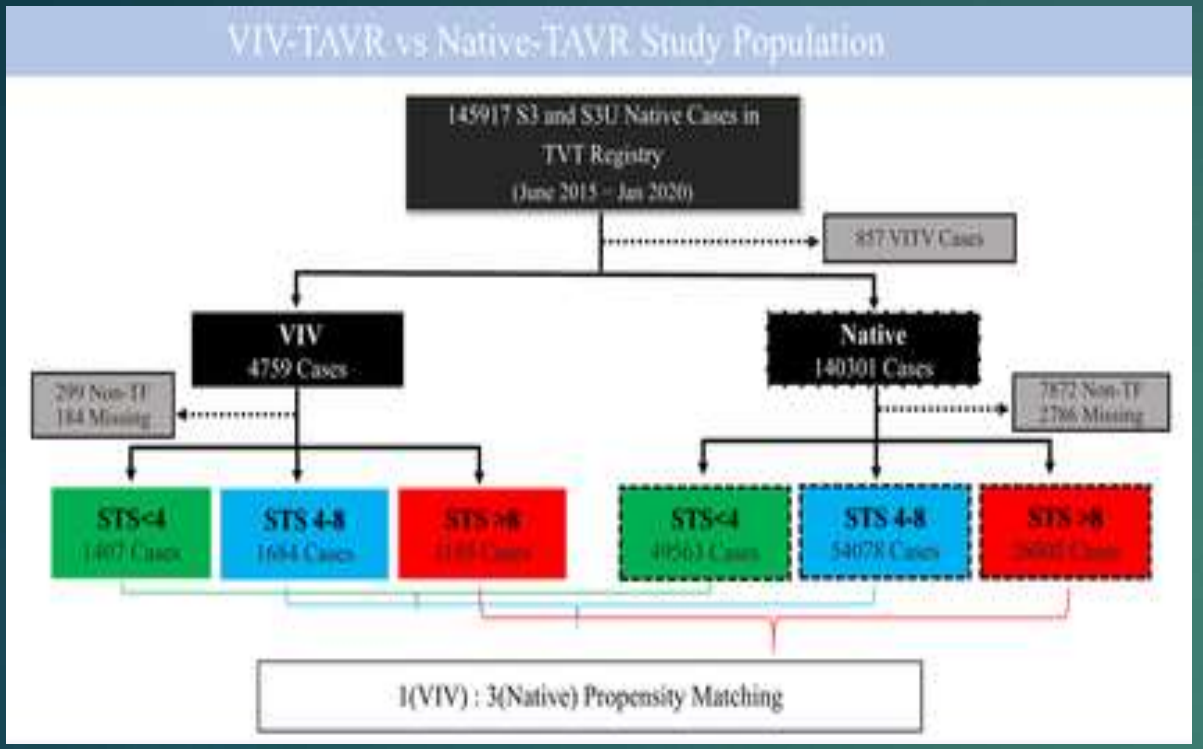


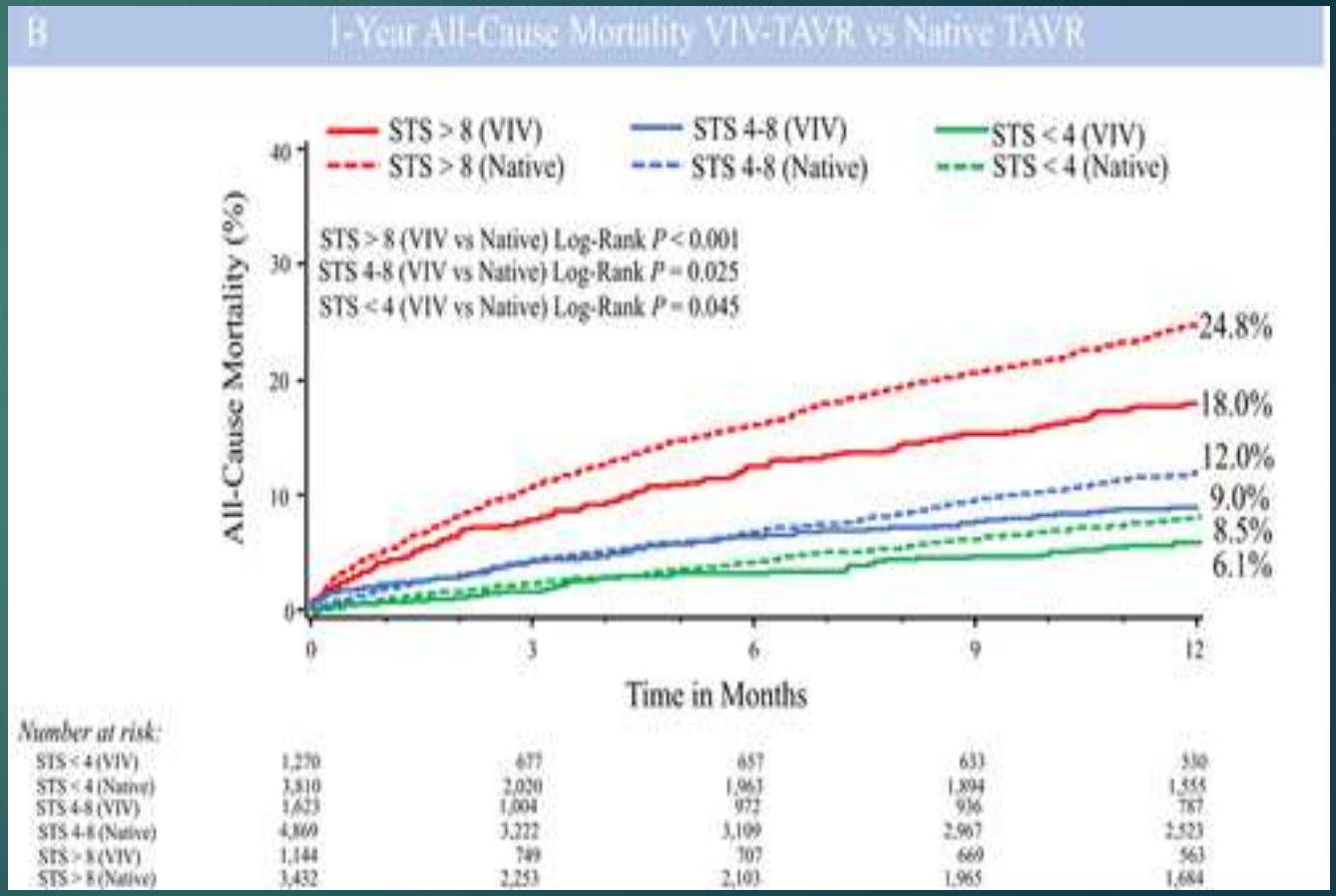
# Large studies of aortic VIV-TAVR in high-risk patients

| | VIVID Aortic | PARTNER 2 | CoreValve US | VIVA | TVT |
|---|---|---|---|---|---|
| N | 2,318 | 365 | 227 | 202 | 1,150 |
| Age (years) | 78 | 79 | 77 | 80 | 79 |
| STS (mean) | 8.8% | 9.1% | 9.0% | 6.6% | 6.9% |
| Outcomes at 30 days | | | | | |
| Mortality | 4.4% | 2.7% | 2.2% | 2.5% | 2.9% |
| Stroke | 1.4%** | 2.7% | 0.9% | 3.0% | 1.7% |
| Coronary obstruction | 2.3% | 0.8% | 0.9% | 2.0% | 0.6% |
| Annular rupture | 0% | 0% | 0% | 0% | 0% |
| PVL >=moderate | 5.2% | 3.2% | 3.5% | 2.0% | 3.3% |
| Conversion to open surgery | 0.7% | 0.6% | 0.5% | 0.5% | 0.2% |
| New pacemaker | 6.7% | 1.9% | 8.1% | 7.0% | 3.0% |
| Mean gradient (median | 16.2 | 17.7 | 17.0 | 12.2 | 16.0 |
| Valve area (cm2) | 1.2 | 1.1 | 1.4 | 1.5 | 1.3 |
| Length of stay (days) | 7 | 5 | - | 7 | 3 |
| Mortality at 1 year | 13.3% | 12.4% | 14.6% | - | 11.7% |

*unpublished 2012-2017 update, **major stroke only

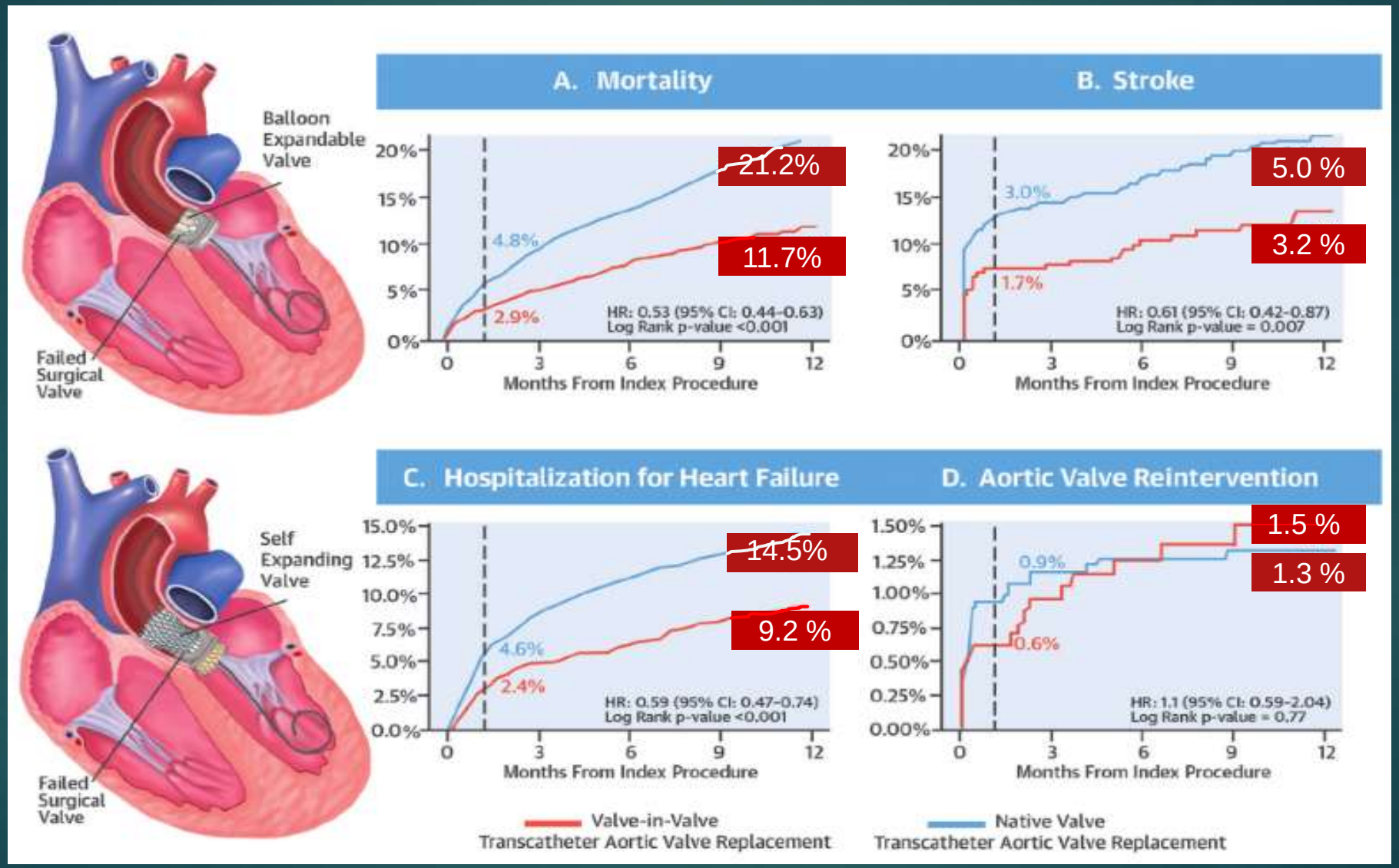
# Valve-In Valve TAVR vs. Native TAVR



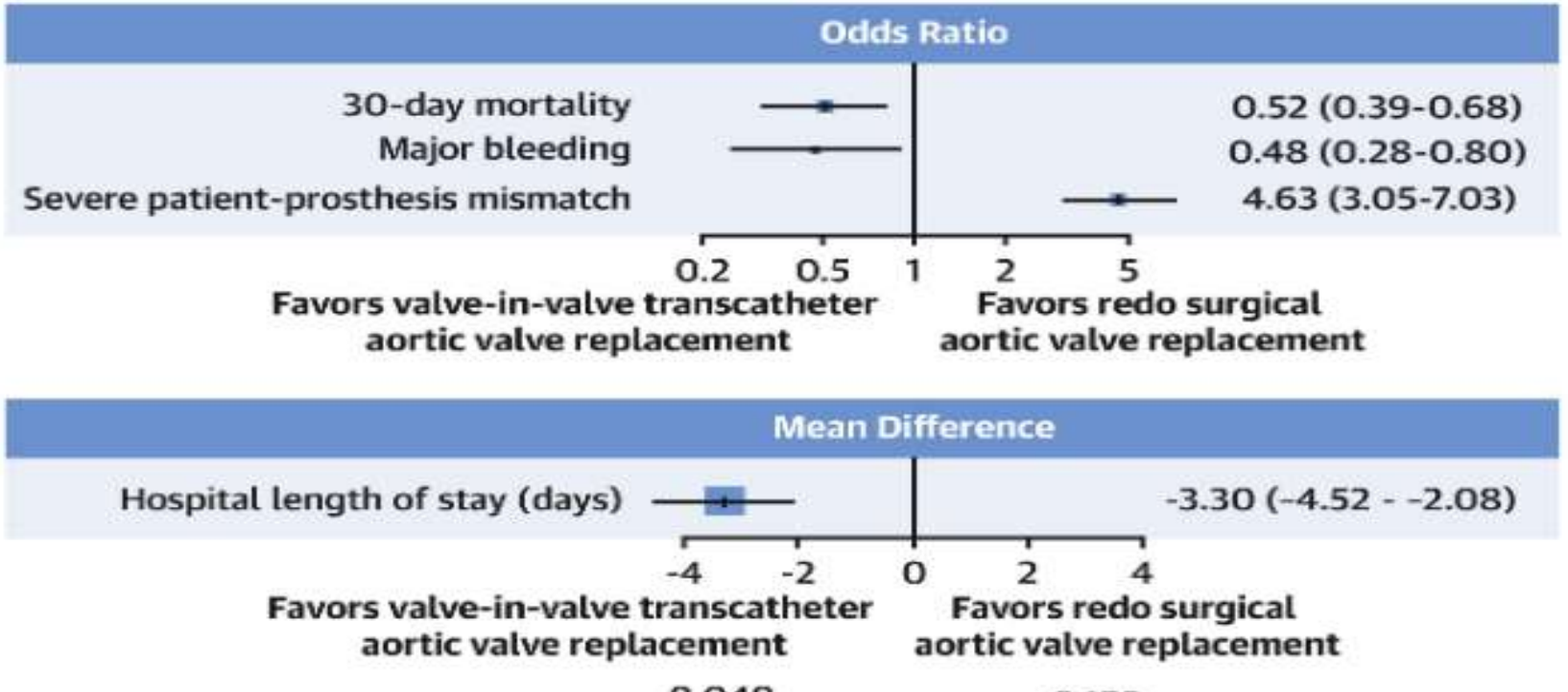

Kaneko T, et al., Circ Cardiovasc Interv. 2021 May;14(5)

# ViV TAVR Vs. Native TAVR




*Tuzcu, E.M. et al. JACC 2018*

# ViV TAVR Versus redo-SAVR




*Sa, M.P.B.O. et al. JACC Intv. 2021;14(2):211-20*

# ViV TAVR vs. Redo-SAVR: 30 day mortality and 1 year mortality…

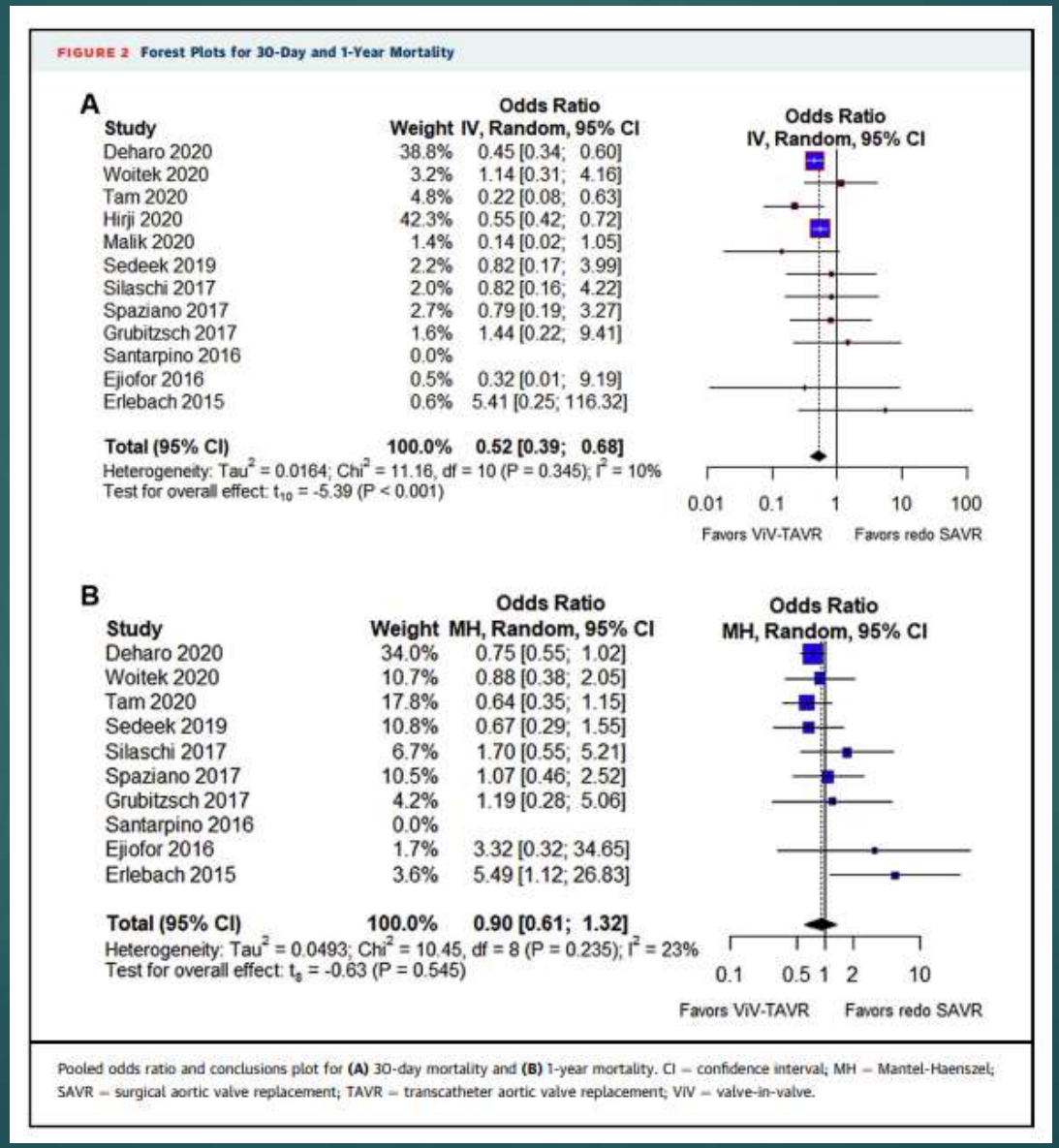


FIGURE 2 Forest Plots for 30-Day and 1-Year Mortality

**A**

| Study | Weight | Odds Ratio IV, Random, 95% CI |
|---|---|---|
| Deharo 2020 | 38.8% | 0.45 [0.34; 0.60] |
| Woitek 2020 | 3.2% | 1.14 [0.31; 4.16] |
| Tam 2020 | 4.8% | 0.22 [0.08; 0.63] |
| Hirji 2020 | 42.3% | 0.55 [0.42; 0.72] |
| Malik 2020 | 1.4% | 0.14 [0.02; 1.05] |
| Sedeek 2019 | 2.2% | 0.82 [0.17; 3.99] |
| Silaschi 2017 | 2.0% | 0.82 [0.16; 4.22] |
| Spaziano 2017 | 2.7% | 0.79 [0.19; 3.27] |
| Grubitzsch 2017 | 1.6% | 1.44 [0.22; 9.41] |
| Santarpino 2016 | 0.0% | |
| Ejiofor 2016 | 0.5% | 0.32 [0.01; 9.19] |
| Erlebach 2015 | 0.6% | 5.41 [0.25; 116.32] |
| **Total (95% CI)** | **100.0%** | **0.52 [0.39; 0.68]** |

Heterogeneity: $Tau^2 = 0.0164$; $Chi^2 = 11.16$, df = 10 (P = 0.345); $I^2 = 10\%$
Test for overall effect: $t_{10} = -5.39$ (P < 0.001)

Odds Ratio IV, Random, 95% CI

0.01 0.1 1 10 100

Favors ViV-TAVR Favors redo SAVR

**B**

| Study | Weight | Odds Ratio MH, Random, 95% CI |
|---|---|---|
| Deharo 2020 | 34.0% | 0.75 [0.55; 1.02] |
| Woitek 2020 | 10.7% | 0.88 [0.38; 2.05] |
| Tam 2020 | 17.8% | 0.64 [0.35; 1.15] |
| Sedeek 2019 | 10.8% | 0.67 [0.29; 1.55] |
| Silaschi 2017 | 6.7% | 1.70 [0.55; 5.21] |
| Spaziano 2017 | 10.5% | 1.07 [0.46; 2.52] |
| Grubitzsch 2017 | 4.2% | 1.19 [0.28; 5.06] |
| Santarpino 2016 | 0.0% | |
| Ejiofor 2016 | 1.7% | 3.32 [0.32; 34.65] |
| Erlebach 2015 | 3.6% | 5.49 [1.12; 26.83] |
| **Total (95% CI)** | **100.0%** | **0.90 [0.61; 1.32]** |

Heterogeneity: $Tau^2 = 0.0493$; $Chi^2 = 10.45$, df = 8 (P = 0.235); $I^2 = 23\%$
Test for overall effect: $t_8 = -0.63$ (P = 0.545)

Odds Ratio MH, Random, 95% CI

0.1 0.5 1 2 10

Favors ViV-TAVR Favors redo SAVR

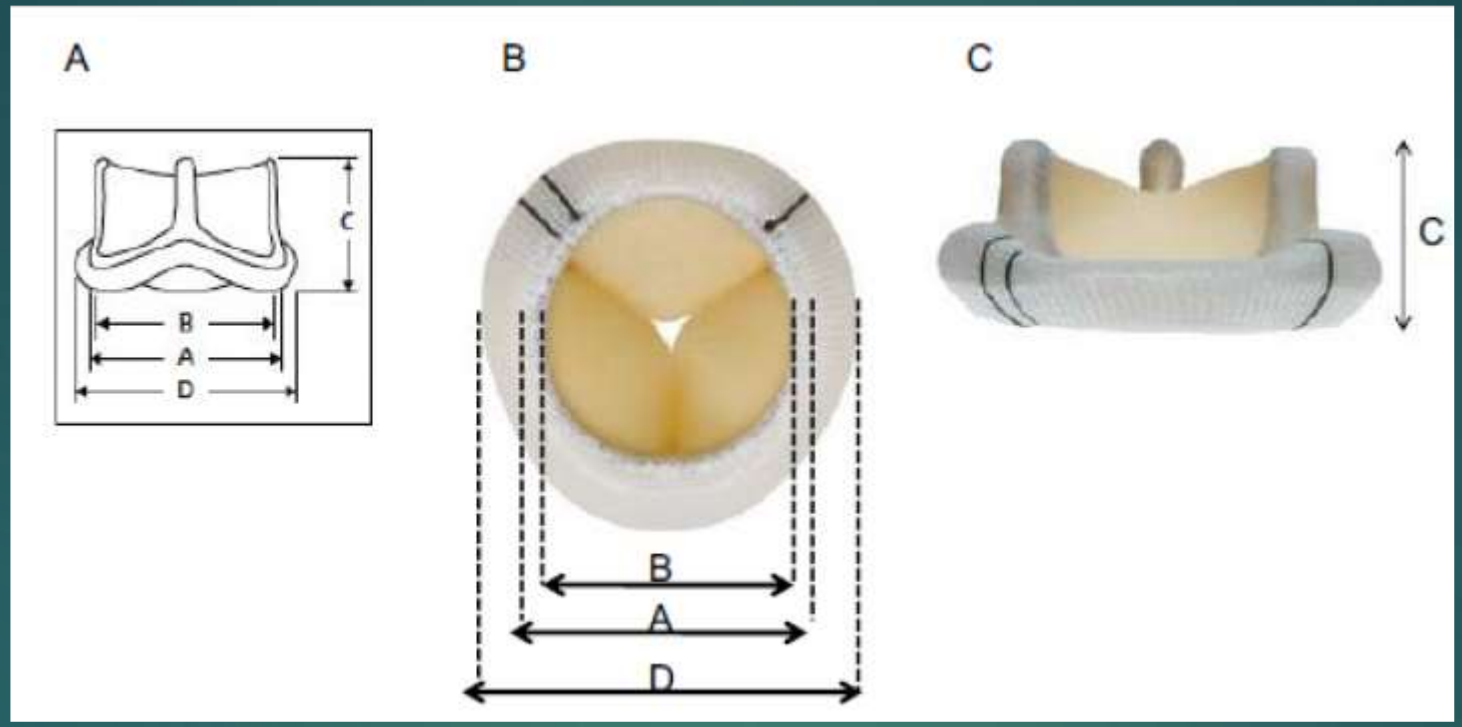
Pooled odds ratio and conclusions plot for **(A)** 30-day mortality and **(B)** 1-year mortality. CI = confidence interval; MH = Mantel-Haenszel; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; ViV = valve-in-valve.

*Sa, M.P.B.O. et al. JACC Intv. 2021;14(2):211-20*

# Valve-in-valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves

1. ViV TAVR Outcomes
2. Preprocedural Planning for ViV TAVR

# Dimensions of Stented Bioprosthetic Valves




( A) Diagrammatic representation of stented bioprosthetic valve dimensions

A outer stent diameter

B inner stent diameter

C prosthesis height

D outer sewing ring diameter.

(B) Inferior (ventricular) view of stented bioprosthesis.

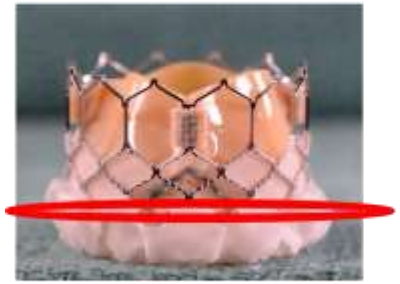
(C) Side view of stented bioprosthesis.

Piazza, N, et al. JACC Cardiovasc Interv. 2011;4:721-32.

# Which is the appropriated implant place?

- Valve should be positioned based on neo-annulus
  - Sapien – ***10-15 % below***
  - CoreValve – ***3-4 mm below or less***

**Sewing ring**

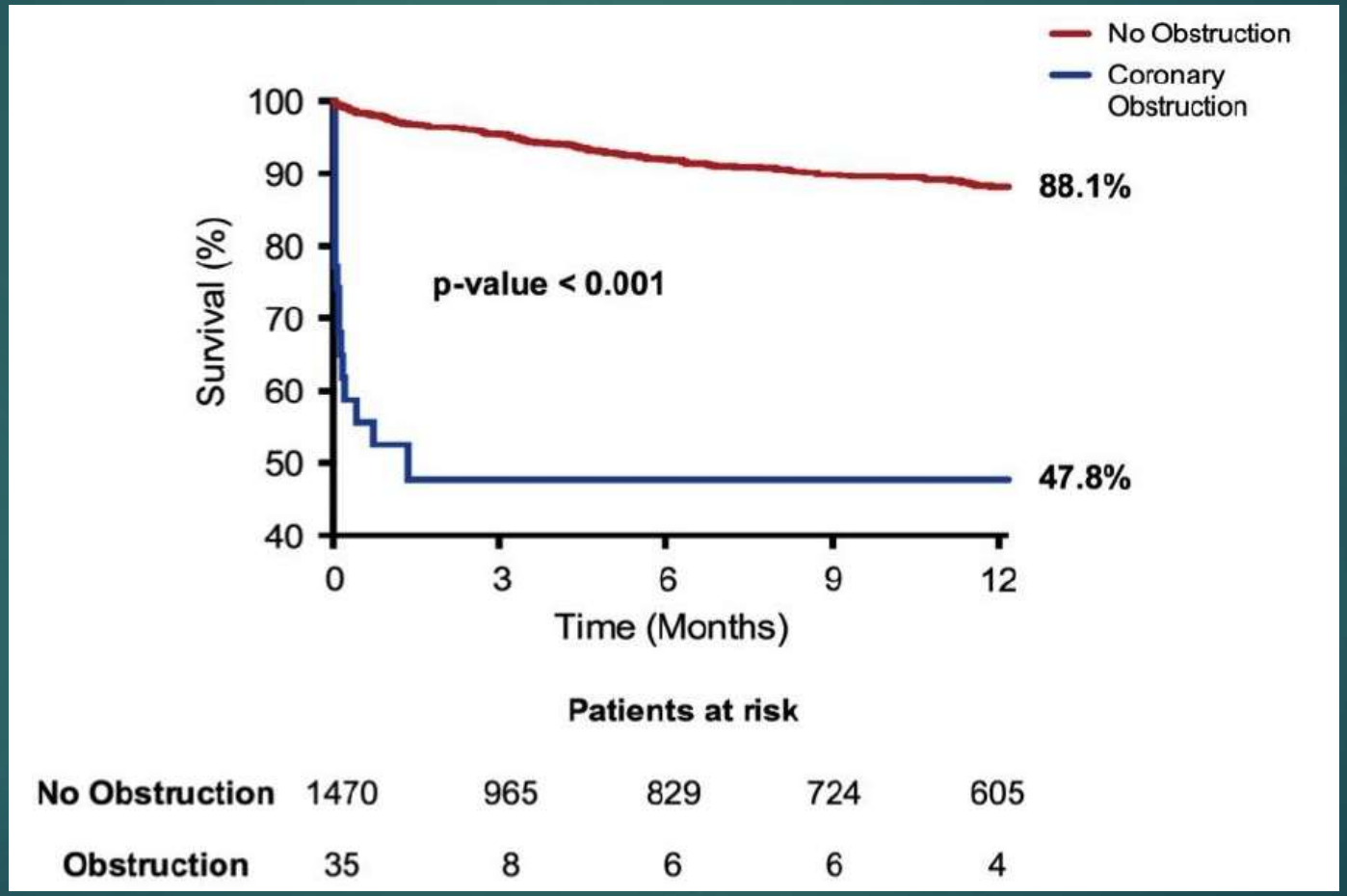


Sapien 3
15%

Evolut R
4mm

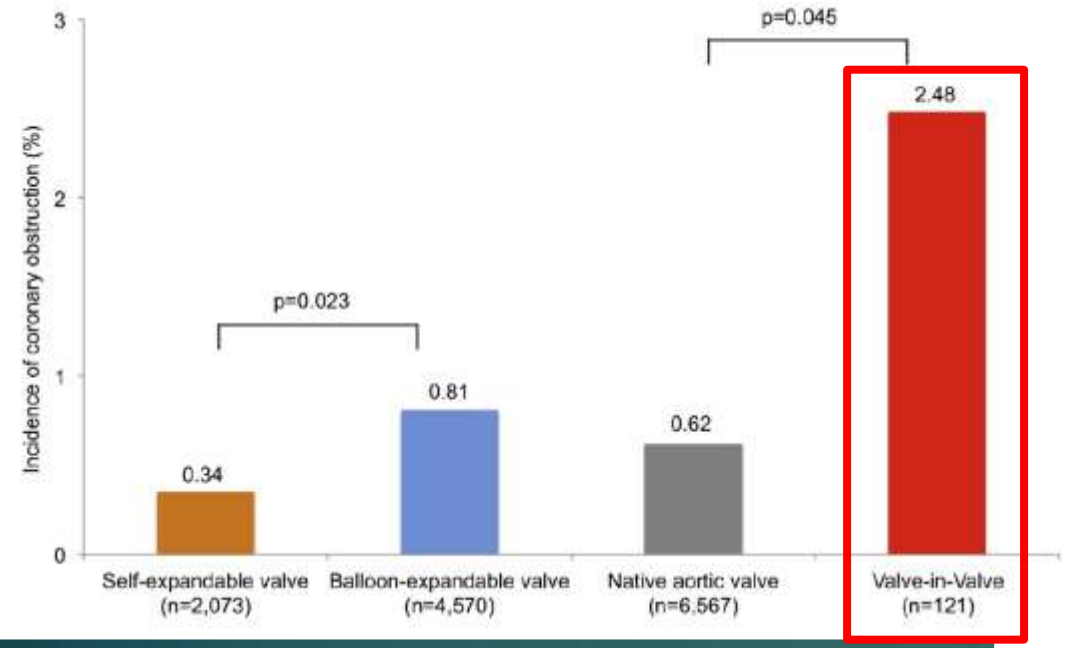
- Malposition leads to improper seal and anchoring
  - Too high
    - Embolization / Coronary occlusion
  - Too low
    - PVL
    - Poor hemodyanamics

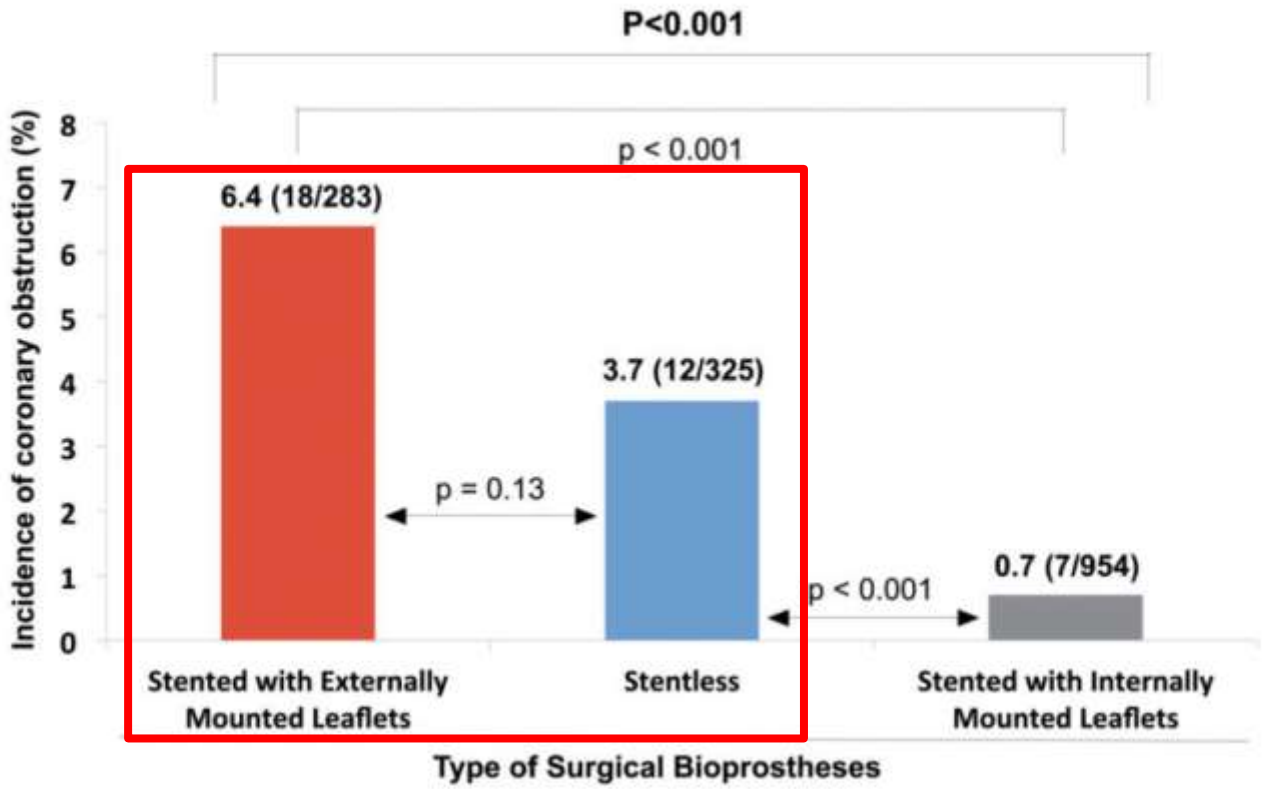
# Coronary Obstruction after Valve-in-Valve procedure




*Ribeiro HB et al. TCT 2016*

# Coronary obstruction is more common during VIV procedure

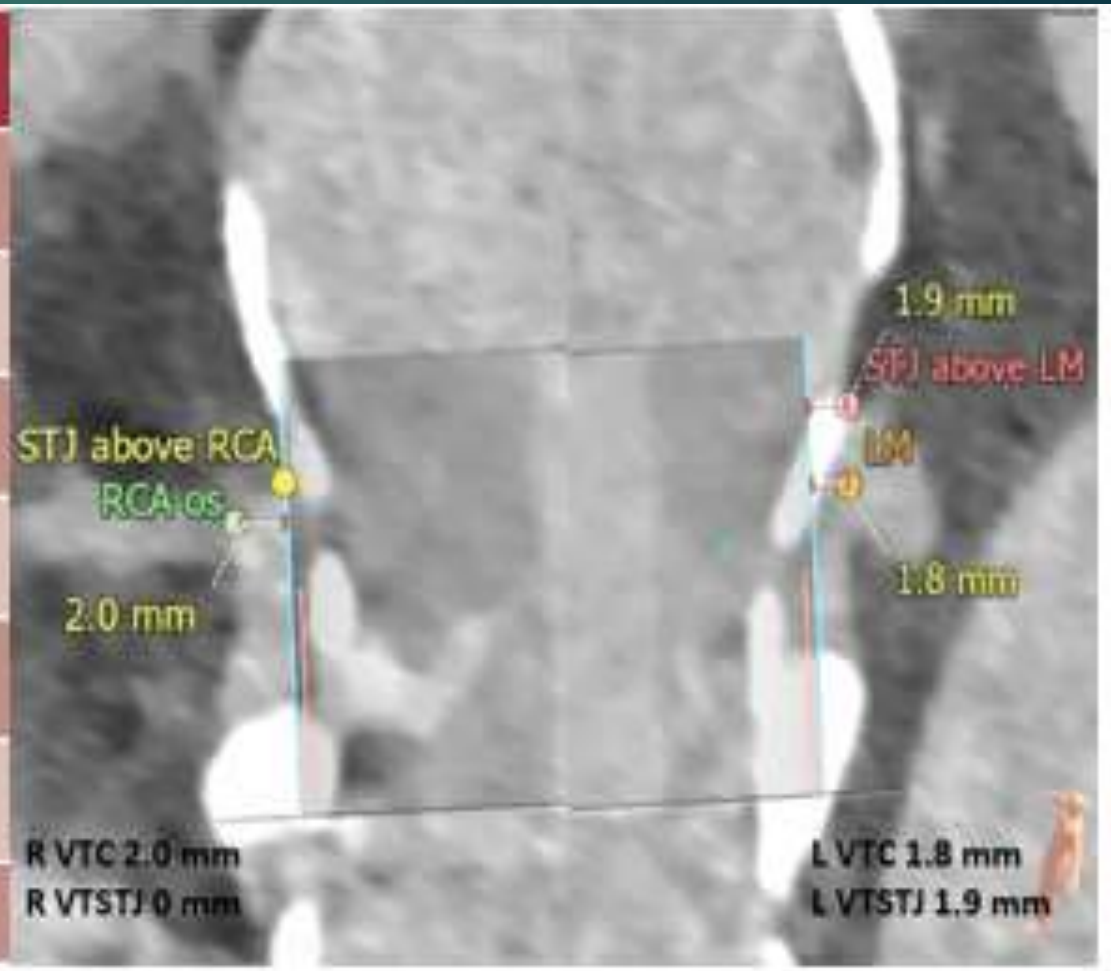



Ribeiro H et al. J Am Coll Cardiol 2013;62:1552–62
Ribeiro H et al. VIVID registry. EHJ 2017 (in press)

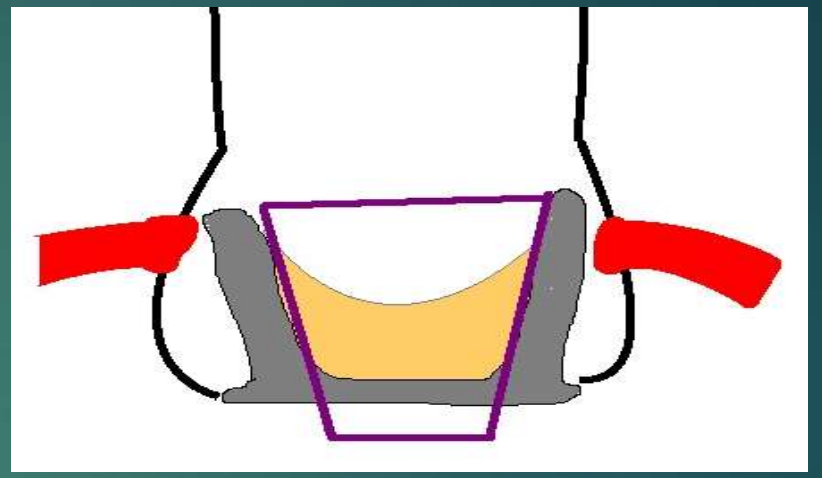
# Predictors for coronary obstruction with ViV TAVR

| Risk factors | High obstruction risk |
|---|---|
| Coronary height | <10 mm |
| Sinus width | <30 mm |
| Bioprosthetic leaflet length | Above coronary ostia |
| STJ height | Below coronary leaflets |
| Prosthetic leaflet orientation | Externally mounted |
| Valve-to-coronary distance | <4 mm |
| Valve-to-STJ distance | <2 mm |



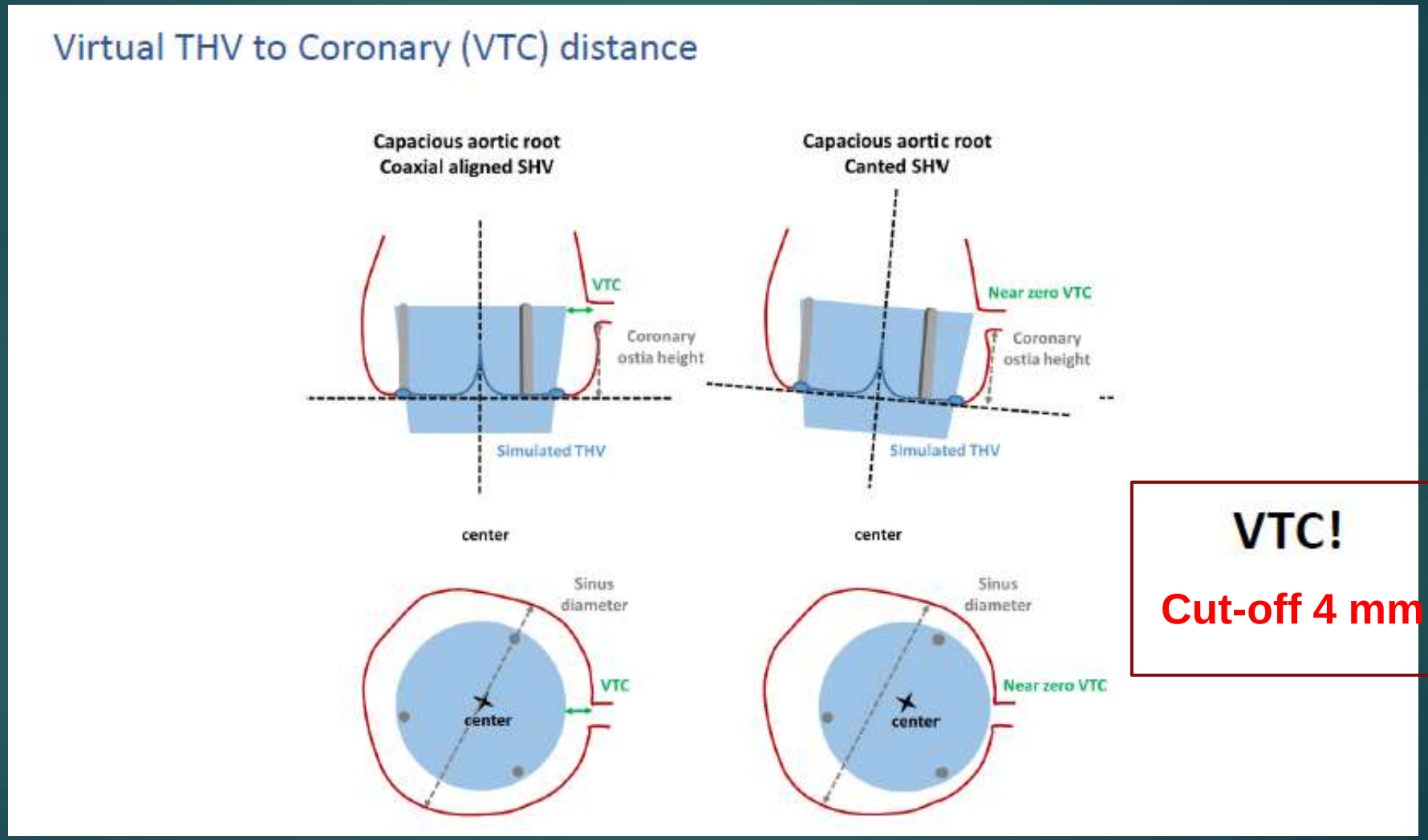
# Risk Factors for Coronary Obstruction

- Smaller anatomy
- Narrow sinuses
- Oversizing- Stent post deflection
- Valves with leaflet outside the stent



Low → High

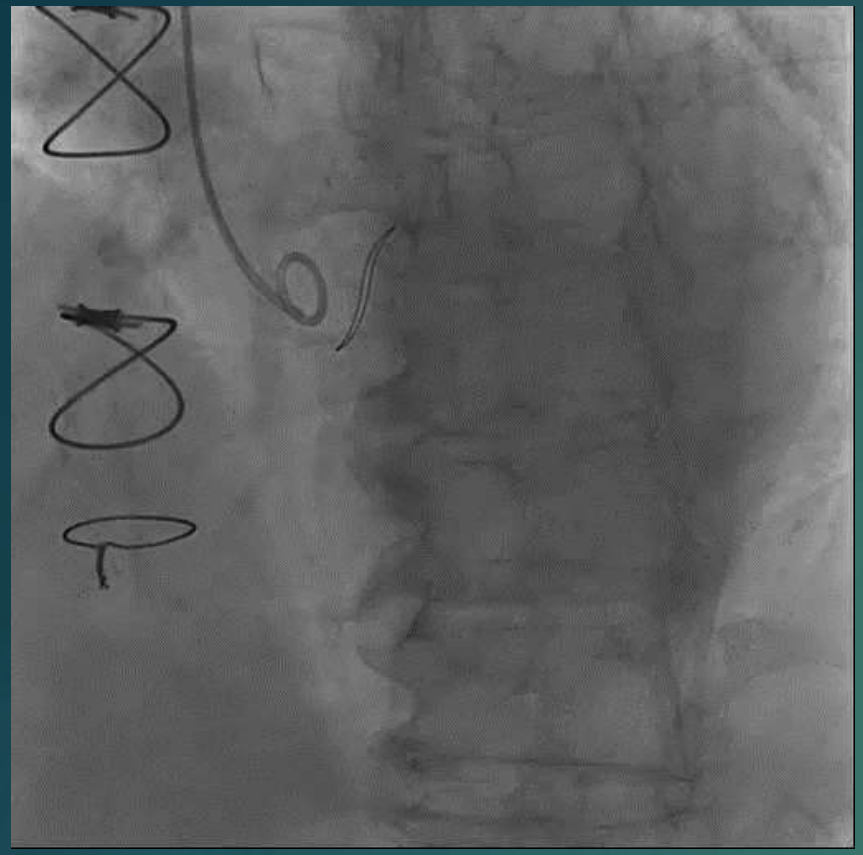
# MSCT: Assessment and Measurements for ViV procedures




**VTC!**

**Cut-off 4 mm**

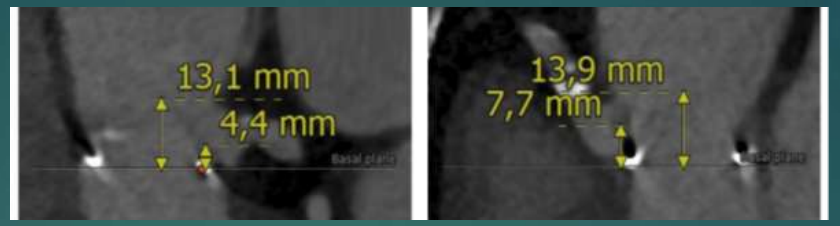
Blanke et al. 2016



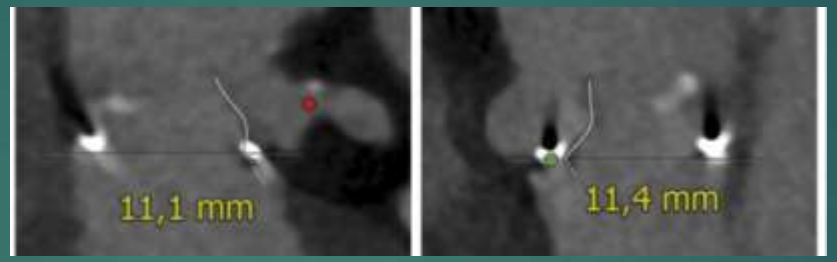
F/84, NYHA III, Bioprosthetic valve failure: severe AS, 0.6cm2, 86/56mmHg, 4.6m/s

- **STS PROM 8.257%**
- **145cm 84 kg BSA 1.74**
- **HTN, pAF/AFL**
- **s/p SAVR d/t AS: Sorin Soprano 20mm, ‘11.1**
- **h/p PTE d/t DVT, ’14.4**

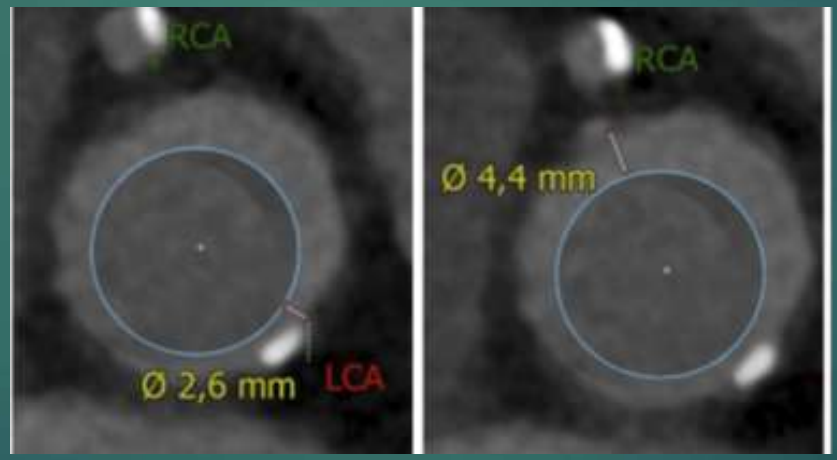
## Short coronary height



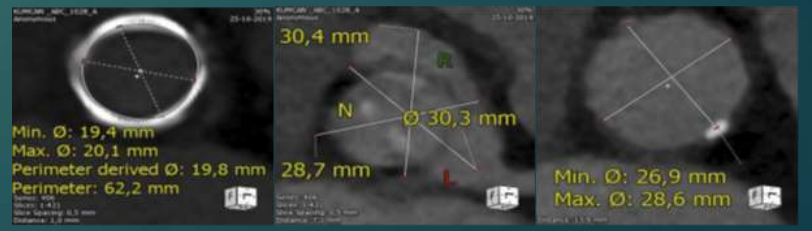

## Longer leaflet length




## Short VTC



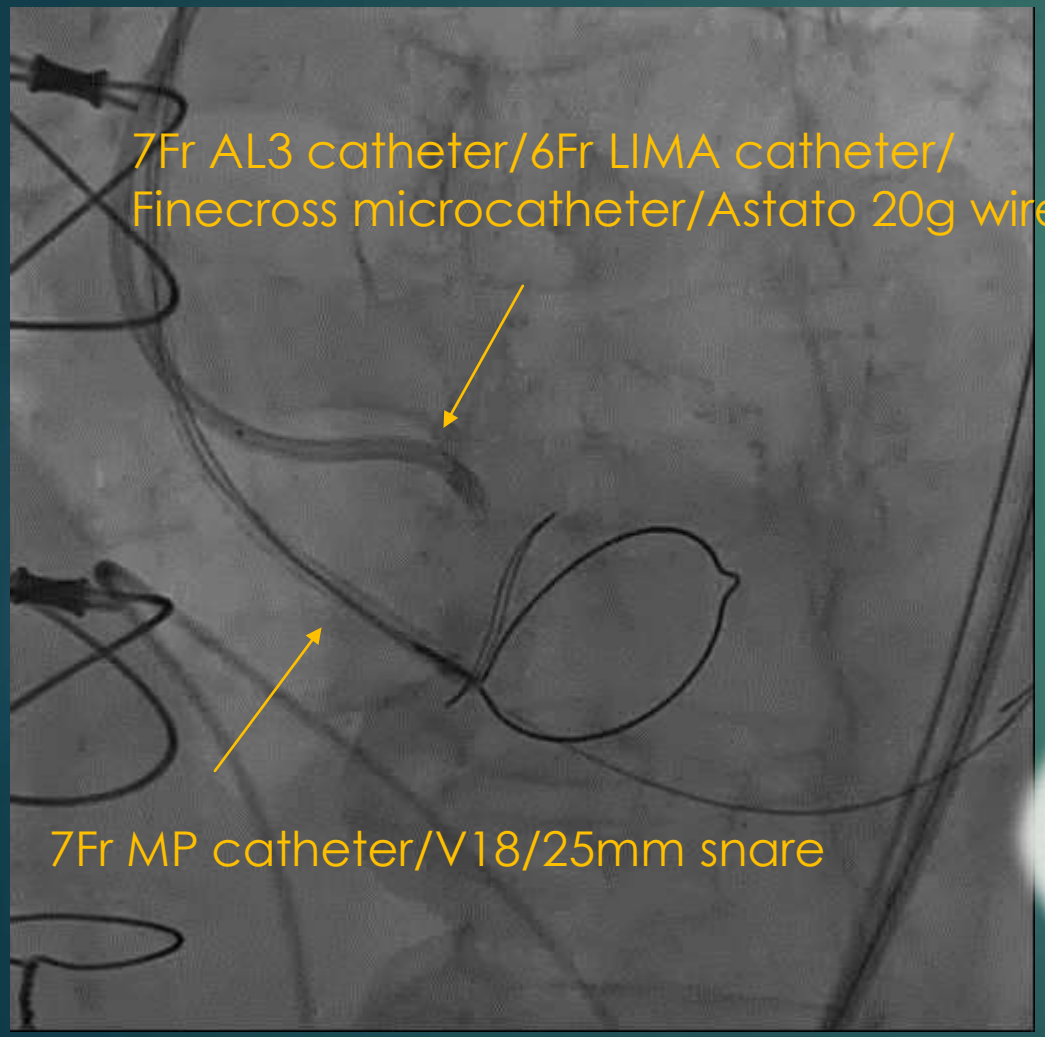


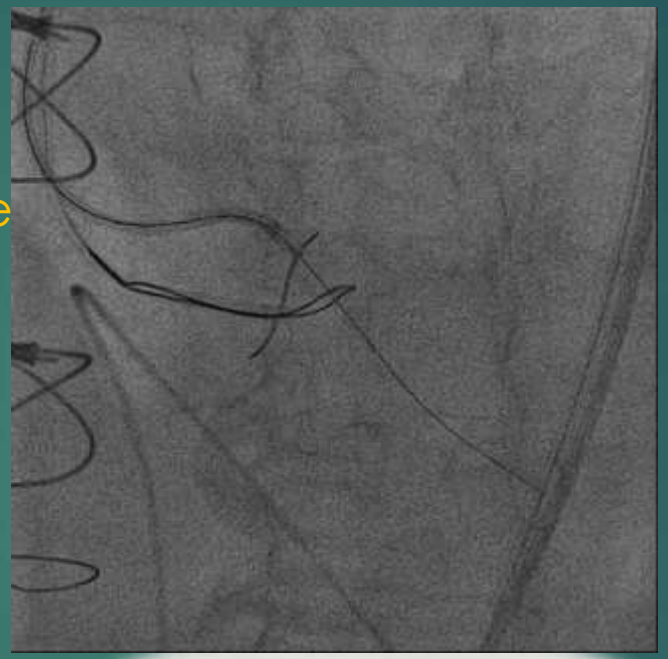



***Coronary obstruction risk is very high !!***

# This is the first valve-in valve TAVR with Basilica in Korea

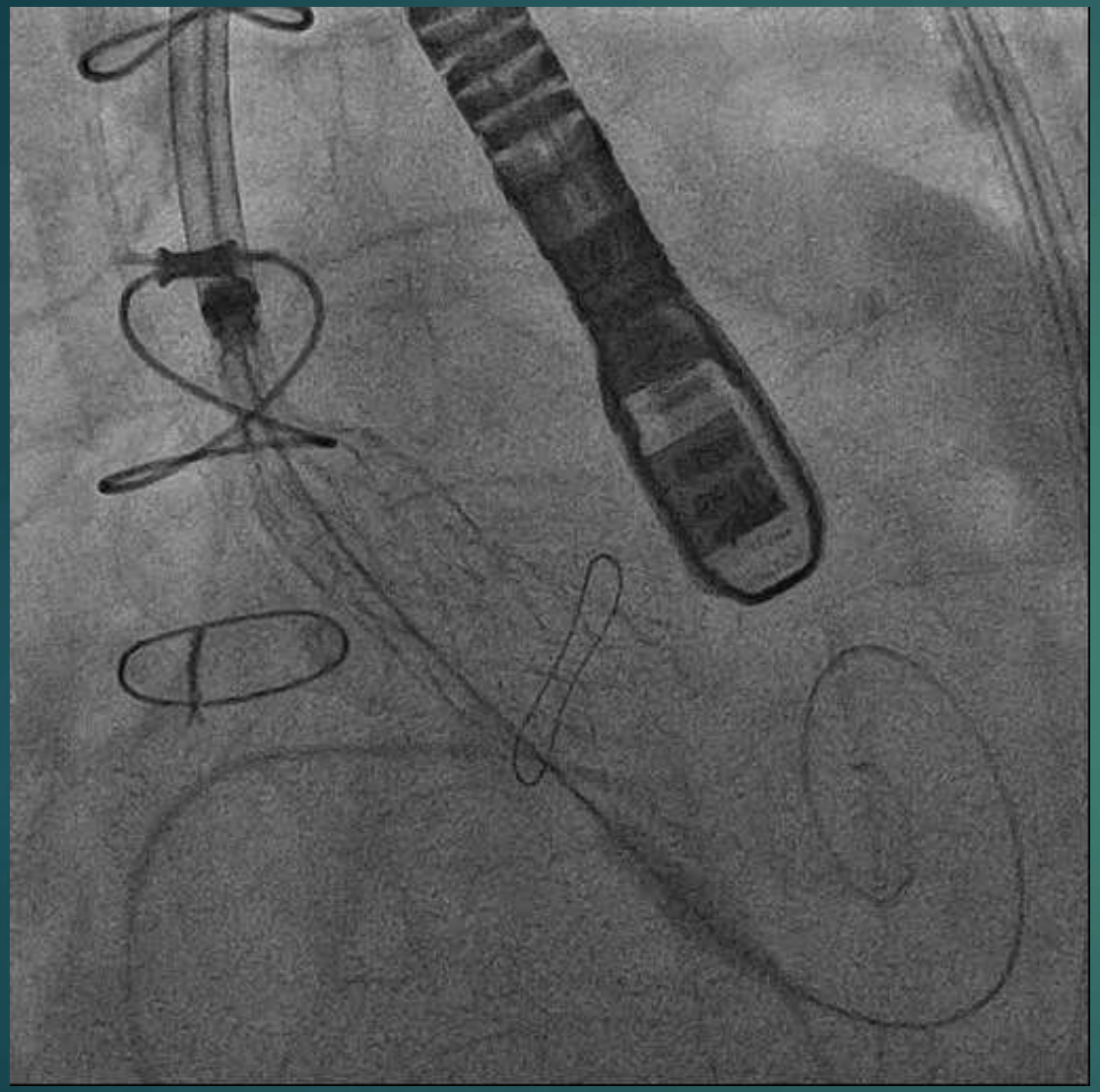
## Snare & traversal catheter location

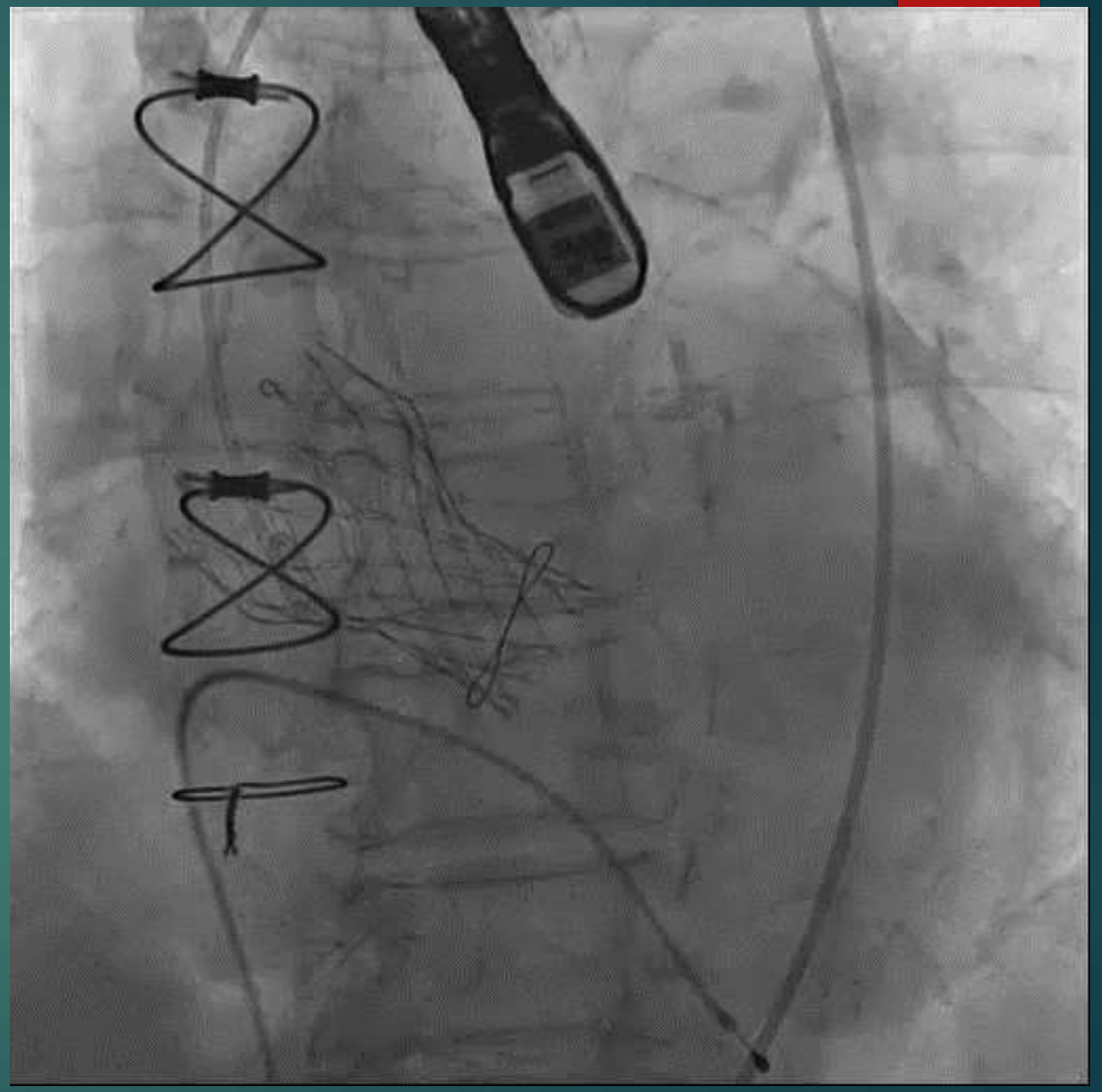


## & leaflet laceration

# This is the first valve-in valve TAVR with Basilica in Korea





**CoreValve pro 23mm**, Procedure time 170 min, Mean pressure gradient 11.5 mmHg, AR index 47.2, no coronary obstruction

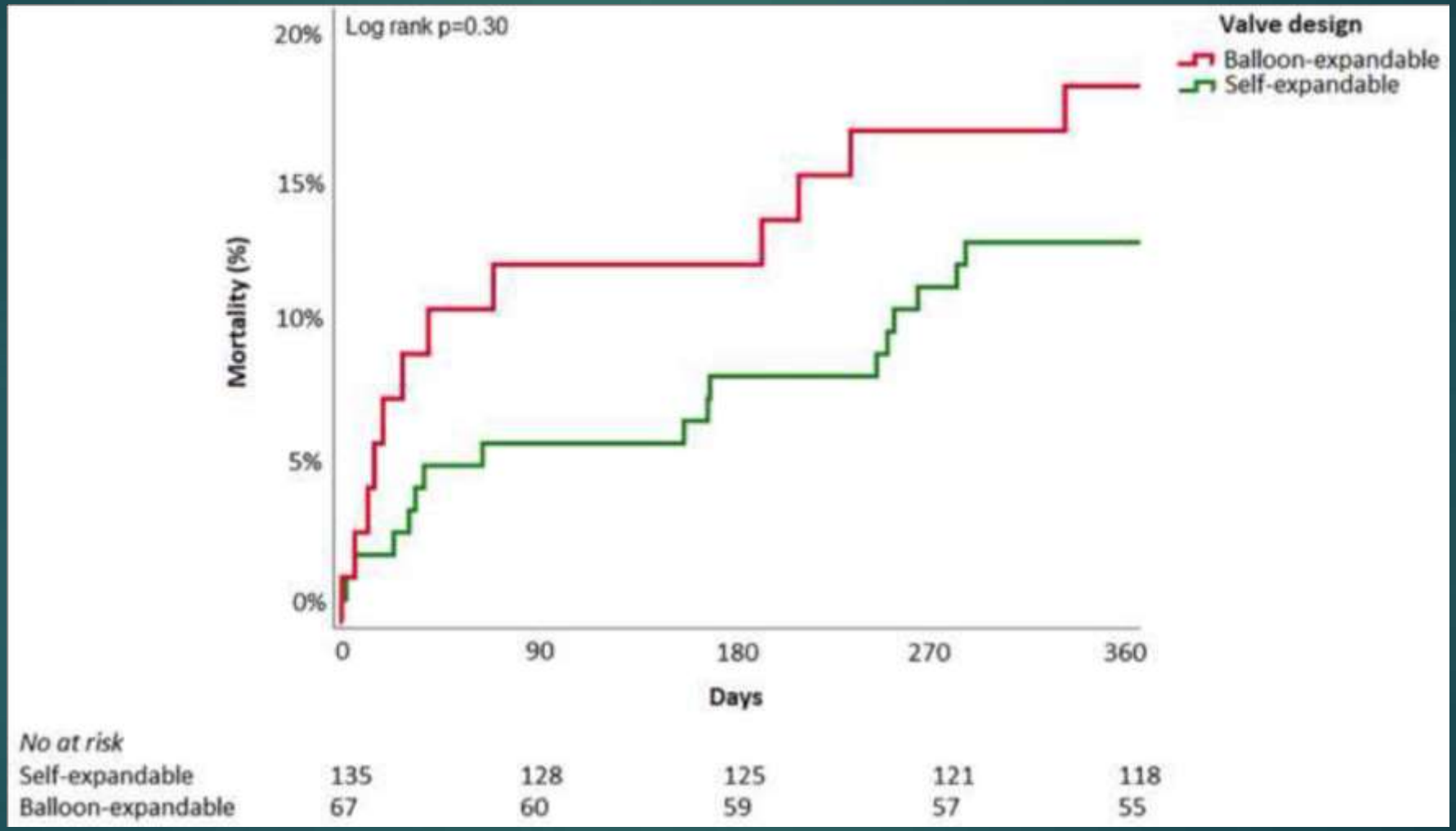
# Valve-in-valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves and Adjunctive Therapies

1. ViV TAVR Outcomes
2. Preprocedural Planning for ViV TAVR
3. Choice of Transcatheter Heart Valve for ViV TAVR

# Choice of Transcatheter Heart Valve for ViV TAVR

1. Individual patient's anatomy
2. A plan for lifetime valve management,
3. Careful attention to the risk of coronary obstruction,
4. Feasibility of future coronary re-access,
5. Hemodynamic results.

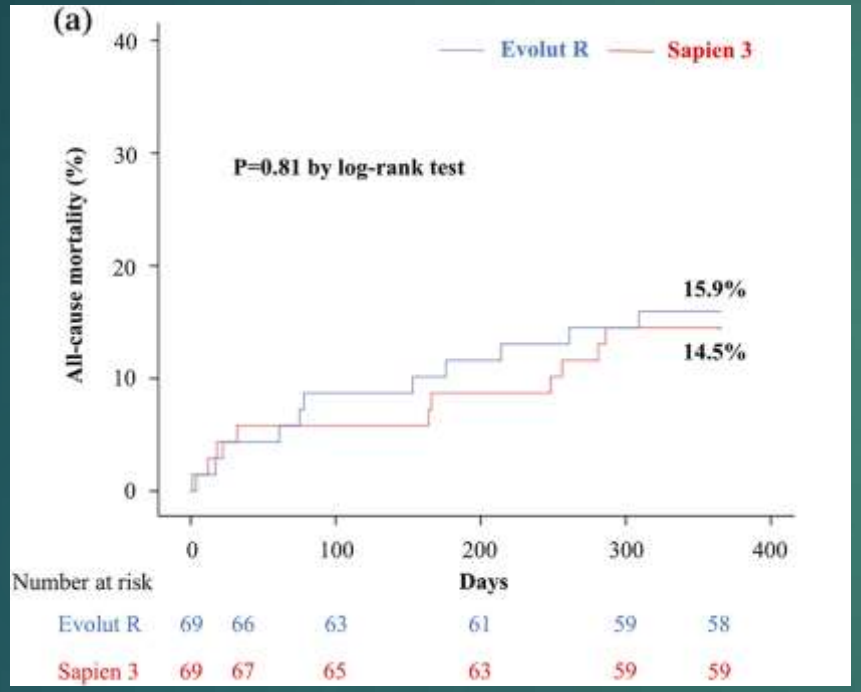
# Balloon-expandable vs. Self-expandable outcome in Valve-in-Valve




van Nieuwkerk AC.et al. Am J Cardiol. 2022 Jun 1;172:81-89

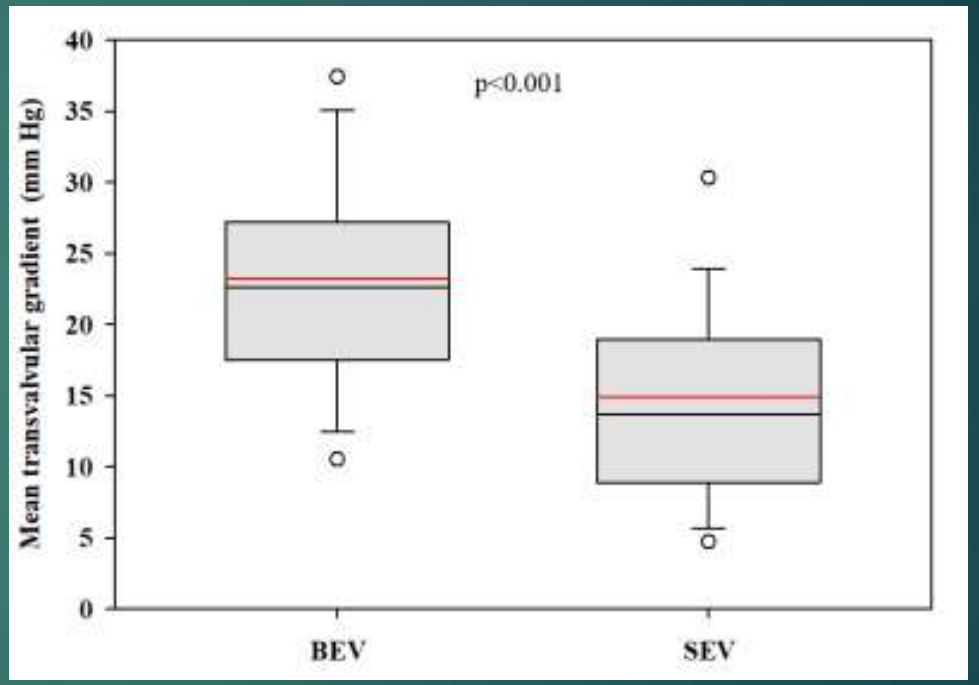
# Balloon-expandable vs. Self-expandable In small aortic annulus (≤23mm)

All-cause mortality




Hase H, et al., The OCEAN-TAVI registry. Catheter Cardiovasc Interv. 2021 May 1;97(6):E875-E886.

Mean PG by echocardiography after 30day of procedure




Rodés-Cabau J, et al., The LYTEN Trial. J Am Coll Cardiol. 2022 May 13:S0735-1097(22)04978-6.

# Feasibility of future coronary re-access

Consideration for the feasibility of a future TAVR-in-TAVR or TAVR-in-TAVR in-SAVR should also be considered for the younger and lower-risk populations, who may potentially require three valves in their lifetime.

The height and intra-annular position of a BEV may be advantageous over the design of SEVs in regard to coronary re-access and risk for coronary obstruction during ViV TAVR or future redo TAVR procedures.

In contrast, a SEV may allow for retrieval or repositioning if there is evidence of impending coronary obstruction, with the trade-off of the risk of leaflets of the supra-annular SEV reaching the STJ, thus making coronary re-access challenging and potentially prohibiting a future redo TAVR.

# Valve-in-valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves and Adjunctive Therapies

1. ViV TAVR Outcomes
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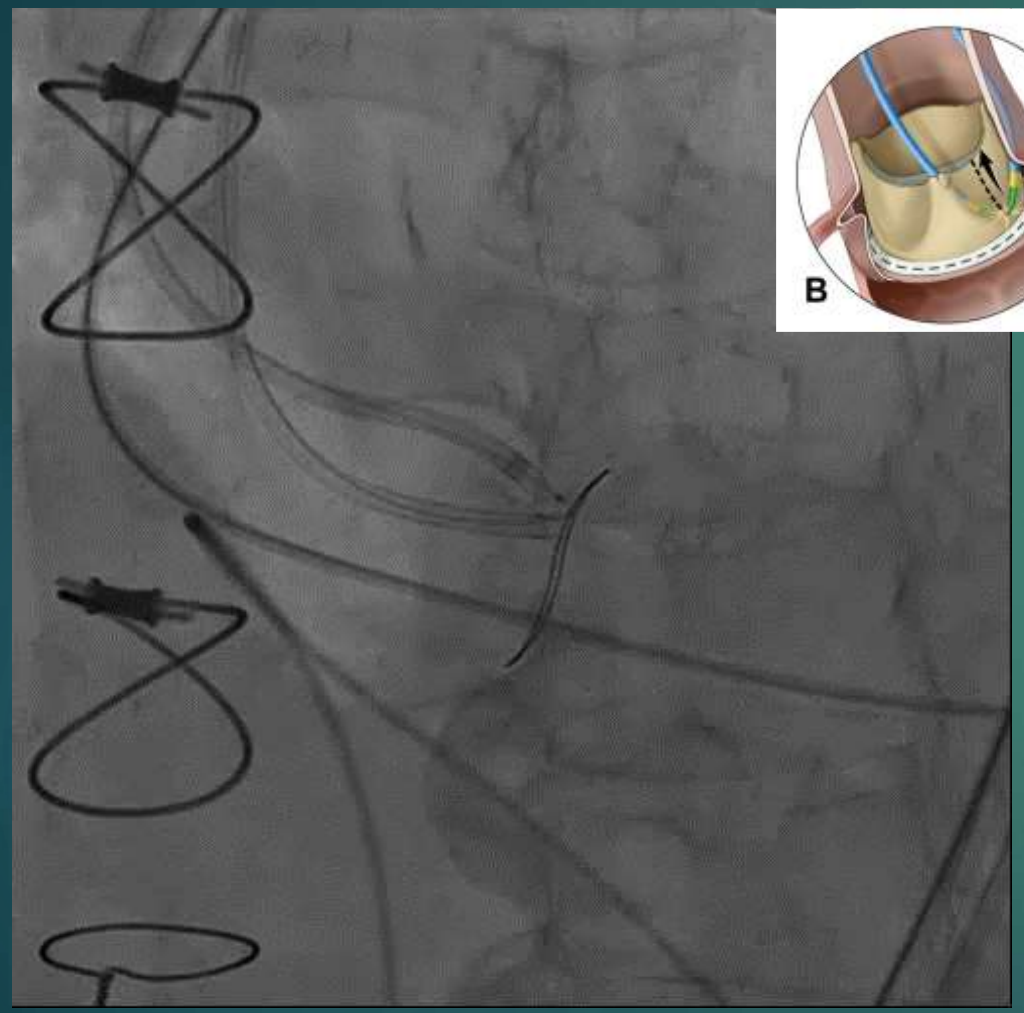
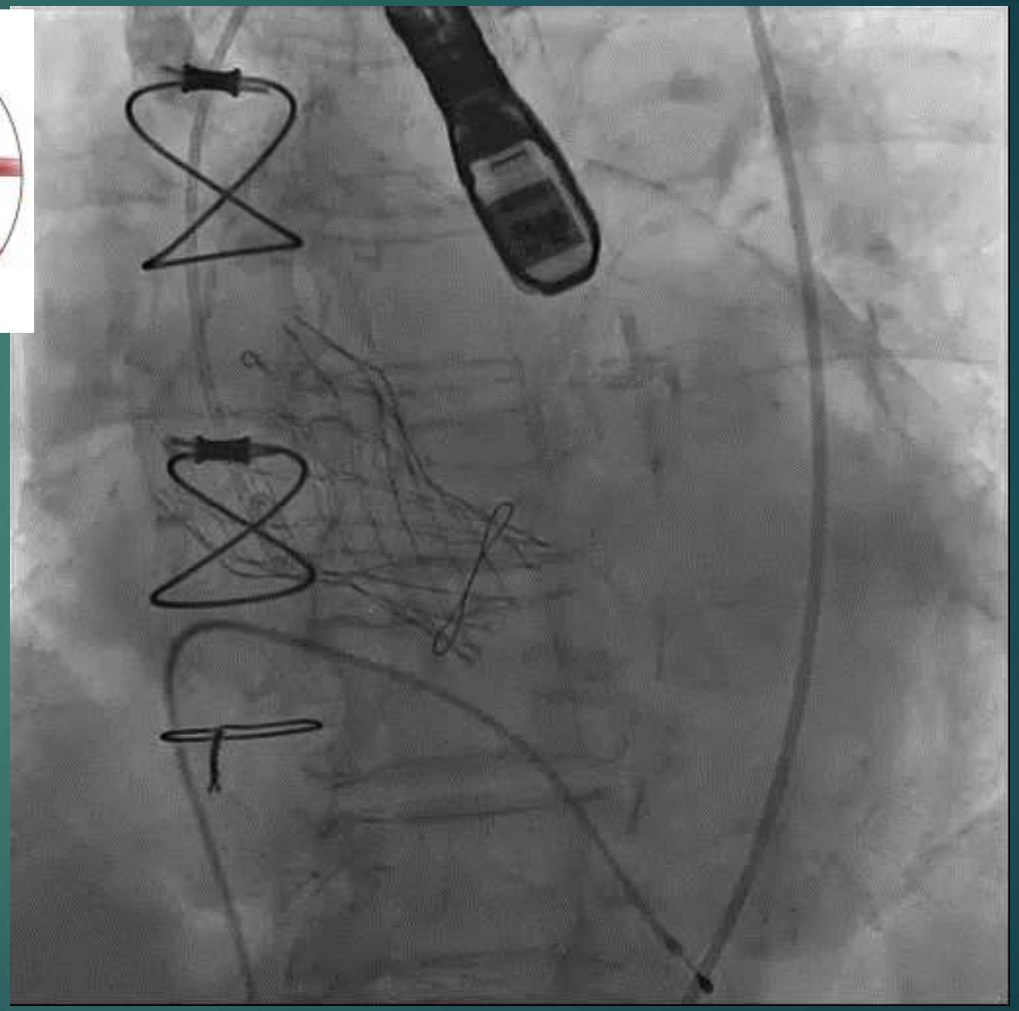
3. Choice of Transcatheter Heart Valve for ViV TAVR
4. **Pitfalls of ViV TAVR**
    1. Coronary Obstruction Risk and Mitigation Strategies

# Successful BASILICA case – the first in Korea






70W



CoreValve Pro 23mm

*Slide courtesy of Dr. Hyungdon Kook*

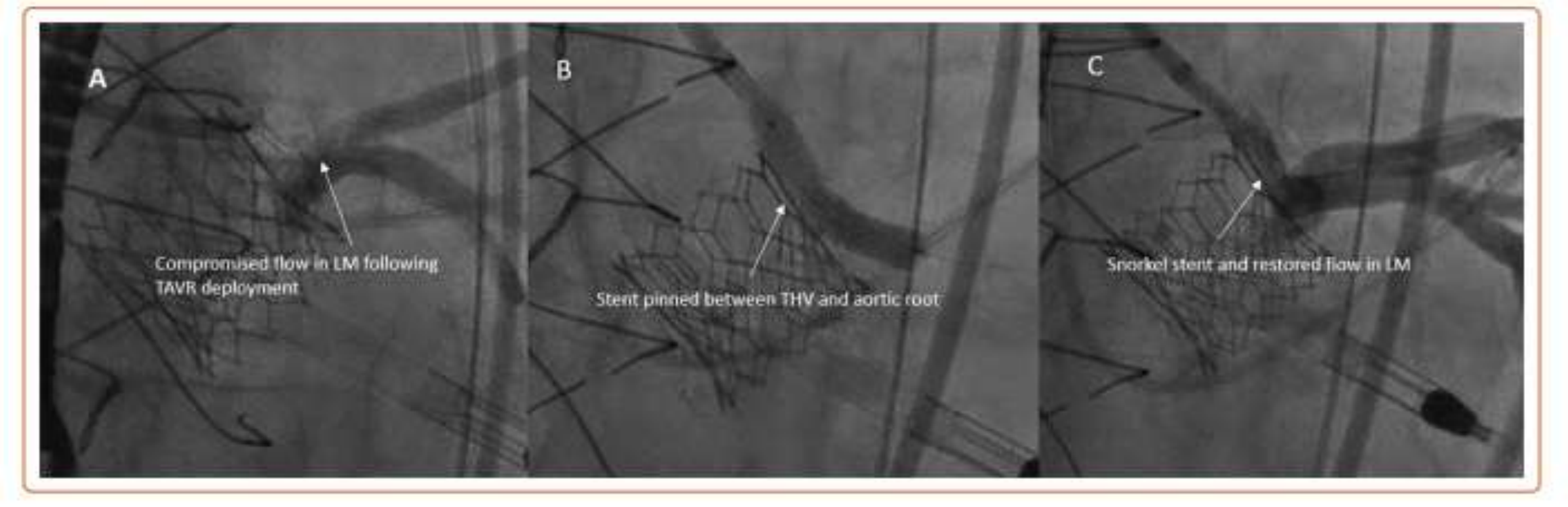
## 1. 214-patient multicenter International BASILICA registry

- Procedural success (defined as successful traversal and laceration without mortality, coronary obstruction, or emergency intervention): 86.9% of patients,
- stroke rate: only 2.8% with judicious use of cerebral embolic protection.

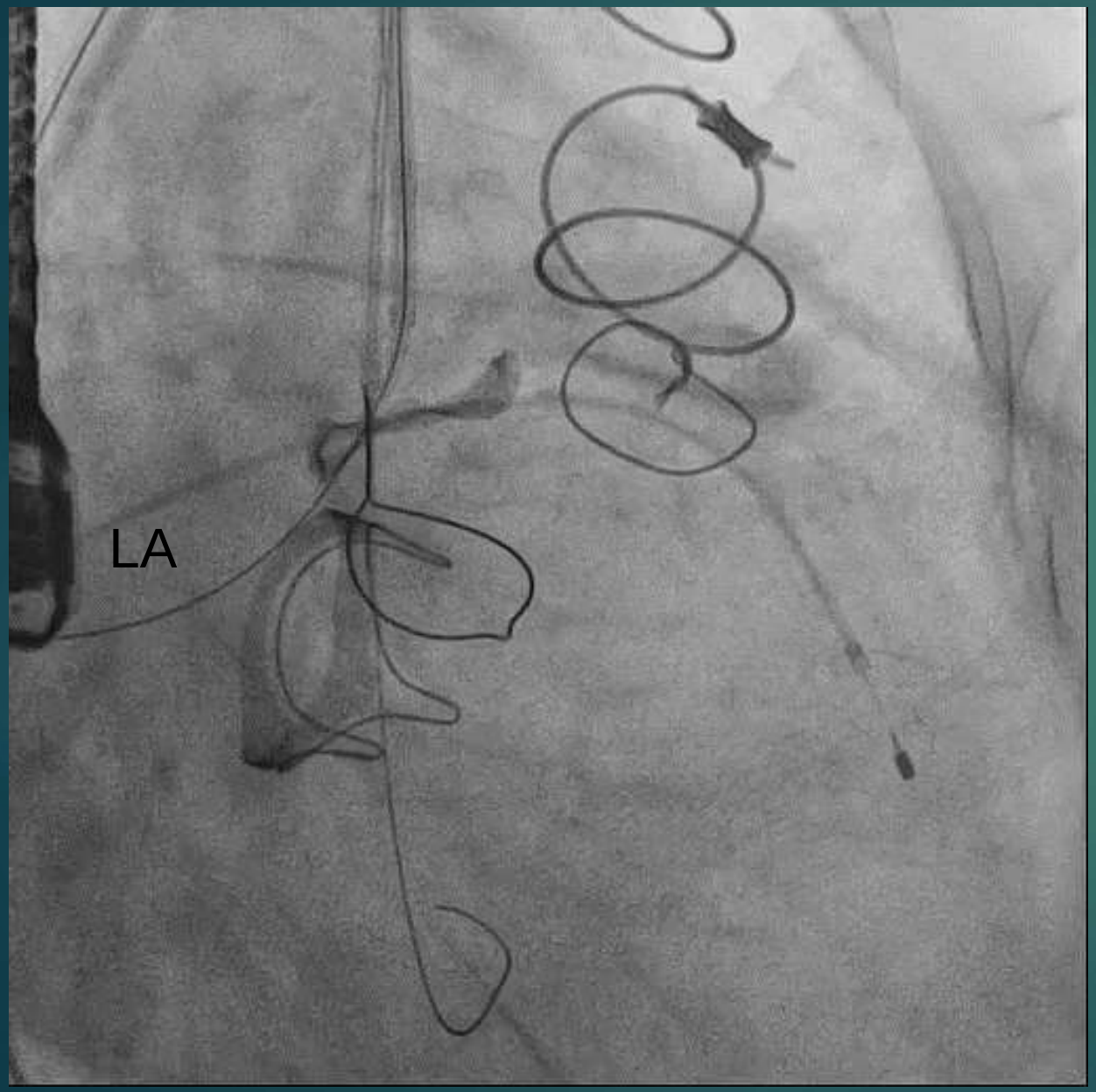
## 2. Failed coronary protection even after BASILICA

1. commissural malalignment or obstruction related to the skirt of the THV.
2. challenging anatomy, such as very narrow VTCs (<2mm),
3. diffusely calcified leaflets,
4. TAVR-in-TAVR procedures, due to inadequate leaflet splay despite otherwise successful leaflet laceration (balloon assisised BASILICA)

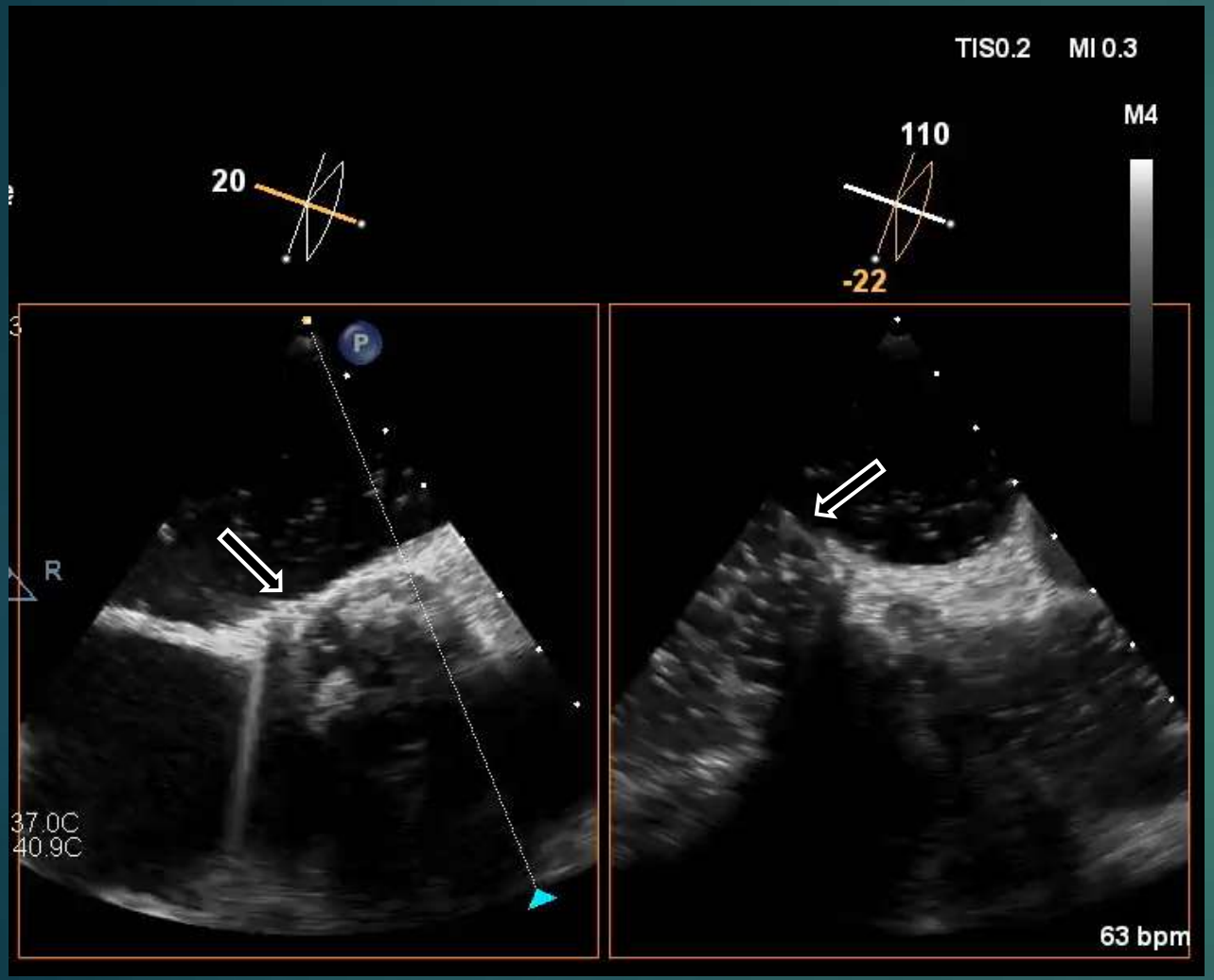
# Rescue Snorkel Stenting for Acute Coronary Obstruction of the Left Main Coronary Artery



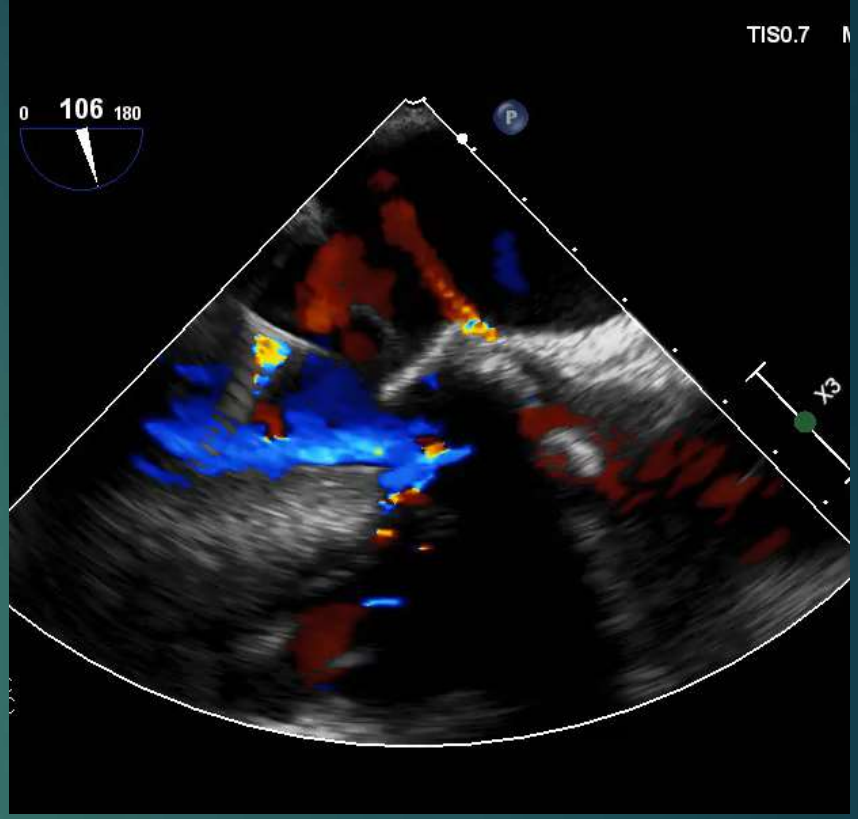
# Failed wire traversal : Aorta to LA

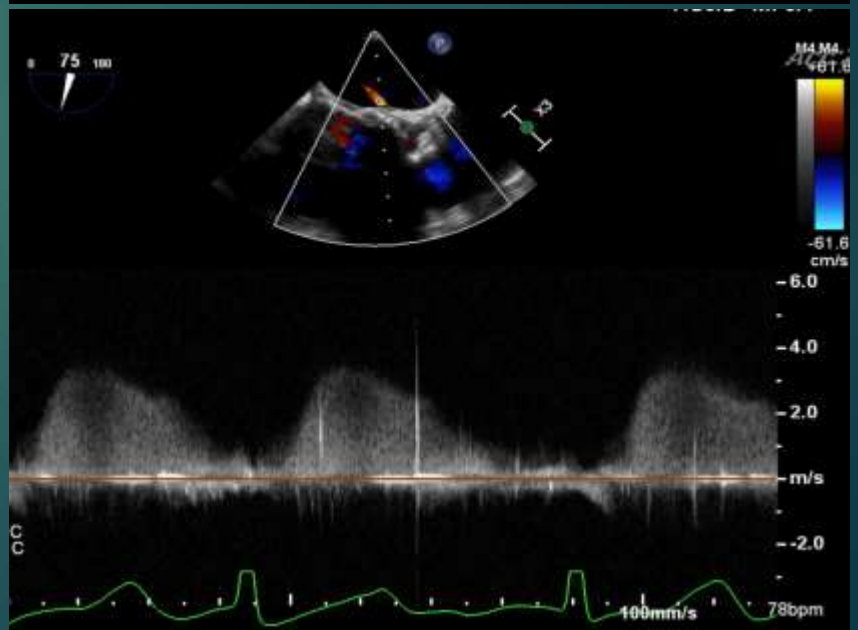



# Intra-procedural TEE

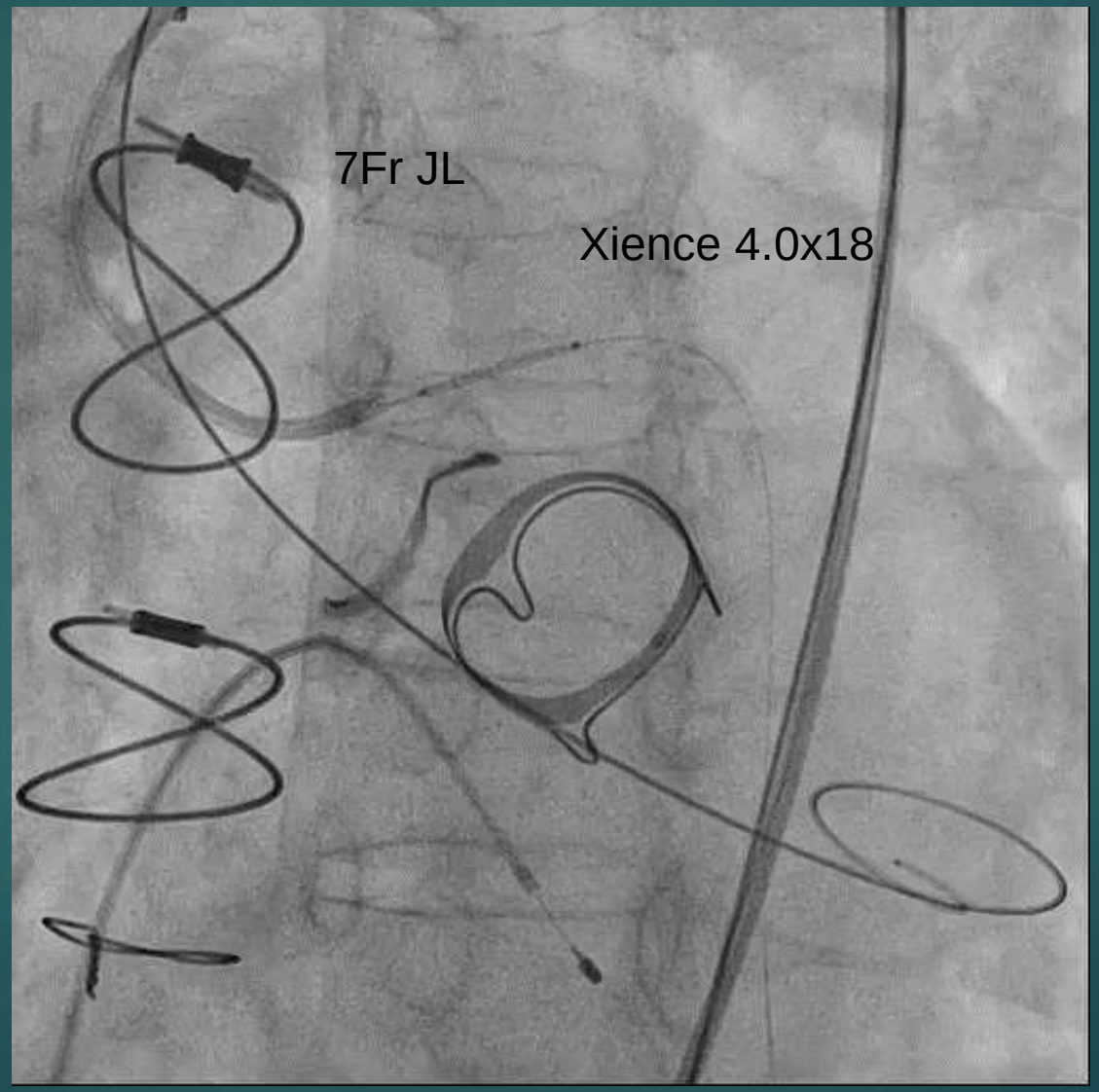



Wire penetration into the LA

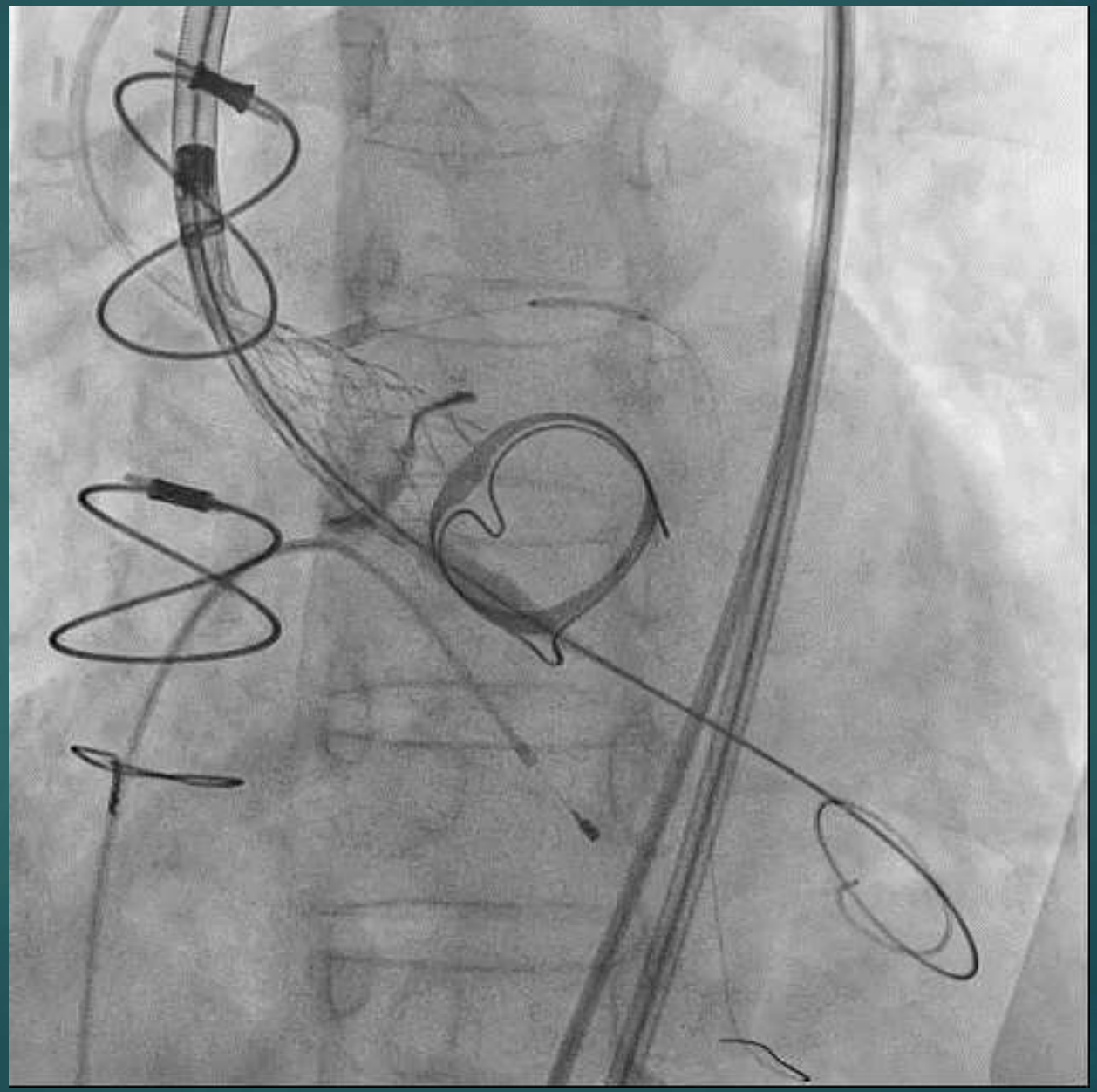


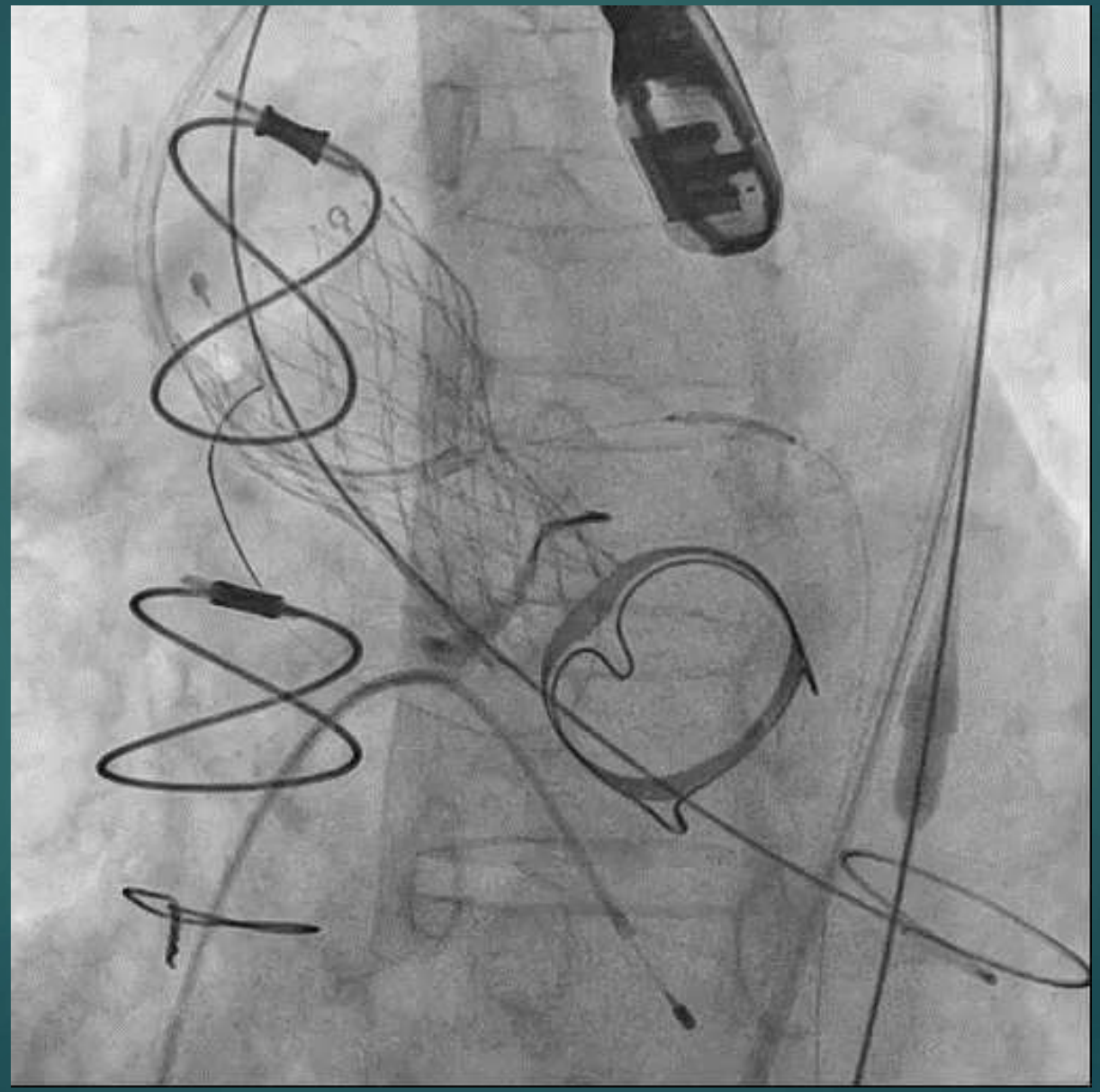
# Attempting Snokeling or Chimmney technique by Coronary Protection after BASILICA failed



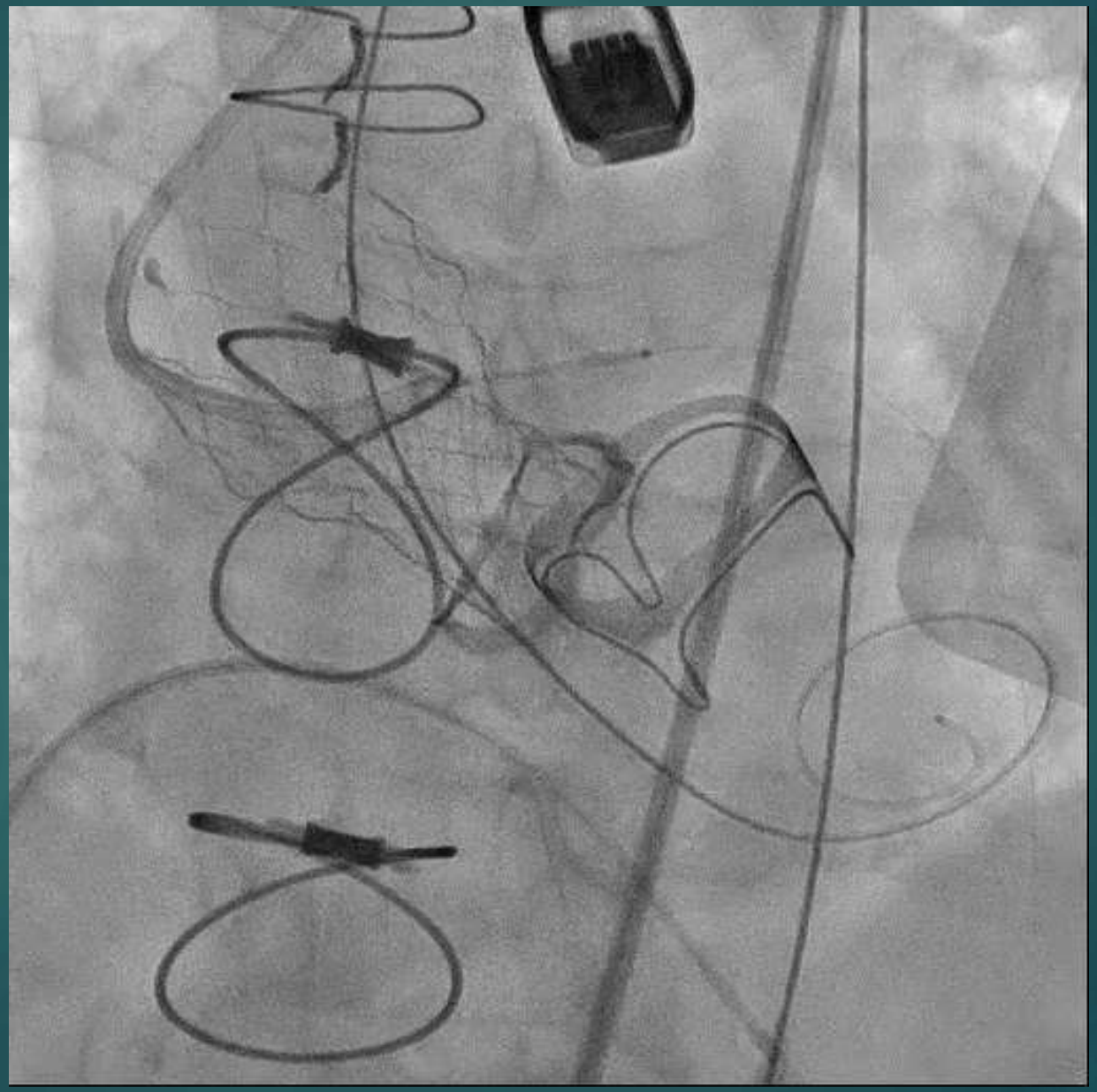
# Evolut Pro 23 mm ViV

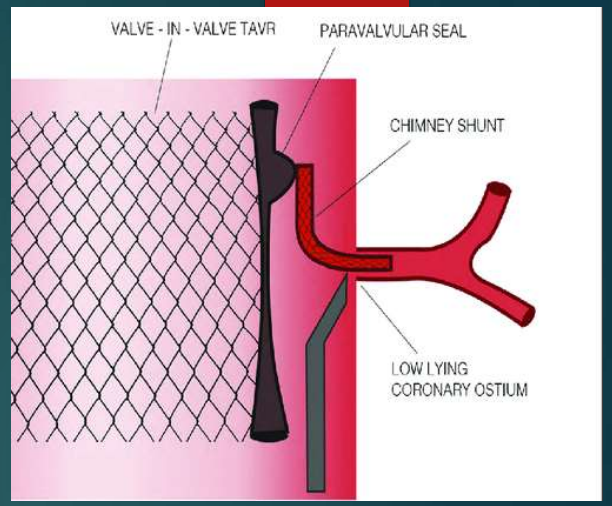


# LM  was compromised after THV deployment

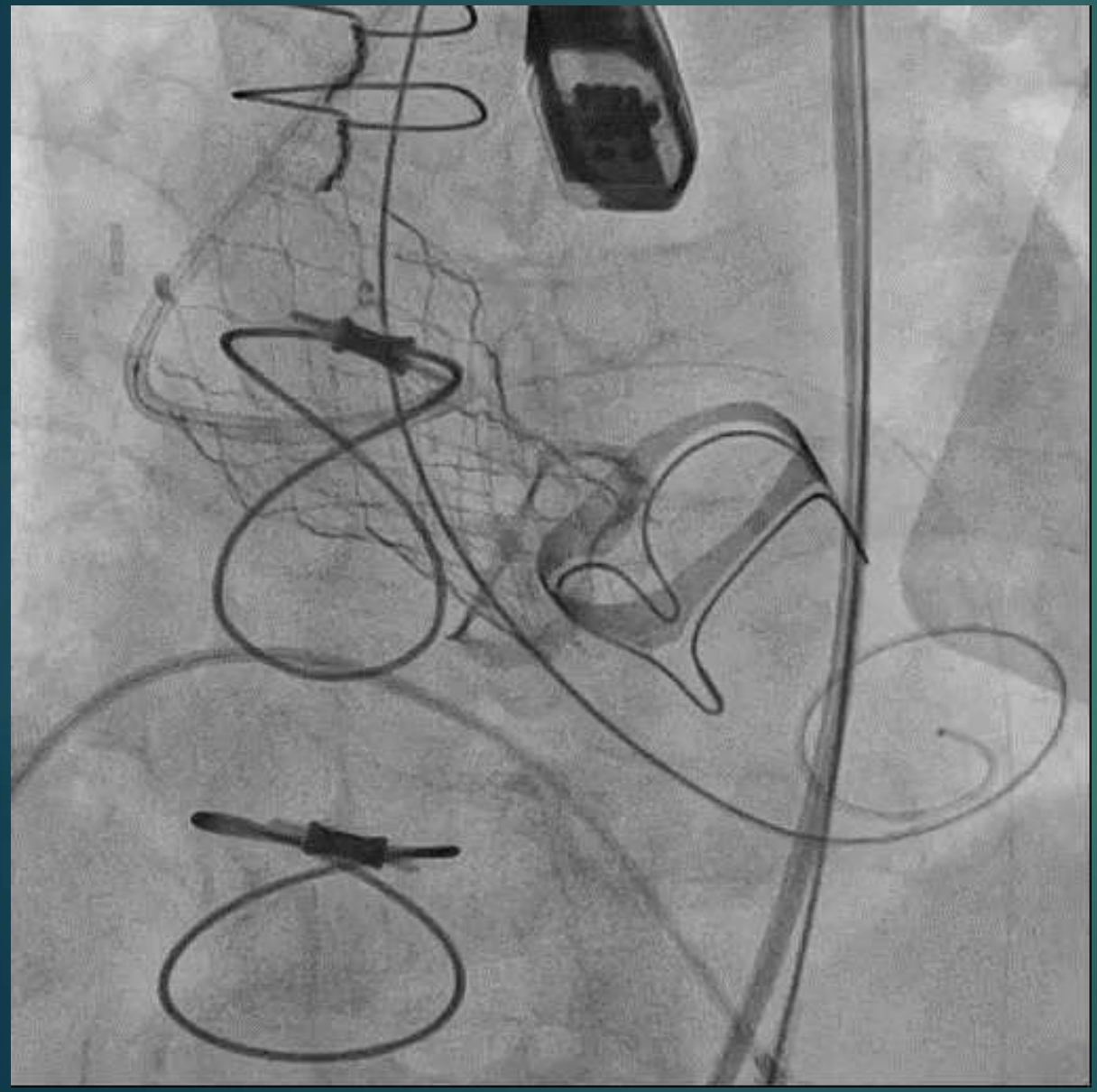


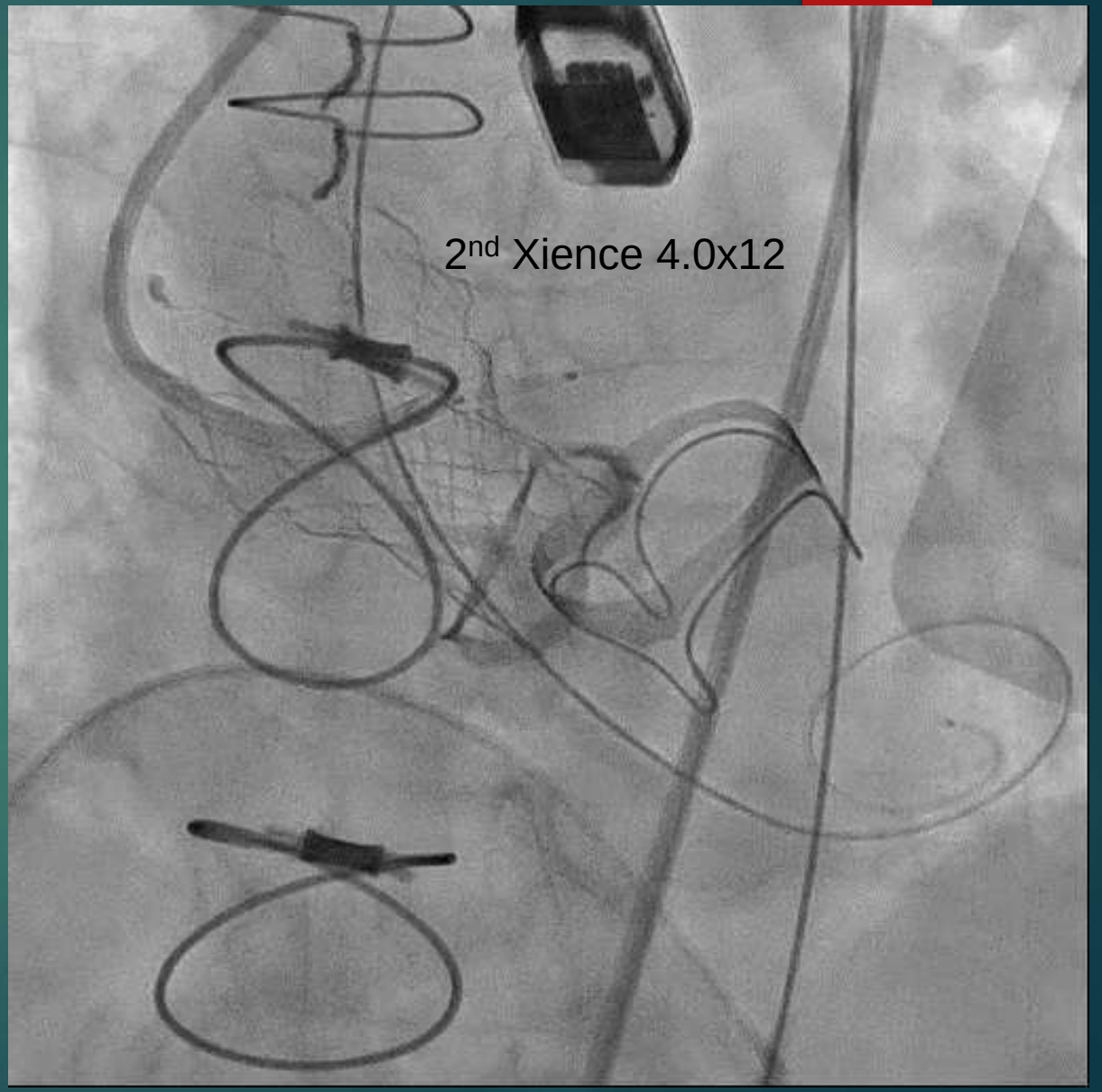
# Chimney-Snorkel stenting



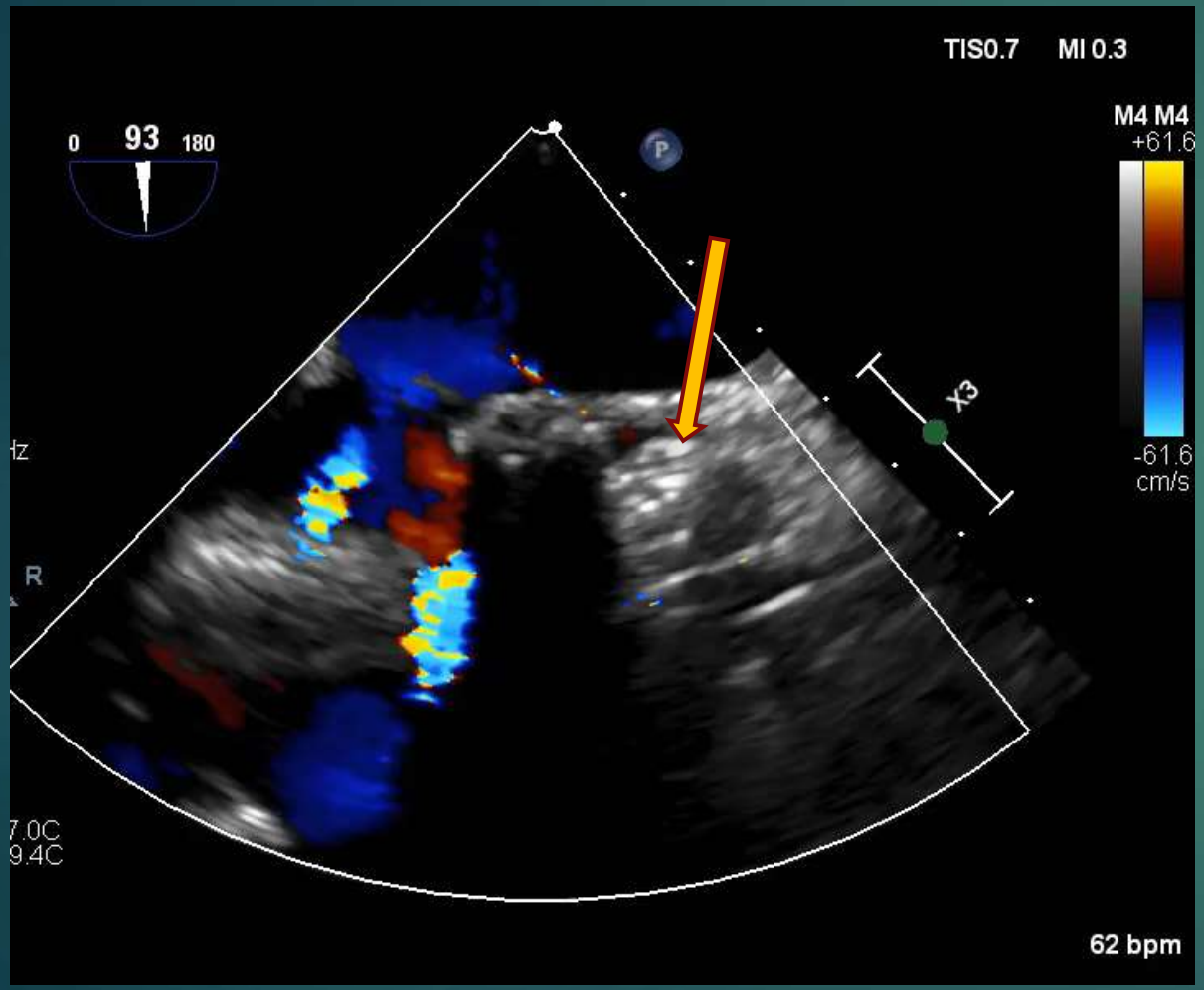


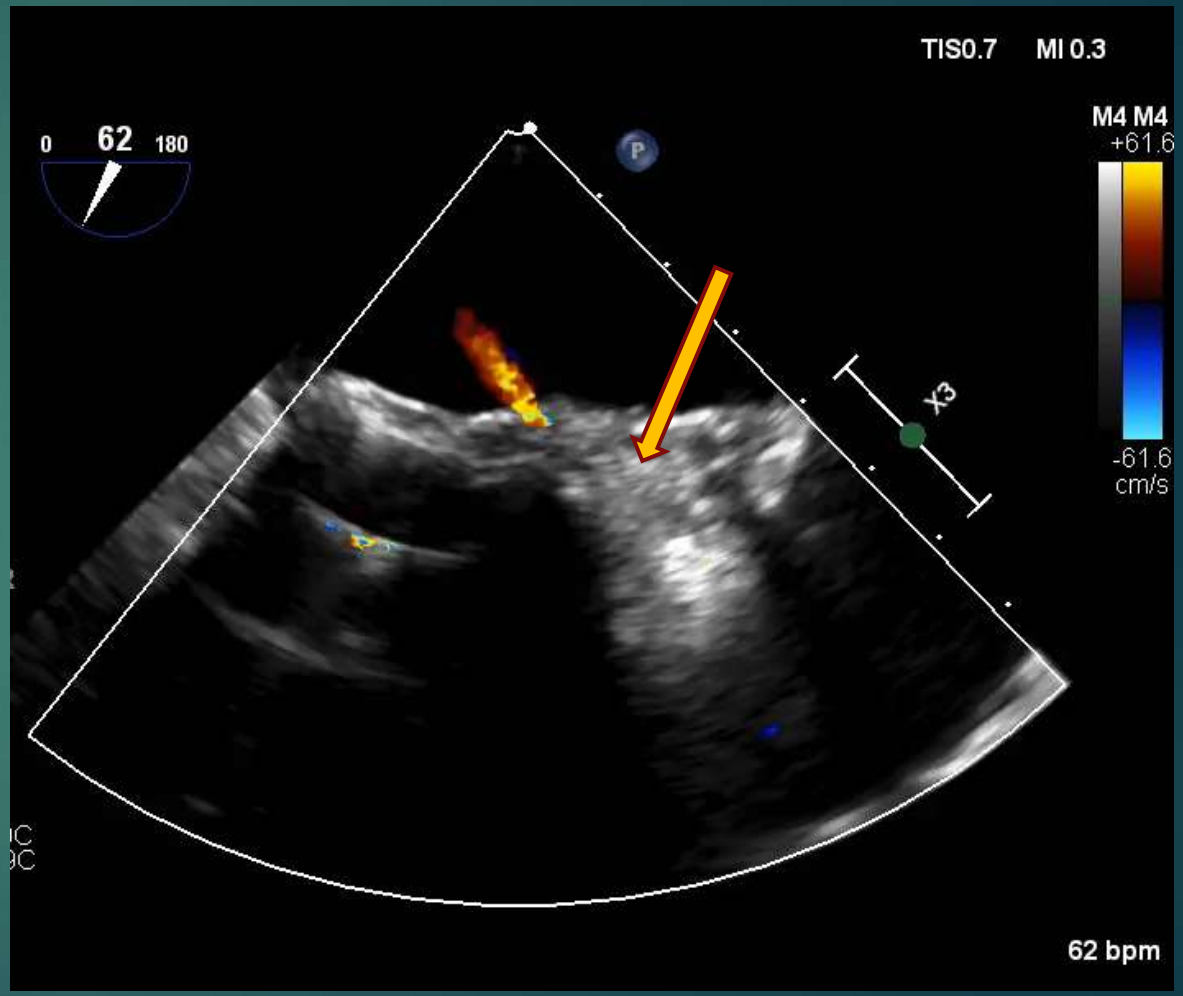
# Chimney Stenting



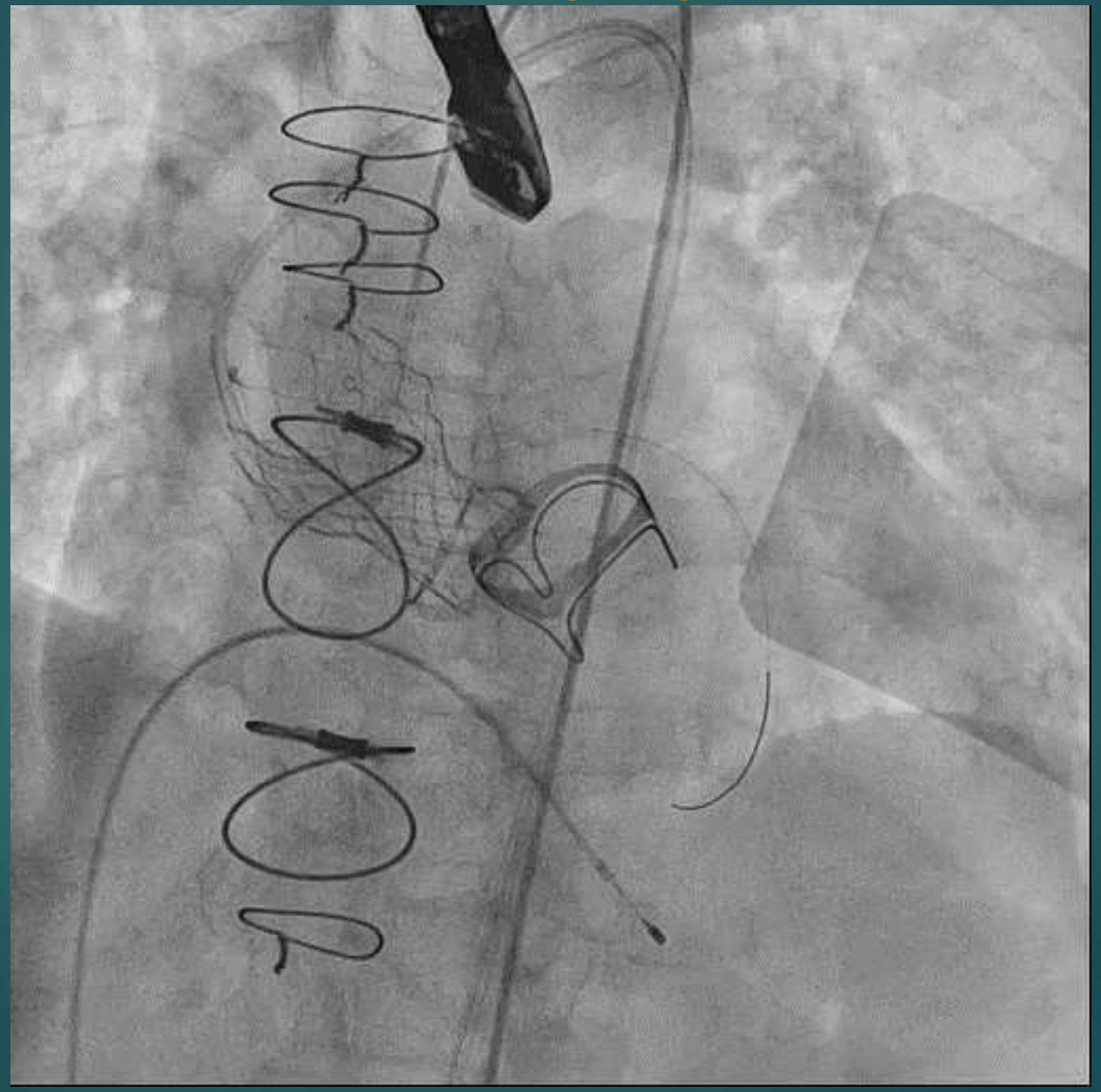


# Chimney Stenting



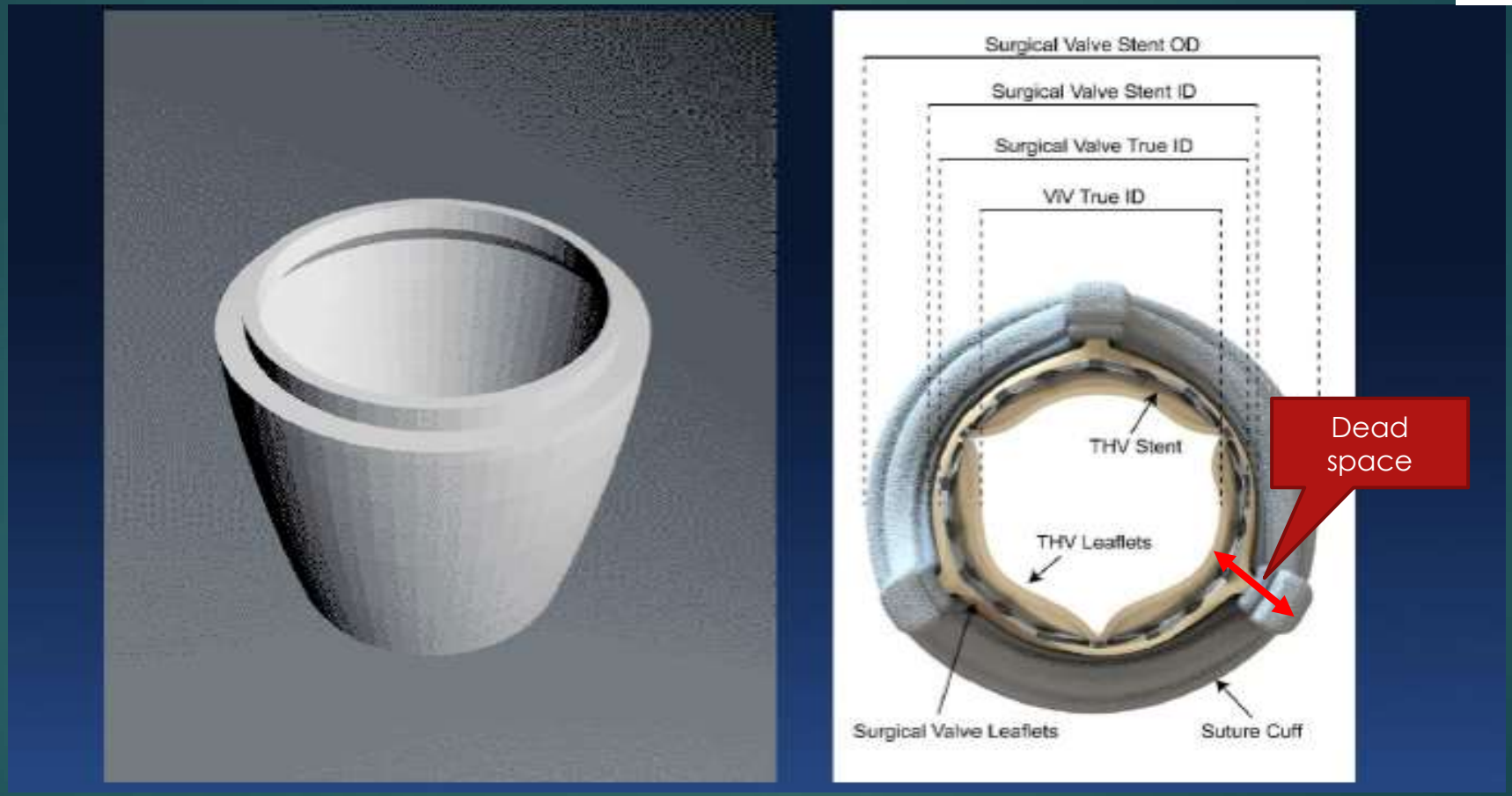
# Final Angiogram



# Valve-in-valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves and Adjunctive Therapies

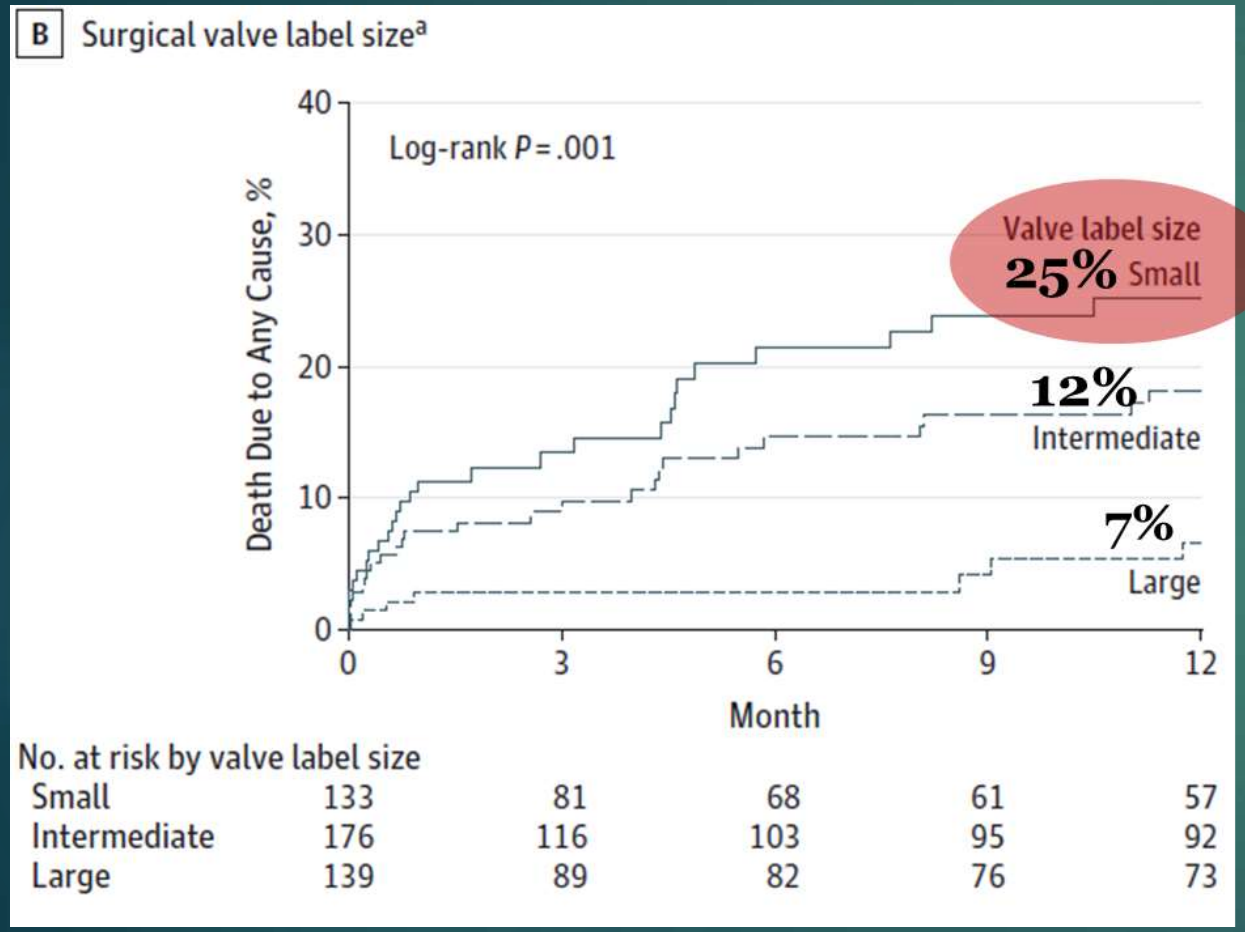
1. **ViV TAVR Outcomes**
2. **Preprocedural Planning for ViV TAVR**
3. **Choice of Transcatheter Heart Valve for ViV TAVR**
4. **Pitfalls of ViV TAVR**
    1. Coronary Obstruction Risk and Mitigation Strategies
5. **Patient–Prosthesis Mismatch**

# VIV is not “Just putting a valve inside another”




**We create a poor and inefficient hemodynamic situation**

# Impact of Surgical Valve Size on 1-Year Mortality




## VIVID Registry

- **459 pts with failed surgical bioprostheses treated with ViV TAVR (59% balloon expandable, 41% self-expanding)**
- **Patients stratified based on size of original surgical valve**
  - ***Small ≤ 21 (n=133)***
  - ***Medium 22-24 (n=176)***
  - ***Large ≥ 25 (n=139)***
- **Small surgical valve independently associated with 1-year mortality (HR 2.04, p=0.02)**

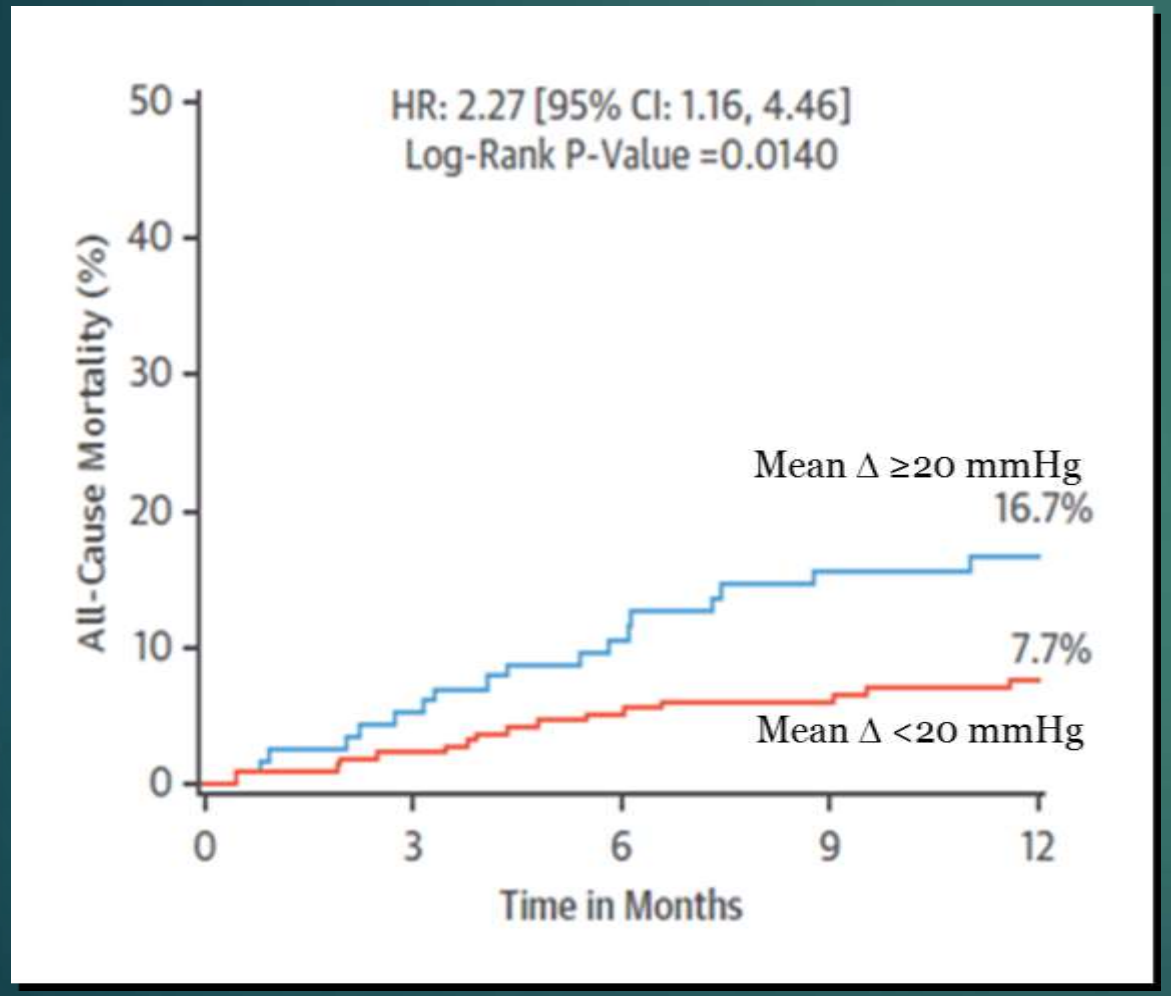
The incidence of **severe PPM** following ViV TAVR was **31.8%,**

The smaller the surgical valve, the higher the mortality!

# Proposed strategies to avoid severe PPM

1. The use of a supra-annular SEV,
2. Higher implant depths,
3. Performing bioprosthetic valve fracture (BVF) in patients with small surgical valves and residual gradients >20 mmHg

# Impact of Residual Gradient on 1-Year Mortality

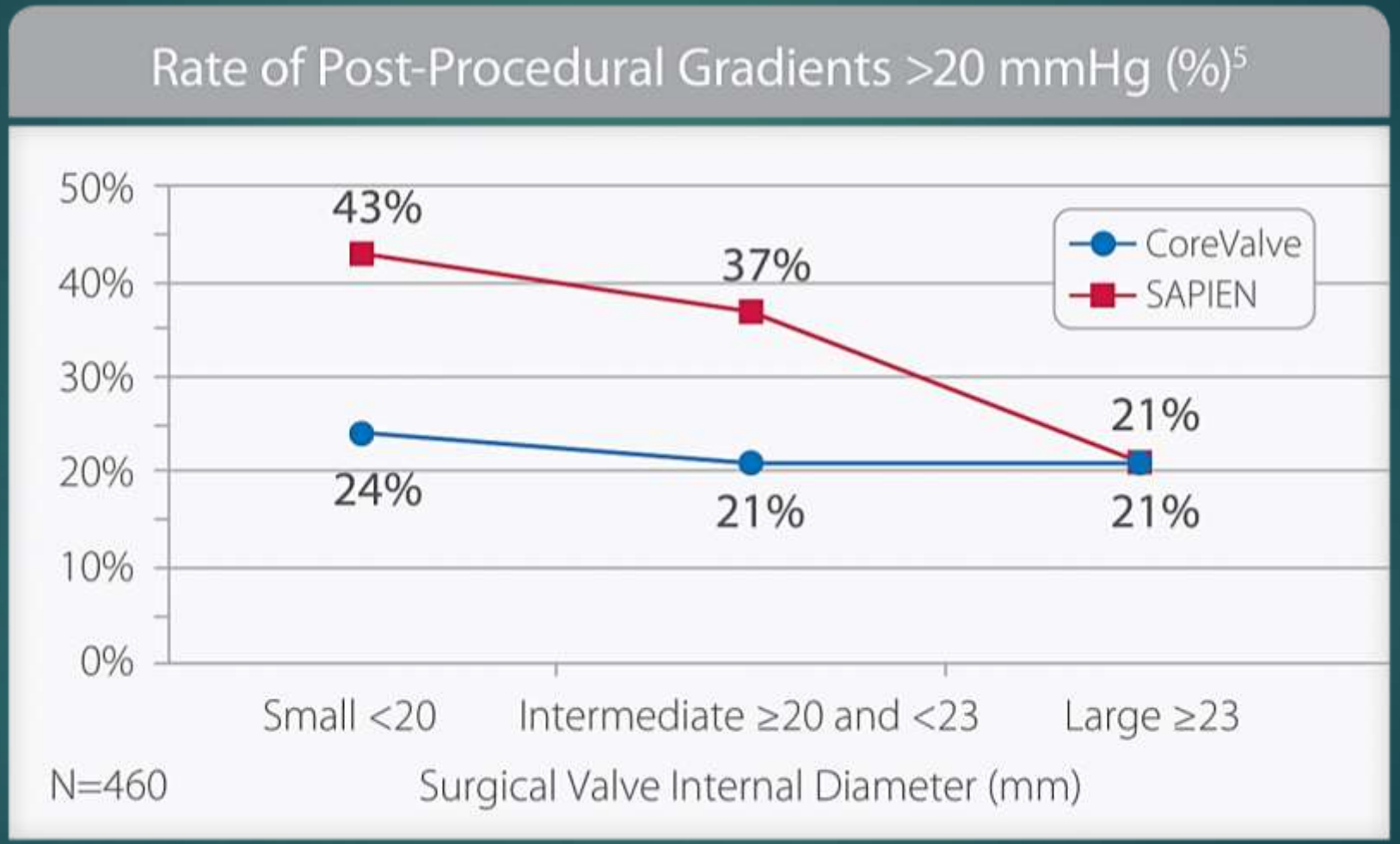



- Etiology of high gradients
  - Incomplete expansion
  - Uneven expansion
  - Russian Doll effect

PARTNER ViV Study
Webb J, et al. JACC 2017; 69:2253-62

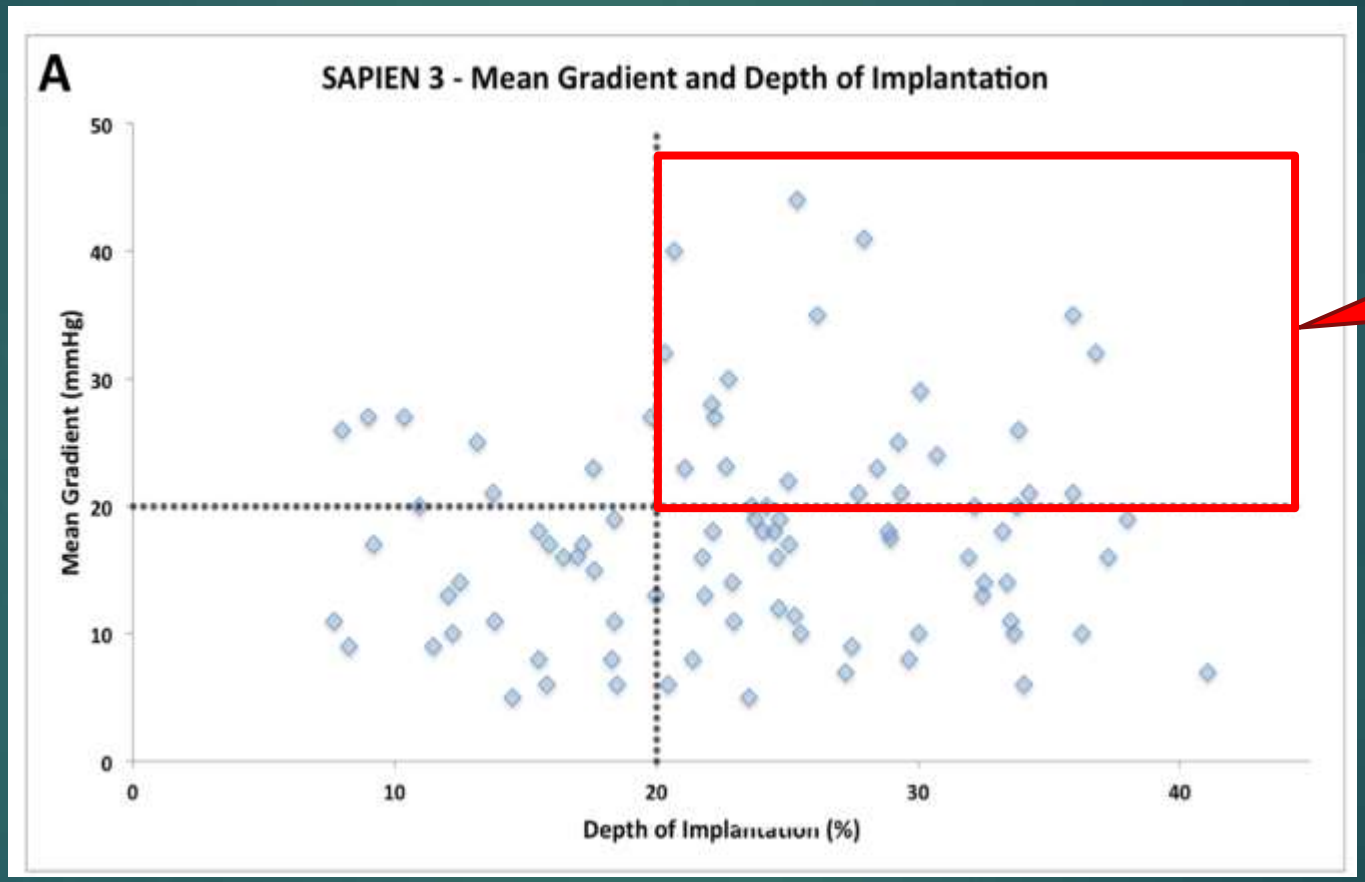
# Global Valve-in-Valve Registry

## Hemodynamic Results




Dvir et al., TCT. Miami, Fl. Oct 2012

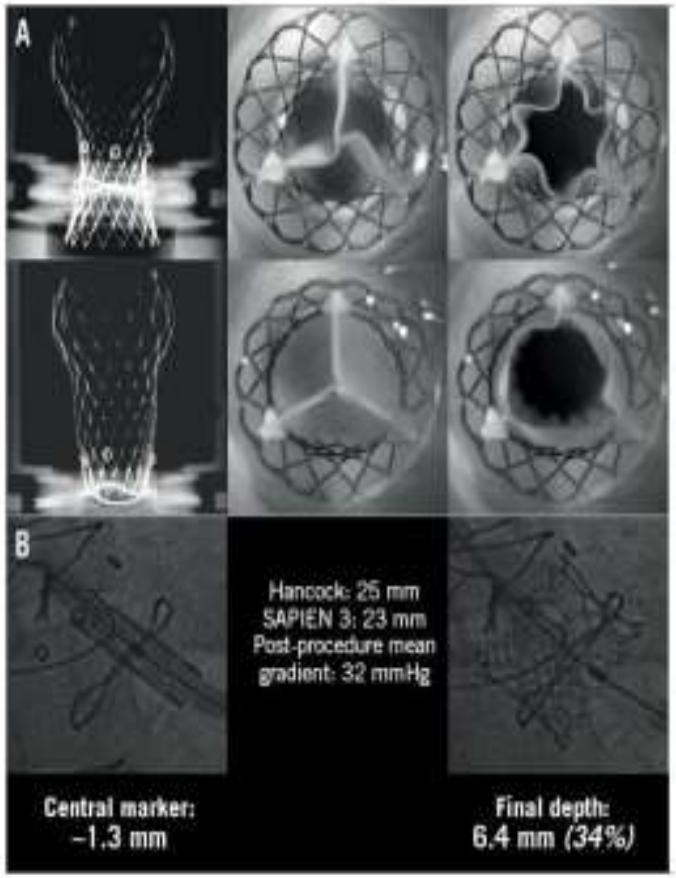
# Implant depth determines gradients for SAPIEN 3 ViV

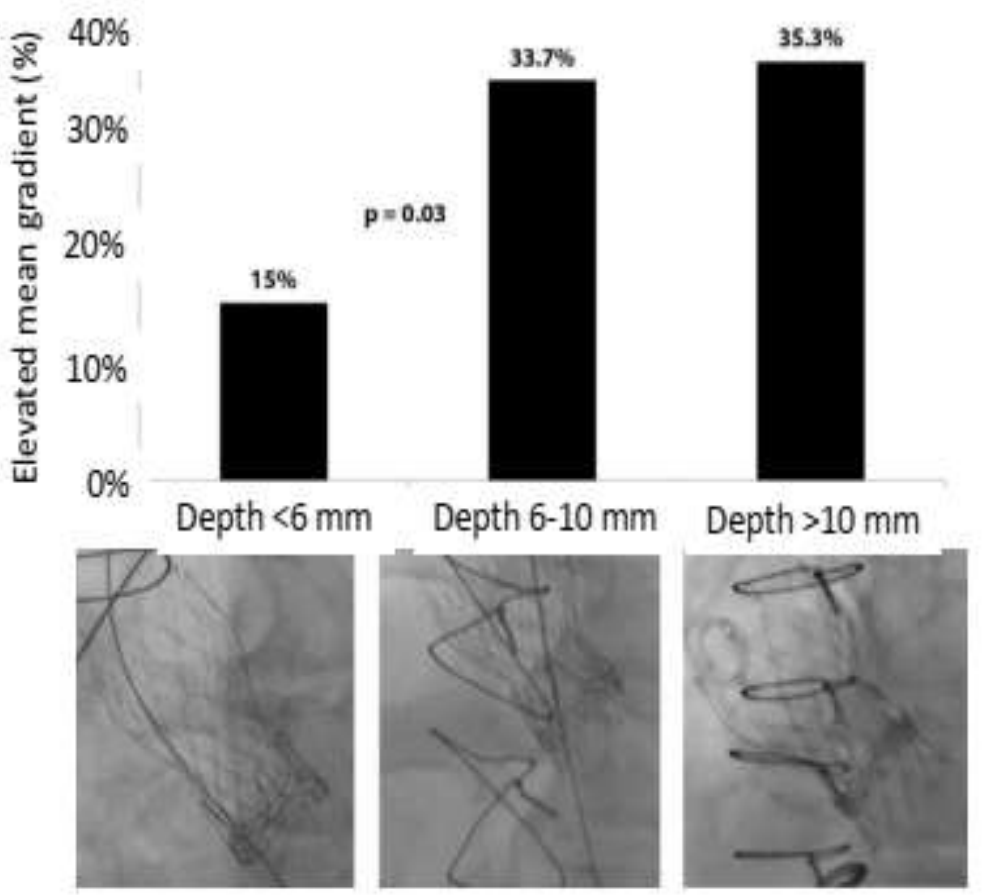



Gradient >20mmHg may occur with deep implants

Valve-in-Valve International Data (VIVID) Registry
Dvir, et al. JAMA 2014

# High Implants give Lowest Gradients!

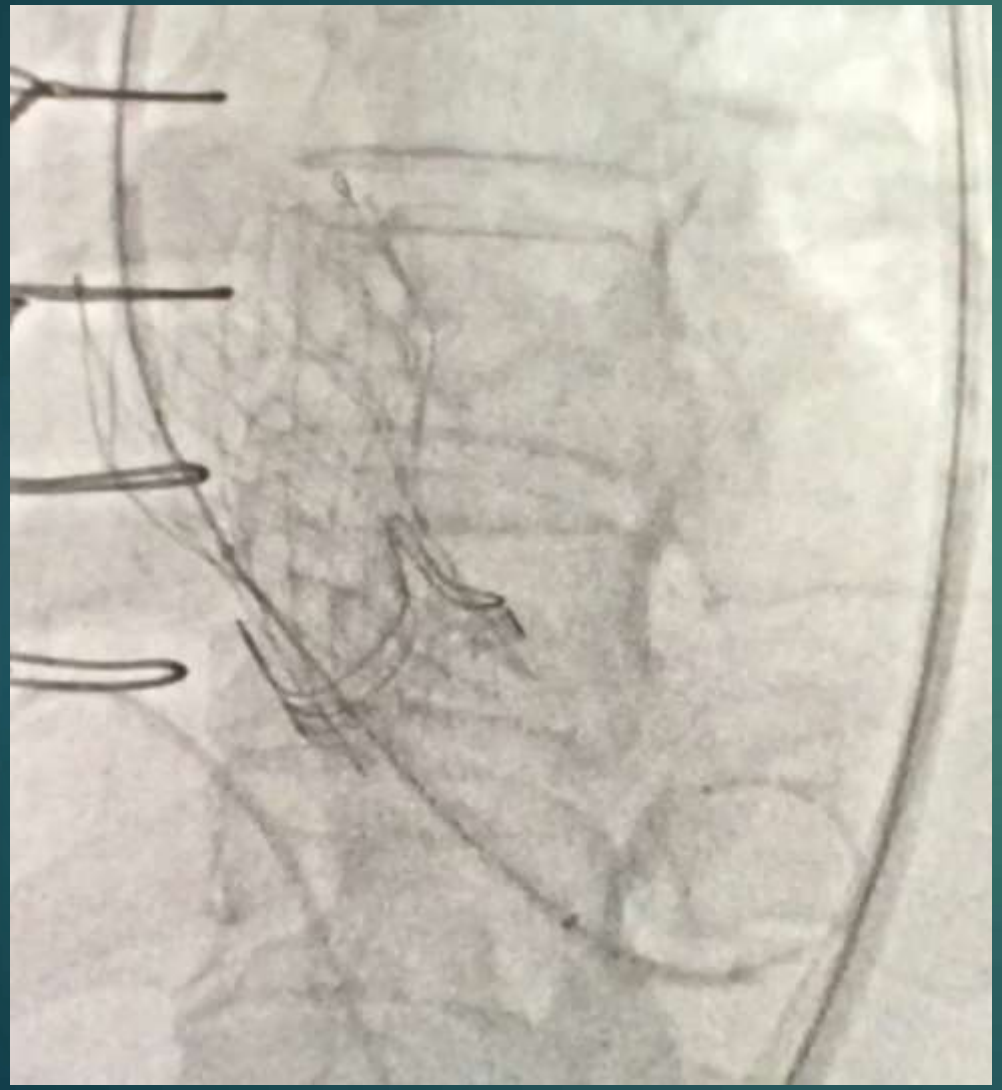


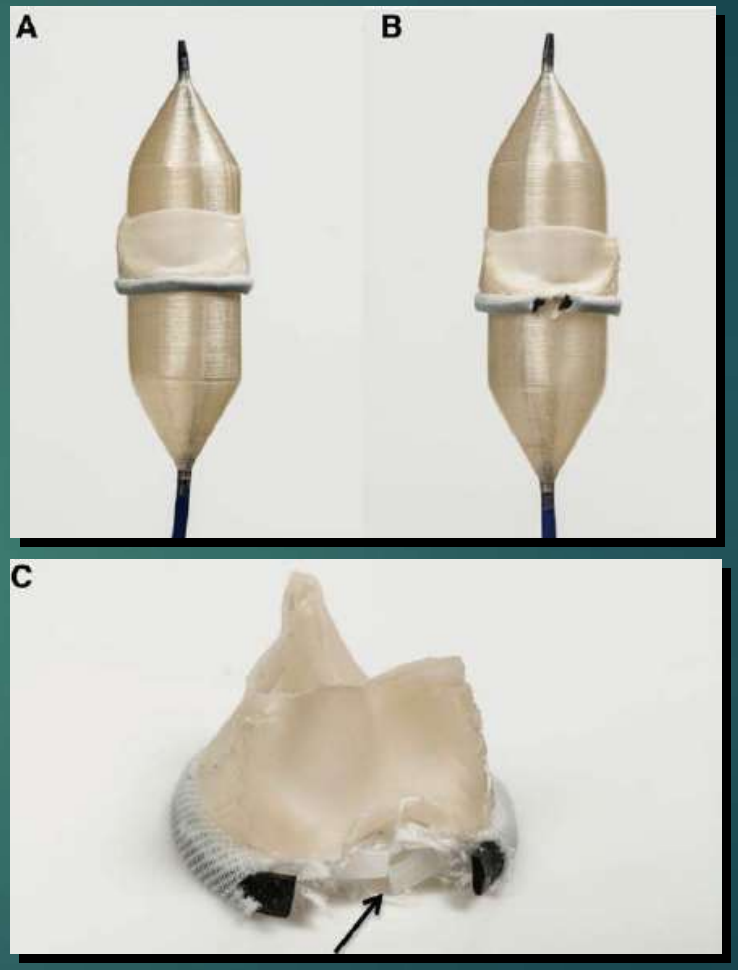




Simonato et al. Circ Cardiovasc Interv 2015

*Simonato et al. Cir. Cardiovasc Interv 2015*

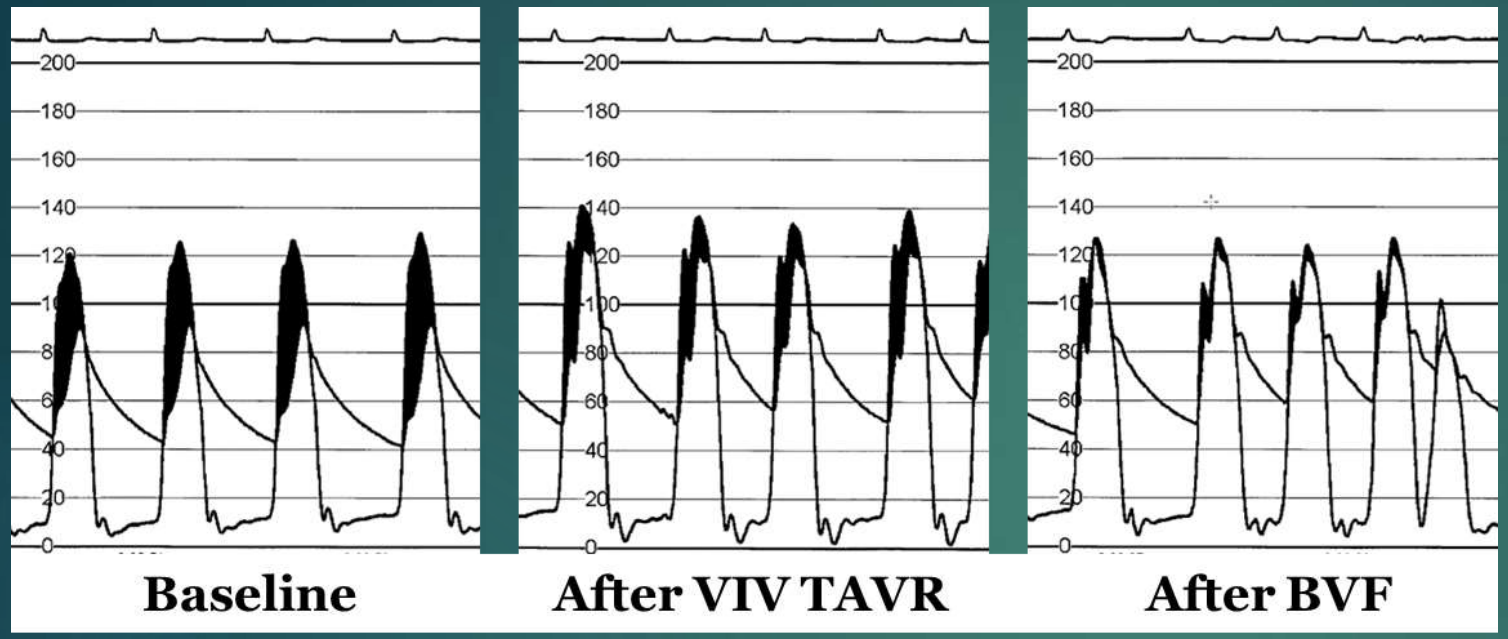
# Fracturing the Ring of small bioprostheses






Nielsen-Kudsk JE, et al. Circ Cardiovasc Intv 2015

# Bioprosthetic Valve Fracture




Structural Heart Disease

**Bioprosthetic Valve Fracture Improves the Hemodynamic Results of Valve-in-Valve Transcatheter Aortic Valve Replacement**

Adnan K. Chhatriwalla, MD; Keith B. Allen, MD; John T. Saxon, MD; David J. Cohen, MD, MSc; Sanjeev Aggarwal, MD; Anthony J. Hart, MD; Suzanne J. Baron, MD, MSc; Danny Dvir, MD; A. Michael Borkon, MD

rger

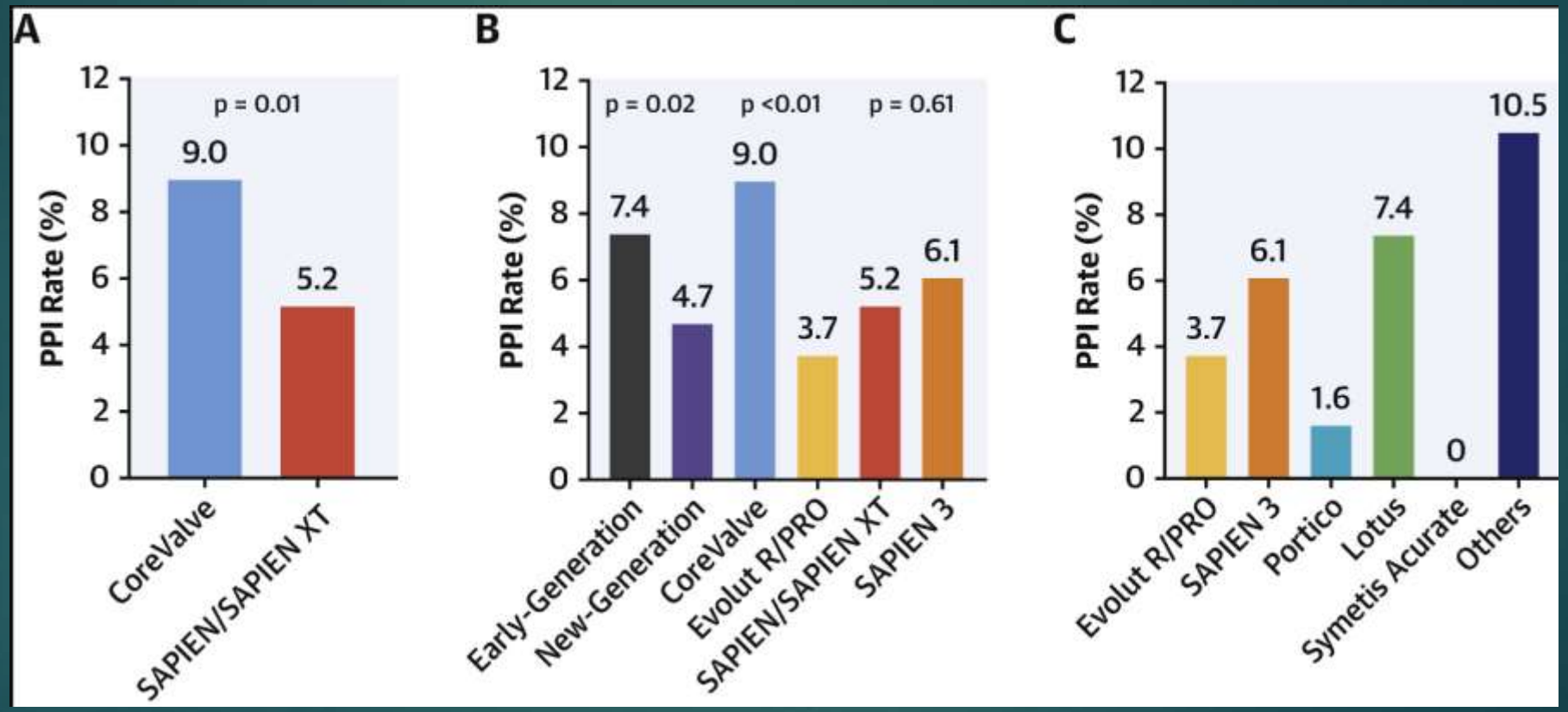
mHg

| Manufacturer/ Brand | Valve Size | Bard TRU Balloon Fracture/Pressure |
|---|---|---|
| St. Jude Trifecta | 19 mm<br>21 mm | NO<br>NO |
| St. Jude Biocor Epic | 21 mm | YES / 8 ATM |
| Medtronic Mosaic | 19 mm<br>21 mm | YES / 10 ATM<br>YES / 10 ATM |
| Medtronic Hancock II | 21 mm | NO |
| Sorin Mitroflow | 19 mm<br>21 mm | YES / 12 ATM<br>YES / 12 ATM |
| Edwards MagnaEase | 19 mm<br>21 mm | YES / 18 ATM<br>YES / 18 ATM |
| Edwards Magna | 19 mm<br>21 mm | YES / 24 ATM<br>YES / 24 ATM |

K Allen et al. Annals of Thoracic Surgery 2017

# Permanent pacemaker implantation after Valve-in-valve

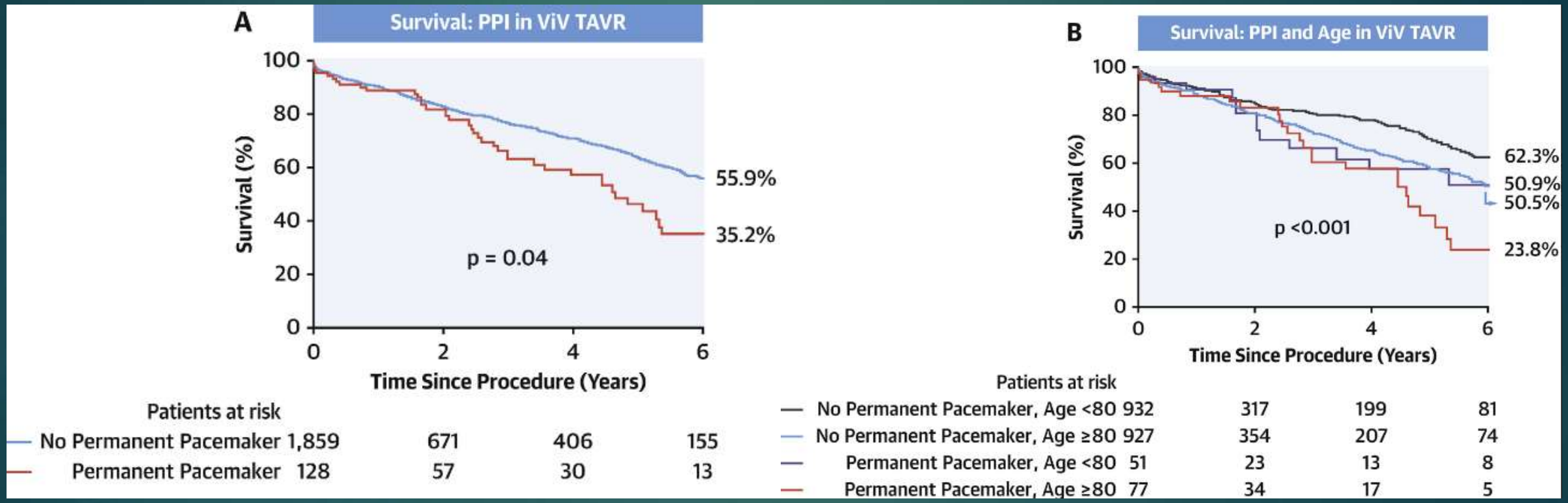
## PPI rate after ViV-TAVR for Early- and New-generation Devices




Alperi A, et al., VIVID Registry. J Am Coll Cardiol. 2021 May 11;77(18):2263-2273

# Permanent pacemaker implantation after Valve-in-valve

## Survival curve After ViV-TAVR by PPI and Age




Alperi A, et al., VIVID Registry. J Am Coll Cardiol. 2021 May 11;77(18):2263-2273

# In Summary

- ViV TAVR is a viable, less invasive option for patients with degenerated aortic bioprostheses, with the potential for improved short-term morbidity and mortality when compared with redo-SAVR.
- 
- ViV TAVR requires close attention to individual patient anatomy, as well as a plan for lifetime valve management with careful attention to the risk of acute coronary obstruction, feasibility of future coronary re-access, and hemodynamic results.

- The risk for coronary obstruction can be mitigated with careful preprocedural CT planning and the use of techniques, such as snorkel stenting or BASILICA.

- Bioprosthetic valve fracture may help address patient–prosthesis mismatch following ViV TAVR.