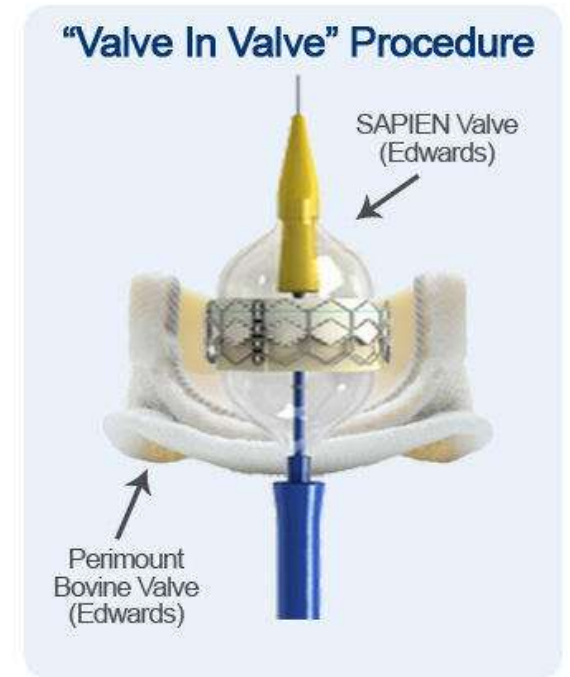




# Patient-Prosthesis Mismatch After VIV TAVR, How to Overcome?



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Professor of Medicine, Cheng-Hsin General Hospital and  
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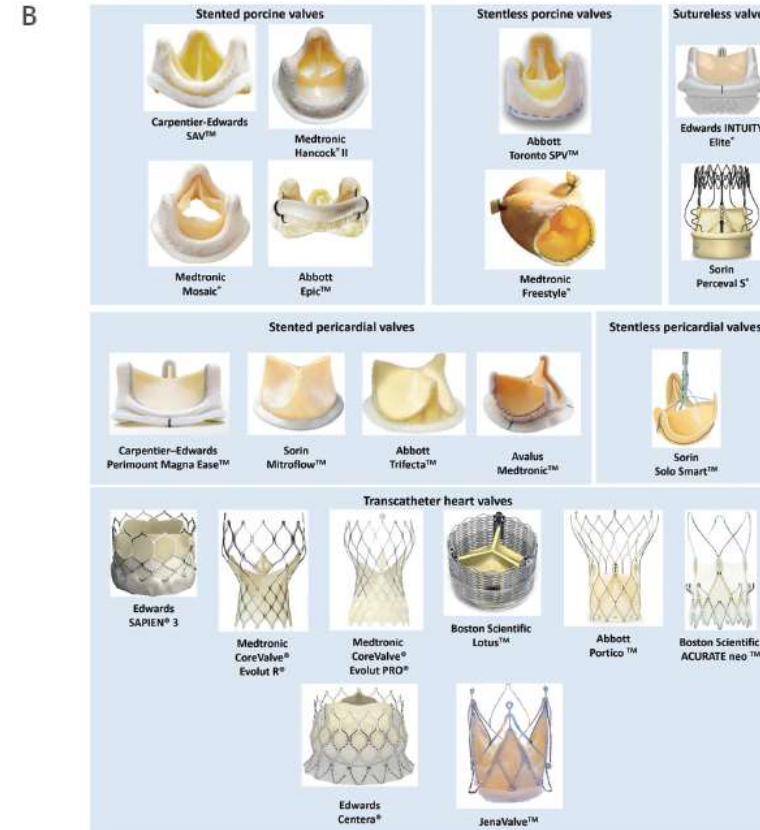
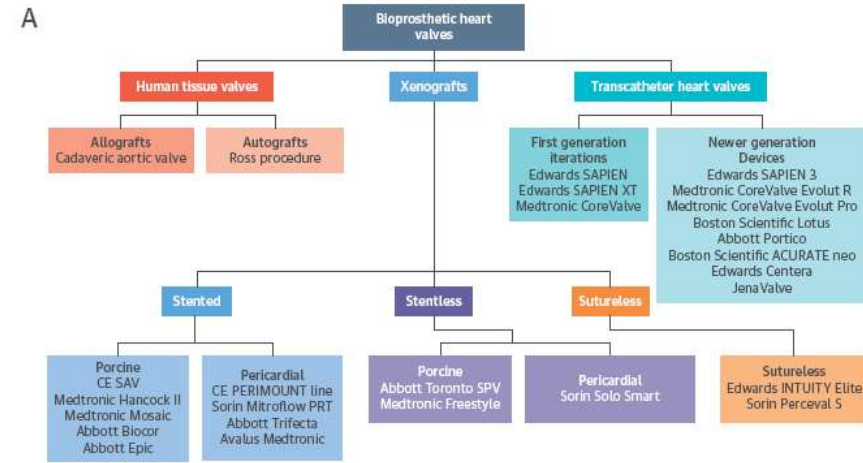


# Aortic Bioprosthesis

(J Am Coll Cardiol 2017;70:1013-28)

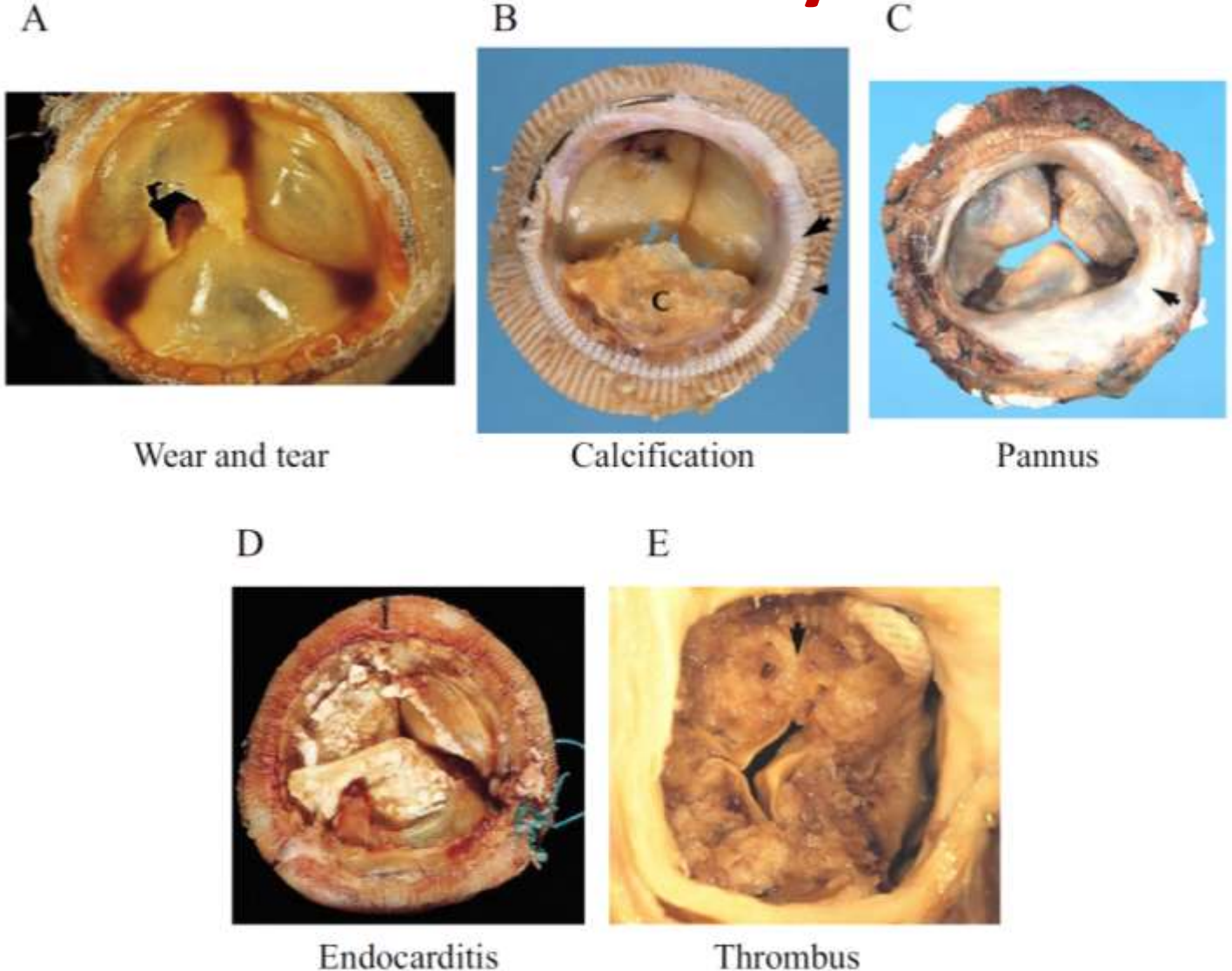
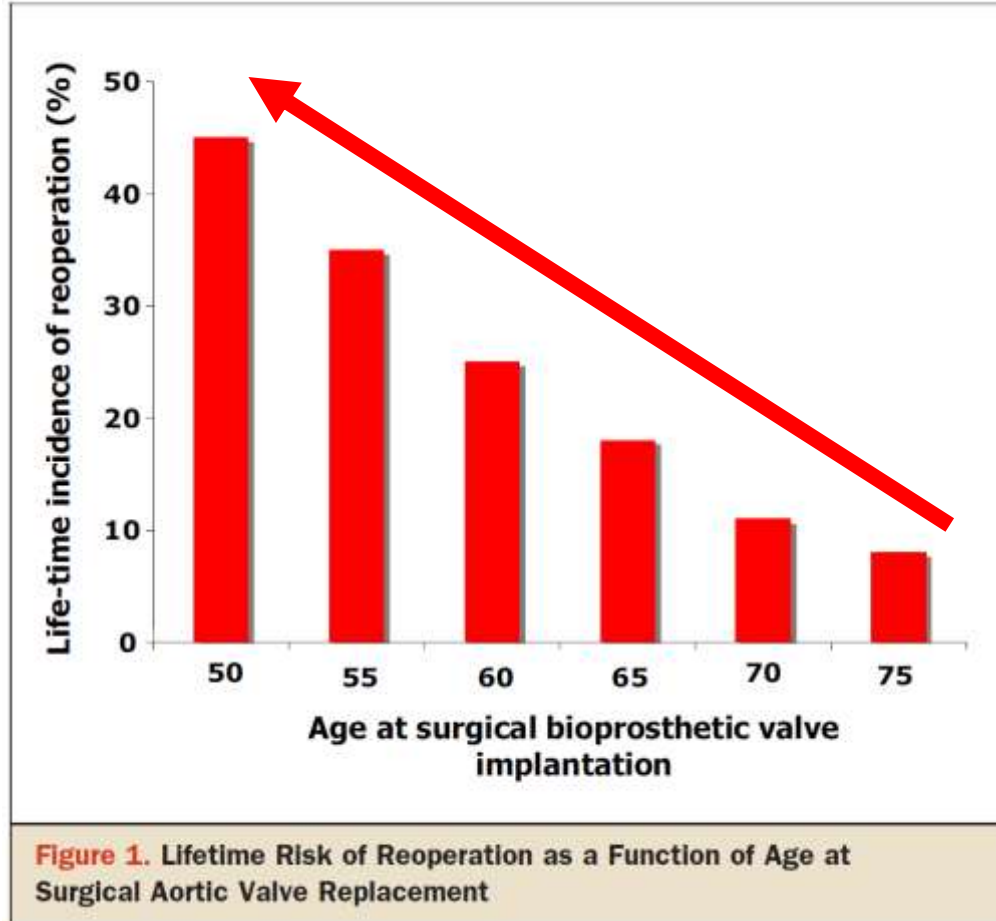
➤ In recent 2 decades, there has been **a considerable increase in the use of aortic bioprostheses** (vs. mechanical prostheses) for treating aortic valve disease, and this tendency is likely to continue in the near future.

FIGURE 1 Main Surgical and Transcatheter Aortic Bioprostheses



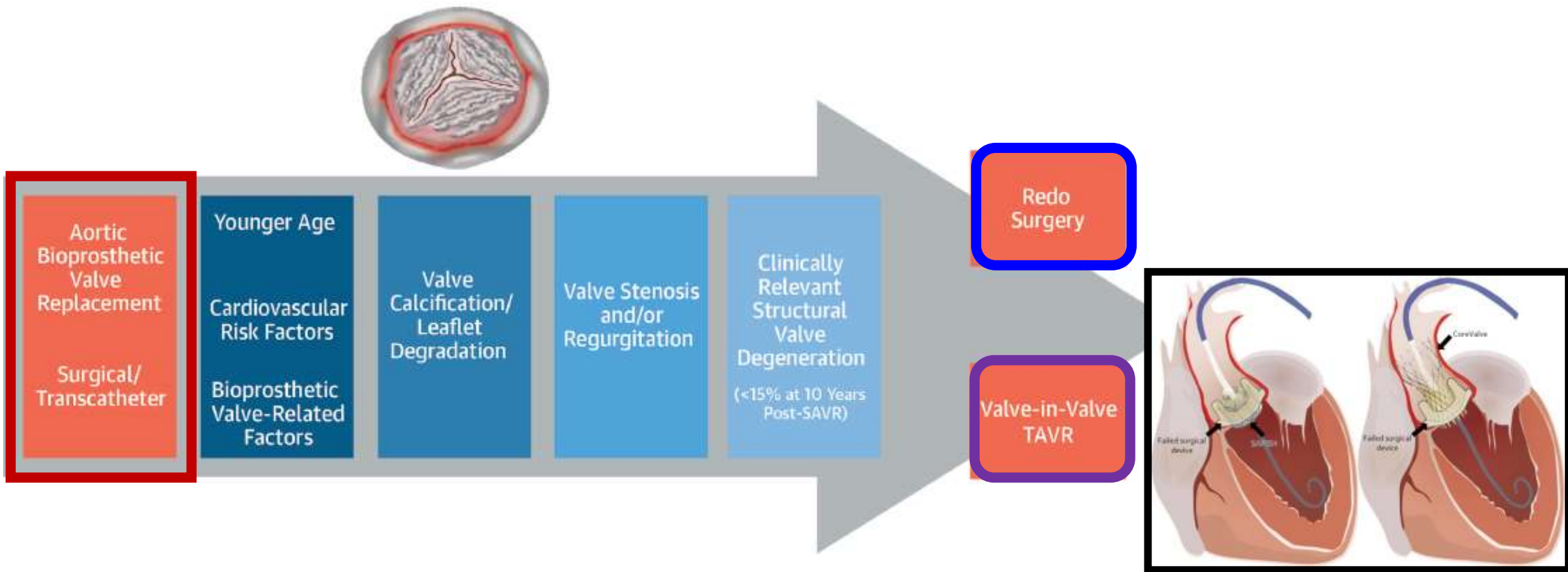
# With time, bioprosthetic tissue can be expected to deteriorate and eventually fail.

The lifetime risk of reoperation is higher in younger patients undergoing SAVR.



# Is Transcatheter Valve-in-Valve the first line therapy for failed valvular bioprosthesis?

**CENTRAL ILLUSTRATION** Structural Valve Degeneration Following Surgical or Transcatheter Aortic Bioprosthesis Implantation

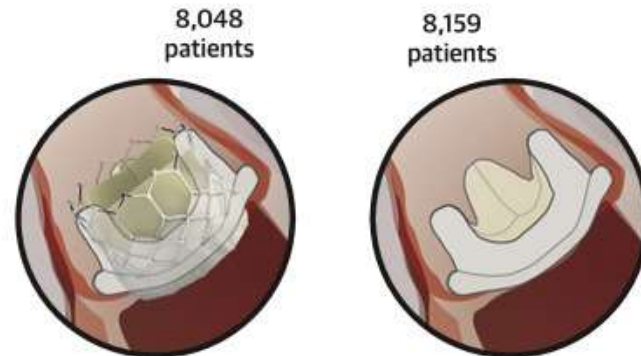
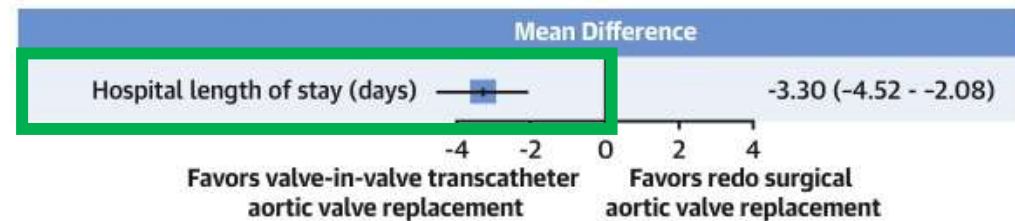
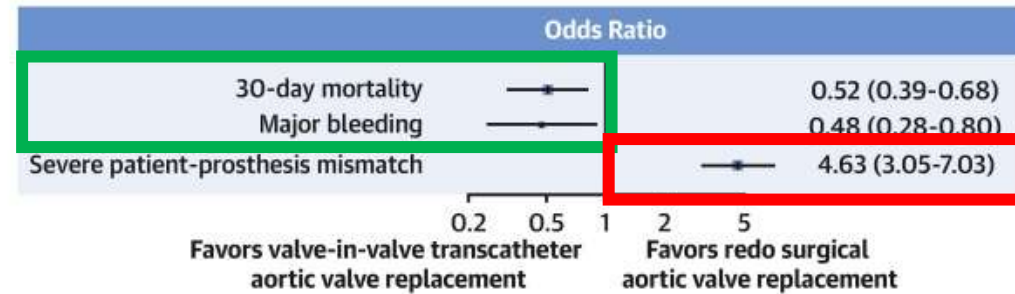


# Valve-in-Valve Transcatheter Aortic Valve Replacement Versus Redo Surgical Aortic Valve Replacement

An Updated Meta-Analysis

- Current data showed that TAVR-in-SAVR is associated with lower rates of 30-day mortality, and major bleeding, as well as with shorter hospital stay.
- But **higher** rates of **severe patient-prosthesis mismatch**, especially in **small surgical valves**.

**CENTRAL ILLUSTRATION: ViV-TAVR Is Associated With Lower Rates of 30-Day Mortality, and Major Bleeding, But Higher Rates of Severe Patient-Prosthesis Mismatch**



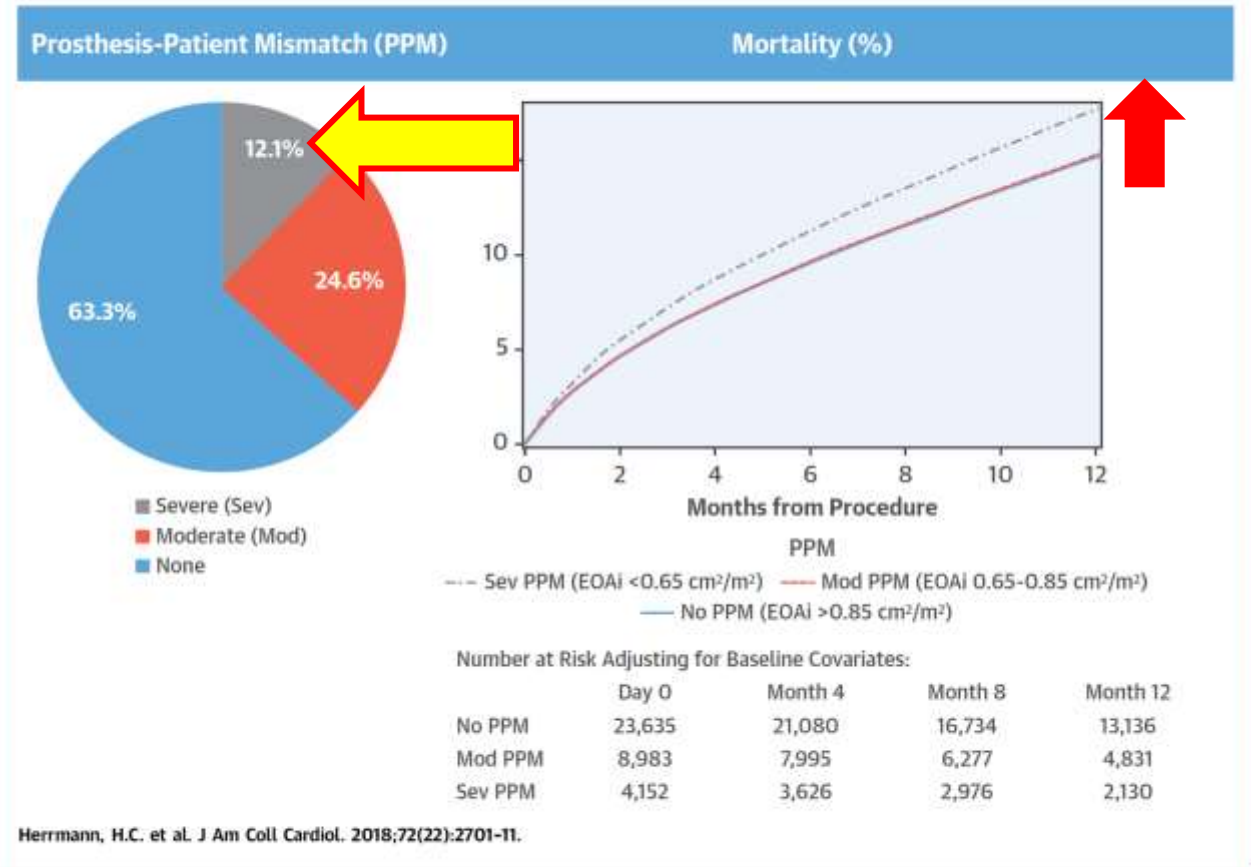
# Prosthesis-Patient Mismatch in Patients Undergoing Transcatheter Aortic Valve Replacement

From the STS/ACC TVT Registry

2014-2017; N = 62.125

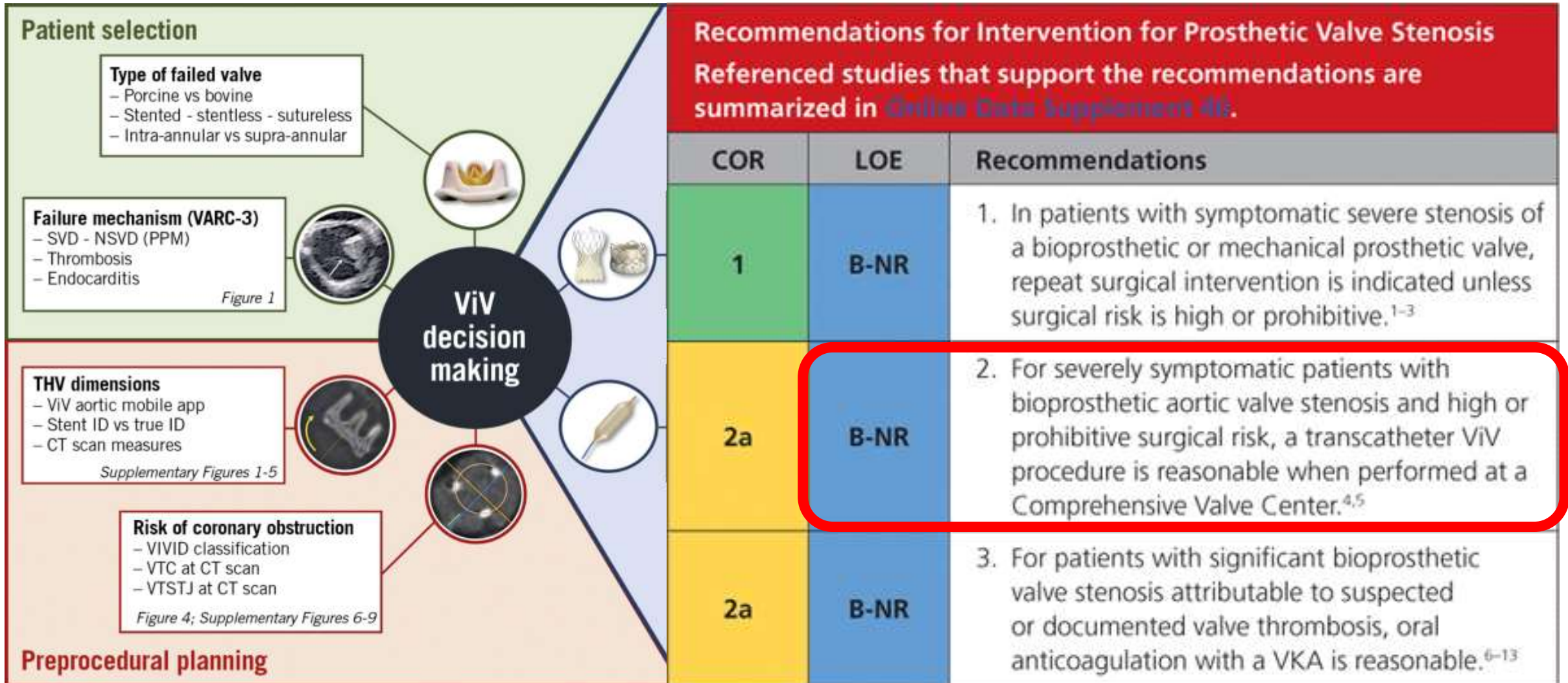
- Severe PPM after TAVR was present in **12%** of patients and was **associated with higher mortality and HF rehospitalization at 1 year.**
- Predictors of severe PPM included **small ( $\leq 23$ -mm diameter) valve prosthesis, valve-in-valve procedure**, larger body surface area, female sex, younger age, non-white/Hispanic race, lower EF, atrial fibrillation, and severe MR or TR.

**CENTRAL ILLUSTRATION** Incidence and Effect on Survival of Severe Prosthesis-Patient Mismatch After Transcatheter Aortic Valve Replacement



This figure shows the incidence of PPM in the entire study population (N = 62,125) and the adjusted 1-year mortality for 37,470 patients with Centers for Medicare & Medicaid Services Medicare claims linkage. It demonstrates that severe PPM is common after TAVR and is associated with greater 1-year mortality (hazard ratio: 1.19). Further investigation is warranted into prevention of severe PPM in patients undergoing TAVR. EOAI = effective orifice area index; TAVR = transcatheter aortic valve replacement.

# PPM is one of the Key Considerations for TAVR-in-SAVR vs. Redo SAVR



# Valve In Valve

By UBQO Limited

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Updated: May 18, 2015

Version: 4.0

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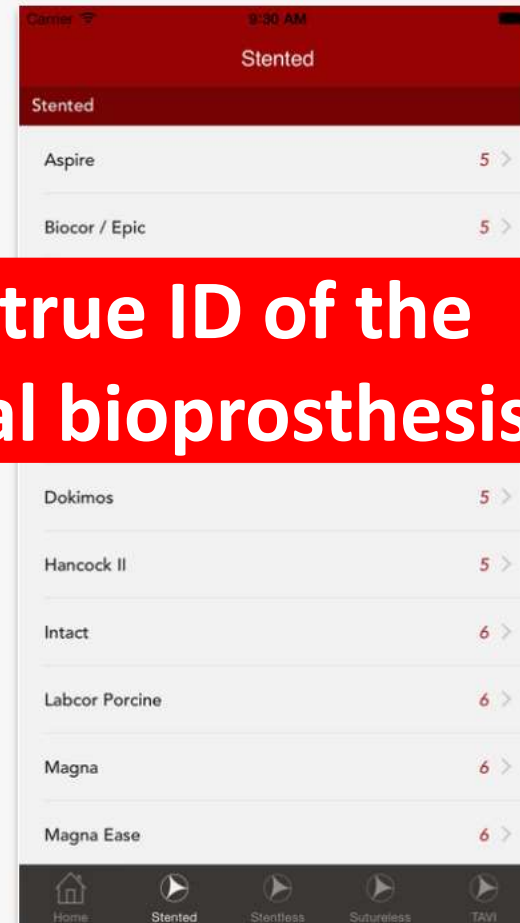
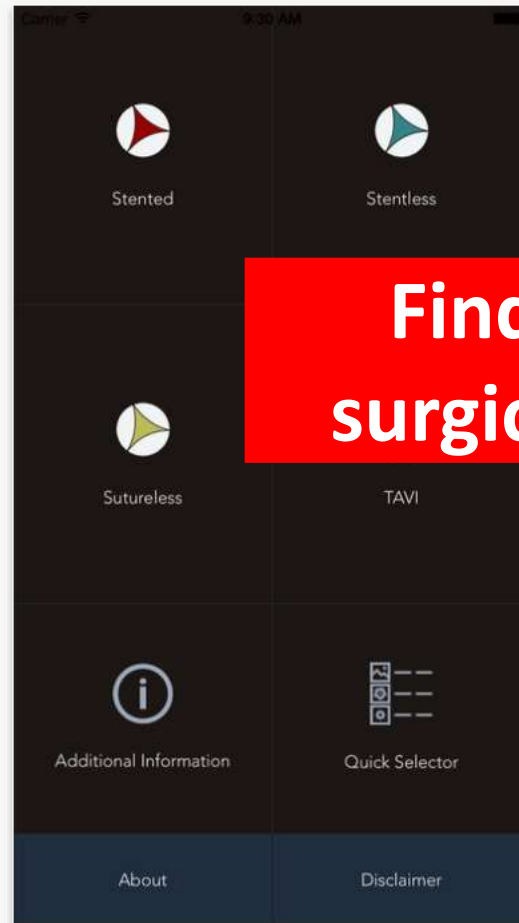
# App for transcatheter VIV measurements

## Description

An instant guide to Valve in Valve procedures for clinicians

## Screenshots

iPhone | iPad



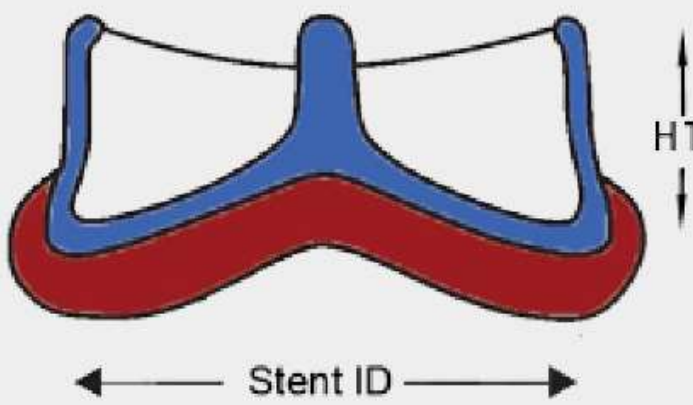
Find true ID of the surgical bioprosthesis




# App-derived vs. CT-derived measurements

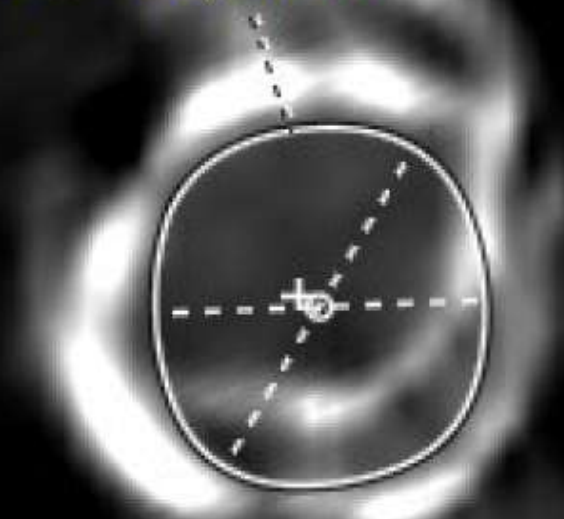
Medtronic Hancock II, 21mm, implantation 11 yrs ago

< Hancock II Valve Size



Stent Internal Diameter	18.5
 True ID	16.5
Height	15

Min. Ø: 15,4 mm  
Max. Ø: 17,3 mm  
Perimeter derived Ø: 16,5 mm  
Perimeter: 51,9 mm

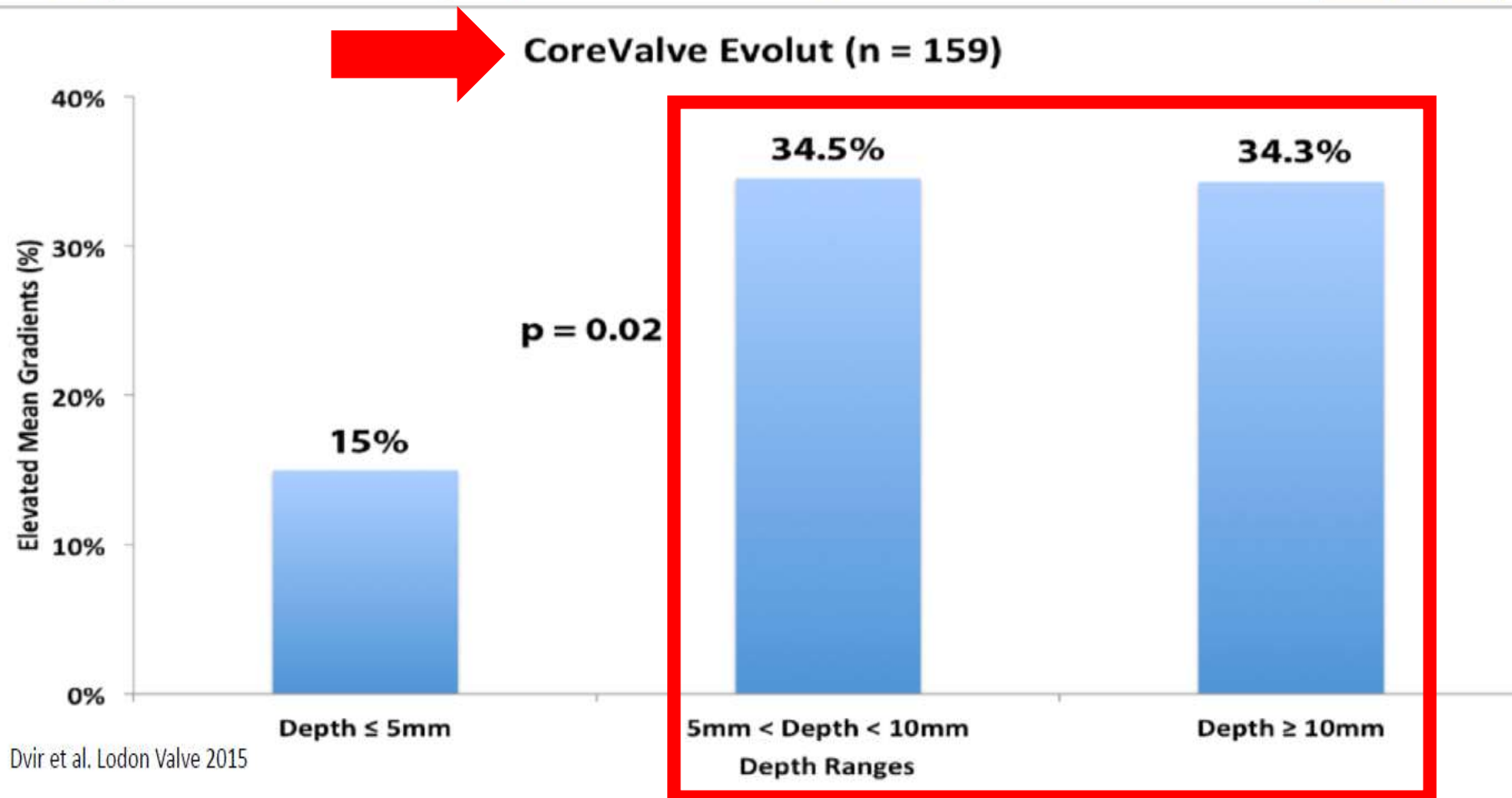


# The implantation depth matters!

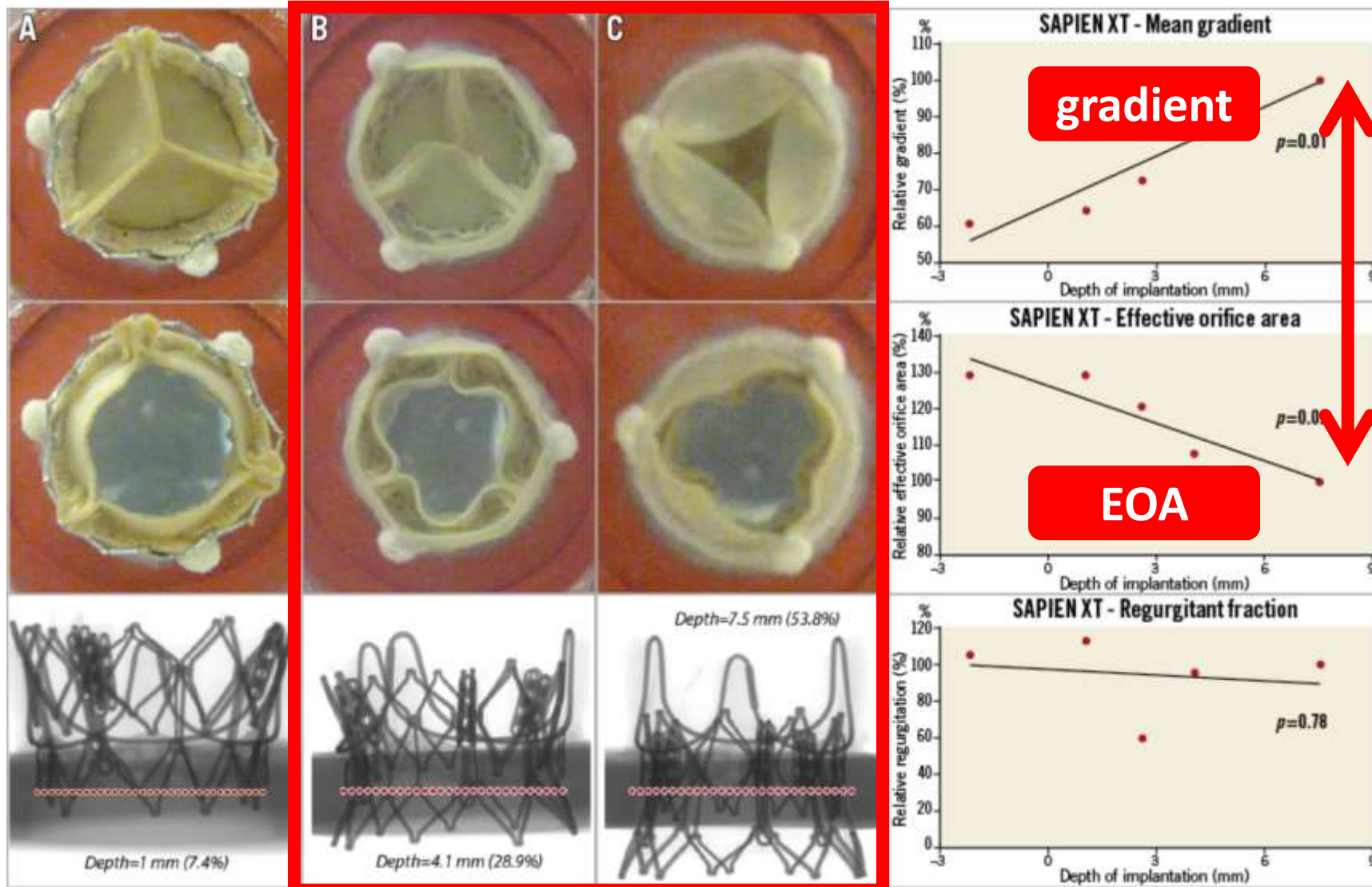
PCR 2015  
london valves



## Implantation Depth and Gradients

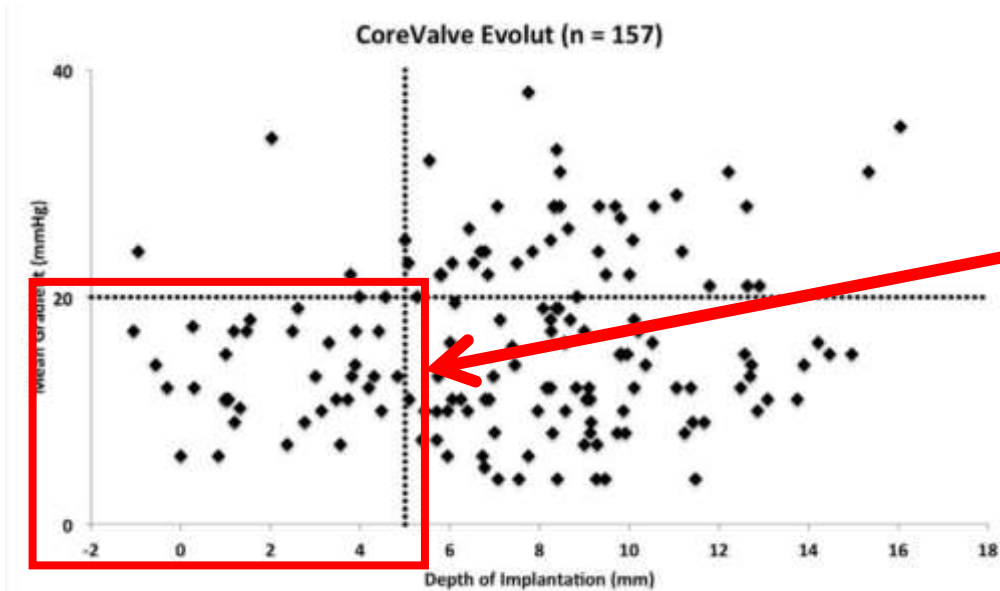


# Implantation Depth and Pressure Gradient of XT

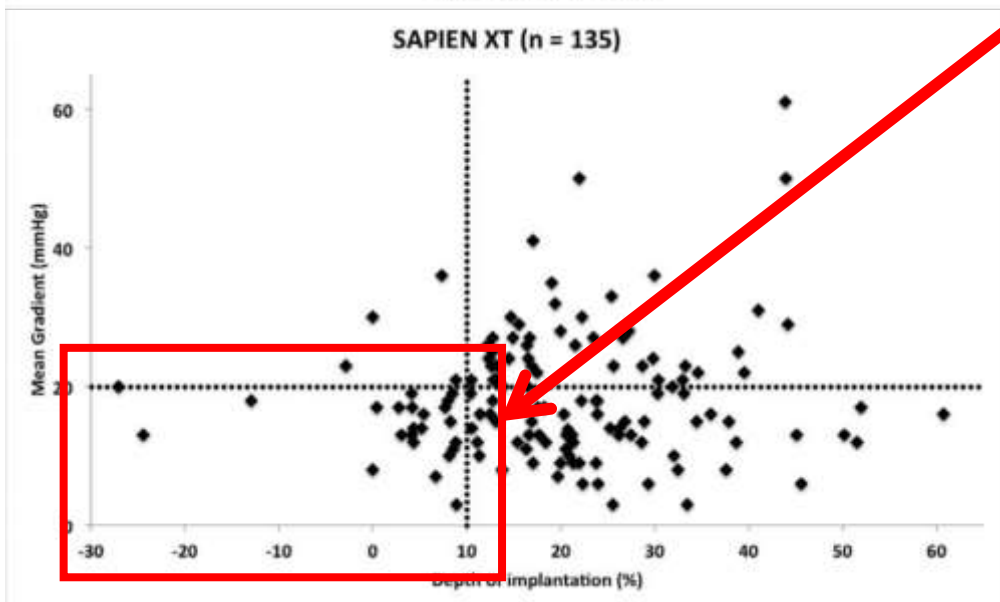


front reintercession invaritib gnituz evliev-ni-ovliev ni rihqub nothninqimti fo nothulave ovliev ni  
 -ovliev-  
 M. J. ...  
 ...

# Balloon Expandable Valve vs. Self Expandable Valve



**CoreValve (26mm)**  
implantation depth  
**> 5 mm**



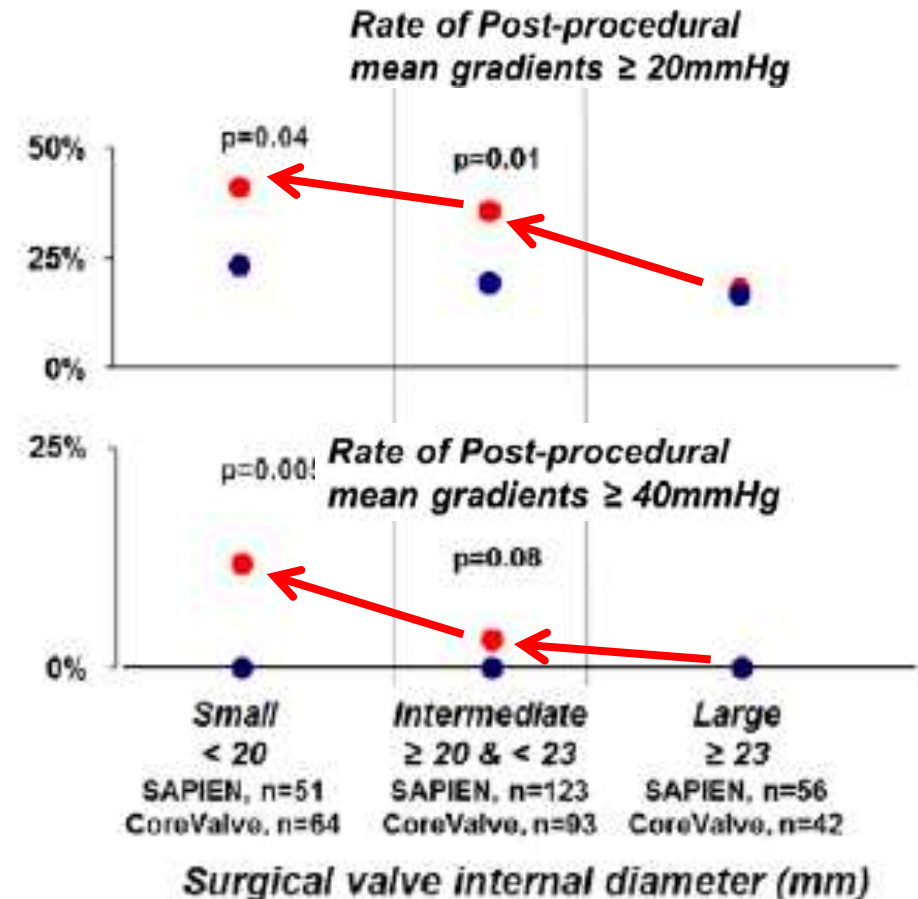
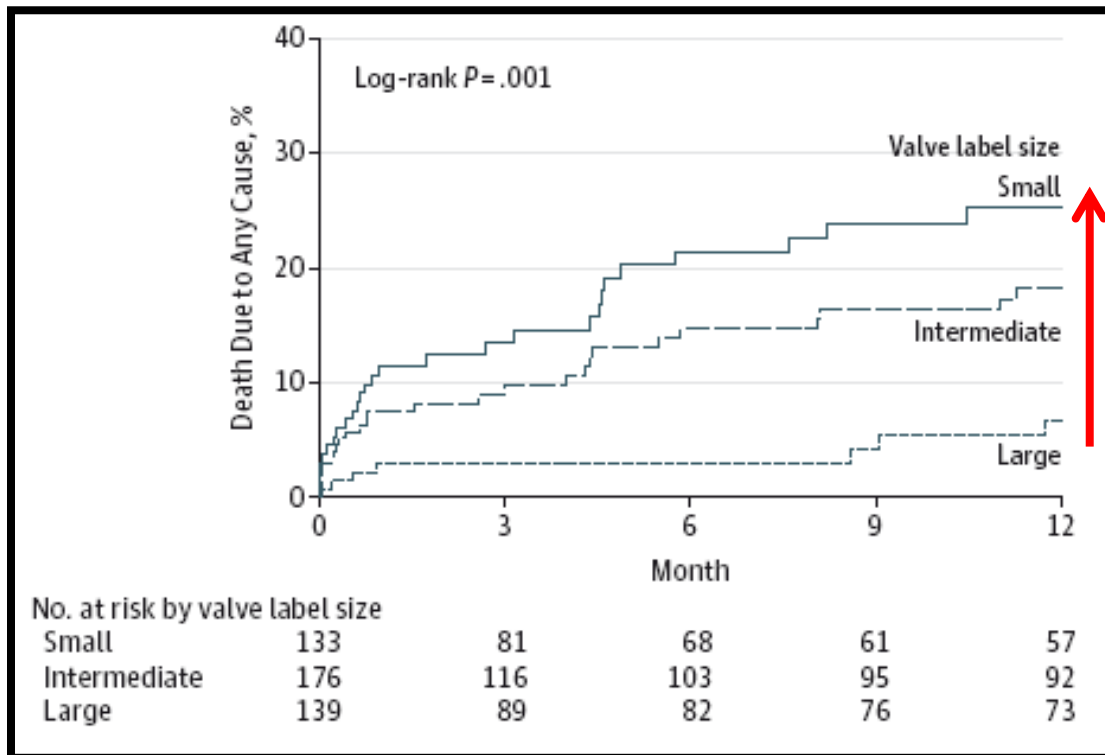
**Sapien XT**  
implantation depth  
**> 10%** (3 mm in 23  
mm Sapien XT)

are associated with  
**higher pressure  
gradient.**

# The device chosen matters, especially in smaller surgical valves!

In the Edwards SAPIEN group, there was a negative trend between the bioprosthesis size and high post-procedural gradients rates

## Surgical valve label size



**Zoro-tolerance policy against PPM must be adopted.**

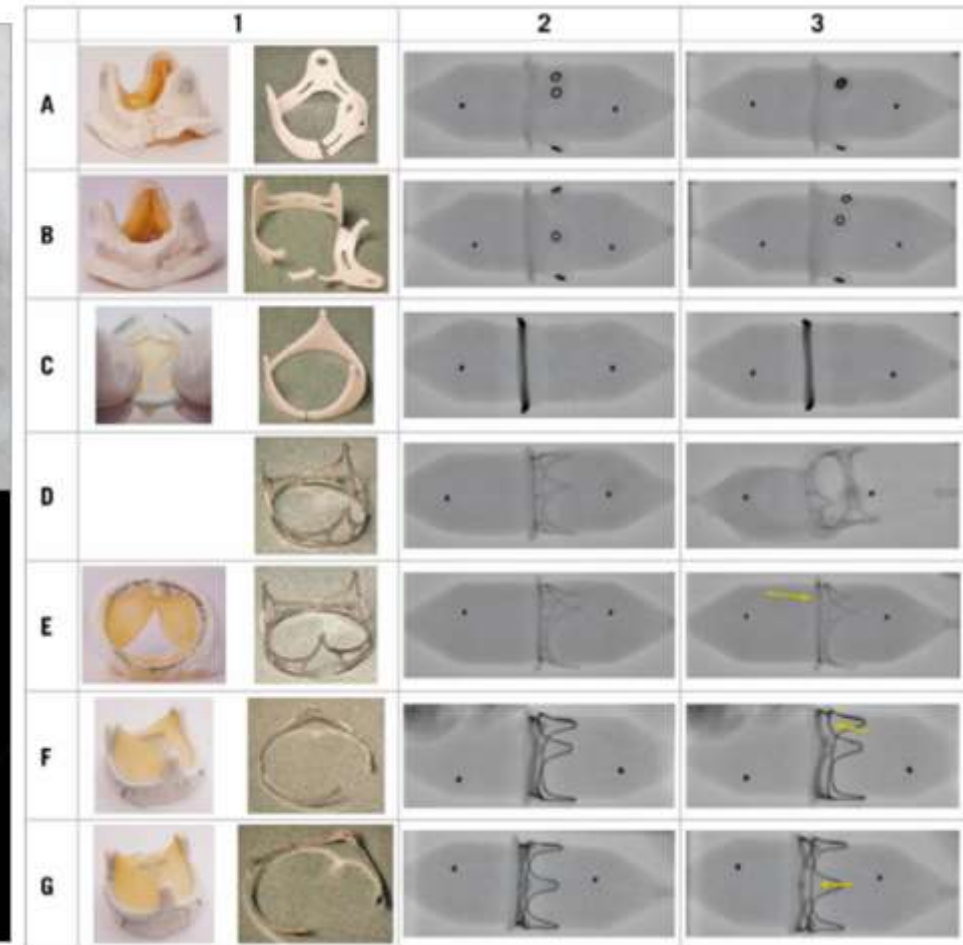
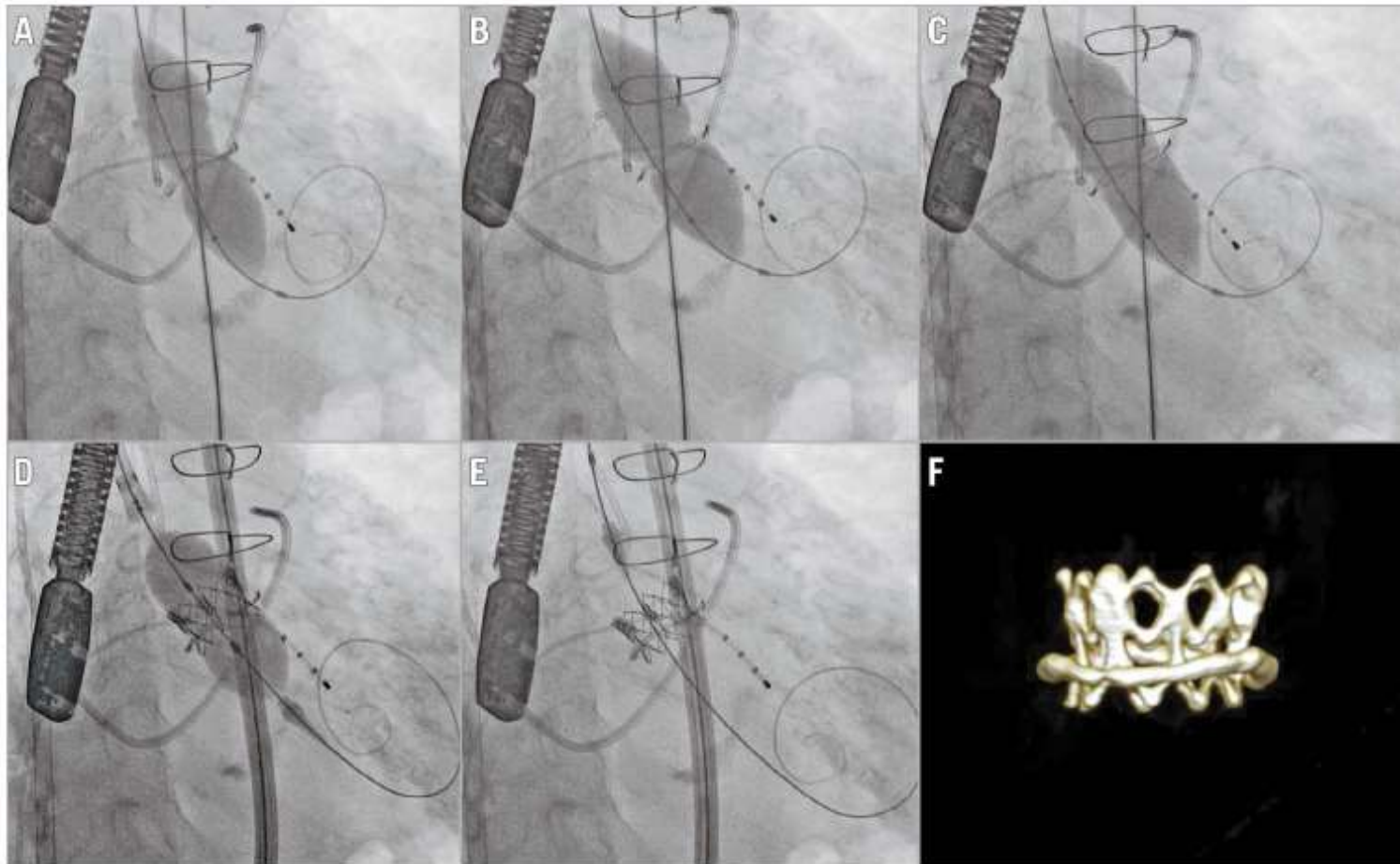
..... **HOW TO** .....

**OVERCOME**

**CHALLENGES**

# BVF as an adjunct to ViV TAVR is safe and effective.

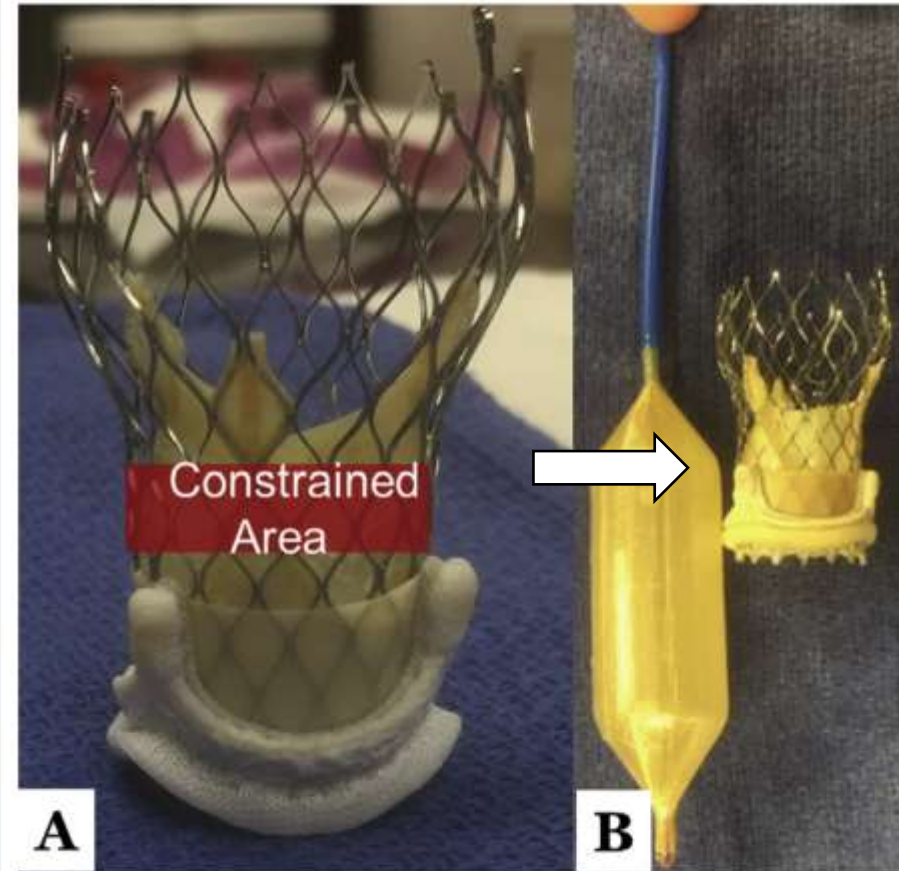
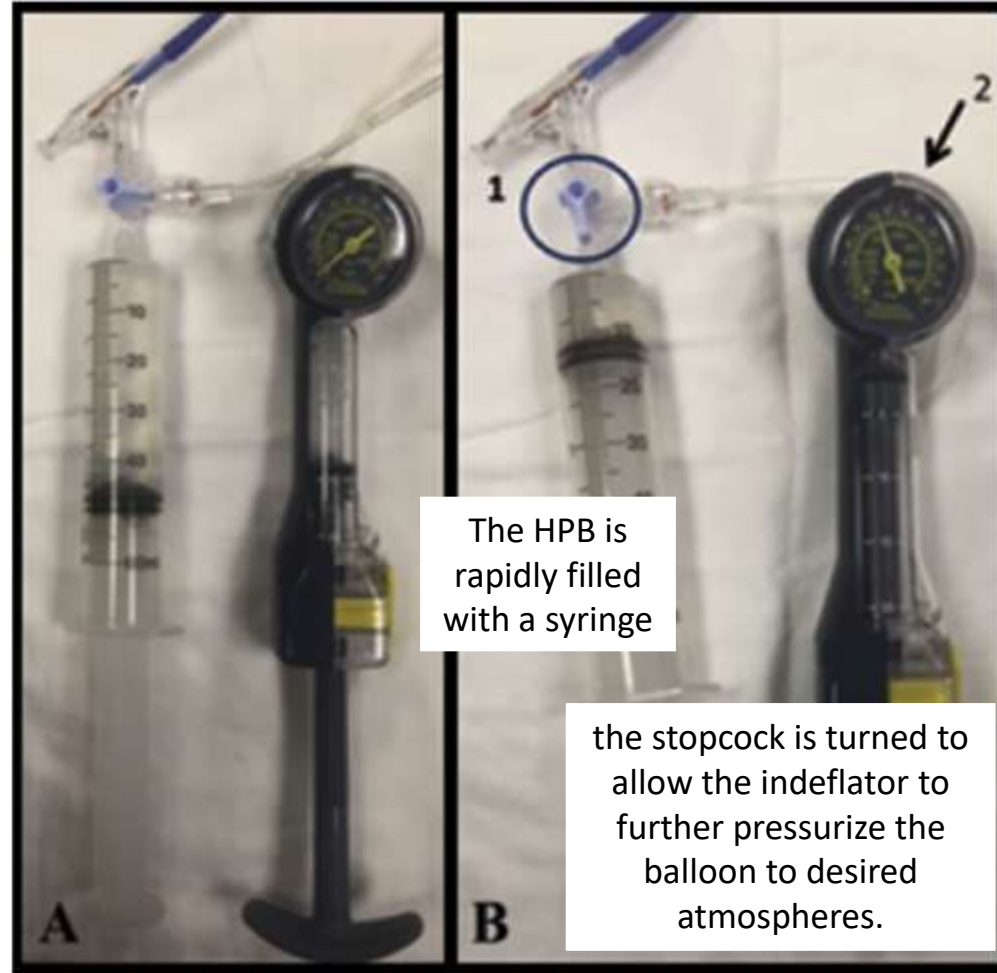
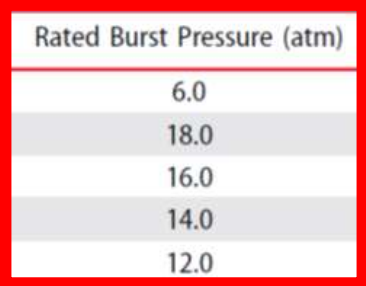
It allows for optimal THV expansion and improved hemodynamic profile, particularly in small, stenotic bioprosthetic valves.



# Two-step Inflation

**Table 3.** Summary of non-compliant balloons used for bioprosthetic valve fracture.

Balloon Type	Manufacturer	Balloon Sizes (mm)	Nominal Pressures (atm)	Rated Burst Pressure (atm)
TRUE® DILATATION	Bard Peripheral Vascular Inc., Tempe, AZ, USA	18, 20, 21, 22, 23, 24, 25, 26, 28	3.0	6.0
ATLAS® GOLD PTA	Bard Peripheral Vascular Inc., Tempe, AZ, USA	12, 14, 16	6.0	18.0
		18, 20	6.0	16.0
		22, 24	4.0	14.0
		26	4.0	12.0
VIDA™ PTV	Bard Peripheral Vascular Inc., Tempe, AZ, USA	12, 14, 16, 18, 20, 22, 24, 26	-	-



**Constrained diameter is 20 mm for 23 mm Evolut R and 22 mm for 26 mm Evolut R**

**Fig 1.** (A) High-pressure balloon (HPB) inflation was performed with a single-balloon technique. Balloon size was 1 mm larger than the labeled surgical valve size. If HPB inflation with a single balloon did not result in valve ring fracture, then an additional attempt was made using (B) a "kissing" double balloon technique with two Dorado balloons (C.R. Bard, Murray Hill, NJ) whose combined diameter was 1 mm larger than the labeled valve size.



**Trifecta and Hancock II surgical bioprostheses could not be fractured using any HPB inflation technique (balloon rupture occurred before fracture during all attempts).**

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

1. Balloons sized 1 mm larger than valve size.  
2. Medtronic Mosaic and Sorin Mitroflow have no metal in ring therefore appearance after fracture unchanged.

# Expanding Indications for Bioprosthetic Valve Fracture and Bioprosthetic Valve Remodeling

Who Is Most Likely to Benefit?

- Many surgical valves are amenable to BVF, while some others can be **stretched or remodeled**.
- However, the long-term outcomes of BVF and BVR and their effect on THV durability are yet to be determined.

**Table.** Bioprosthetic Valves That Can Be Fractured or Remodeled With a High-Pressure Balloon Inflation

Valves That Can Be Fractured	Valves That Can Be Remodeled	Valves That Cannot Be Fractured or Remodeled
Biocor Epic	Inspiris	Avalus
Magna	Carpentier-Edwards Standard	Hancock II
Magna Ease	Carpentier-Edwards SAV	
Mitroflow	Perimount (older generation)	
Mosaic	Trifecta	
Perimount (newer generation)		

# Performing BVF after VIV TAVR and using larger balloon appears to achieve the best hemodynamic results.

**TABLE 3. Univariable and multivariable predictors of final mean gradient following bioprosthetic valve fracture (BVF) (N = 75)**

Variable	Univariate association		Multivariable association	
	Beta weight* (95% confidence interval)	P value	Beta weight* (95% confidence interval)	P value
BVF after VIV TAVR vs BVF first	8.81 (4.76 to 12.86)	<.001	8.6.4 (3.87 to 13.41)	<.0001
Self-expandable THV type	0.09 (-2.97 to 3.15)	.95	0.99 (-2.85 to 4.82)	.61
THV right sized vs up sized	-0.77 (-3.75 to 2.21)	.61	0.38 (-4.05 to 4.81)	.86
Surgical valve true ID				
Small vs large	3.23 (-3.40 to 10.86)	.40	4.27 (-6.74 to 15.27)	.43
Intermediate vs large	3.48 (-4.21 to 11.18)	.37	4.16 (-5.63 to 13.95)	.40
Baseline mean gradient (mm Hg)	0.06 (-0.04 to 0.15)	.24	0.10 (-0.010 to 0.209)	.075
Mode of valve failure				
Insufficiency vs mixed	-2.35 (-8.28 to 3.58)	.43	-0.22 (-6.40 to 5.96)	.94
Stenosis vs mixed	0.27 (-4.82 to 5.35)	.92	0.86 (-6.09 to 4.36)	.74
BVF balloon size minus surgical valve true ID $\geq 3$ mm vs $< 3$ mm	4.62 (0.57 to 8.66)	.026	4.76 (10.27 to 9.24)	.038
THV size				
20 mm vs 23 mm	3.53 (-1.68 to 8.75)	.18	0.042 (-6.91 to 7.00)	.99
23 mm vs 26 mm	1.77 (-2.21 to 5.37)	.38	-0.22 (-6.09 to 4.36)	.93

BVF, Bioprosthetic valve fracture; VIV TAVR, valve in valve transcatheter aortic valve replacement; THV, transcatheter heart valve; ID, internal diameter. \*Beta weight represents the effect of the specific factor on the final mean transvalvular gradient in millimeters mercury.

# PPM PREVENTION

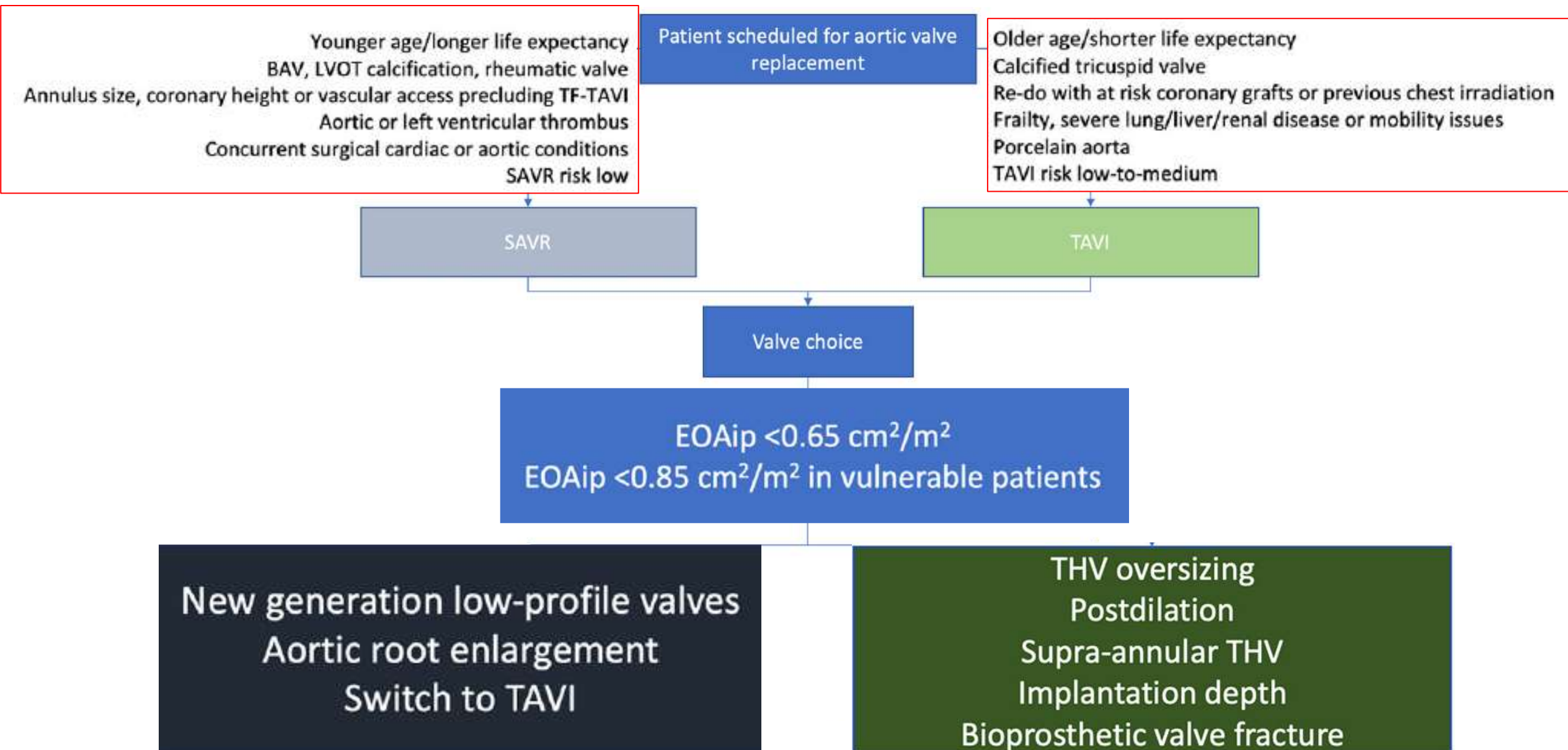
AN OUNCE OF  
PREVENTION IS WORTH A  
POUND IN CURE

*Benjamin Franklin*



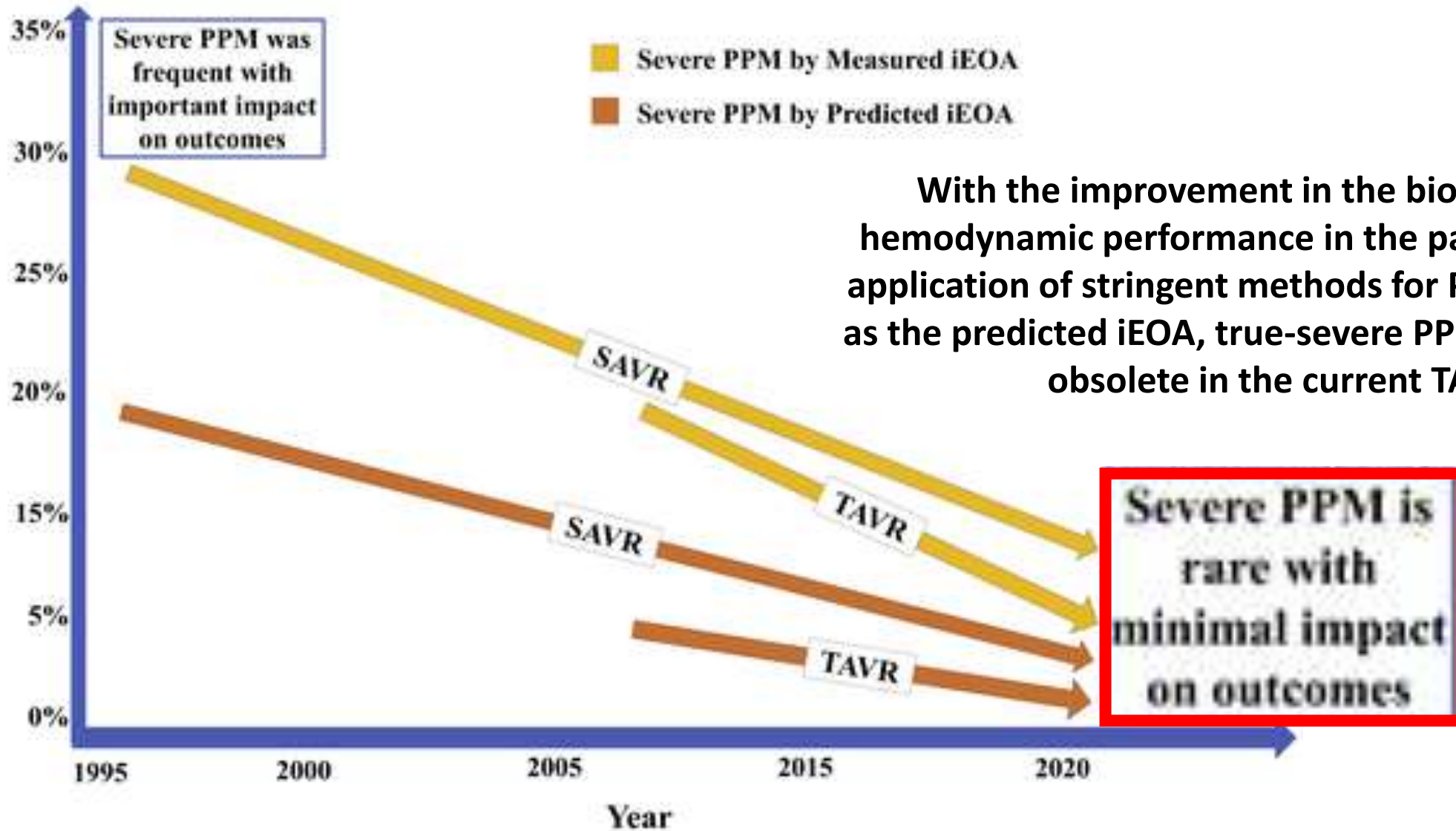
**SAVA-MDT exploring options to prevent PPM, including the implantation of newer generation prosthetic valves, aortic root enlargement and TAVI**

# PPM: Prevention is better than intervention



# True-severe PPM has become quasi obsolete in the current TAVR era

Incidence of Severe PPM (%)



With the improvement in the bioprosthetic valve hemodynamic performance in the past decades and the application of stringent methods for PPM definition, such as the predicted iEOA, true-severe PPM has become quasi obsolete in the current TAVR era.

Severe PPM is rare with minimal impact on outcomes

# Conclusions

- Valve-in-valve (VIV) implantation is **an acceptable alternative** to re-do open SAVR for elderly high surgical risk patients with bioprosthetic failure.
- **Proper sizing, selection of an appropriate device**, and pay attention to the **implantation depth** are the keys to success in VIV TAVR.
- However, **higher rates of severe patient-prosthesis mismatch** was noted in **VIV TAVR**, especially in **small surgical valves**.
- **For small surgical valve, a retrievable, recapturable supra-annular self-expanding THVs allowing reposition may be a better option.**
- **Post-dilatation, including fracturing of bioprosthesis stent in VIV TAVR**, in case of an increased gradient, should be done to achieve the best hemodynamic results.