HUMANITAS
GAVAZZENI

TAVI:
dall'evidenza scientifica alla pratica clinica

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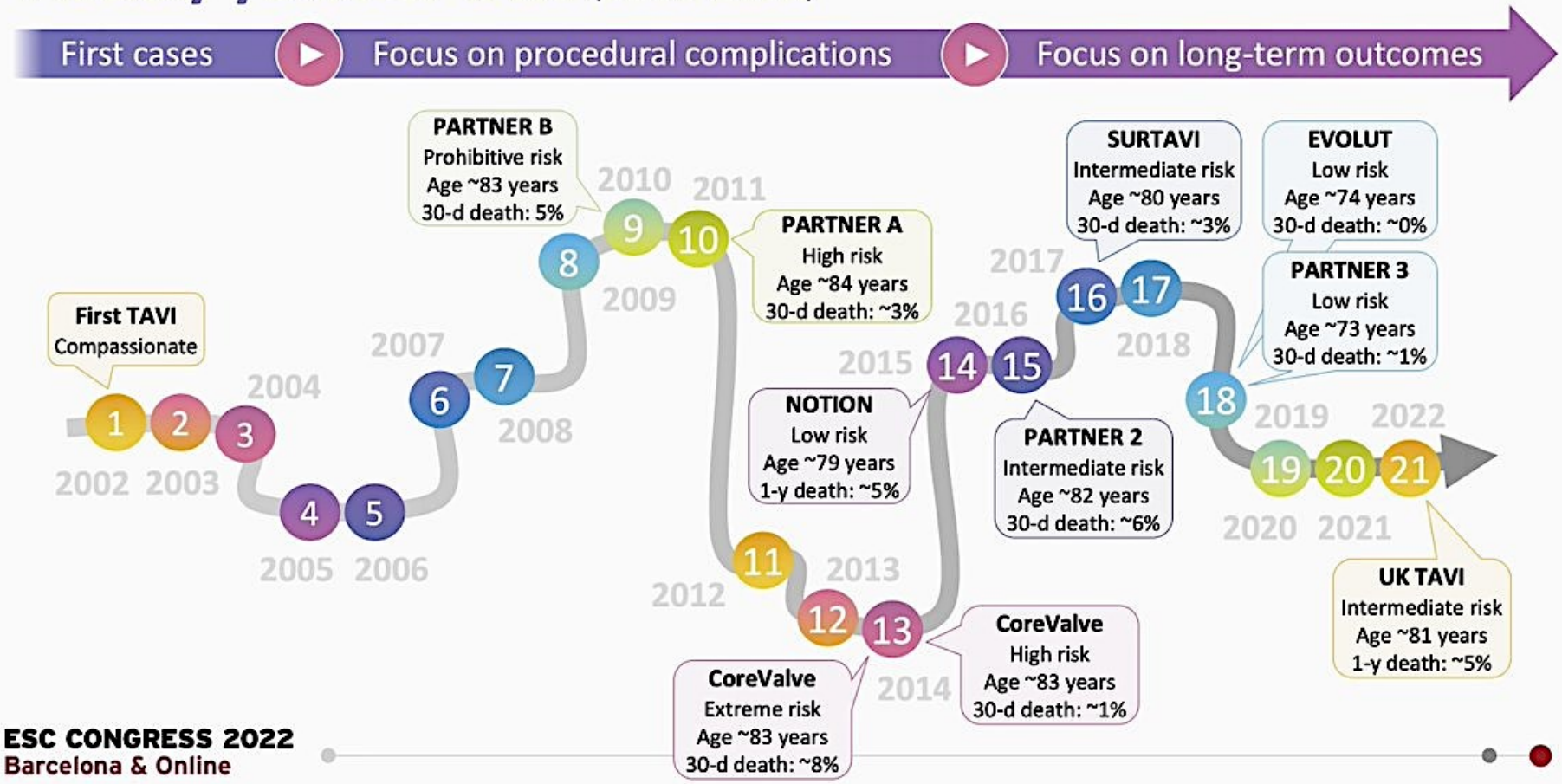
Disclosures

I have the following **potential conflicts of interest** to report:

- Receipt of grants/research support
- Receipt of honoraria and travel support

Medtronic

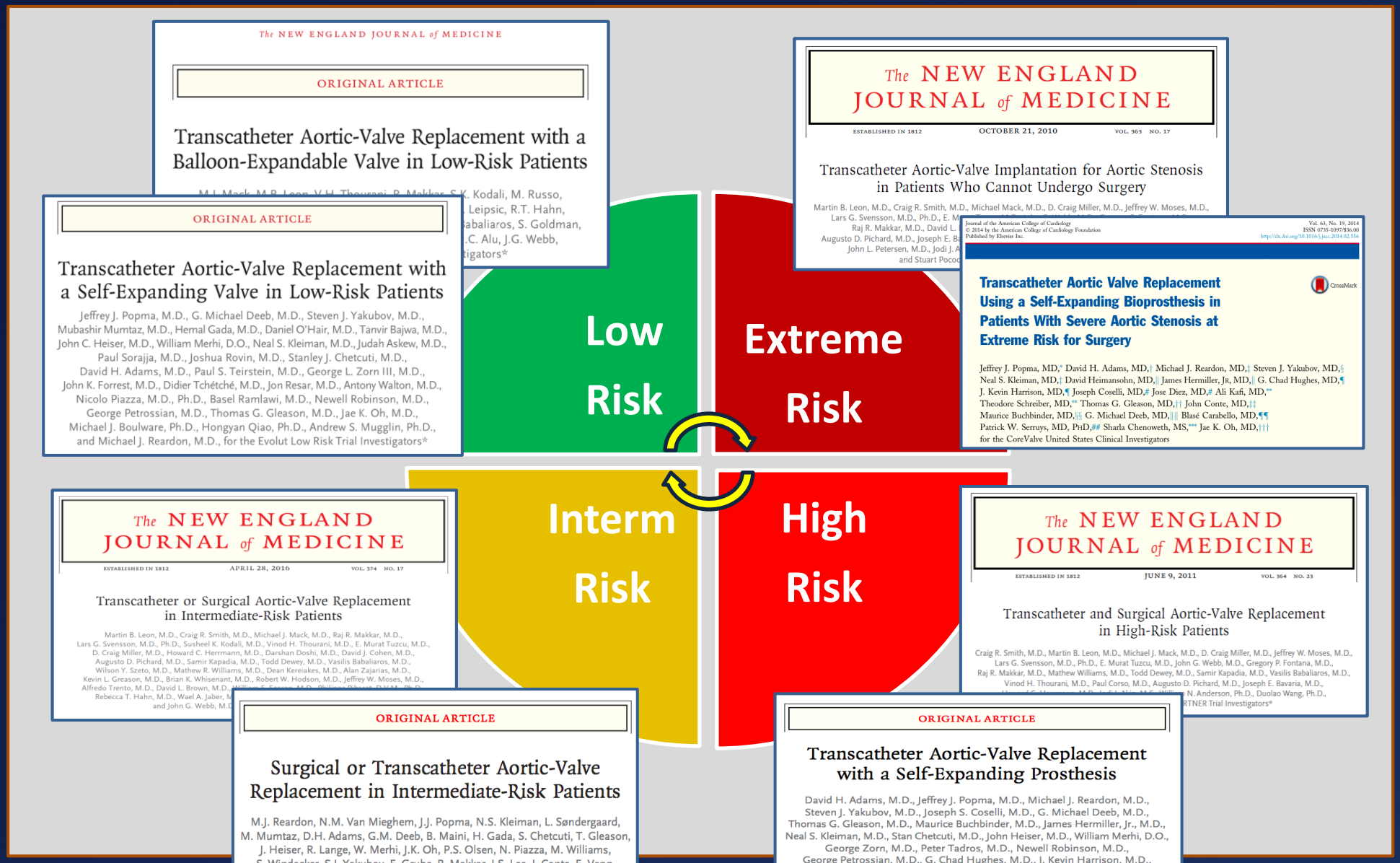
Twenty years of TAVI (2002-2022)



ESC CONGRESS 2022
Barcelona & Online

Capodanno D. @ ESC 2022

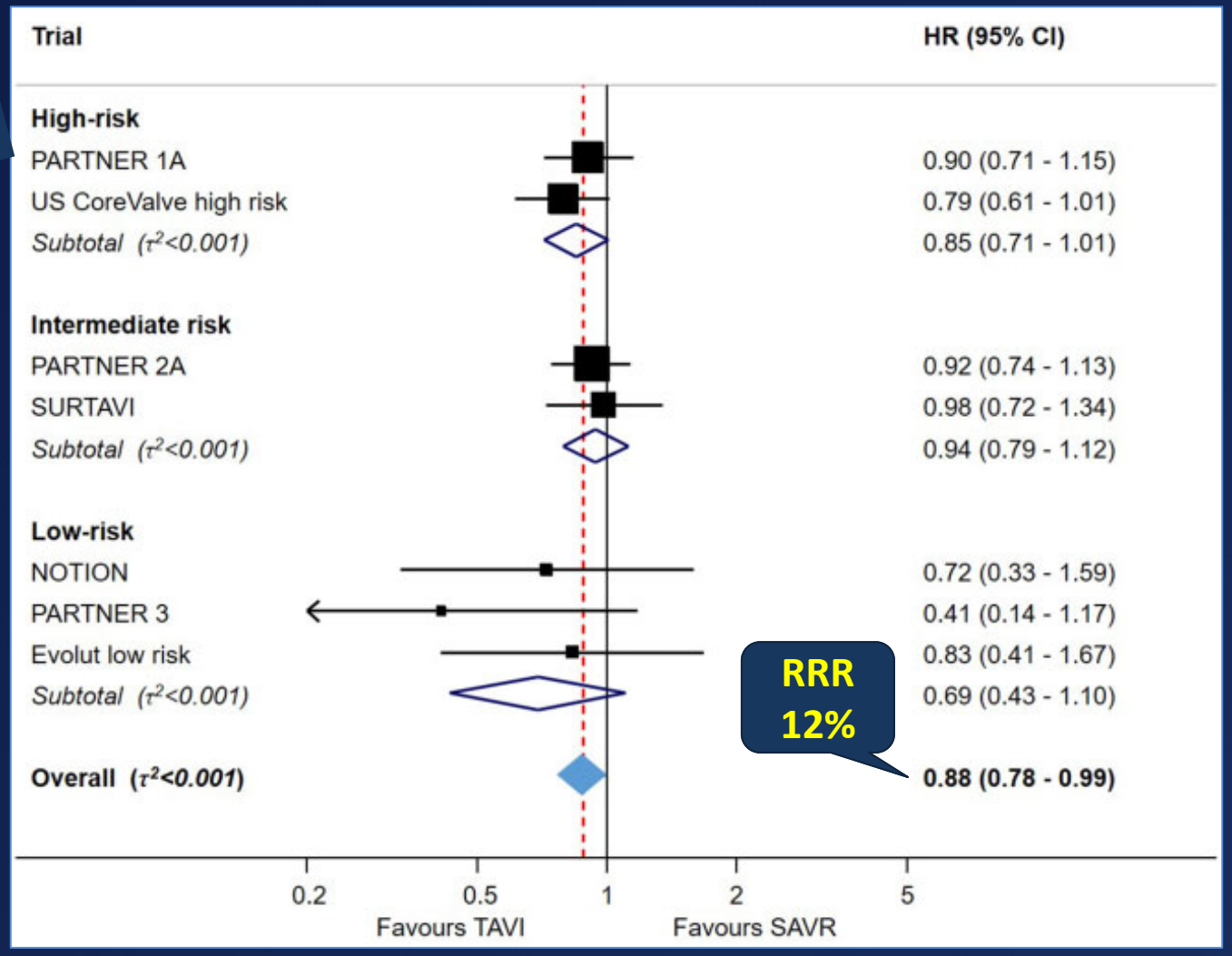
Clinical Evidence: An 8-Year Journey



TAVI vs SAVR:
Meta-Analysis Of 7 RCT (n=8020 pts)

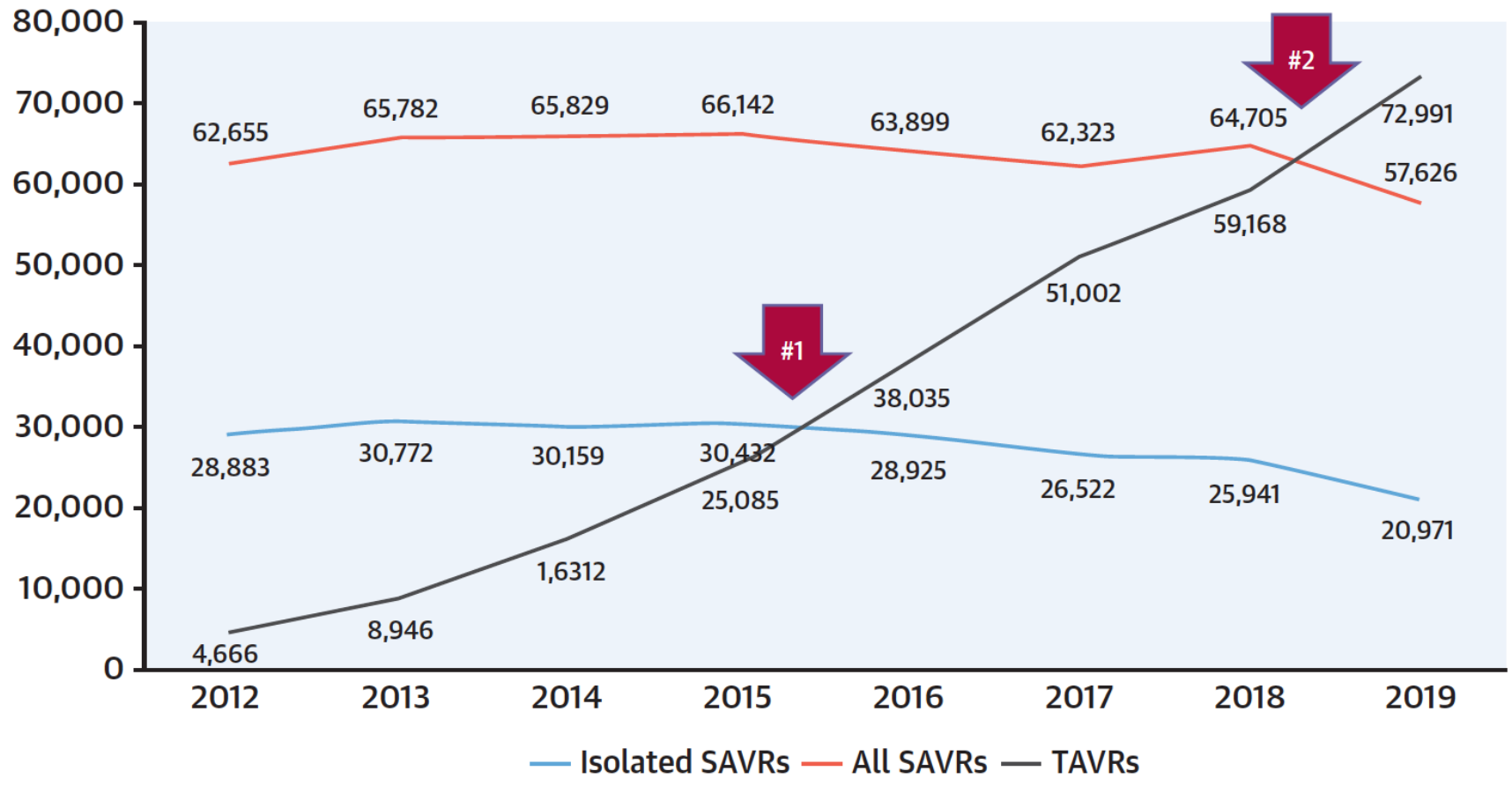
Siontis et al. Eur Heart J 2019

2-year All-cause mortality



Siontis et al. EHJ 2019 Oct 7;40(38):3143-3153

FIGURE 2 Annual Volumes of TAVR and SAVR



From 2011 to 2019: data on 276,316

Carroll et al. JACC 2020 Nov 24;76(21):2492-2516

TAVI in Low-Risk Patients

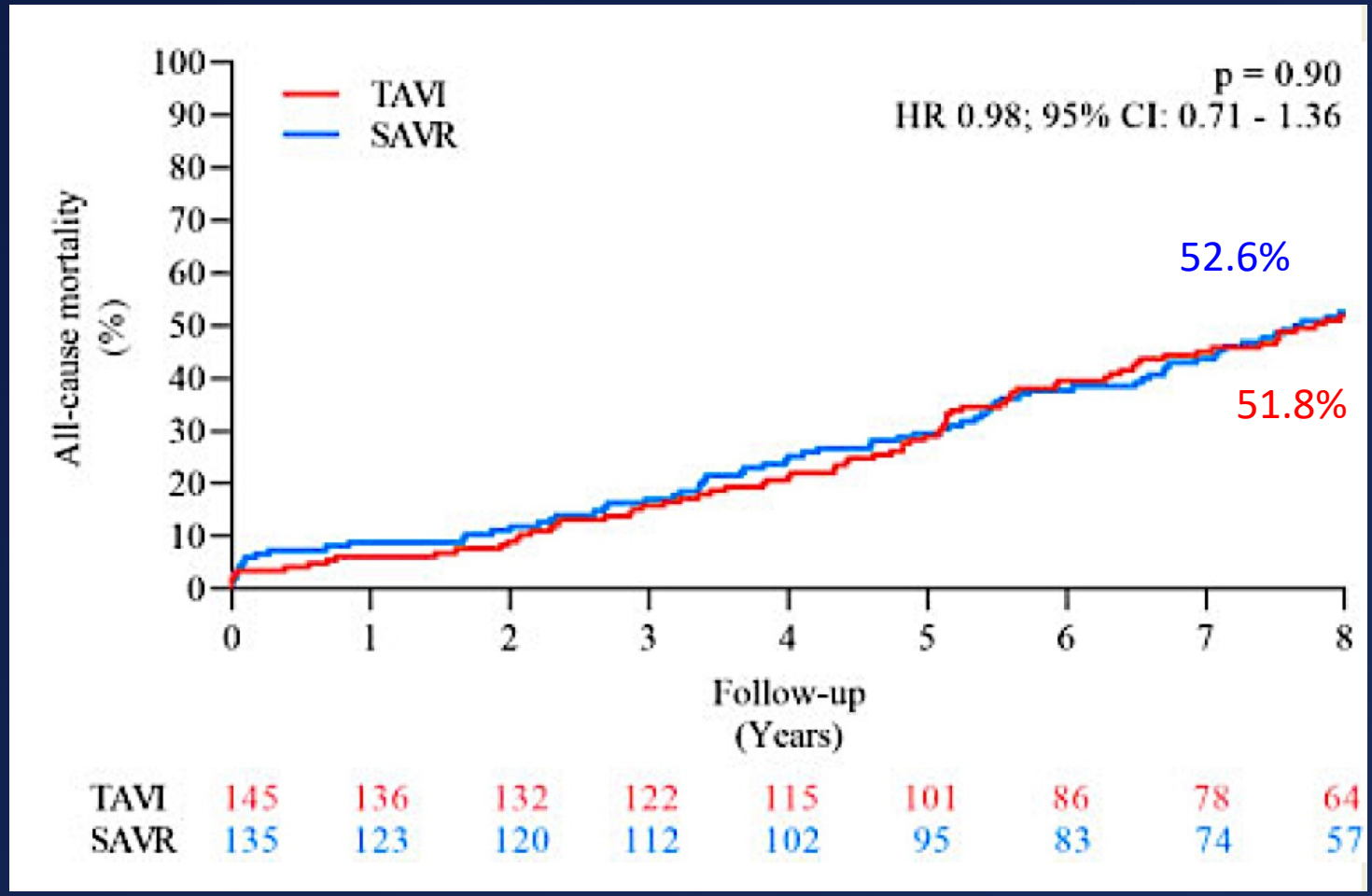
PARTNER 3 → *TAVR was shown to be **superior** to SAVR at 1 year (death, stroke, re-hospitalization: 8.5% versus 15.1%, P=0001) and at 2 years (11.5% versus 17.4%, P=0.007)*

EVOLUT Low Risk → *TAVR was **non-inferior** to SAVR at 2 years (death or disabling stroke: 5.3% versus 6.7%)*

NOTION → ***No difference** in death/MI/stroke at 5 years after TAVR compared to SAVR (38.0% vs. 36.3%)*

Mack MJ et al. N Engl J Med. 2019; Popma JJ et al. N Engl J Med. 2019; Thyregod HGH et al. Circulation. 2019

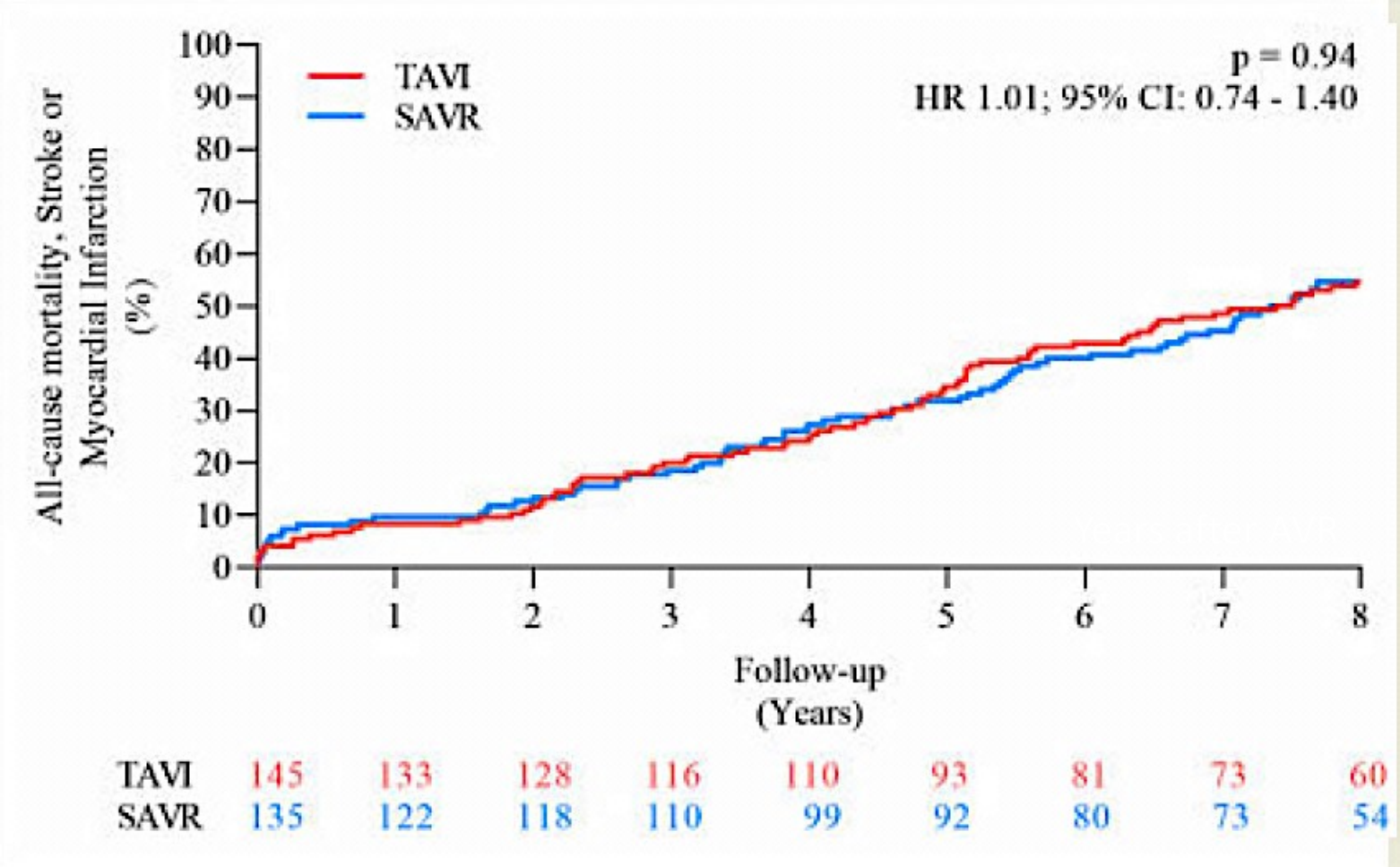
NOTION Trial @ 8-year



Out of 133 patients still alive after 8 years, 8-year echocardiographic data in 102 of the 121 patients (84.3%)

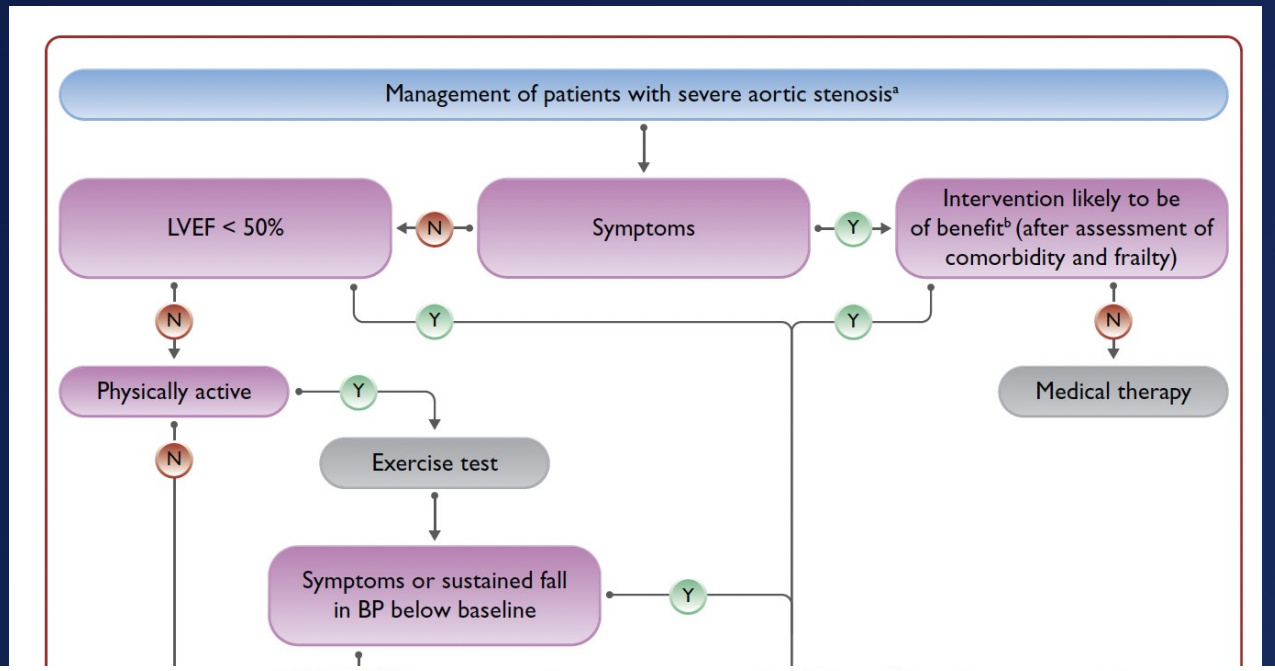
Jørgensen et al. Eur Heart J. 2021 Aug 7;42(30):2912-2919

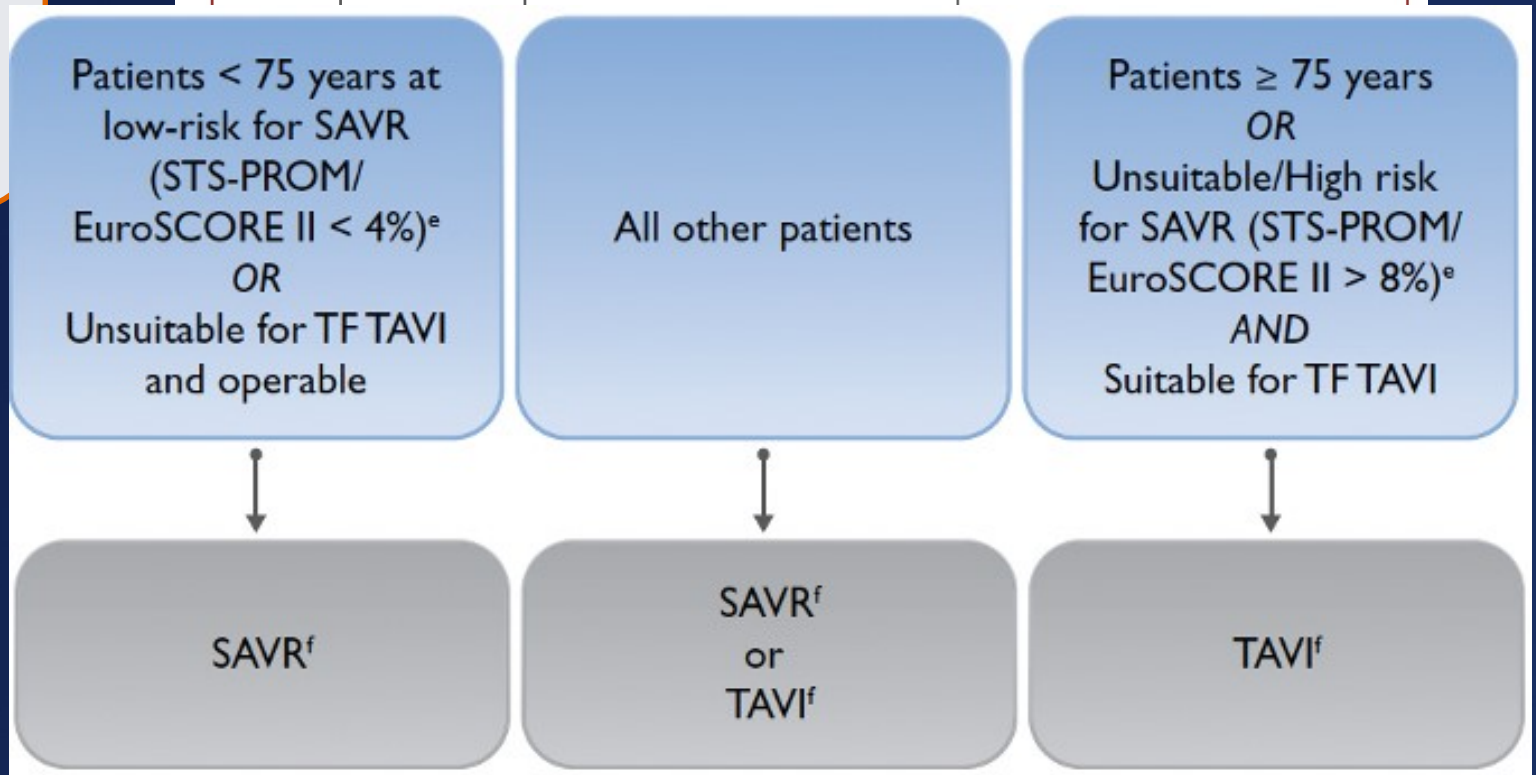
NOTION Trial @ 8-year



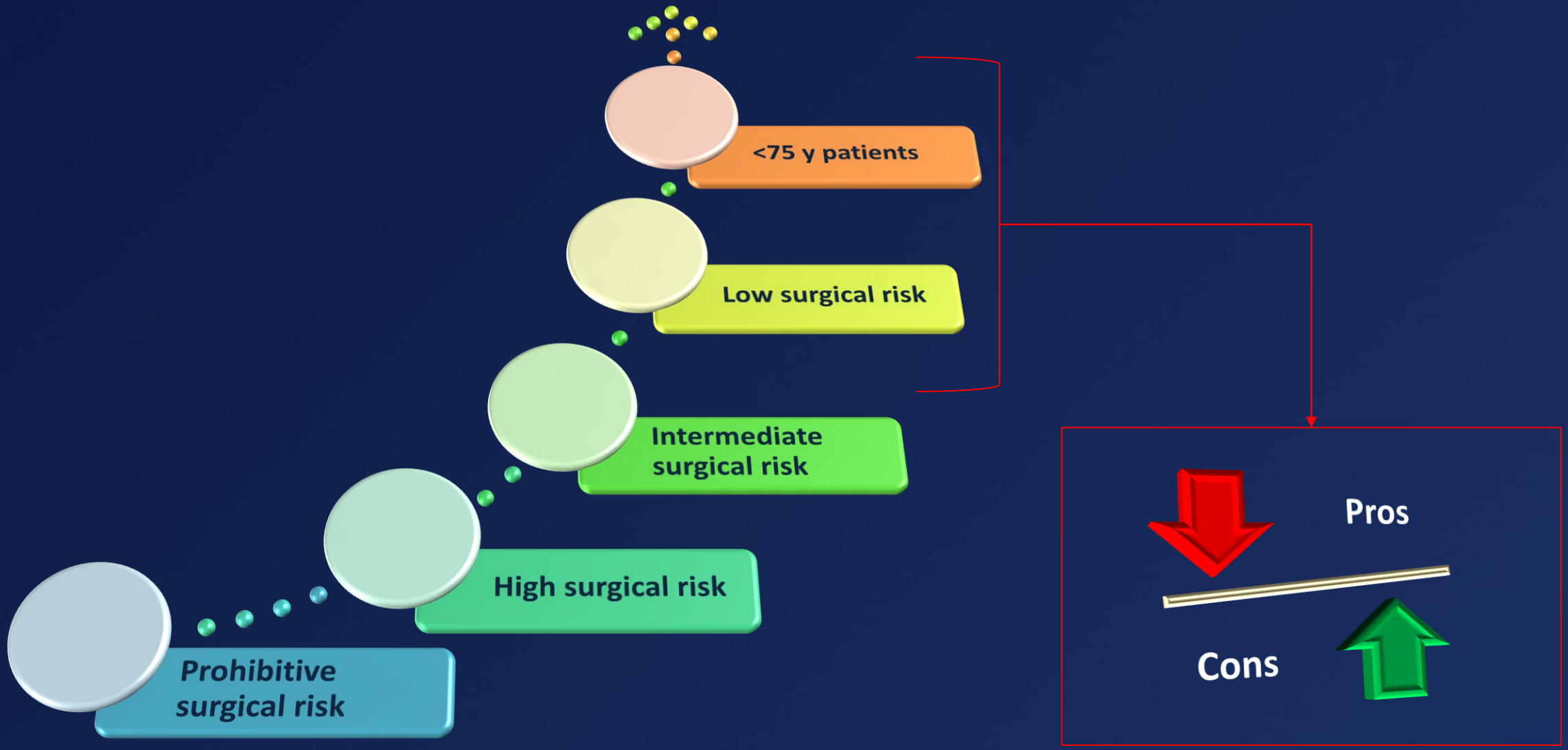
Jørgensen et al. Eur Heart J. 2021 Aug 7;42(30):2912-2919

TAVI vs SAVR Algorithm

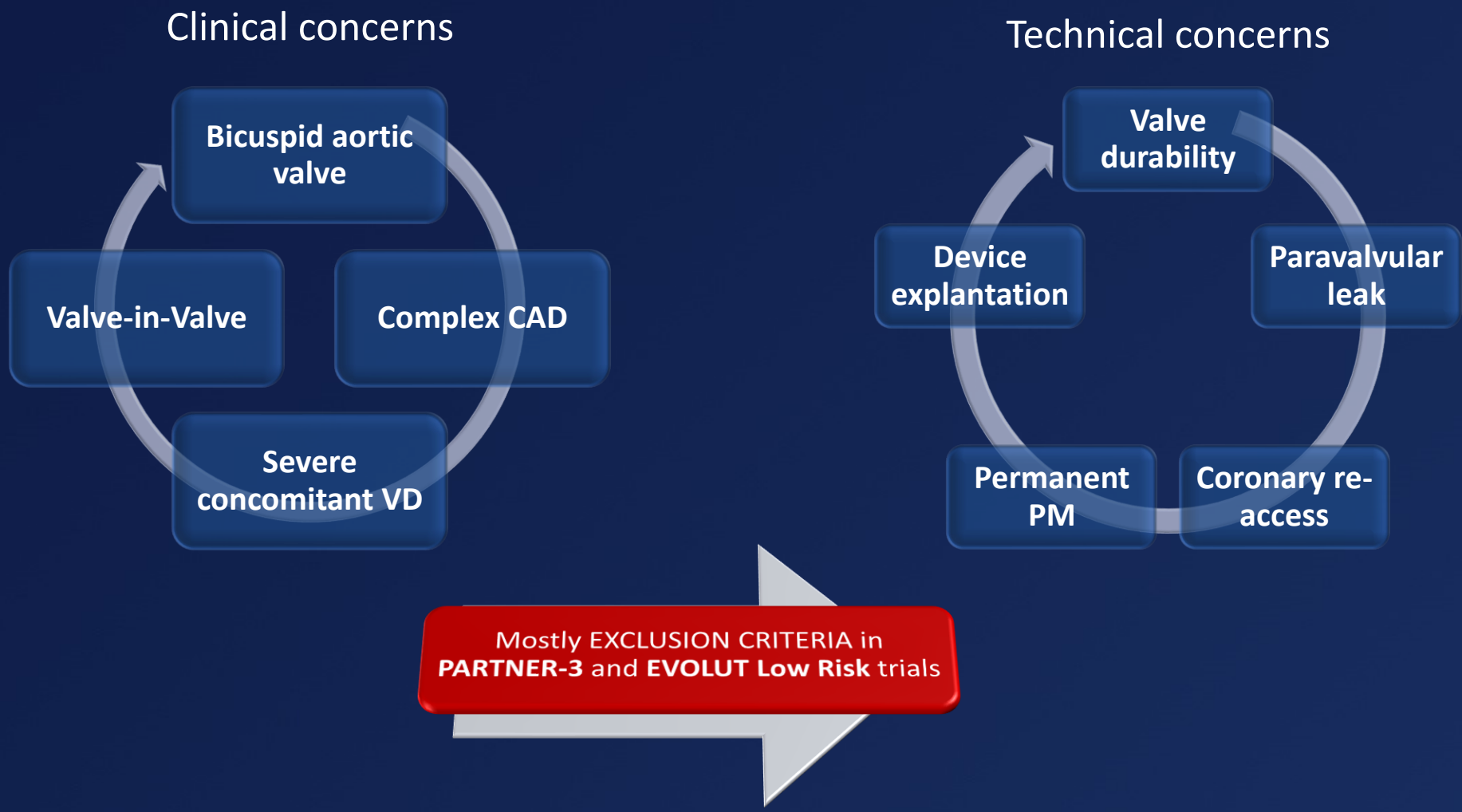




Evolution of TAVI



Expansion of TAVI to Low-Risk Patients

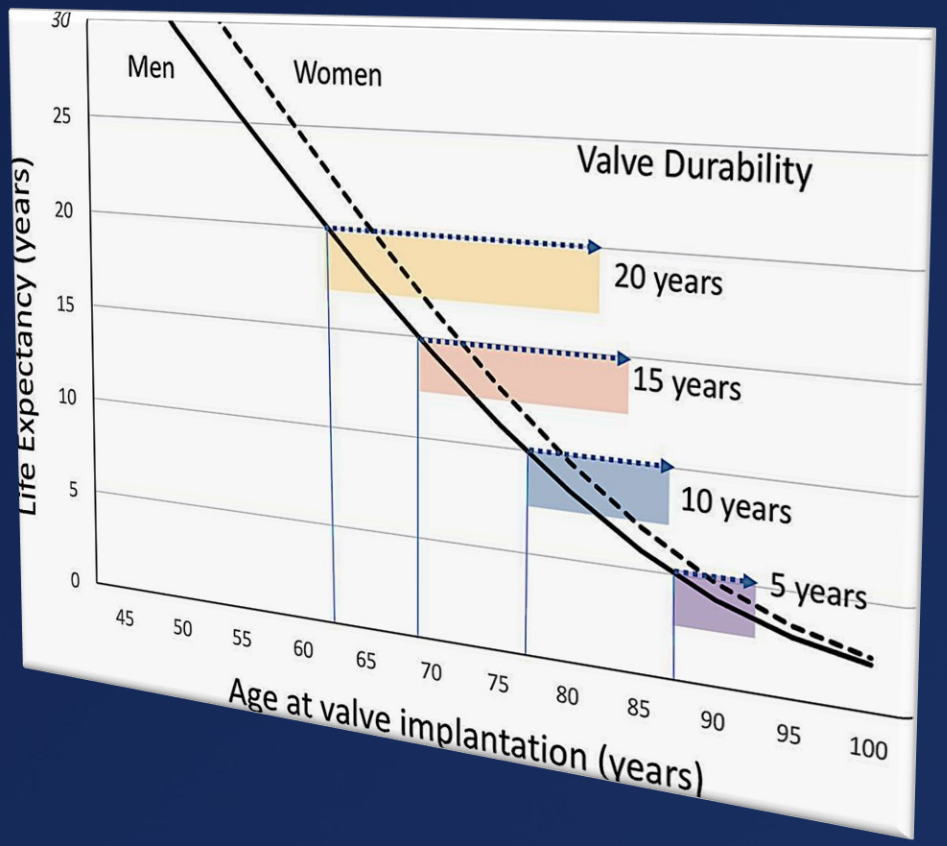


Hanzel GS and Gersh B. Circulation. 2020 Oct 6;142(14):1317-1319.

Valve Durability

Patients from 60 to 70 year old undergoing aortic valve replacement will likely require at least 1 additional valve intervention throughout their lifetime.

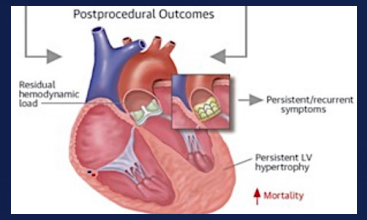
- **TAVI ViV** are currently standard practice, but more evidence is needed:
  - *how often this can be repeated*
  - *impact on patient-prosthesis mismatch.*
- **Re-do TAVI** may be complex or not always feasible:
  - *TAVR explantation is a challenging surgical procedure and is associated with a high mortality rate*



Bagur R et al. Heart. 2017 Nov;103(22):1756-1759.

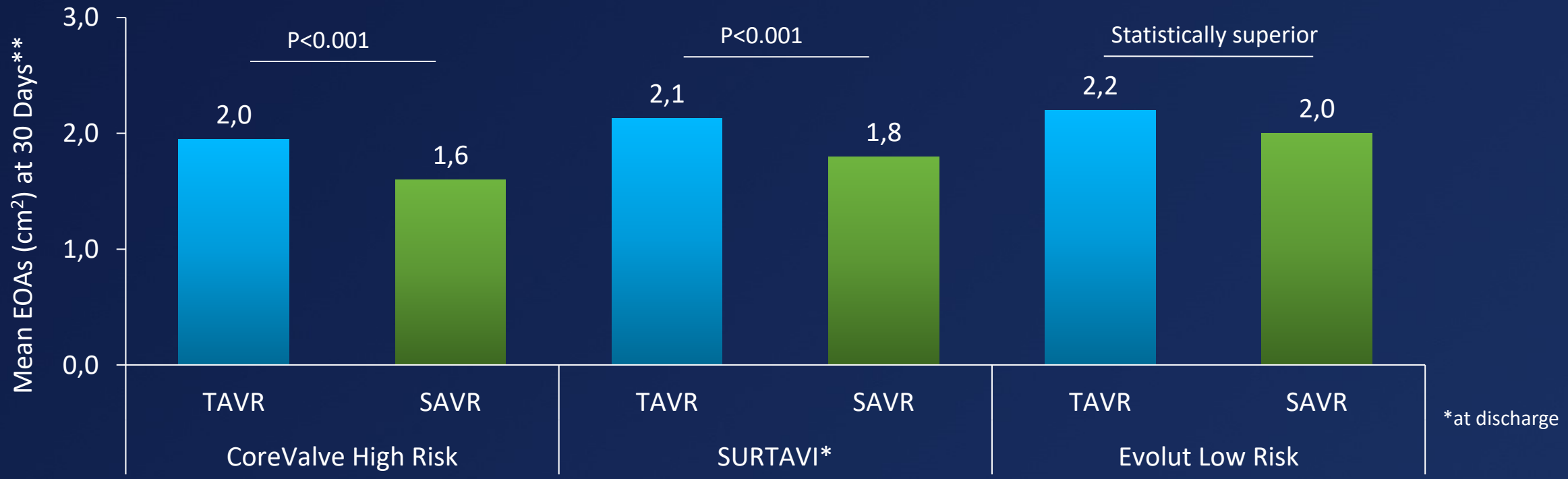
TAVI vs SAVR Hemodynamics

TAVI Delivers Larger EOAs



TAVI can achieve larger EOAs than SAVR with supra-annular valves delivering the largest EOAs. Mean EOAs of the supra-annular CoreValve, Evolut R, and Evolut PRO valves range from 1.9 to 2.2 cm^2 in clinical trials.

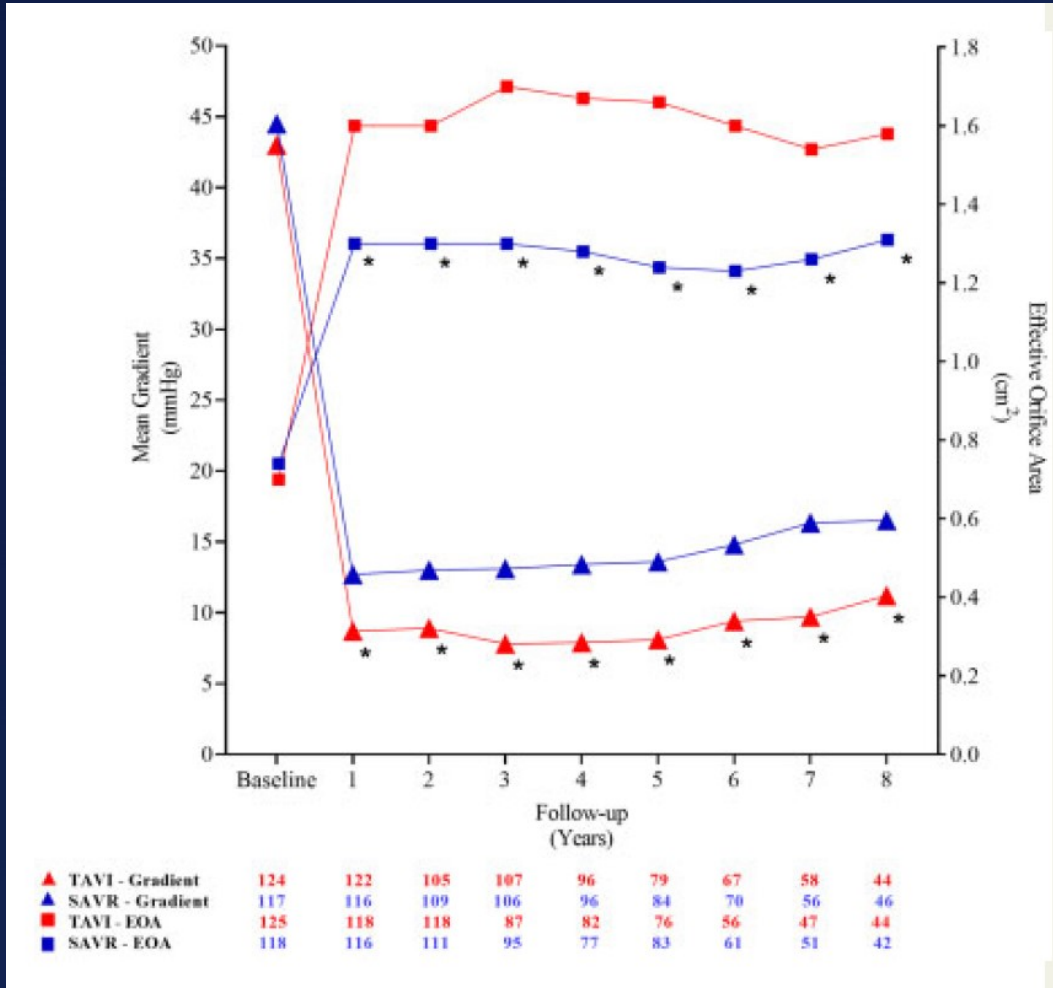
CoreValve and Evolut TAVs have shown superior EOAs compared to SAVR in randomized clinical trials.

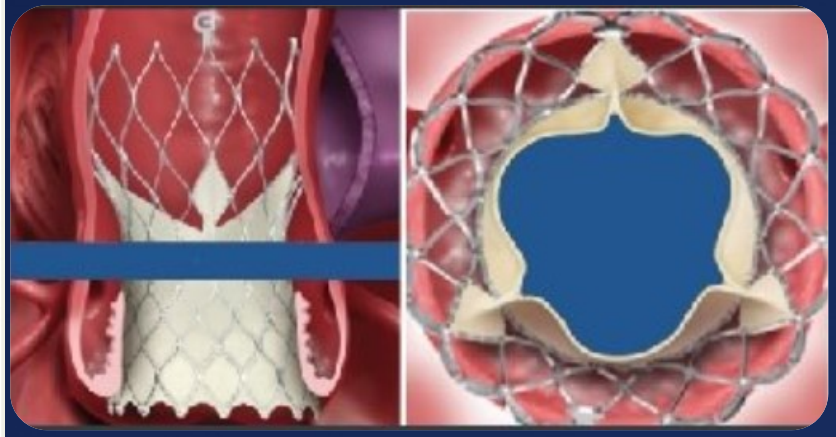


References from left to right: Adams, et al., *N Engl J Med* 2014; 370: 1790-8; [2]Manoharan, et al., *J Am Coll Cardiol Intv* 2015;8: 1359-67; [3]Williams, et al., presented at ACC 2016; [4]Van Mieghem et al. Presented at TCT 2017; [5]Grube et al., JACC 2017;70:845-53; [6]Forrest et al., JACC: Cardiovascular Interventions Jan 2018;11:160-168; [7]Popma P, et al. NEJM 2019; 380:1706-15.

NOTION Trial @ 8-year

Aortic Valve Performance

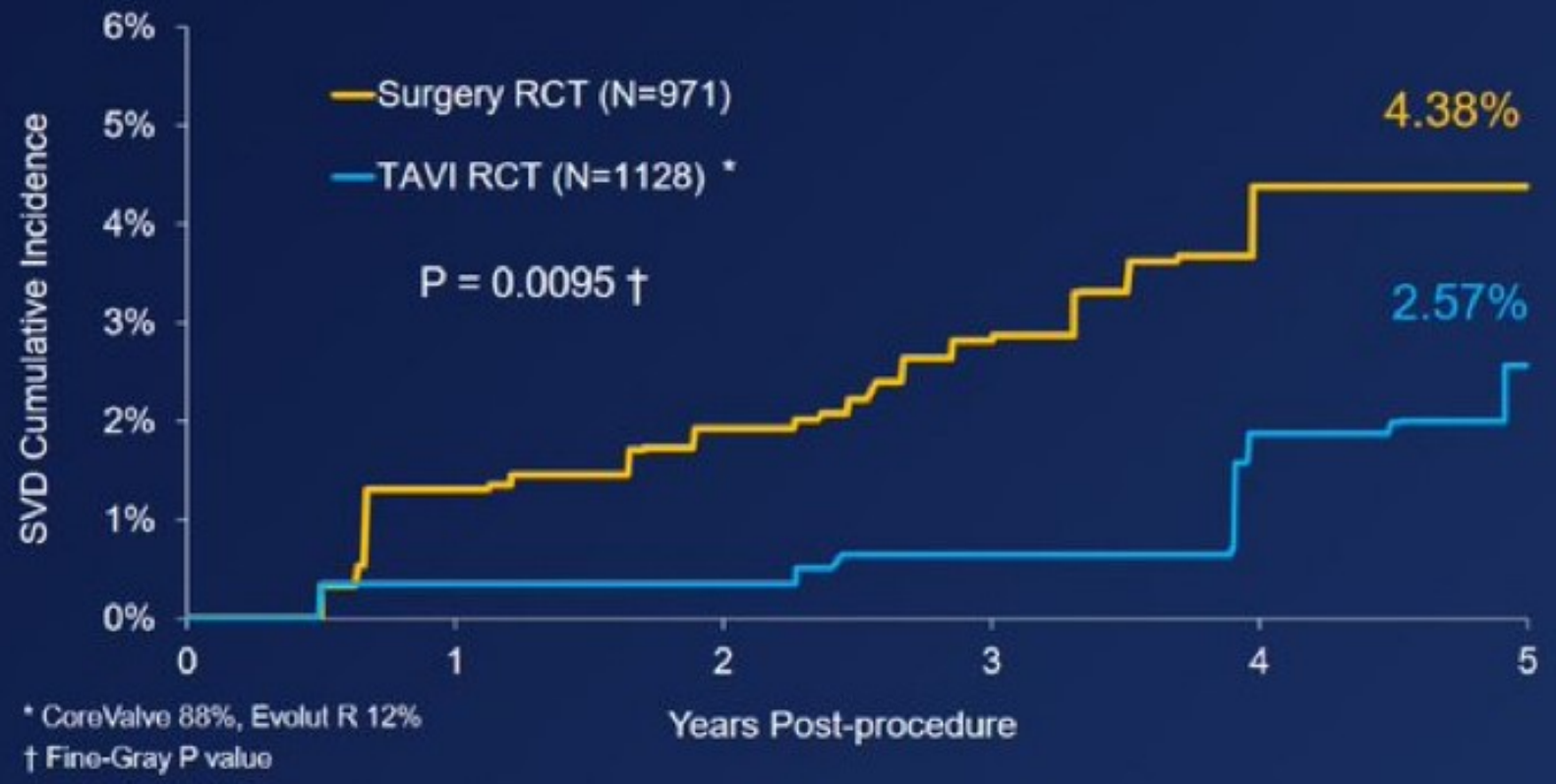




LVEF 52± 8.0% in TAVI pts
LVEF 54± 8.2% in SAVR pts
@ 8 years FU *P=0.14*

Jørgensen et al. Eur Heart J. 2021 Aug 7;42(30):2912-2919

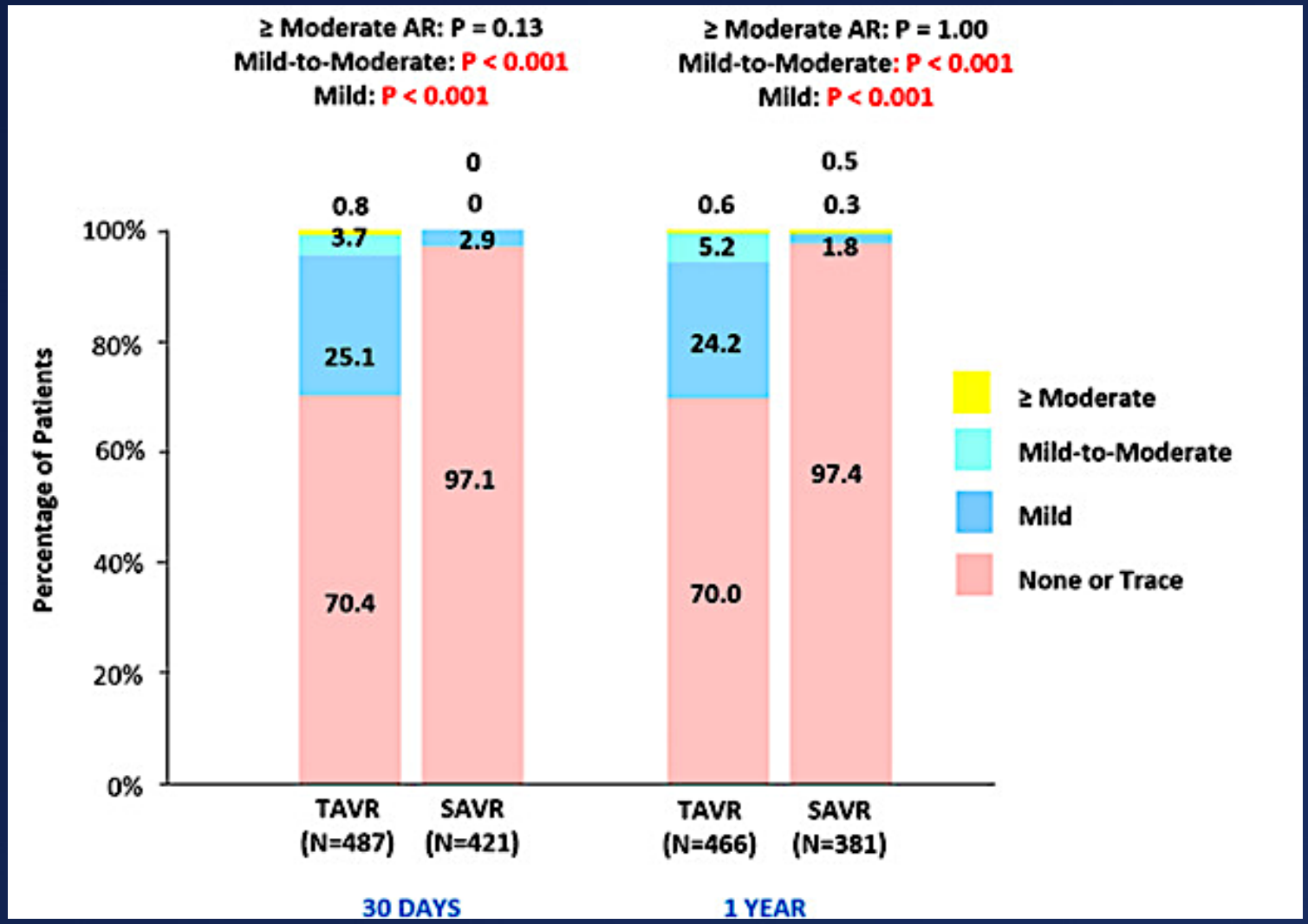
COREVALVE EVOLUT POOLED ANALYSIS
Structural valve deterioration at 5 years



Reardon et al. @ACC 2022

Para-valvular Aortic Regurgitation

PARTNER 3 Trial – Low Risk Patients



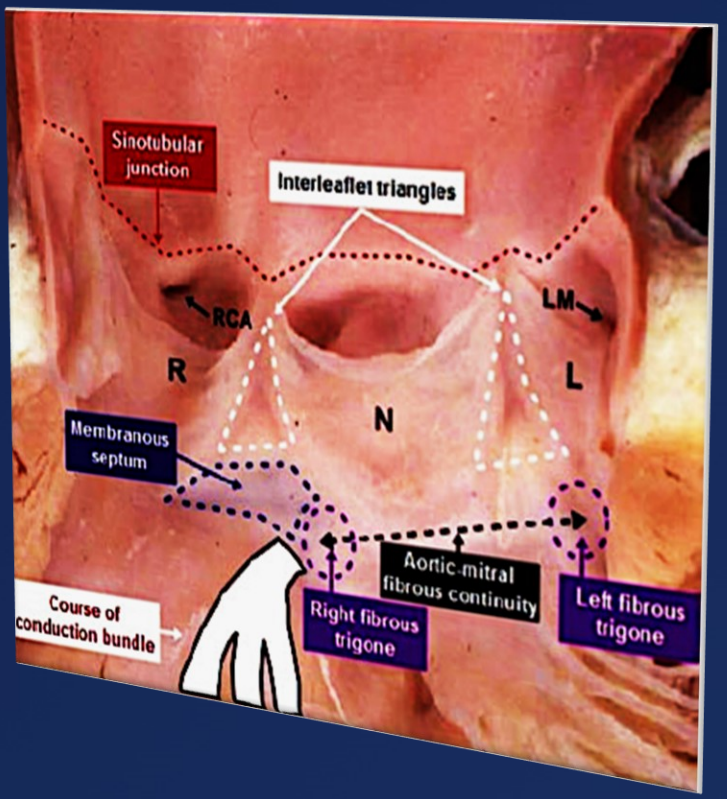
5-class grading scheme

Pibarot P et al. Circulation. 2020 May 12;141(19):1527-1537.

Conduction Disturbances post-TAVI

- Compared with SAVR, TAVI is associated with a 3-fold higher incidence of LBBB and increased incidence of a PPM

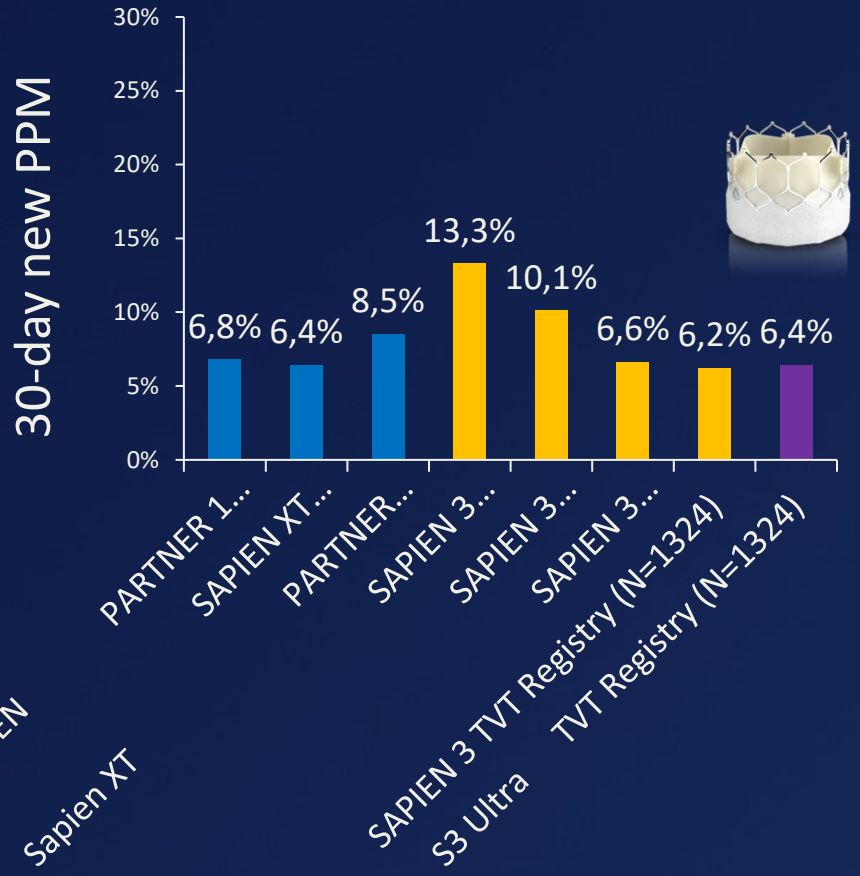
- Right ventricular apical pacing and new LBBB have been associated with a lower EF, increased hospitalizations for HF, and higher mortality.

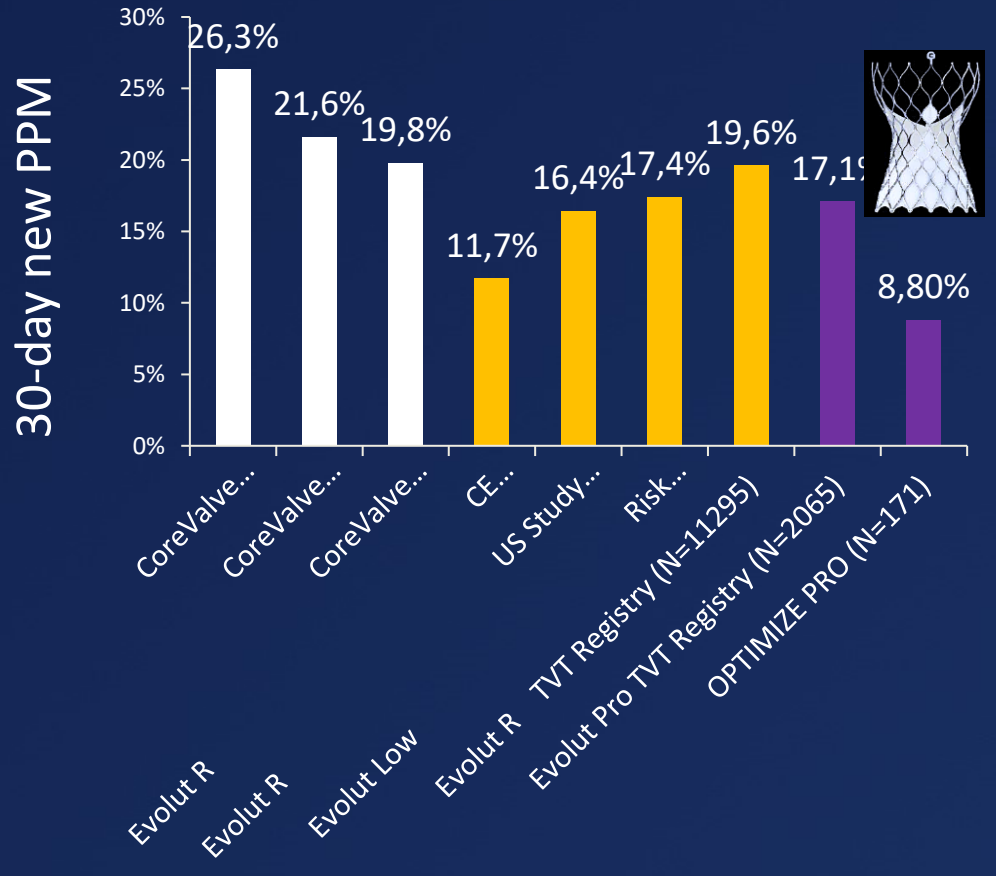


Long-term implications for **younger patients** are of concern and potentially could reduce, or even negate, the early benefit of TAVI over SAVR

PPM with Newer Generation Devices:

Edwards SAPIEN Ultra & Medtronic Evolut R and PRO





The Guidelines

2020 ACC/AHA Guidelines

COR	LOE	RECOMMENDATIONS
1	A	1. For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended (123-125).
1	A	2. For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability (123,126-130).
1	A	3. For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR (123,126-132).

2021 ESC Guidelines

SAVR is recommended in younger patients who are low risk for surgery (<75 years[e] and STS-PROM/EuroSCORE II <4%)[e,f], or in patients who are operable and unsuitable for transfemoral TAVI.[244]	I	B
TAVI is recommended in older patients (≥75 years), or in those who are high risk (STS-PROM/EuroSCORE II[f] >8%) or unsuitable for surgery.[197–206,245]	I	A

Otto C et al. J Am Coll Cardiol. 2021 Feb 2;77(4):450-500; Vahanian A et al. Eur Heart J. 2022 Feb 12;43(7):561-632.

Case presentation

Madame, 68 years

Risk Factors / Lab findings

- No significant CV-RF, Creatinine 0.9 mg/dl

Previous cardiac history

- Previous AVR in 2010 (CARPENTIER EDWARDS N.21)

TRUE ID 19 mm

Clinical presentation

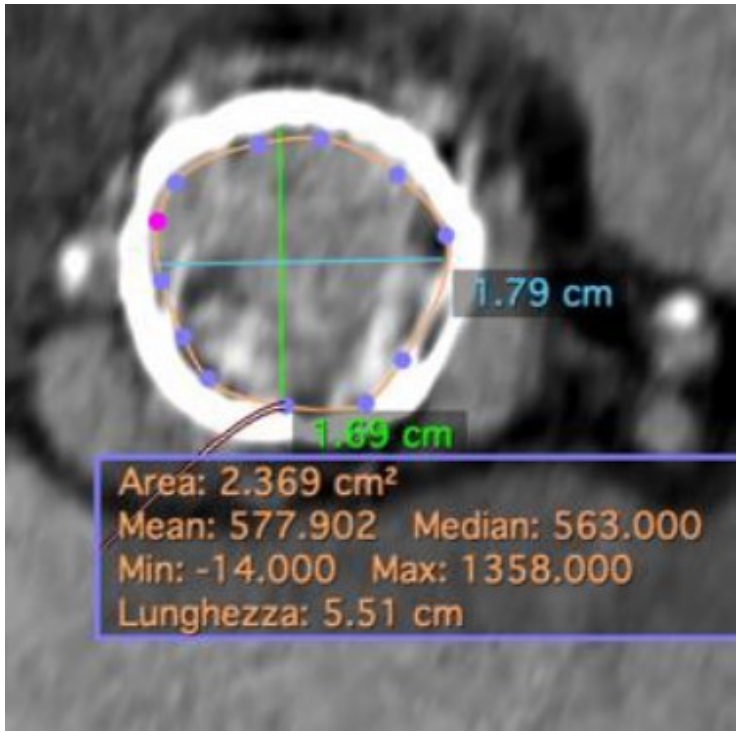
- Worsening shortness of breath (NYHA III)
- **Echo: severe aortic stenosis (mean gradient 41 mmHg, AVA 0.5 cm^2), EF 60%**
- **DVI 0.65**

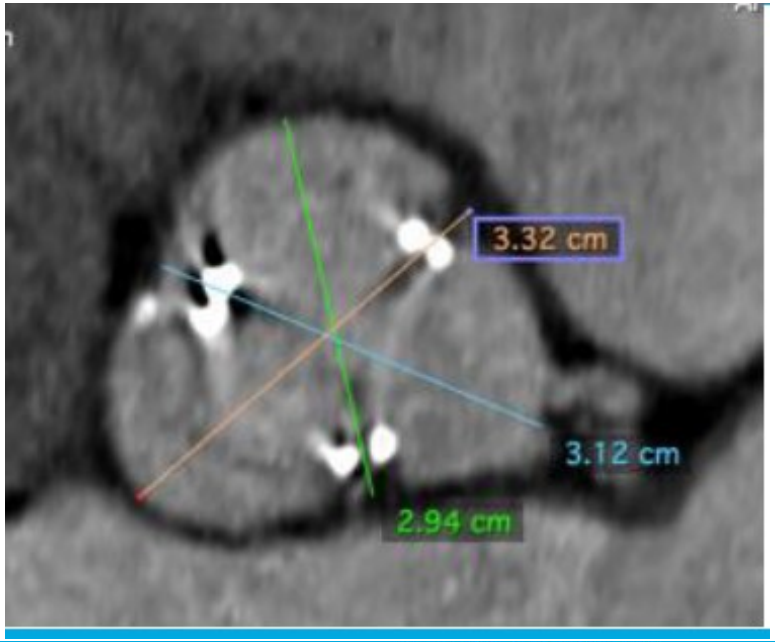
Main comorbidities

- Primary hypothyroidism under replacement therapy

STS-PROM 1,48

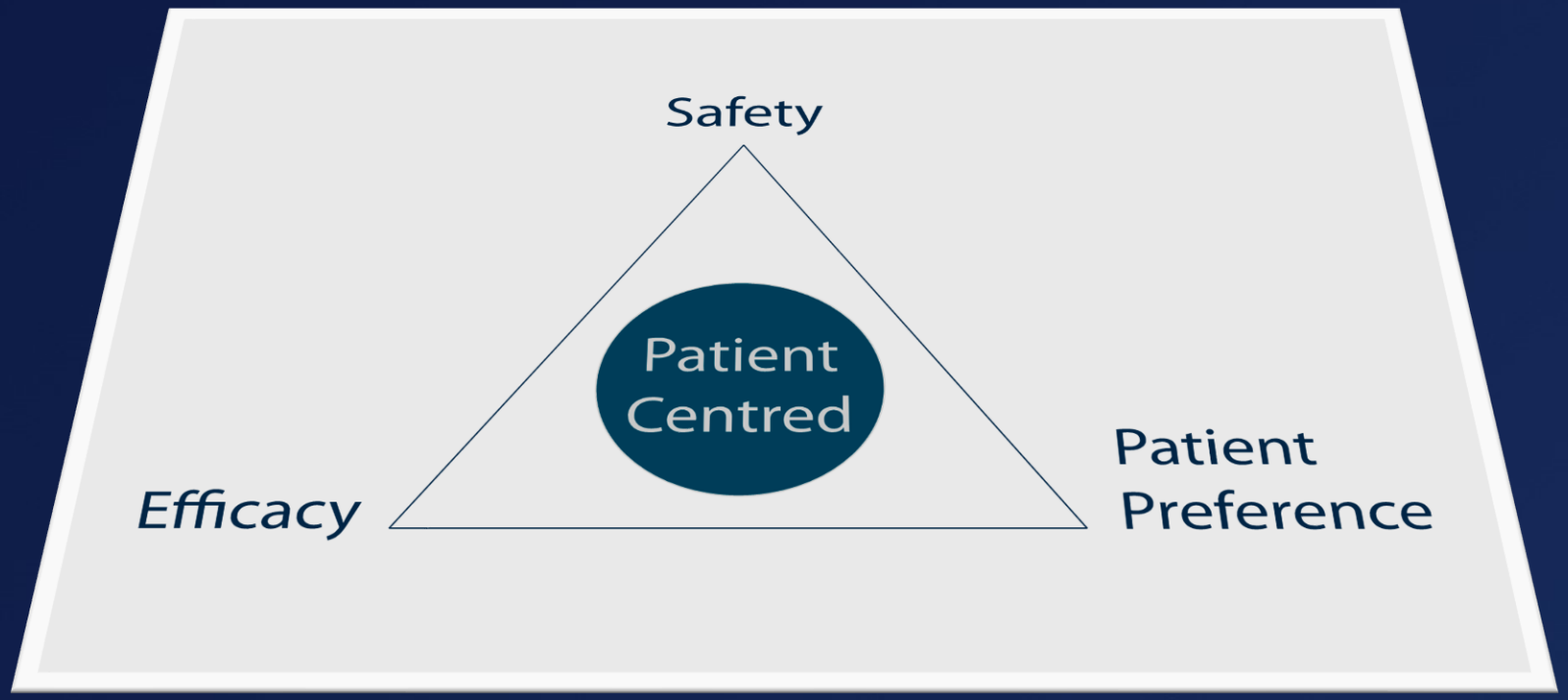
Angio-CT





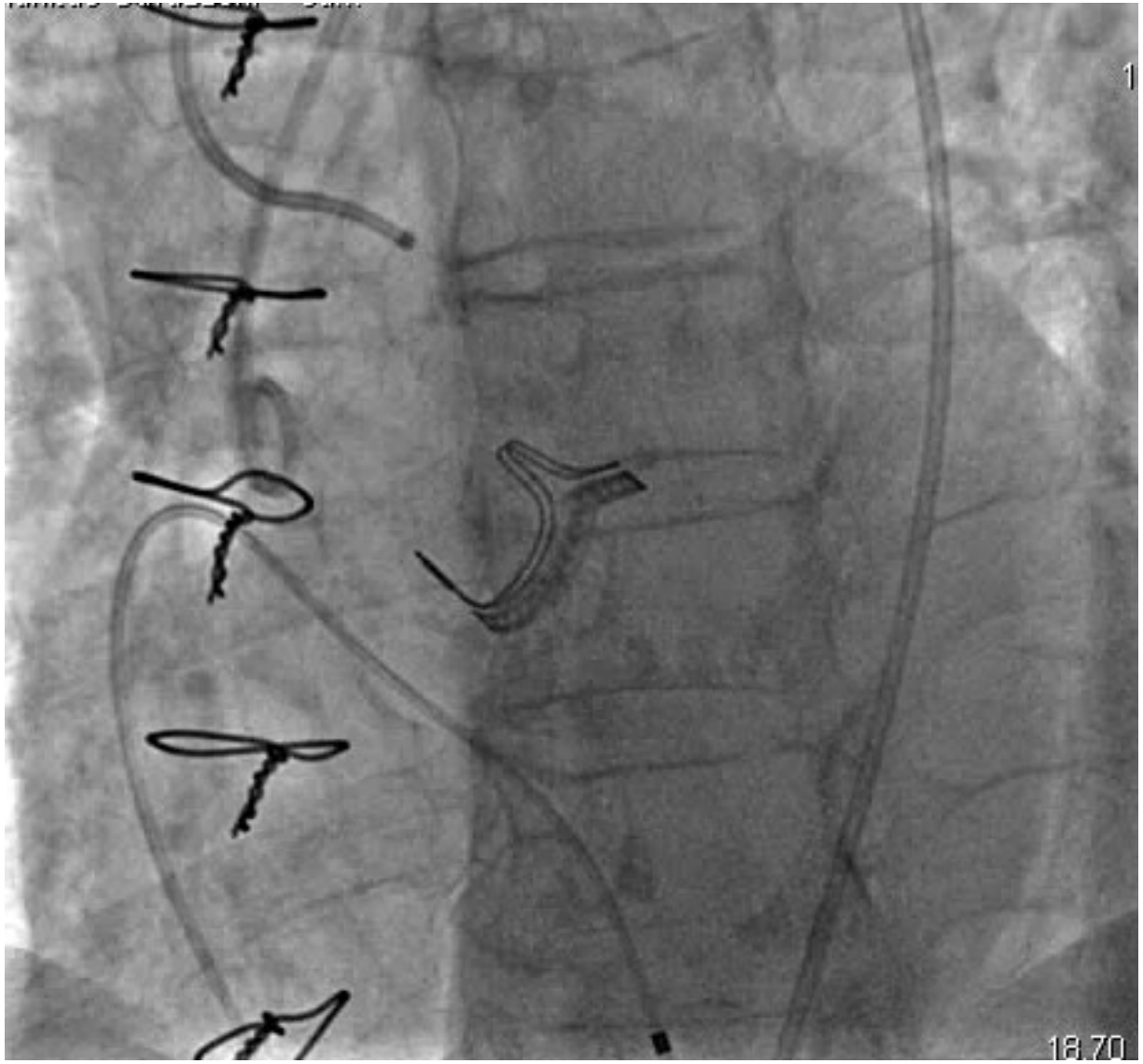
ALTEZZA CORONARIE	
Csx 8,6 mm	Cdx 11,8 mm

Adoption of interventional procedures

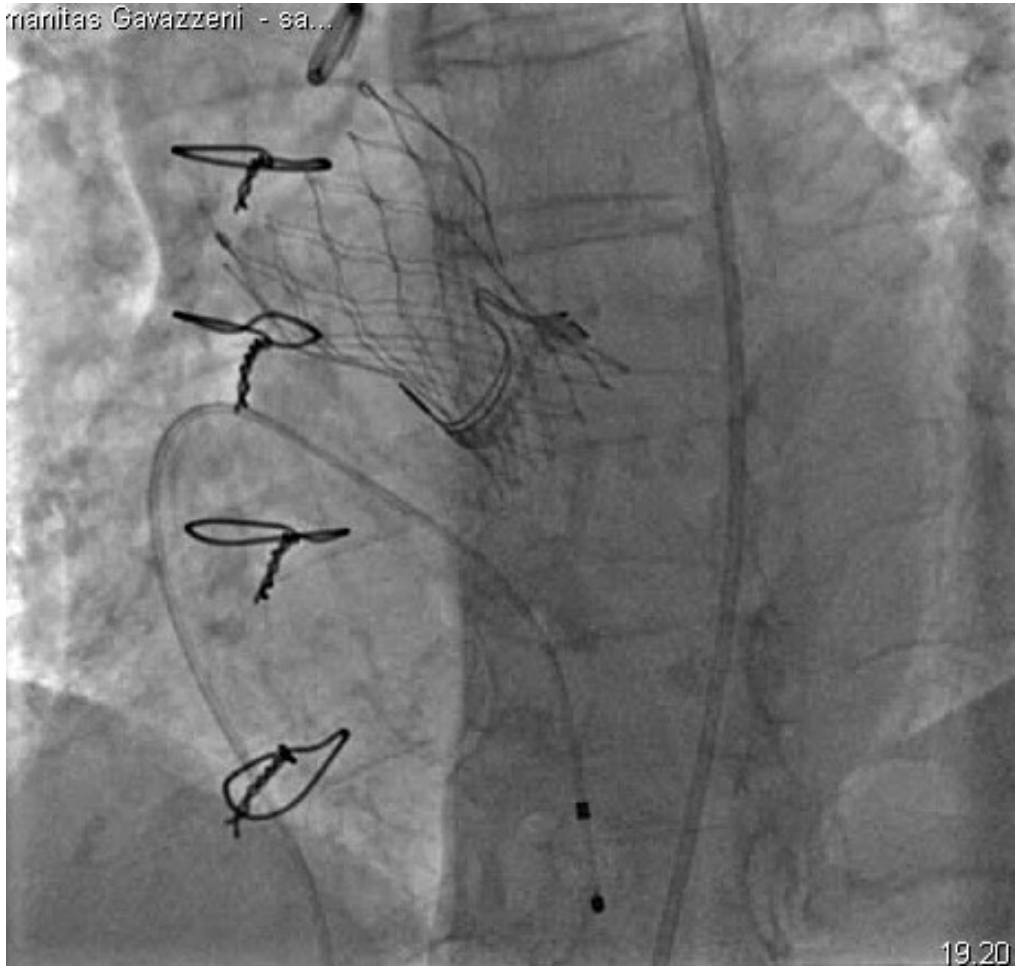


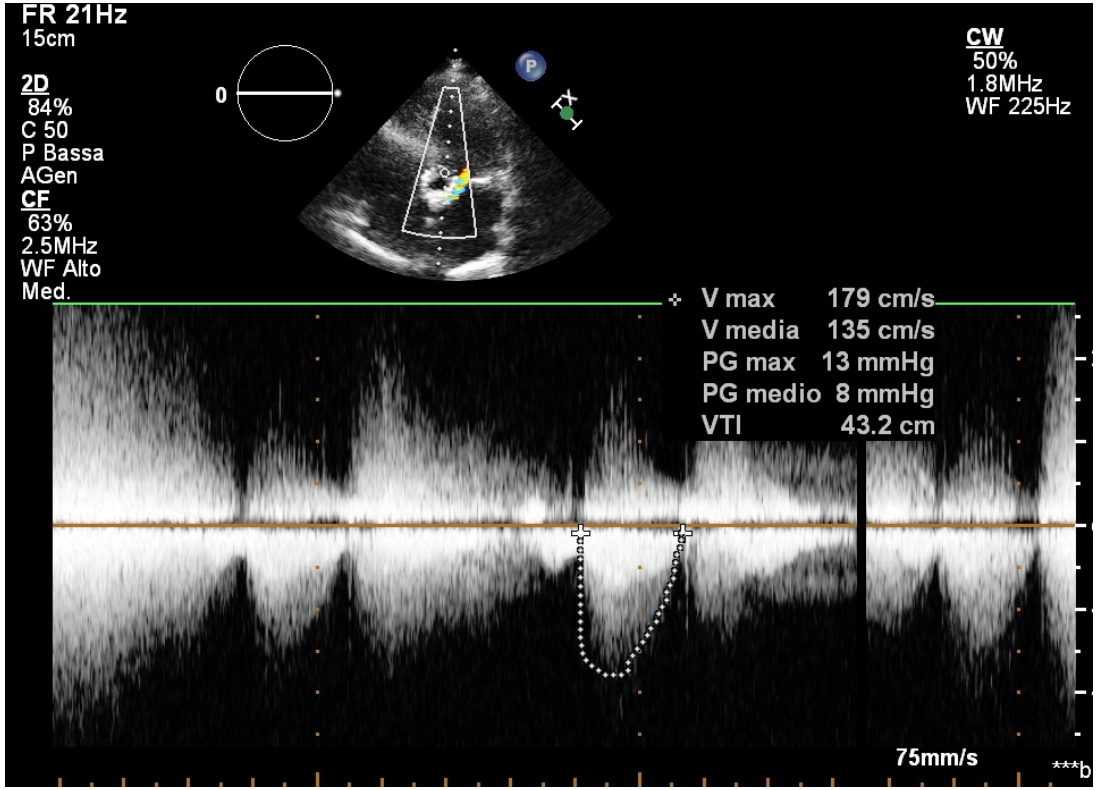
Beating Heart Interventions

Basal angiogram



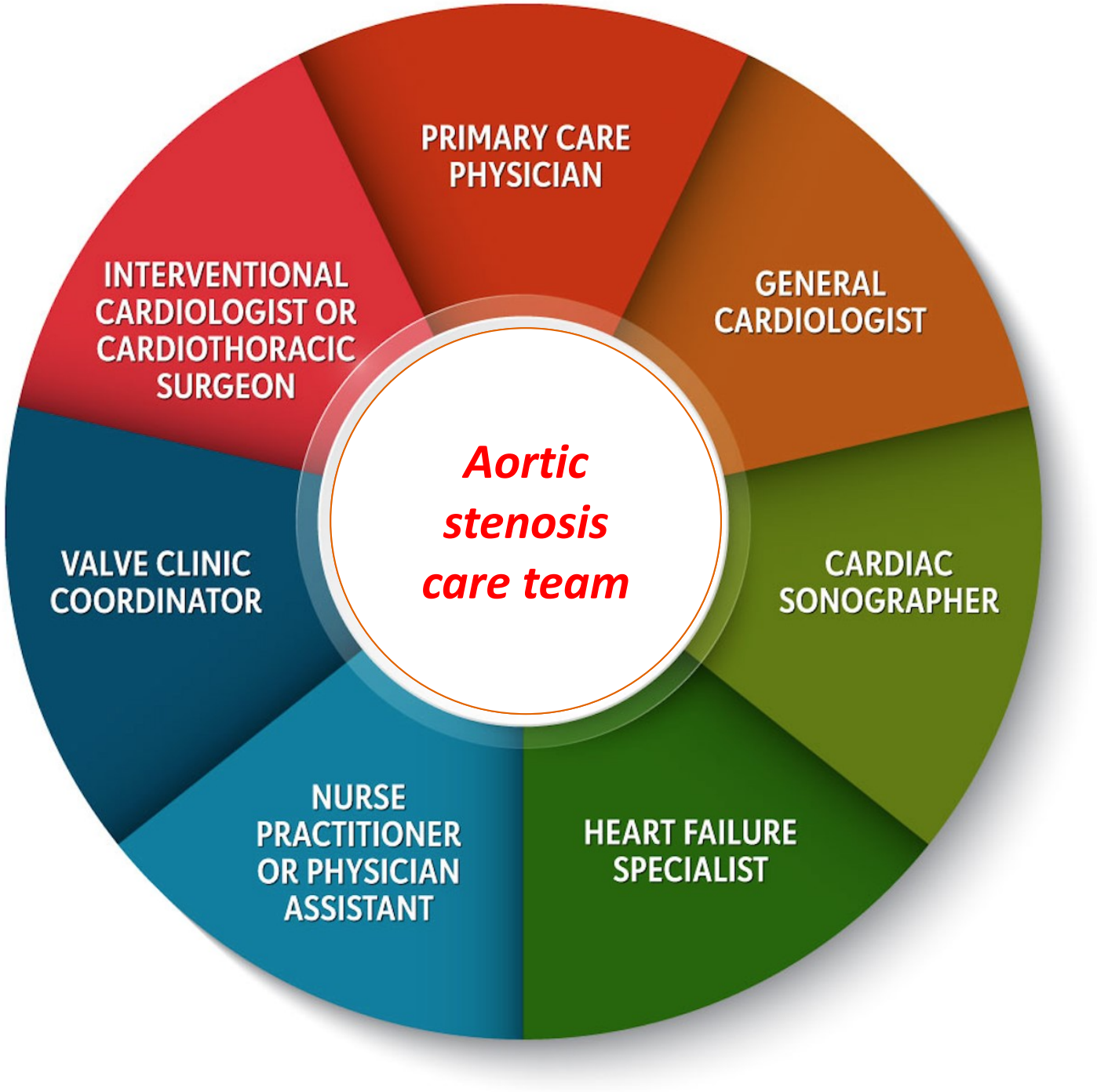
Final result





Conclusions

- TAVI compared with SAVR resulted in significant survival benefit at short-mid term follow-up, irrespective of baseline surgical risk (through the transfemoral route).
- Structural valve deterioration and valve hemodynamics with TAVI appear at least as good as with SAVR
- The risk of PPI and at least mild PVL remain important concerns in patients undergoing TAVI, although rates of these complications have dropped over time.
- Strategies for the lifetime management of patients with aortic stenosis should be balanced within the heart team and tailored to individual patients, taking into consideration anatomical features, THV type, the need for other procedures and the potential for repeatability.


PRIMARY CARE PHYSICIAN
GENERAL CARDIOLOGIST
CARDIAC SONOGRAPHER
HEART FAILURE SPECIALIST
NURSE PRACTITIONER OR PHYSICIAN ASSISTANT
VALVE CLINIC COORDINATOR
INTERVENTIONAL CARDIOLOGIST OR CARDIOTHORACIC SURGEON
Aortic stenosis care team