ROLE OF SAVR IN ERA OF TAVI

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Modern Era defined by Trials

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Partner 1A 5 year outcomes for high surgical risk patients 2017
Core Valve US high risk 2020
Partner 2A intermediate risk 2020
SURTAVI intermediate risk 2017
NORDIC trial 2024

Partner 3 low risk 2023
Evolut LR low risk 2023

Summary of Trials comparing SAVR vs TAVR

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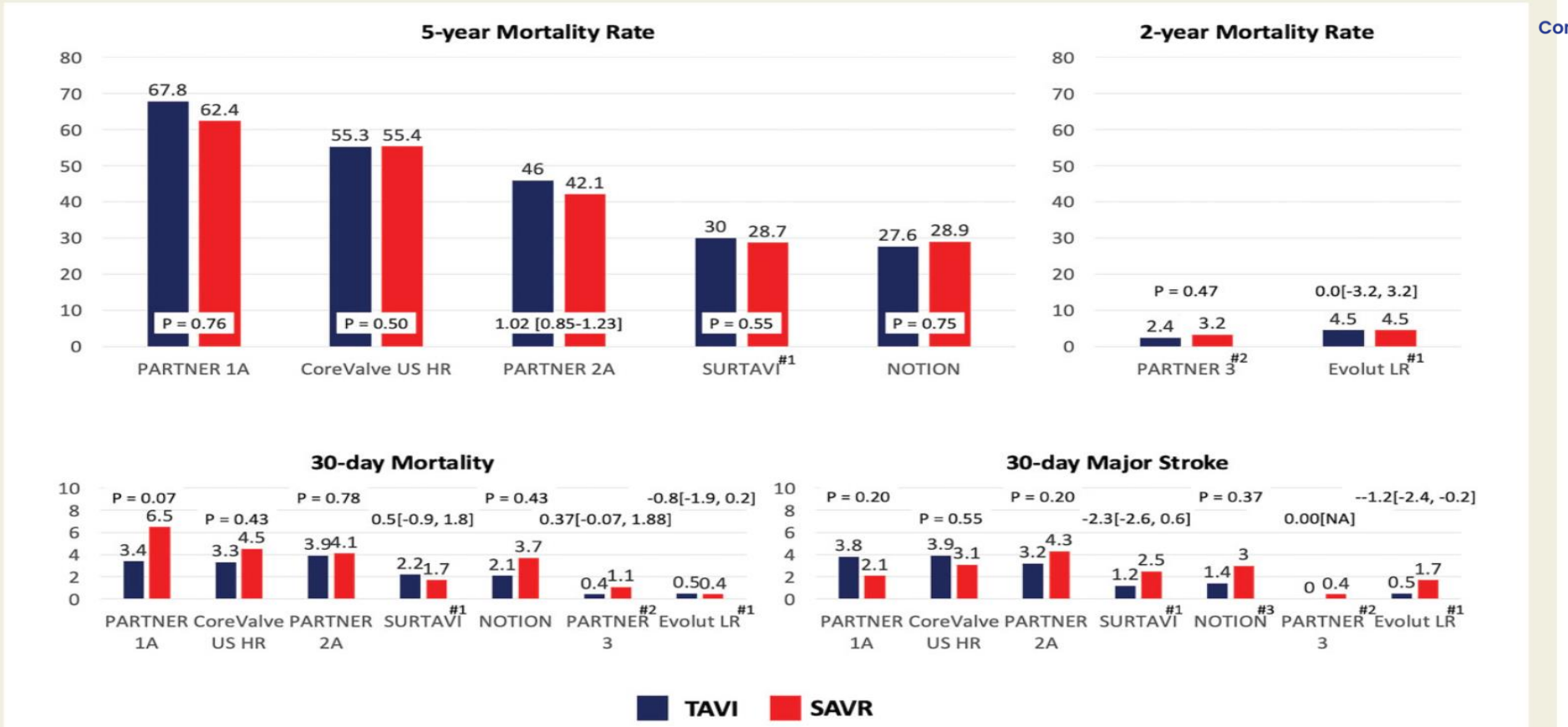
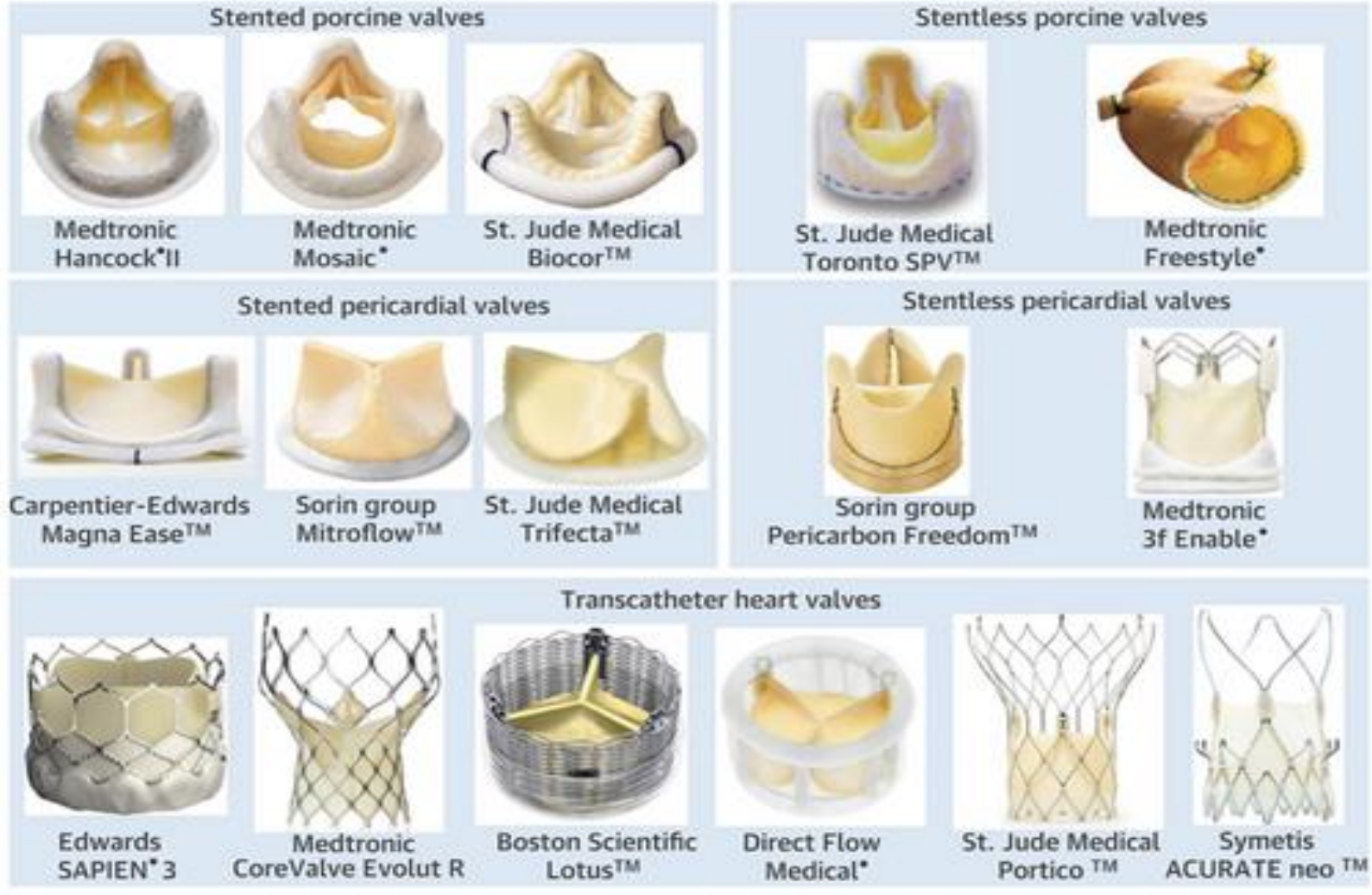
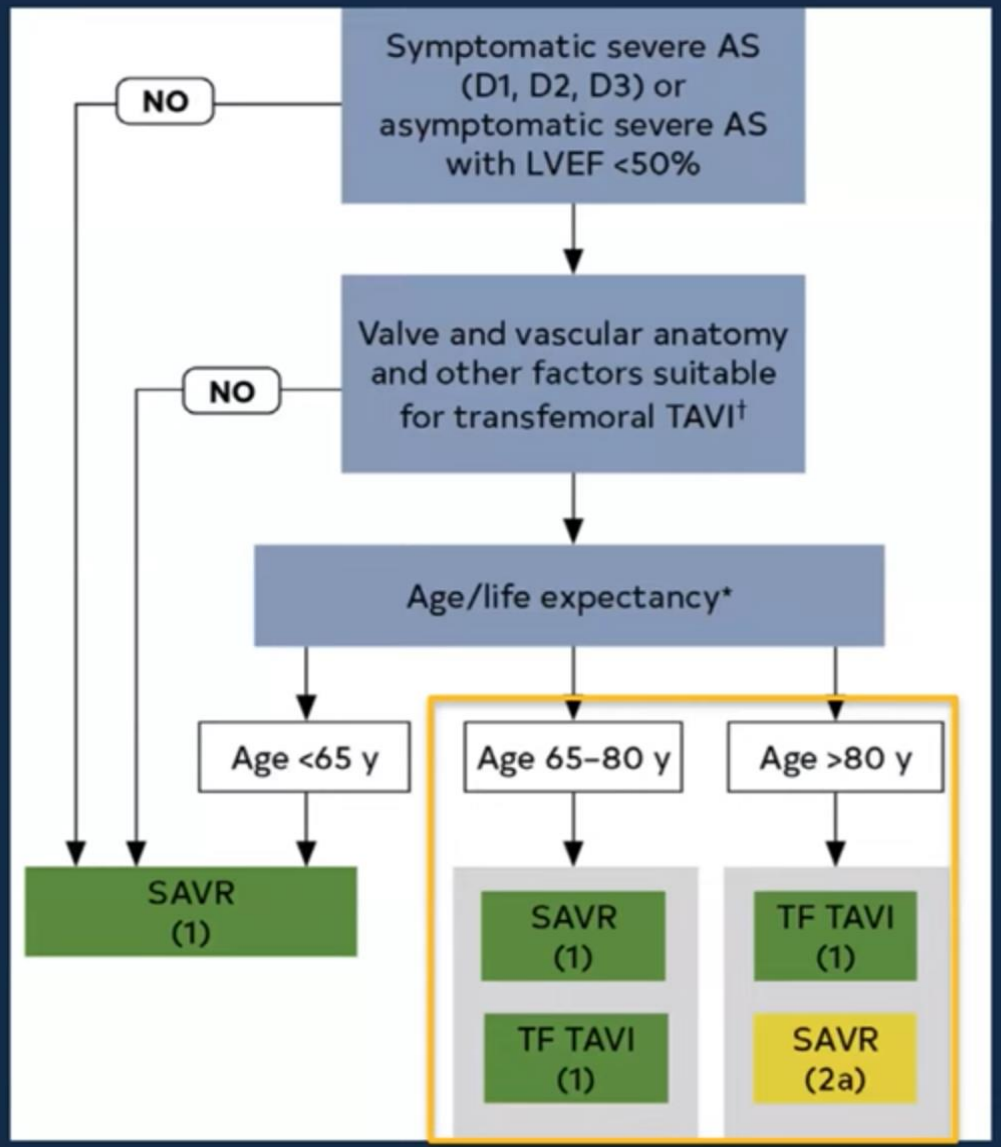


Figure 1 Short- and long-term outcomes of major randomized clinical trials. The results of PARTNER 1A, PARTNER 2A, PARTNER 2B, PARTNER 3, SURTAVI, and PARTNER 3 are provided from intention-to-treat analyses. The results of U.S. CoreValve High risk, NOTION, and Evolut Low Risk are provided from as-treated analyses. #1: Results are provided with differences (transcatheter aortic valve implantation–surgical aortic valve replacement) and 95% Bayesian credible interval. #2: Results are provided with hazard ratios and 95% confidence intervals. #3: Any stoke.

TAVI VALVES/SAVR VALVES

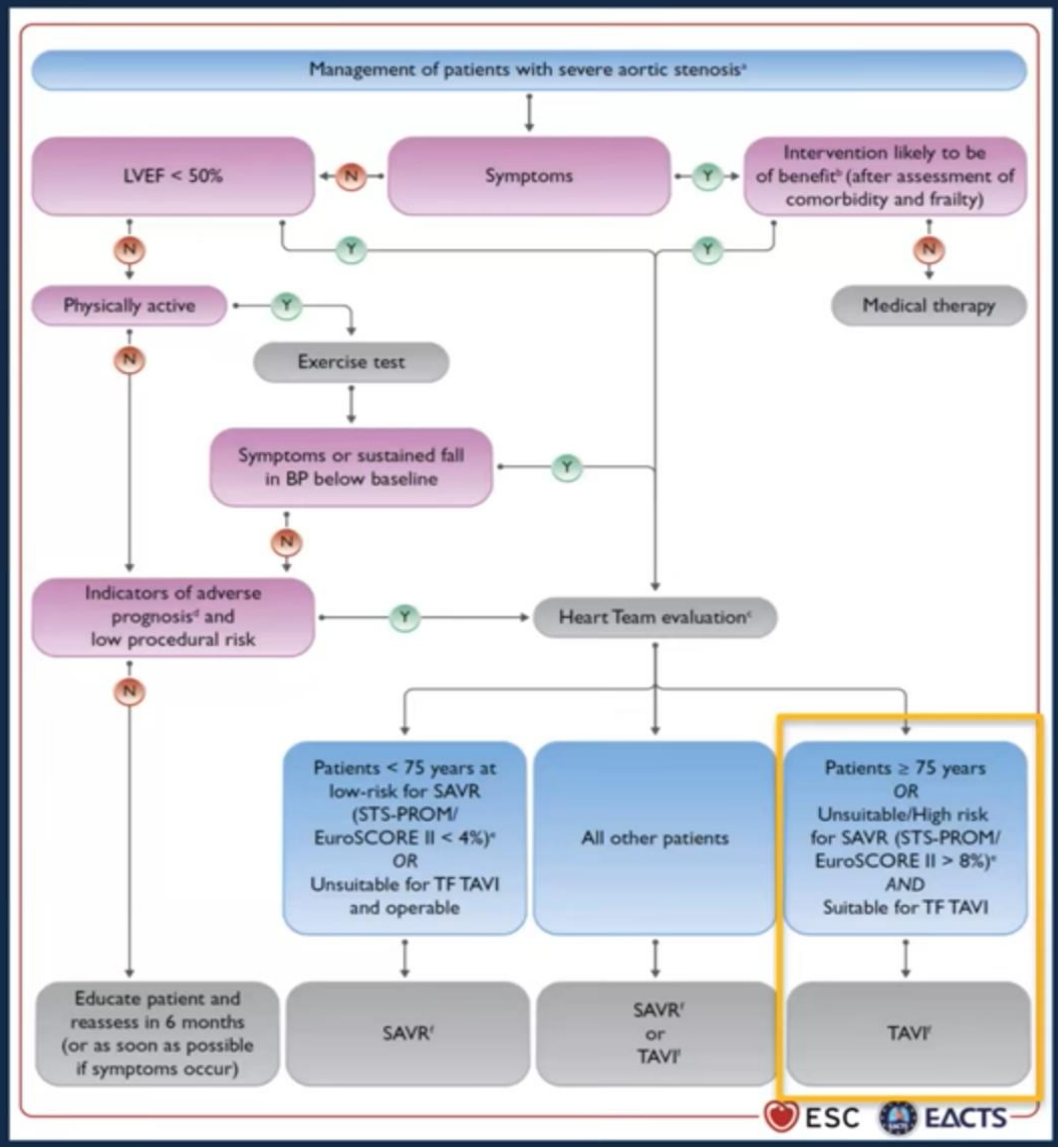


2020 AHA/ACC Guidelines



Otto CM et al, J Am Coll Cardiol 2021;77:450-500

2021 ESC/EACTS Guidelines



Vahanian A et al. Eur Heart J 2022;43:561-632

Exclusion Criteria from randomized trials

Data from these trials cannot be used to extrapolate to other groups of patients

Anatomical criteria	Clinical criteria
• Aortic annulus dimension unsuitable for TAVI devices • Unicuspid or bicuspid aortic valve anatomy • Bulky calcified aortic valve leaflets • Prohibitive left ventricular outflow tract calcification • Non-calcified aortic valve (balloon-expandable TAVI) • Small sinus of Valsalva (self-expanding TAVI) • Aortic root angulation >70° (self-expanding TAVI) • Pre-existing mechanical or bioprosthetic valve in any position • Porcelain aorta • Unfavourable femoral access	• Mixed valve disease (aortic regurgitation, mitral regurgitation, mitral stenosis or tricuspid regurgitation) • Complex coronary artery disease (multivessel disease or left main disease) • Left ventricular dysfunction (LVEF <20%) • Intracardiac mass, thrombus, or vegetation • Hypertrophic obstructive cardiomyopathy • Significant aortopathy requiring ascending aortic replacement • Blood dyscrasias • Haemodynamic instability • Known hypersensitivity or contraindication to antithrombotic therapies • Active gastrointestinal bleeding • Recent acute myocardial infarction • Recent cerebrovascular accident • Severe comorbidities (renal insufficiency, lung disease, liver disease) • Severe pulmonary hypertension • Short estimated life expectancy (<12–24 months)

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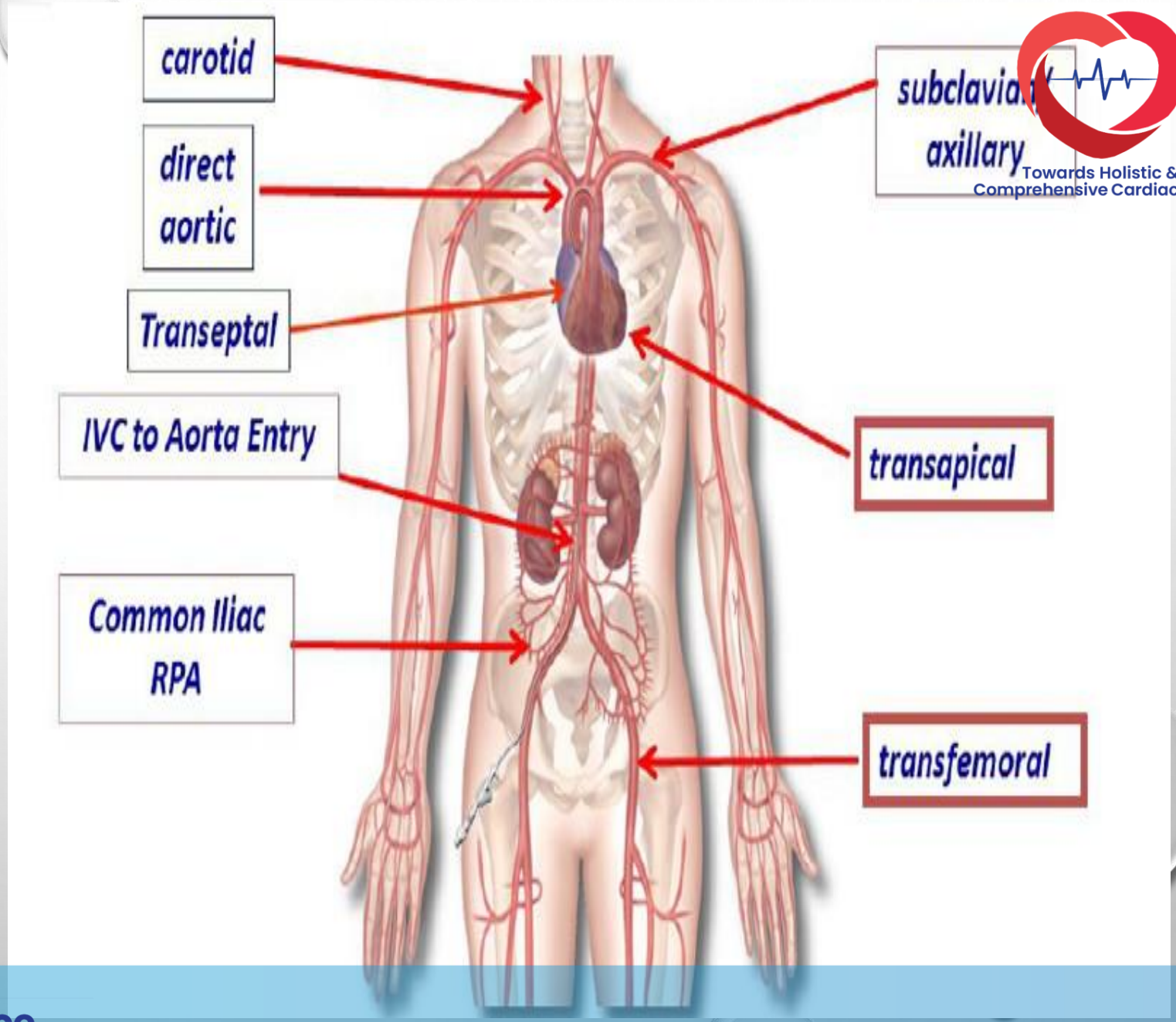
Access for TAVR

Peripheral access is most crucial for TAVR procedures, if transfemoral approach is less favourable, then risk will be higher

SAVR in these cases will be preferred

Large area of grey zone of intermediate risks needs to be discussed



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Femoral access for TAVR

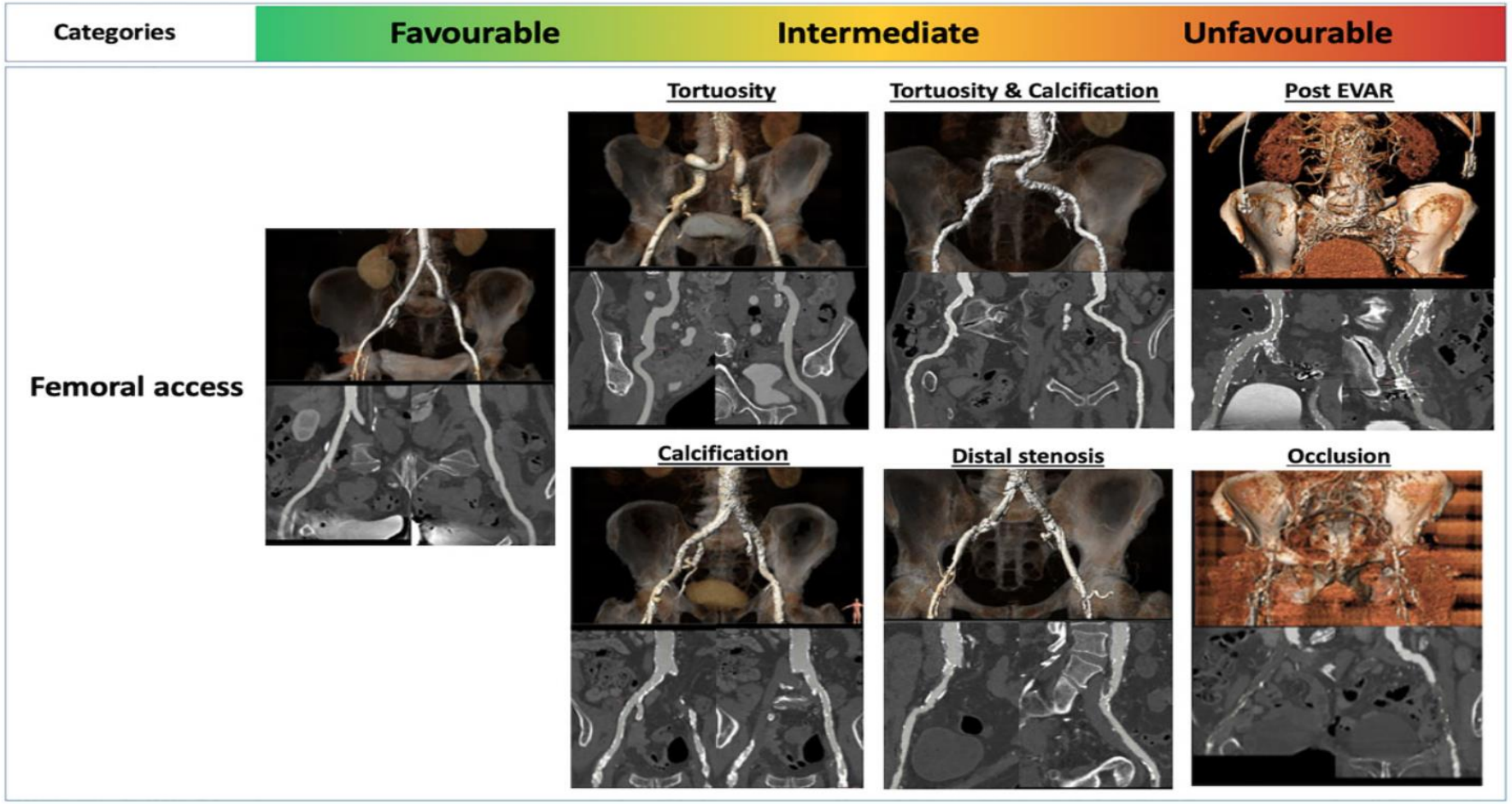


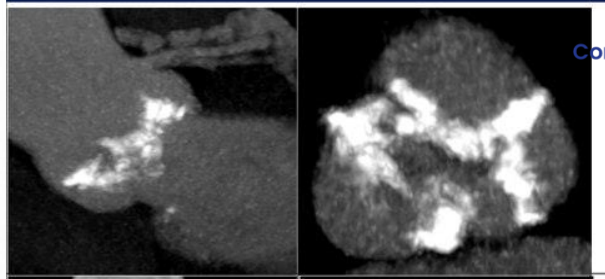
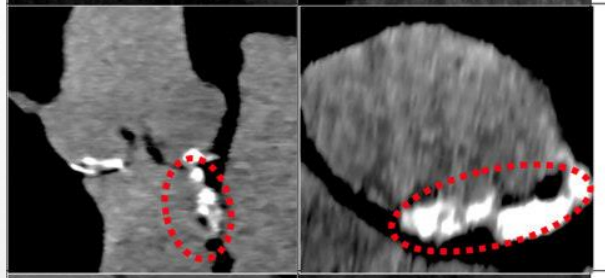
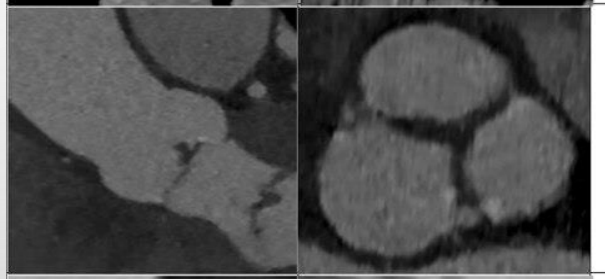
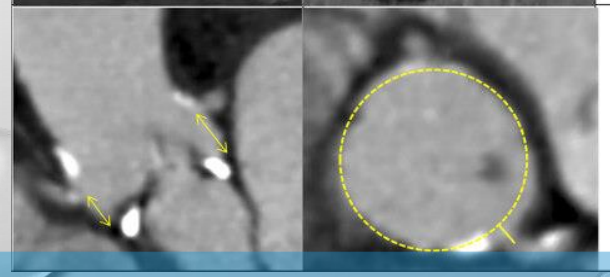
Figure 3 Anatomical risk stratification of femoral access. The category (favourable, intermediate, unfavourable) indicates the suitability for trans-femoral transcatheter aortic valve implantation. EVAR, endovascular aortic repair.

Severely Calcified aortic valve/LVOT

Extensive calcification of the LVOT increases risk of paravalve leaks in TAVR

These patients were excluded from the trials

SAVR is preferred in these cases where debridement of the excess calcium is possible.

Pre-procedural computed tomography analysis	High-risk features	Complication risks
	Bicuspid valve Heavy calcification	PVL PPM TVE Annular Rupture
	LVOT calcification	PVL Annular Rupture iVSD PPM
	Large annulus No calcification	TVE
	ViV procedure Coronary height <10mm VTC < 4mm	Coronary Obstruction

Bicuspid Aortic Valve

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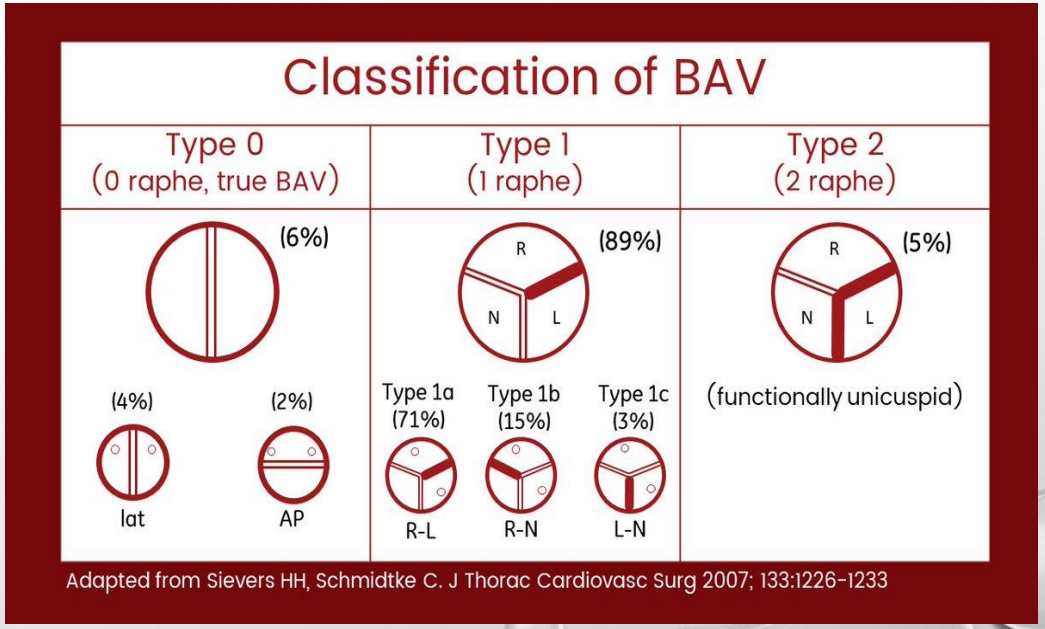
All the landmark trials exclude patients with BAV
Makes up 5-10 % of calcified aortic valves in the treated TAVR groups
Major concerns are the fusion of the raphe, extent and location of bulky eccentric calcification
Associated aortopathy

Aortic root frequently enlarged in BAV

SAVR in this group of patient has excellent outcomes.

Outcomes from STS data base does show good hemodynamics for TAVR but has higher paravalve leaks compared to SAVR

SAVR is preferred options for younger patients with BAV



Bicuspid Aortic Valve

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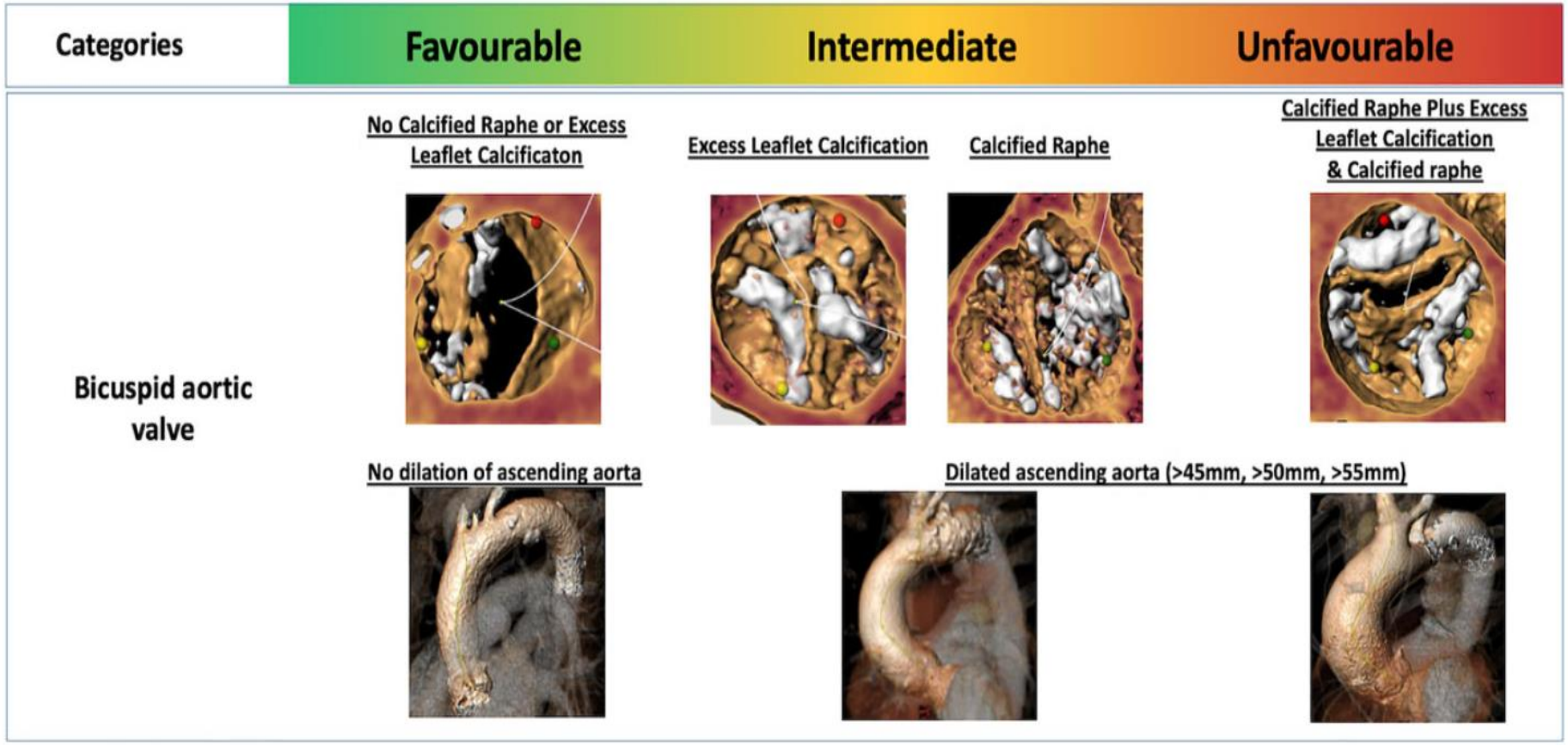

Figure 6 Anatomical risk stratification of bicuspid aortic valve. The category (favourable, intermediate, unfavourable) indicates the suitability for transfemoral transcatheter aortic valve implantation.

Risk of conduction disturbances

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Self expanding THV has increased risk of injury to conduction system,
Need for higher implantation

New onset LBBB occurs in 18-65% of the first gen self expanding valves
And 4 to 30% of the balloon expanded valves

SAVR has less incidence of need for PPM (5-14% for TAVR)
But has higher risk of perioperative atrial fibrillation

SAVR is preferred in younger patients in these group

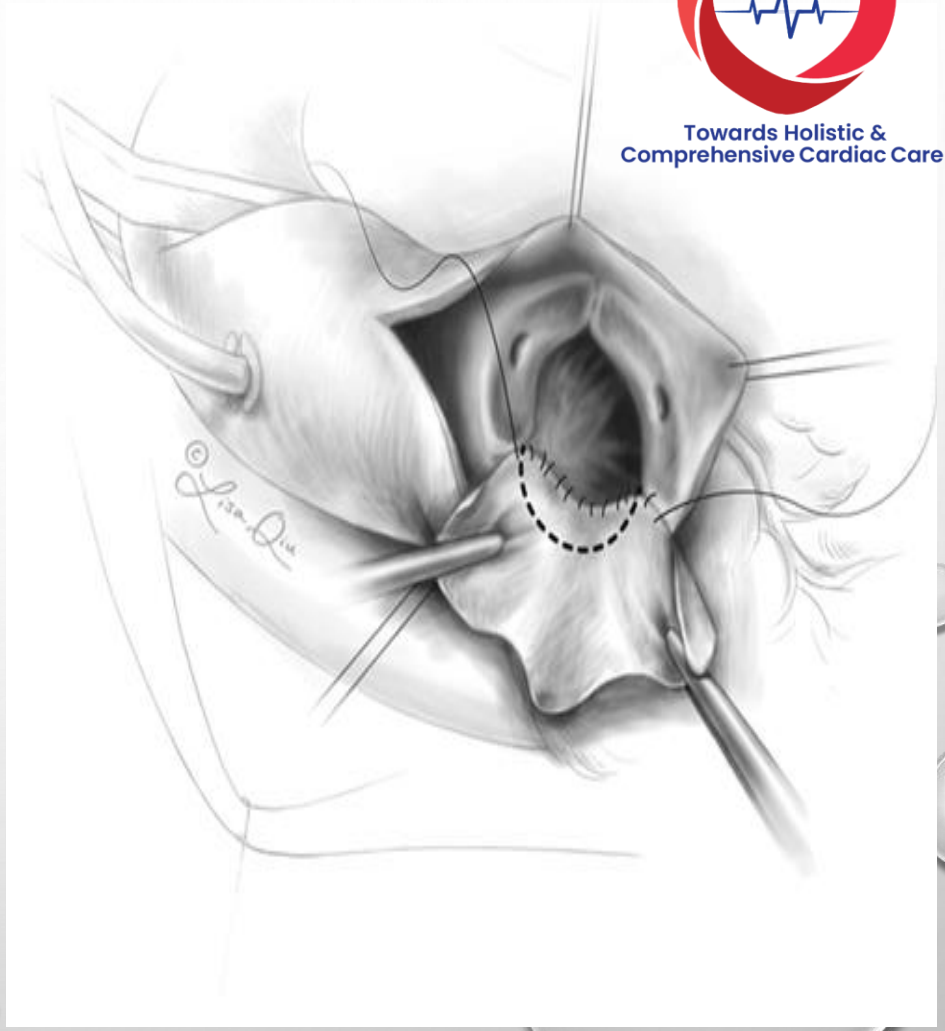
Extreme Annular Dimensions

Too small aortic root, not suitable for TAVR

SAVR allows combined procedure like aortic root enlargement, stentless aortic valves

Similarly for large aortic annulus, largest so far is the Sapien 3 #29mm

Other larger sizes with newer brands



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Non Calcified Aortic Valve

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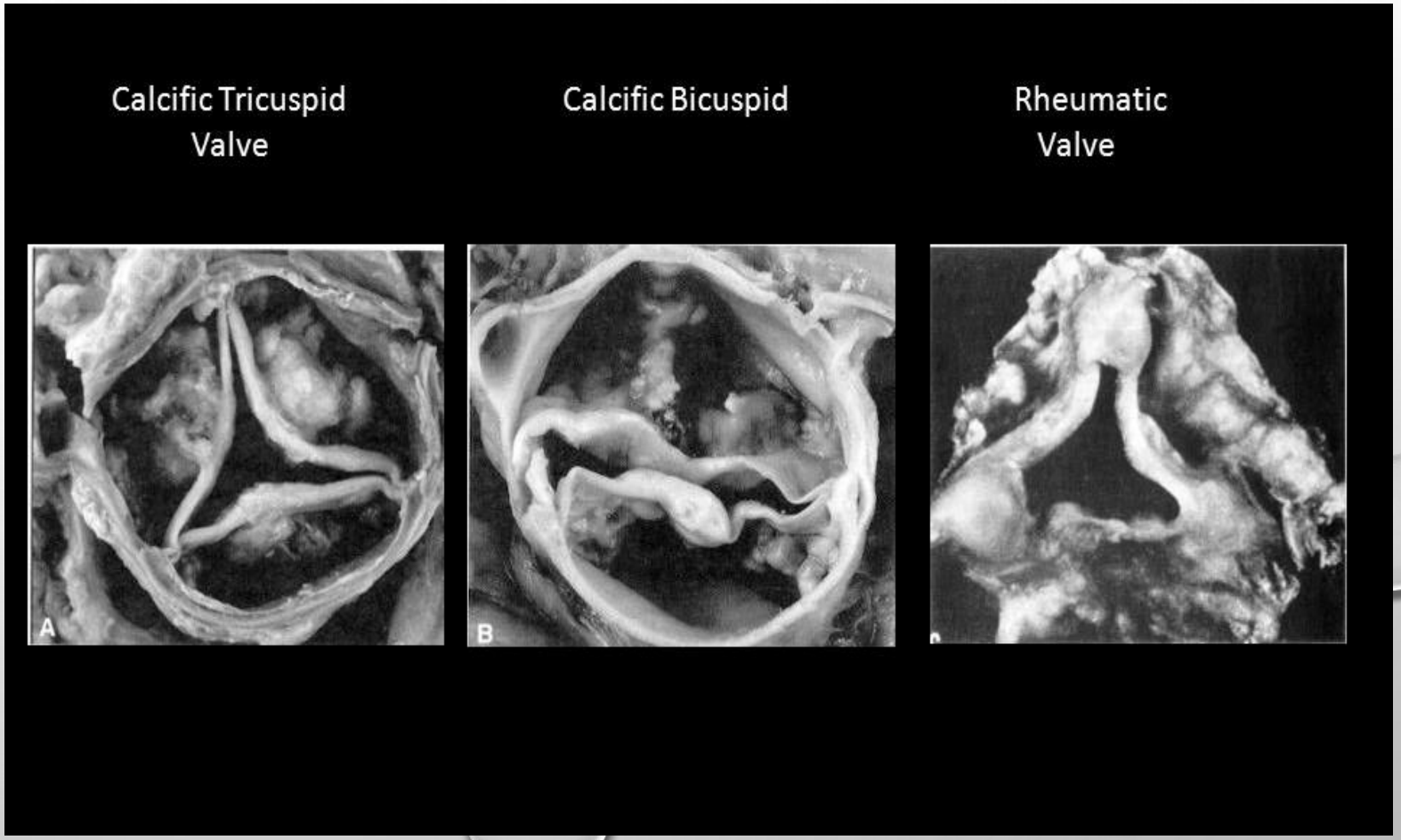
Commonly seen in younger patients,
In this region, Rheumatic AS

SAVR is preferred

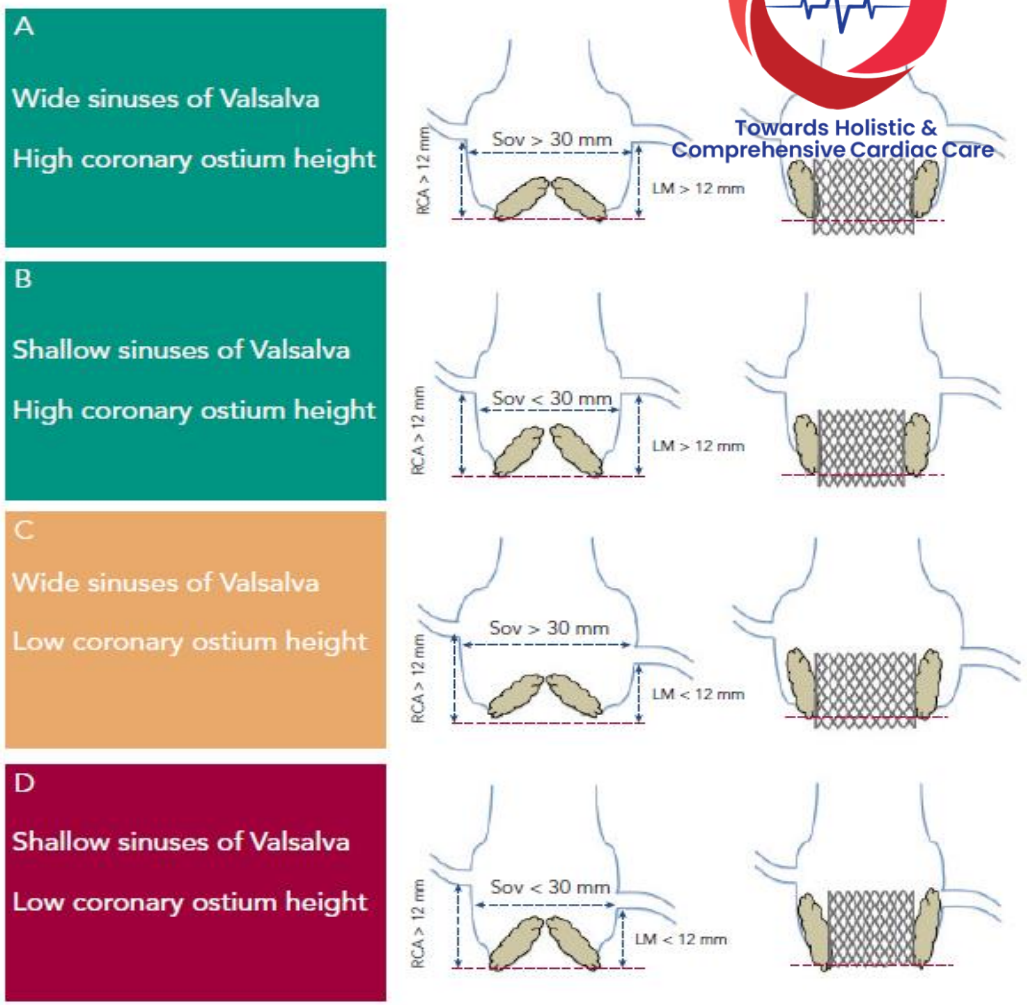
Mechanical valve consideration



Low Take off Coronary Ostia

Increased risk for coronary obstruction with TAVR valves, fatal complication

Figure 1: Schematic Representation of Four Aortic Root Scenarios



(A) Wide sinuses of Valsalva (SoV) and high coronary ostia take off, and (B) shallow SoV and and high coronary ostia take off: in these two cases the risk of coronary occlusion is quite remote. (C) Wide SoV and low coronary ostia take off: a careful individual assessment should be made, also considering the calcium burden at the level of the cusps. Such cases can be performed with success, but more caution should be applied (a protection wire down to the left anterior descending may be considered), (D) shallow SoV and low coronary ostia take off: these cases are at high risk of coronary occlusion and they may represent a contraindication to transcatheter aortic valve implantation (TAVI).

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Horizontal Aorta

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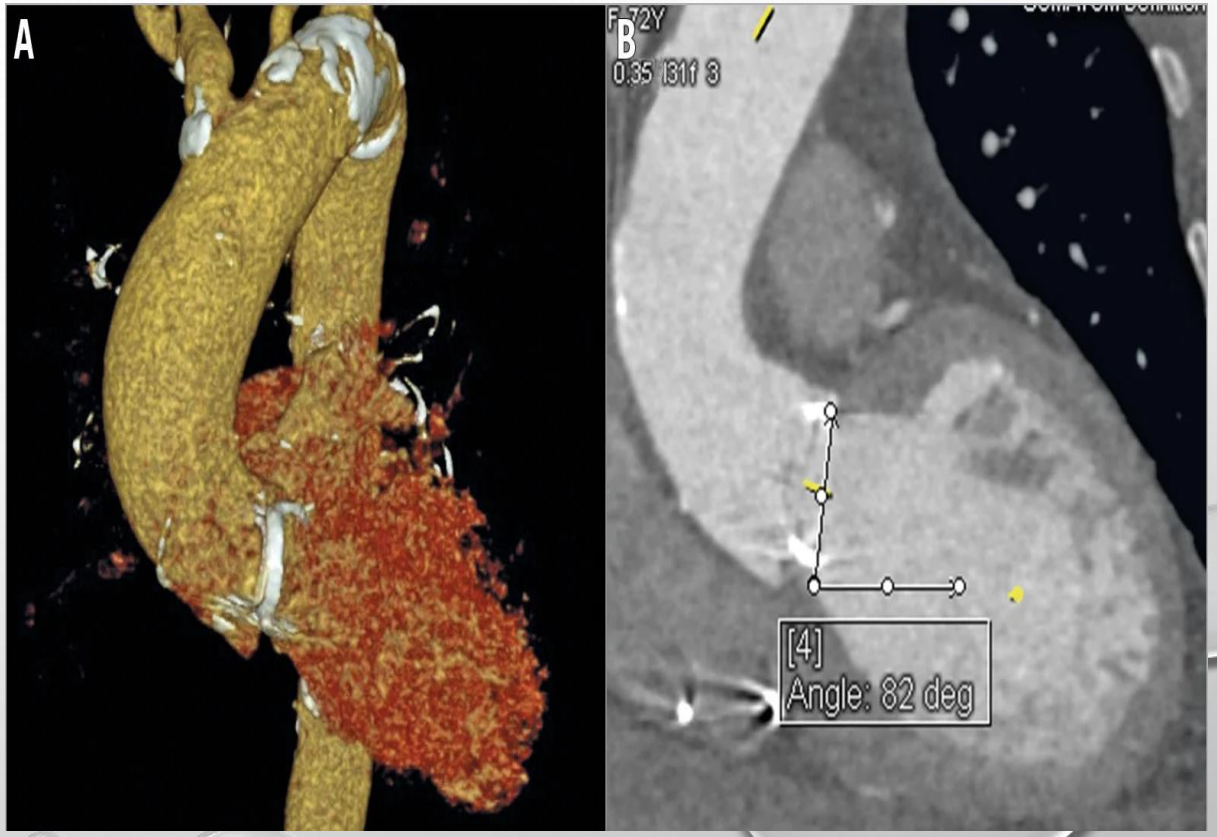
Unfolding of the aorta poses a risk for self expanding THV

More than 70 degrees angulation measured from horizontal plane to the plane of aortic annulus in the coronal view, exclusion criteria for trials



V in V feasibility

Higher risk for both SAVR and TAVR

TAVR risk of coronary obstruction, higher gradients, higher PPM, higher paravalve leaks
Device dislocation, malposition

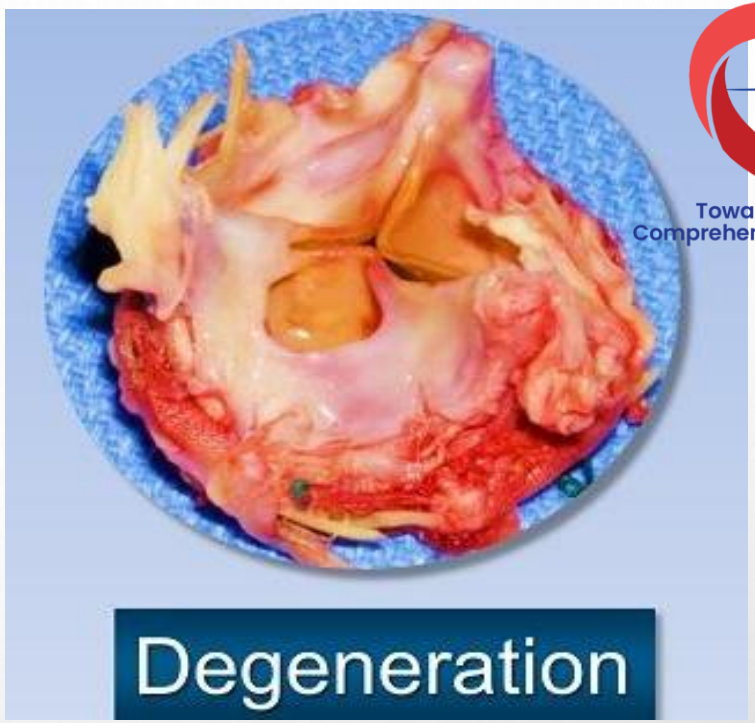
Need to Fracture surgical prosthesis

Open SAVR with direct implantation of THV may be an option

Redo SAVR with root enlargement may be a better, safer option in small aortic prosthesis

Newer valves in first time SAVR Resilia Inspiris Valve V Fit technology to allow for safer ViV

Durability of ViV not known



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Mixed Valve Disease

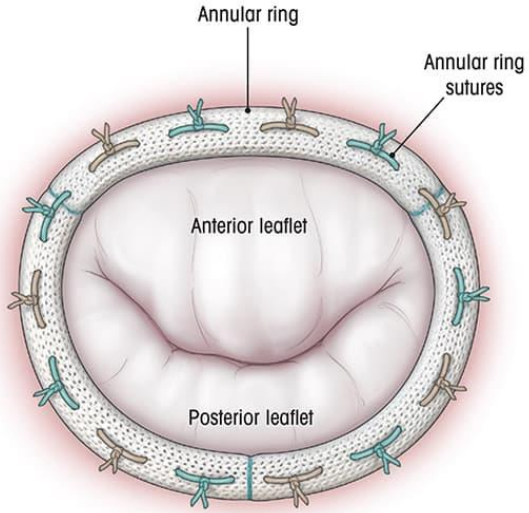
Presence of MS, MR, TR is seen in 30% of patients with severe AS

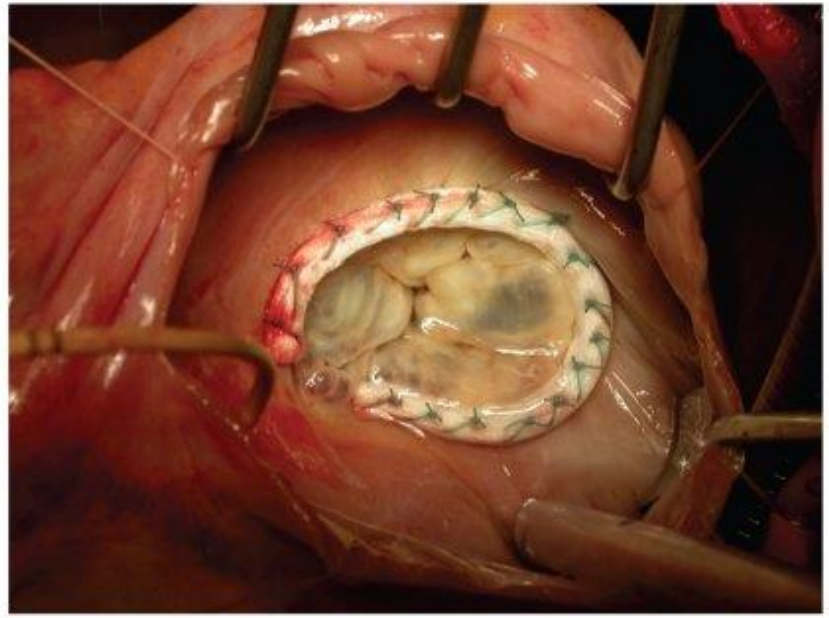
Most of the MR patients improve with TAVR

If it's primary MR with native mitral disease then SAVR with MV repair is preferred
In secondary MR, if severe, SAVR is preferred

Or MV repair after successful TAVI

In AS, MS, SAVR is preferred to replace both the valves
In TR, TAVR, followed by surgical repair of TV is possible





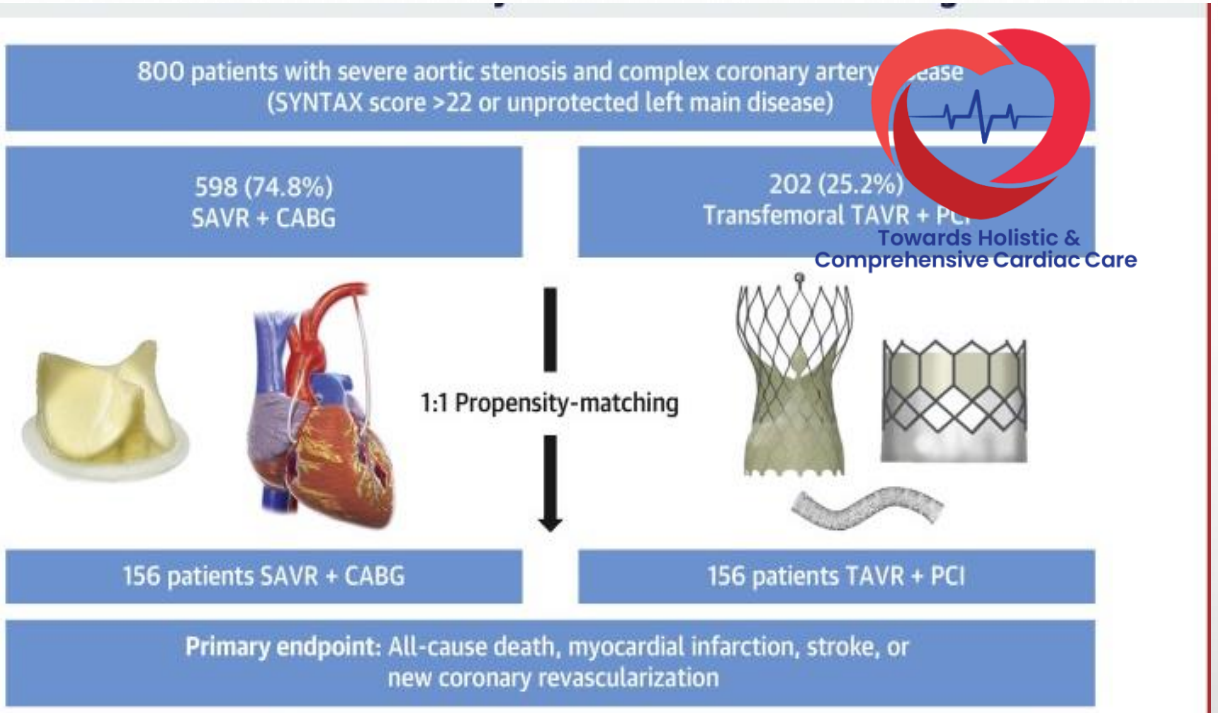
Coronary Artery Disease

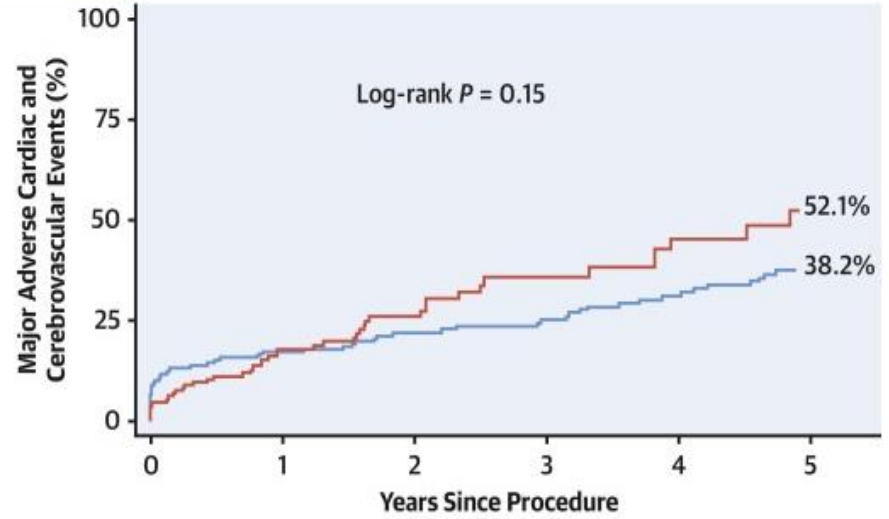
Appears in 30-70% of patients with severe AS

SAVR and CABG preferred unless risks extremely high

PCI and TAVR shows higher reintervention, repeat revascularization

PCI post TAVI is also associated with higher risks for coronary access





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Severe AS with significant CAD strategy

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Age	65	70	75	80	85
Surgical Risk	Low		Intermediate		High
Severity of CAD	3-Vessel disease & SYNTAX >22 LM disease & SYNTAX >32		3-Vessel disease & SYNTAX <=22 LM disease & SYNTAX <=32		1 or 2-Vessel disease, SYNTAX <=22
Diabetes	Yes				No
Coronary Access after TAVI	Hostile		Intermediate		Favorable
Recommendation	*1st:* SAVR+CABG *2nd:* TAVI+PCI		*1st:* SAVR+CABG or TAVI+PCI		*1st:* TAVI+PCI *2nd:* SAVR+CABG

Figure 8 Recommendation for the management of severe aortic valve stenosis and concomitant clinically relevant coronary artery disease requiring intervention. CAD, coronary artery disease; LM, left main; CABG, coronary artery disease; PCI, percutaneous coronary intervention.

Durability of different Surgical Heart Valves

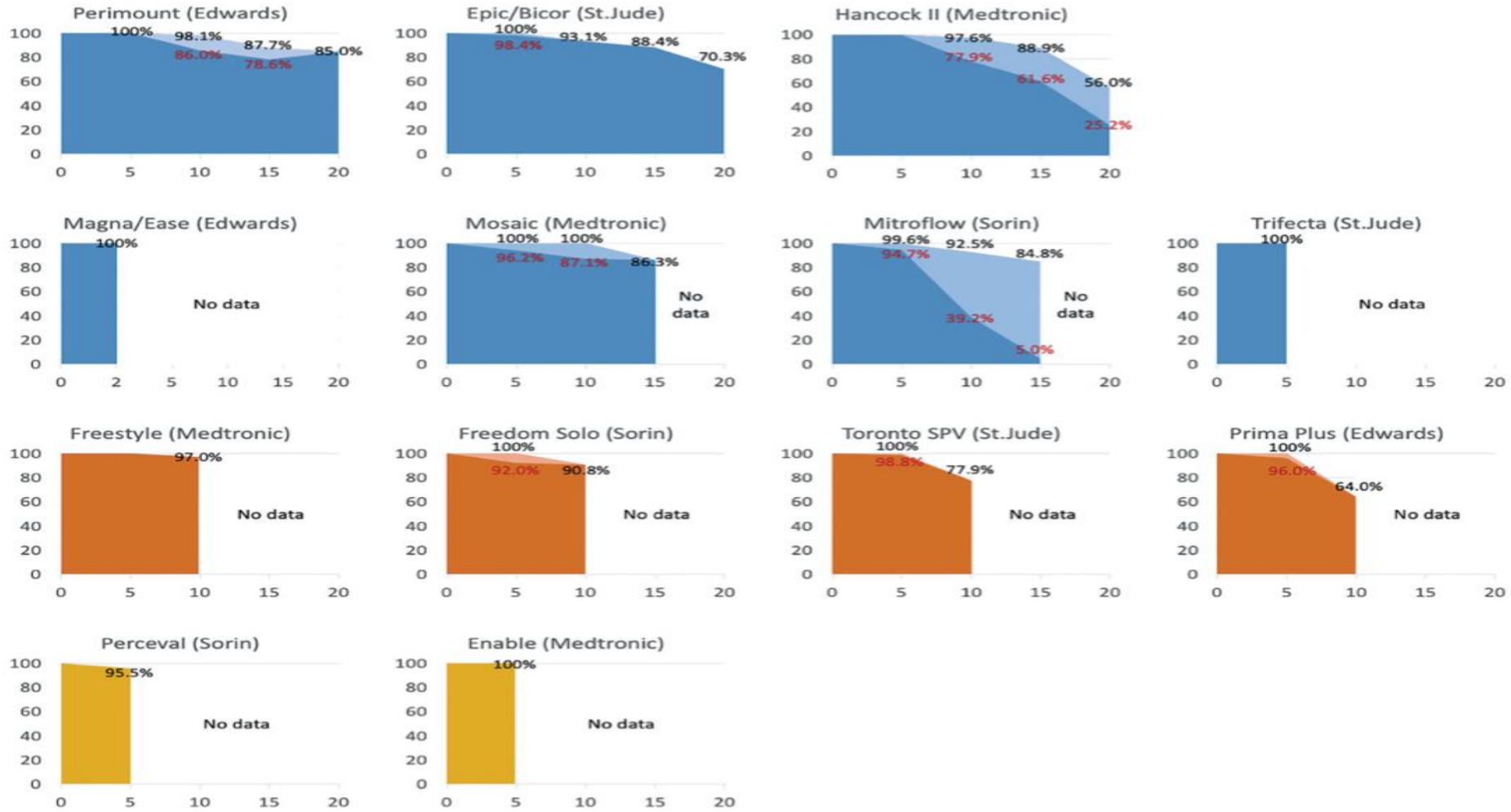

Figure 10 Durability data of surgical aortic bioprostheses. A range of actuarial freedom from SVD for each surgical bioprosthesis, obtained from studies in which these data were available for the whole cohort, is provided.[177]

Durability of TAVR vs SAVR valves

Table 6 Durability data of transcatheter aortic bioprostheses (vs. surgical aortic bioprostheses)

Study	Age	Follow-up	TAVI			SAVR		
			Valve type (*N*)	SVD	BVF	Valve type (*N*)	SVD	BVF
Randomized clinical trials								
NOTION Jorgensen *et al.*[160]	79	8 years	CoreValve (139)	13.9% Moderate: 13.2% Severe: 2.2%	8.7% Re-intervention: 3.6%	Multiple (135)	28.6% Moderate: 27.5% Severe: 6.8%	10.5% Re-intervention: 2.3%
PARTNER 2[a] Pibarot *et al.*[167]	82	4 years	SAPIEN 3 (891) SAPIEN XT (774)	3.9% 9.5%	2.6% 4.7%	Multiple (664)	3.5%	1.3%
CoreValve US High Risk Gleason *et al.*[9]	83	4 years	CoreValve (390)	9.5% Moderate: 9.2% Severe: 0.8%	NA	Multiple (354)	26.6% Moderate: 26.6% Severe: 1.7%	NA
Observational studies								
PS-matched study Tzamalis *et al.*[168]	78	7 years	SAPIEN/SAPIEN XT/CoreValve/ACURATE (209)	Moderate: 9.3% Severe: 10.5%	4.8% Re-intervention: 4.3%	Multiple (198)	Moderate: 2.3% Severe: 4.5%	2.0% Re-intervention: 2.0%
Italian multicentre registry Testa *et al.*[169]	82	8 years	CoreValve (990)	Moderate: 3.0% Severe: 1.6%	2.5%			
UK-TAVR Registry Blackman *et al.*[170]	79	5–6 years	SAPIEN/SAPIEN XT/CoreValve/Portico (241)	Moderate: 8.7% Severe: 0.4%				
French multicentre registry Durand *et al.*[171]	83	7 years		10.8% Moderate: 7.0% Severe: 4.2%	1.9% Re-intervention: 1.0%			
Single centre registry Panico *et al.*[172]	82	8 years	CoreValve (278)	3.6%	2.5%			
FRANCE-2 Registry Didier *et al.*[173]	83	5 years	SAPIEN/SAPIEN XT/CoreValve (4201)	13.3% Moderate: 10.8% Severe: 2.5%				
Single centre registry Deutsch *et al.*[174]	81	7 years	SAPIEN XT/CoreValve (300)	14.9%				
Single centre registry Eltchaninoff *et al.*[175]	83	8 years	SAPIEN/SAPIEN XT (378)	3.2%	0.58%			
Single centre registry Barbanti *et al.*[176]	81	8 years	SAPIEN XT/CoreValve (288)	Severe: 2.4%	4.5%			

SVD and BVF were defined according to the consensus statement by EAPCI/EACTS (Capodanno *et al.*[211]) except for the study below. TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement; SVD, structural valve deterioration; BVF, bioprosthetic valve failure.

[a]SVD and BVF according to the VARC-3 criteria.

Lifetime management of the Aortic Valve Patient

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TAVR will expand to low risk, younger patients
Need to look at durability of the valve

Durability data only up to 7-8 years

Risk of mild PVR, conduction issues, coronary access over the long term, need to be studied

Partner 2 Trial showed higher all cause mortality, and disabling stroke in TAVR arm compared to SAVR

Lifetime Strategies for the aortic valve patient

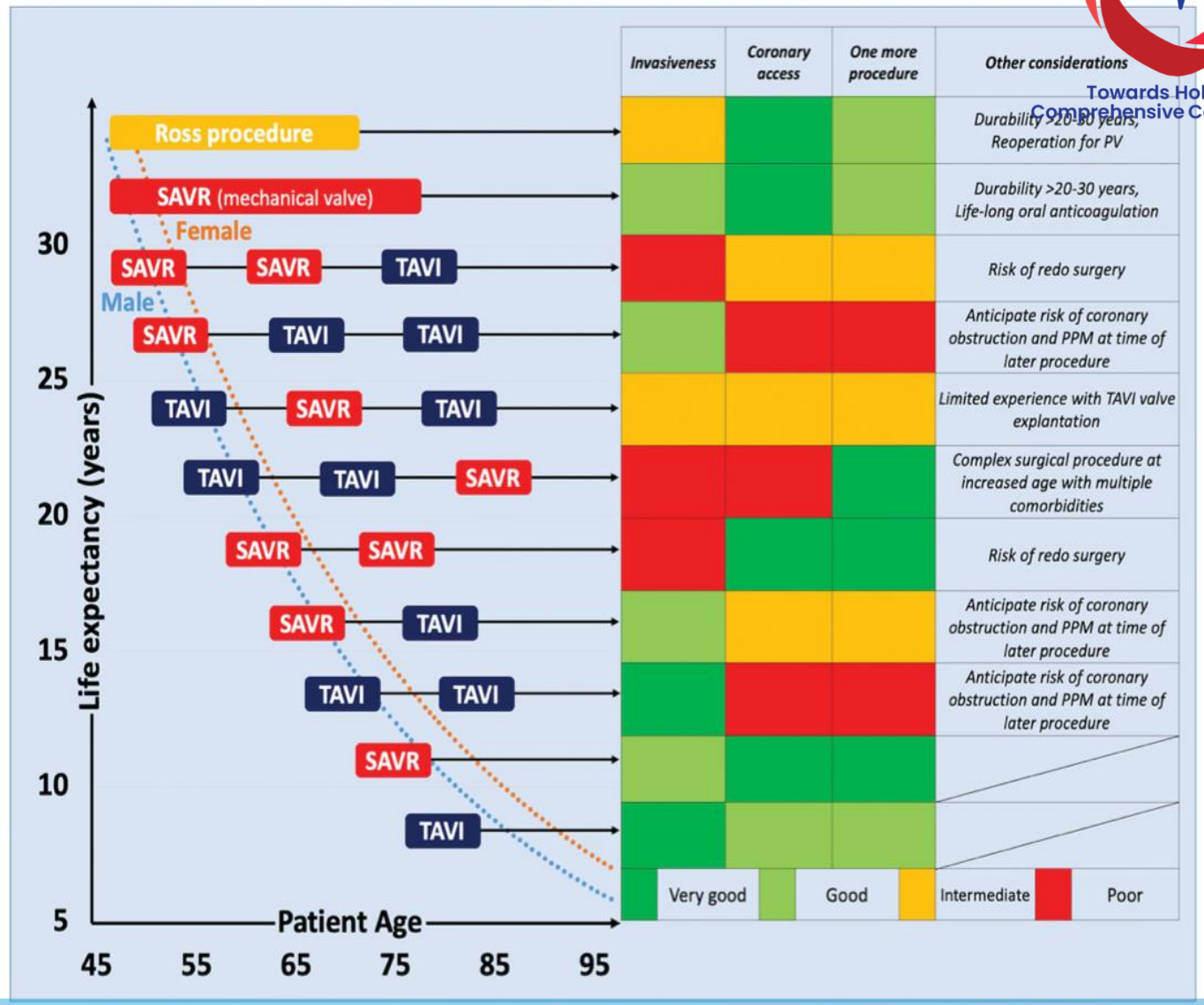

Figure 9 Strategies for lifetime management according to patient's life expectancy. Exponential lifetime curves derived from life expectancy data in Switzerland in 2019 are provided. PV, pulmonary valve; PPM, prosthesis–patient mismatch.

Severe aortic stenosis: Decision Making

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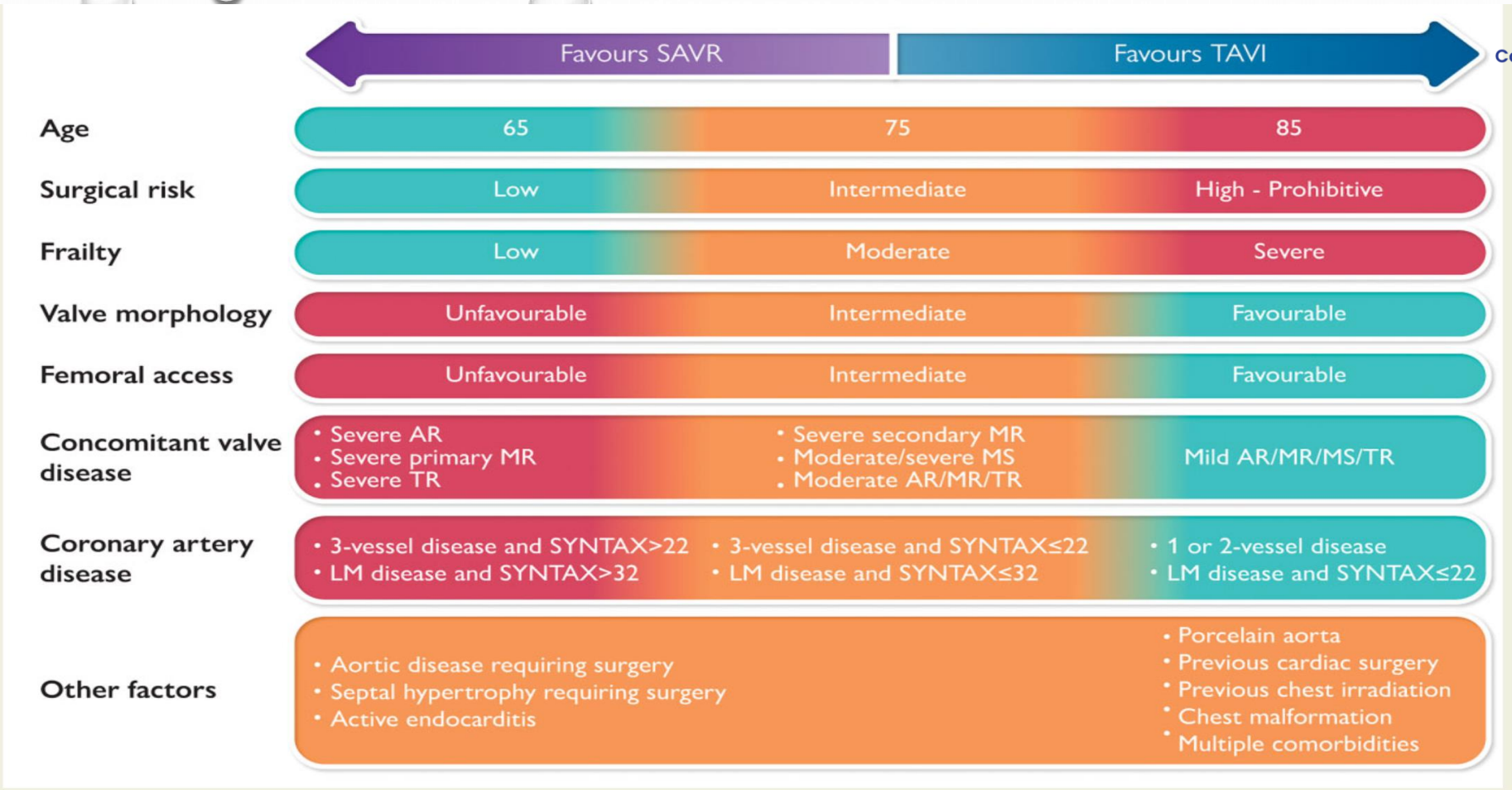

Graphical Abstract Decision-making process between TAVI and SAVR. Refer to *Figures 2*, *4*, and *6* for details of the valve morphology category. Refer to *Figure 3* for details on the femoral access category. Refer to *Figure 7* for more details on concomitant valve disease. Refer to *Figure 8* for more details on coronary artery disease. AR, aortic regurgitation; MR, mitral regurgitation; TR, tricuspid regurgitation; MS, mitral stenosis; LM, left main; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Heart Team Approach

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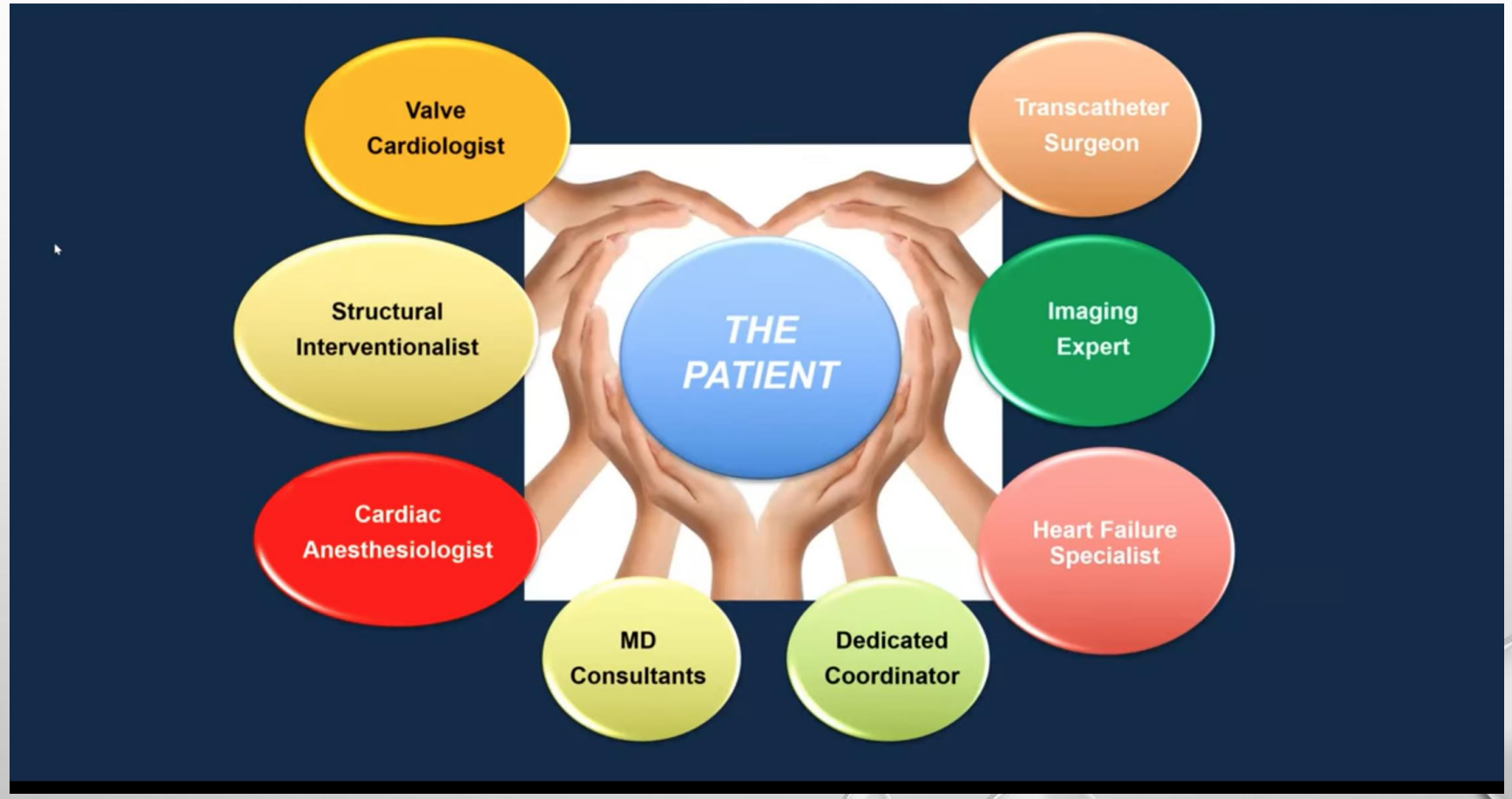

Recent Advances in SAVR

Development of MIS techniques

Non sternotomy approaches, better sternal management

Sutureless valves eg Perceval, cor knot

Newer Valves with expected prolonged durability eg Inspiris Resilia, Avalus

Root enlargement techniques eg Bo Yang Technique

Which cases should you refer for SAVR?

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Bicuspid Aortic valves

Concomitant coronary disease

Mixed valve disease

Ascending aortic disease

Extreme annulus dimensions

Non Calcified Aortic valves

Severely calcified outflow tract

Risk of conduction disturbances

Low take off Coronary ostia

Horizontal aorta

Poor femoral/peripheral access

Future Valve in valve

THANK YOU

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