Can We Improve TAVR Durability Today? Imaging-based Procedural Solutions

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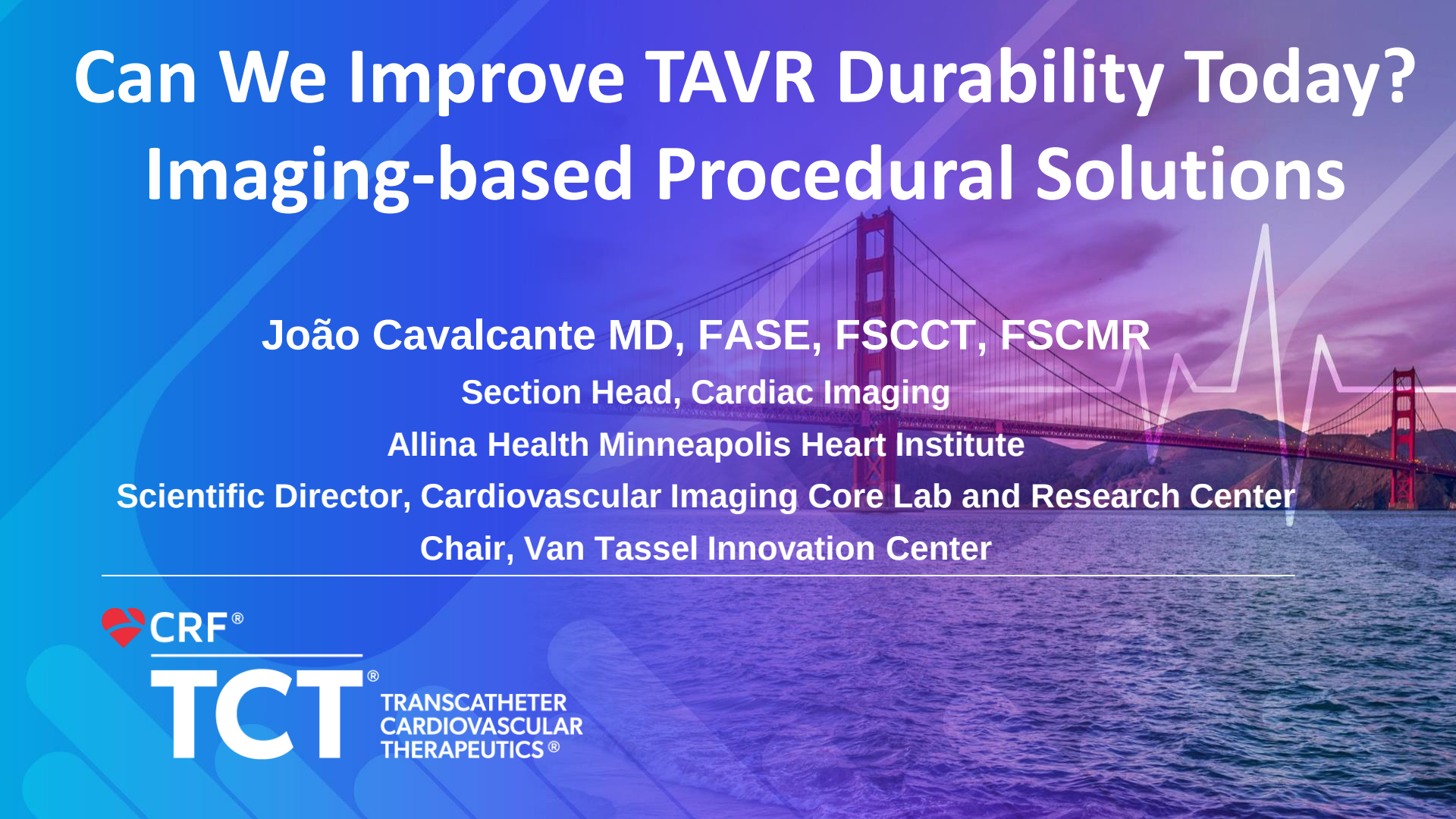

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Disclosures

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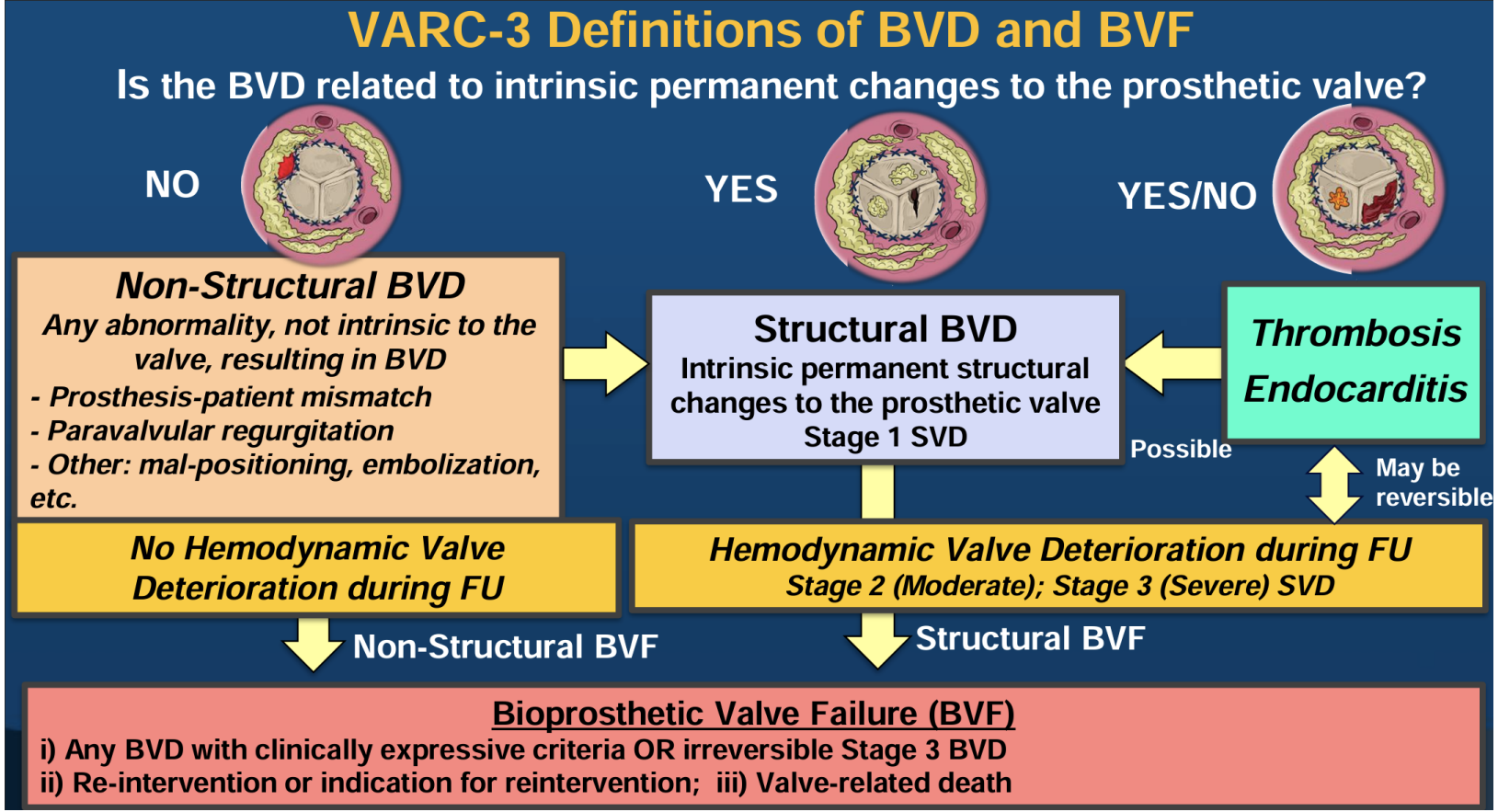
Durability is a Multifactorial and Inter-Related Issue

- The Host AV Leaflet, Anatomy and Surrounding Tissue
- The Host Comorbidities (Age, CKD, Ca^{++} x Phosp, etc)

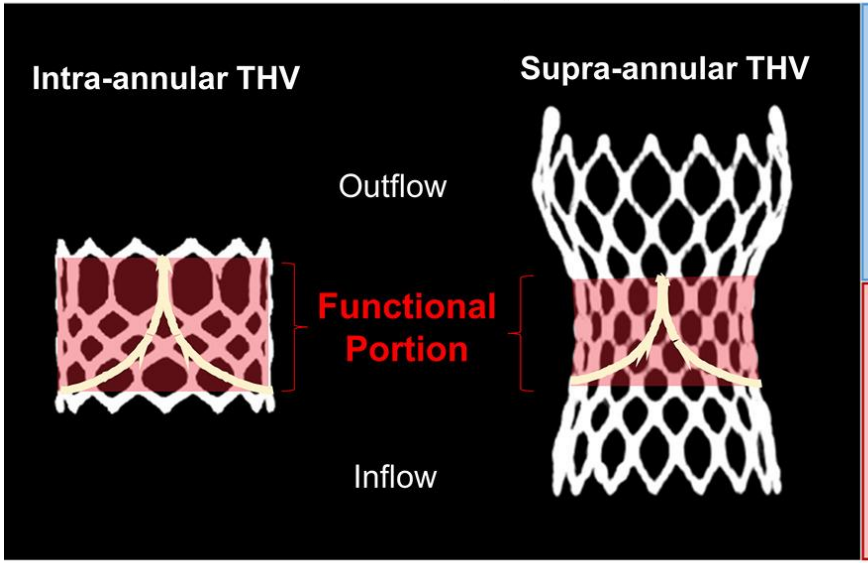
- Prosthetic valve type, valve size/PPM, Frame and Leaflet Design and Leaflet Tissue

- THV device preparation/crimping
- THV Frame Deformation / Frame Expansion
- How it is defined, *and some more we don't know…*

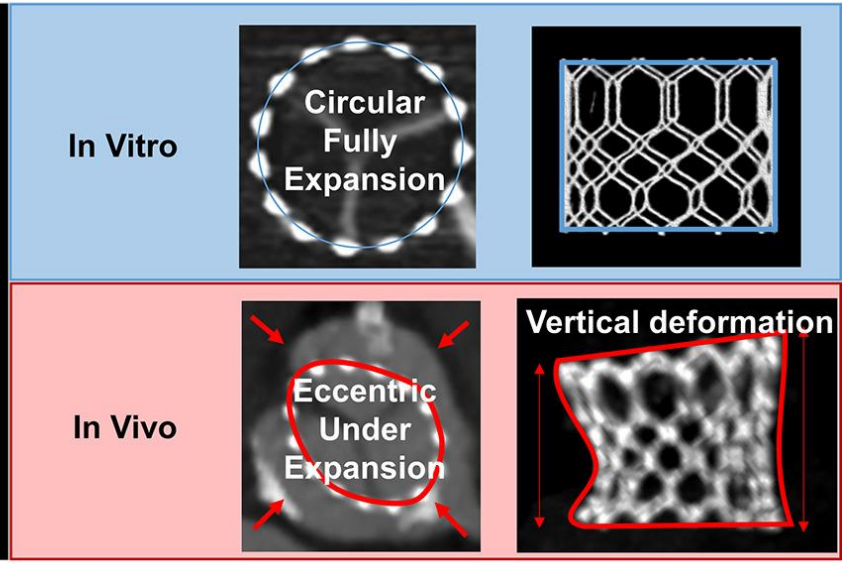


Genereaux P et al. JACC 2021 Jun 1;77(21):2717-2746.

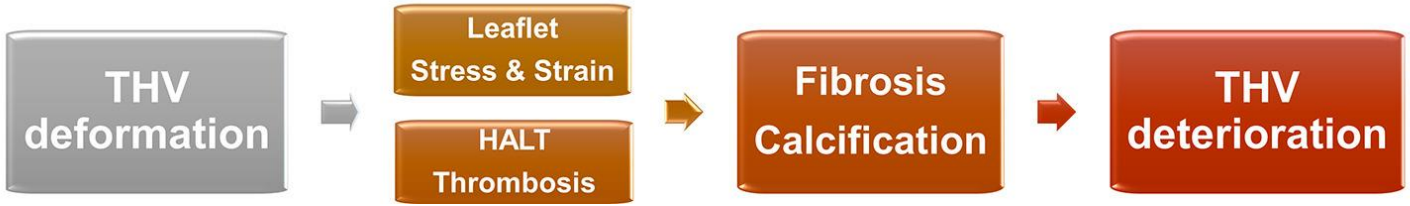
- Deformation at functional portion is crucial



- Deformation is 3D phenomenon



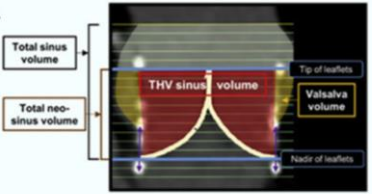
- Deformation could cause THV deterioration via fibrosis and calcification process

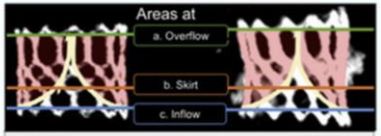


Fukui M, Cavalcante JL, Bapat VN. J Cardiol 2024 Jun;83(6):351-358

THV Shape Matters

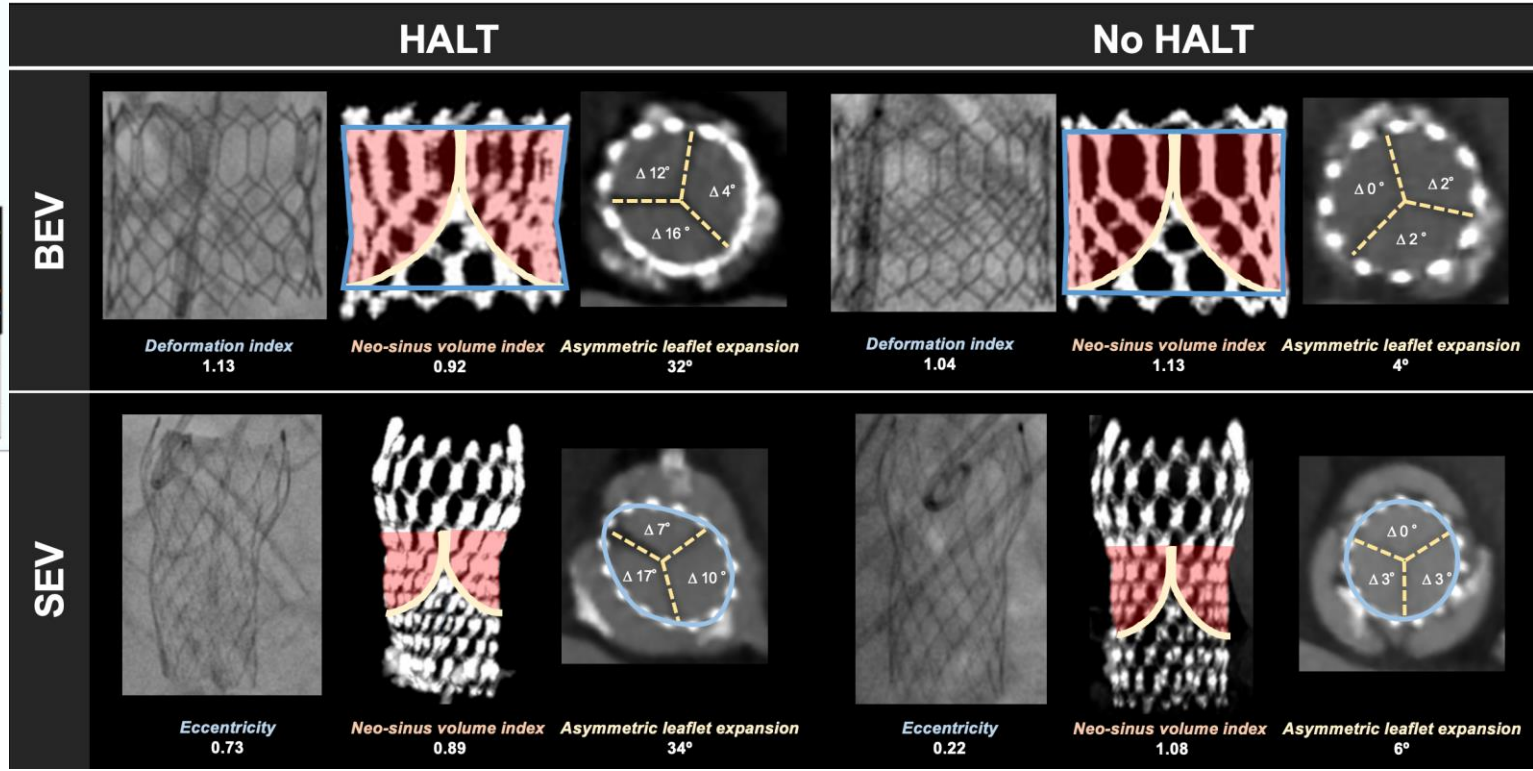
HALT seen in 19% of patients at 30 days CT screening registry
No differences in THV gradients for HALT + vs. HALT -



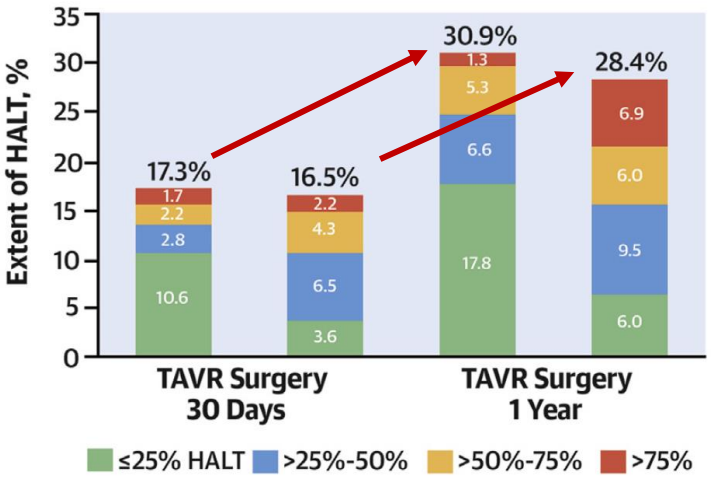


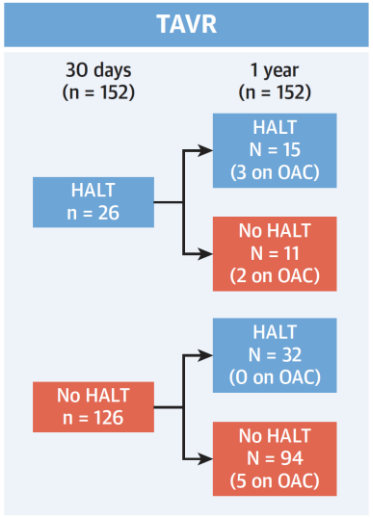
HALT -		HALT +
1.04	THV deformation index = (a + c) / (2 ×b)	1.21
7.2	THV sinus volume (ml)	6.3

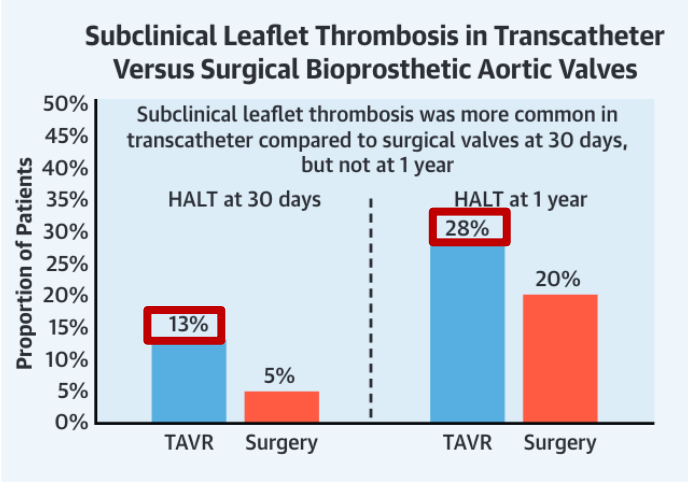
565 patients at 30-days post TAVR
- ***352 S3 (62%);***
- ***213 Evolut R/Pro+ (38%)***



Fukui M et al. Circulation 2022 Aug 9;146(6):480-493

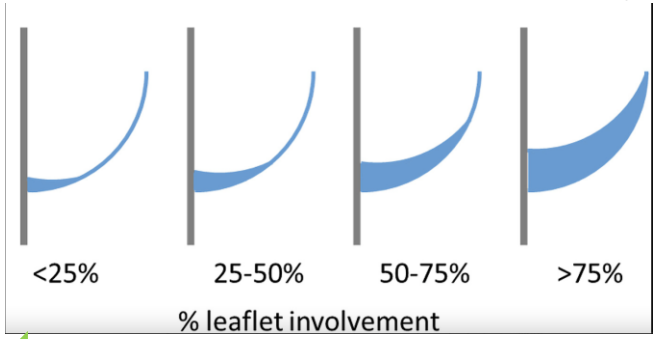






Makkar, R.R. et al. J Am Coll Cardiol. 2020;75(24):3003-15.

Blanke et al. JACC 2020 May 19;75(19):2430-2442.



How Often does HALT Occur and what is its Natural History (⊘AC)?

True finding? Likely to "resolve"

Harder to miss, unlikely to resolve spontaneously

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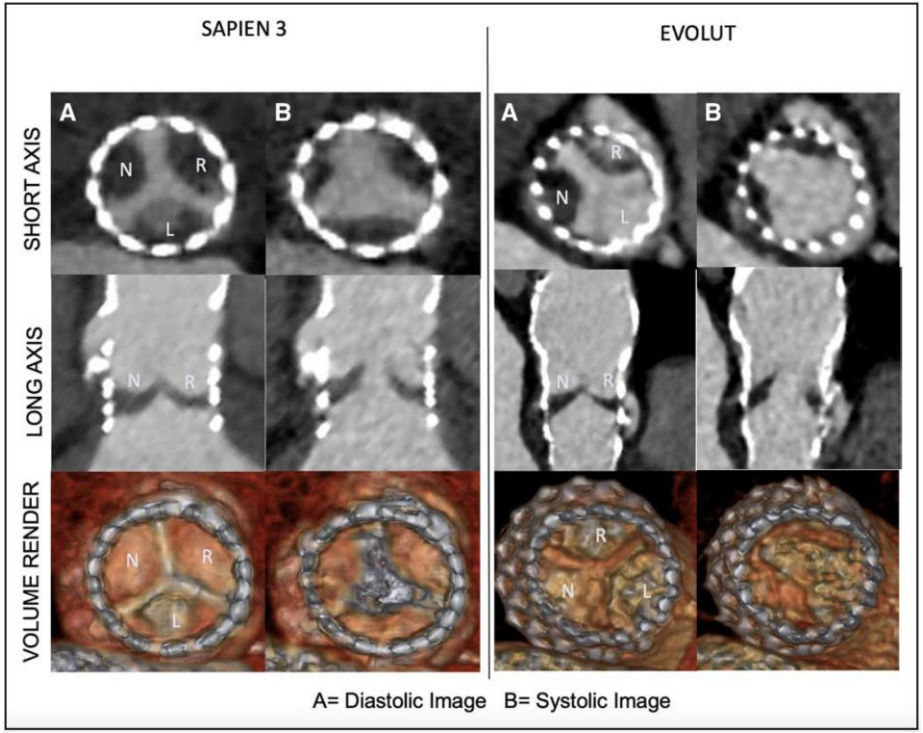
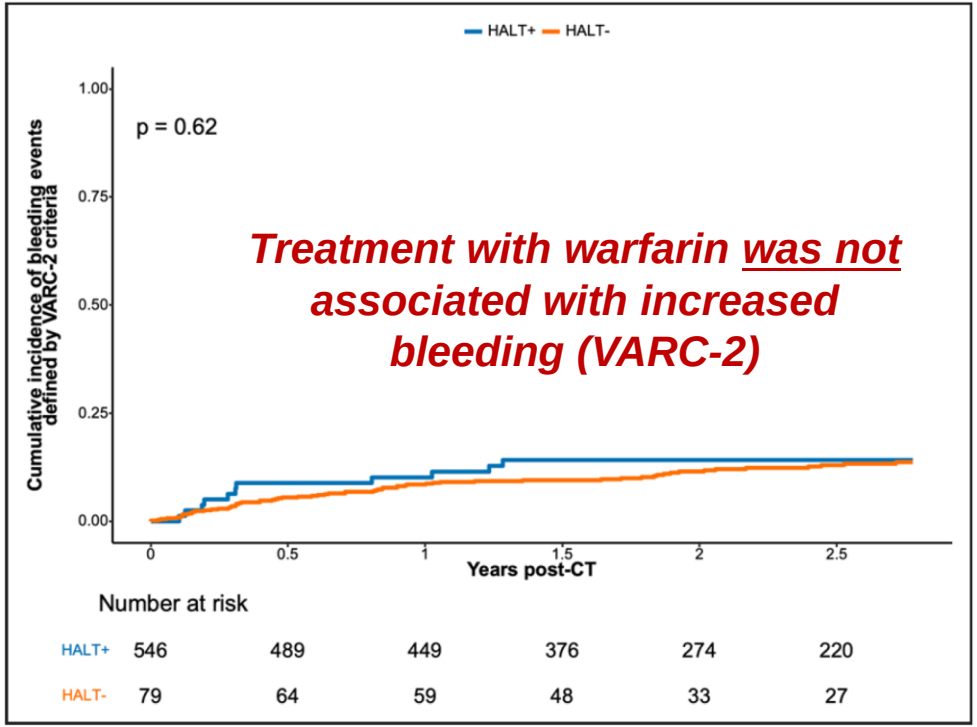
HALT is not a binary process, but rather a graded spectrum





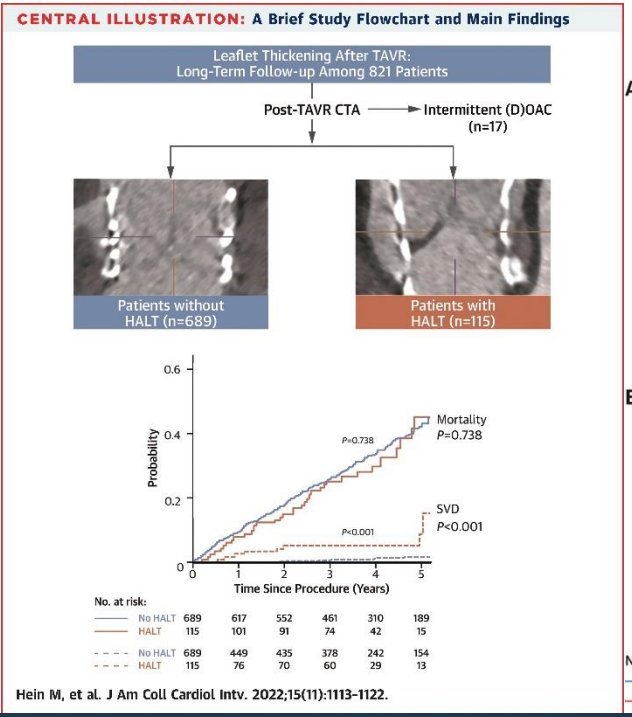
Treatment with warfarin was not associated with increased bleeding (VARC-2)

Treatment with warfarin was associated with resolution of HALT in 82% of patients undergoing serial imaging.

Anticoagulating everyone without HALT increases bleeding risk, and provides no gain…

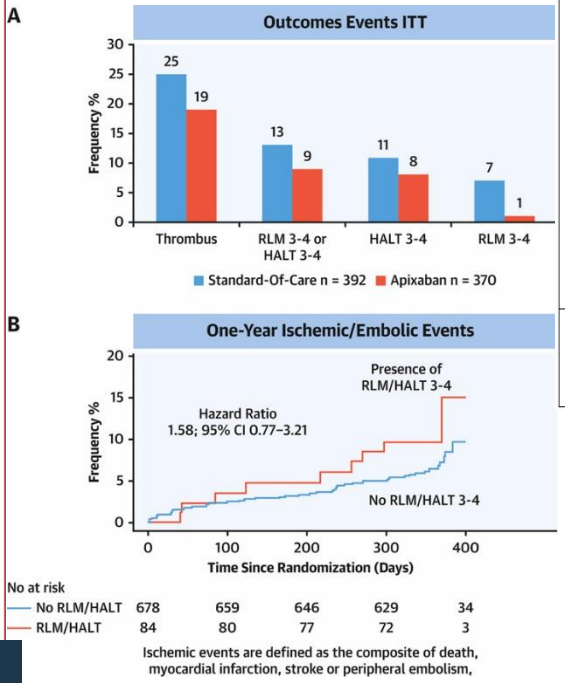
Garcia S et al. Circ Cardiovasc Interv. 2022;15:e011480.

Does HALT Matter?

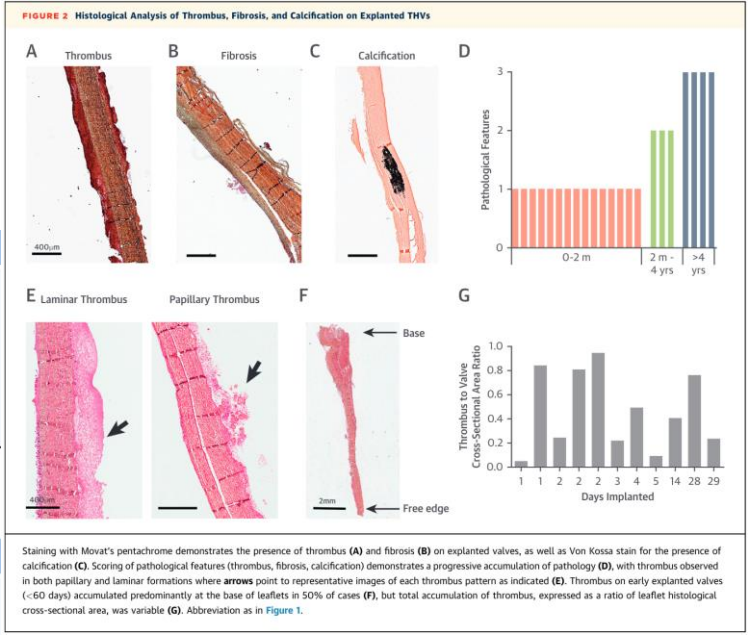


3-year event rate of symptomatic HVD was 9.4% vs 1.5% (with vs without HALT, P < 0.001) (HR: 6.10; 95% CI: 2.59-14.29; P < 0.001

Atlantis-4D



Montalescot et al. JACC Interv 2022 Sep 26;15(18):1794-1804.



"Thrombus was found on all valves, unlike the stated prevalence of 7% to 14% on CT"

THV degeneration appears to occur in a stepwise fashion: thrombus → fibrosis (after 60 days) → calcification after 4 years. Trend toward increased leaflet thickness throughout implantation.

Sellers et al. JACC Imaging. 2019 Jan;12(1):135-145.

Is HALT a Harmless Bystander?

Table 4. One-Year Clinical Outcomes

Variable	All patients (n=565)	HALT (n=108)	No HALT (n=457)	Unadjusted HR (95% CI)	*P* value	Adjusted HR (95% CI)	*P* value
All-cause death	40 (7%)	16 (15%)	24 (5%)	2.90 (1.54–5.46)	0.001	2.98 (1.57–5.63)*	0.001
Cardiac death	18 (3%)	9 (8%)	9 (2%)	4.29 (1.70–10.8)	0.002	4.58 (1.81–11.6)†	0.001
HF hospitalization	35 (6%)	10 (9%)	25 (6%)	1.77 (0.85–3.69)	0.13	1.91 (0.91–4.02)*	0.09
Composite (all cause death + HF hospitalization)	66 (12%)	21 (19%)	45 (10%)	2.08 (1.24–3.49)	0.006	1.94 (1.14–3.30)‡	0.02
Myocardial infarction	9 (2%)	6 (6%)	3 (1%)	4.10 (1.02–16.4)	<0.05		
Stroke/TIA	21 (4%)	8 (7%)	13 (3%)	1.29 (0.54–3.13)	0.57	1.27 (0.50–3.23)†	0.61
Bleeding event	56 (10%)	11 (10%)	45 (10%)	1.07 (0.55–2.07)	0.84	1.03 (0.53–2.00)*	0.92

HALT indicates hypoattenuating leaflet thickening; HF, heart failure; HR, hazard ratio; LV, left ventricular; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality; and TIA, transit ischemic attack.

*Adjusted by age, sex, and log STS-PROM score.

†Adjusted by log STS-PROM score.

‡Adjusted by age, sex, log STS-PROM score, LV ejection fraction at baseline, LV stroke volume index at 30 days after transcatheter aortic valve replacement; and not performed for myocardial infarction because of the small number of the event.

Perhaps not immediately harmful to the patient – but meaningful to the THV durability

Fukui M et al. Circulation 2022 Aug 9;146(6):480-493

What Factors Are Associated with Early Bioprosthetic Valve Deterioration, And What Are The Clinical Implications?

306 Patients underwent TAVR

Early BVD = 44 (14.3%)

Without Early BVD= 262 (85.7%)

HALT
30% vs 5%

Valve Size 20–23 mm
57% vs 23%

BMI >30
45% vs 29%

Higher Incidence With Early BVD:

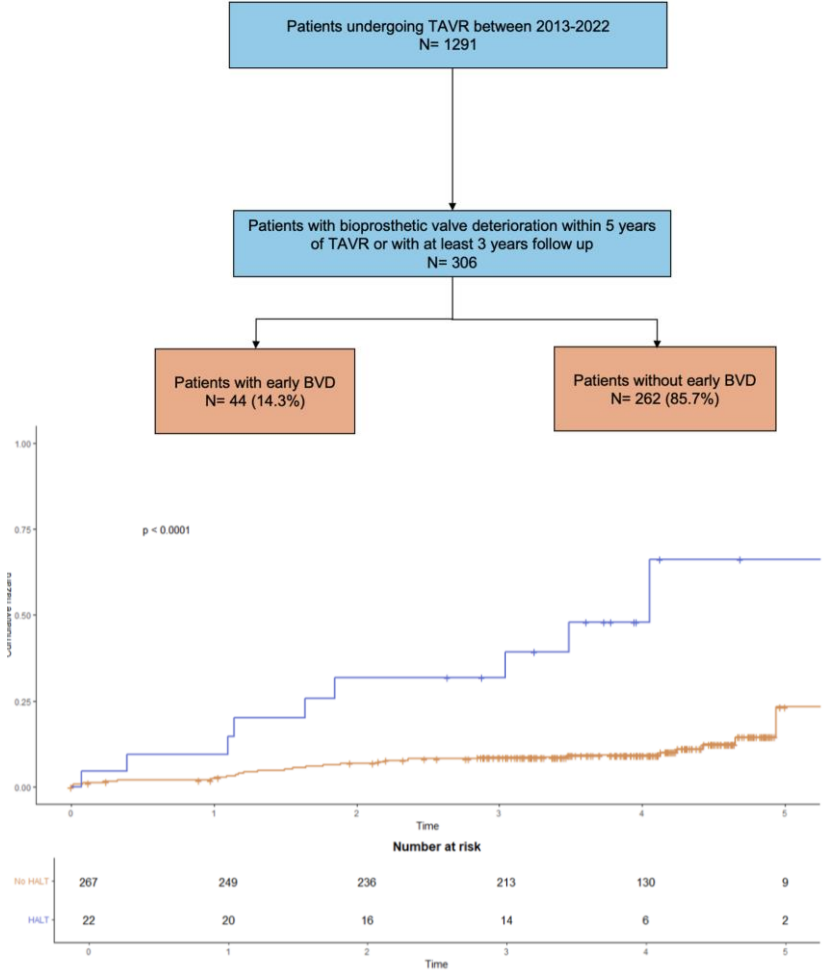
- Heart Failure Hospitalization
- Reintervention (Redo-TAVR)
- Early Mortality

Anticogulation = 4.3% with early BVD

No Anticoagulation = 20.6% with early BVD

Hypoattenuated Leaflet Thickening (HALT), small valve size, increased BMI were associated with higher rates of early BVD. Anticoagulation had a protective effect. Early BVD was associated with higher rates of reintervention, heart failure hospitalization, and early mortality

*BMI: Body Mass Index, HALT: Hypoattenuated Leaflet Thickening, TAVR: Transcatheter Aortic Valve Replacement



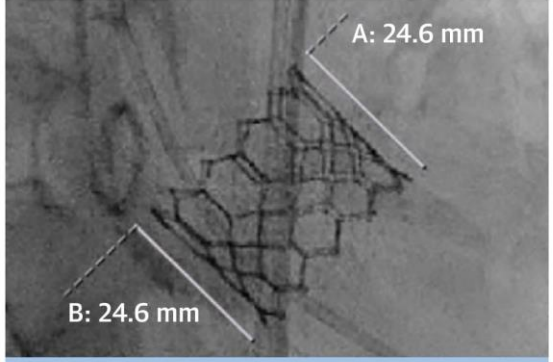
Central Illustration. Risk factors and clinical outcomes associated with early bioprosthetic valve deterioration.

NEWS › Daily News | EuroPCR 2025

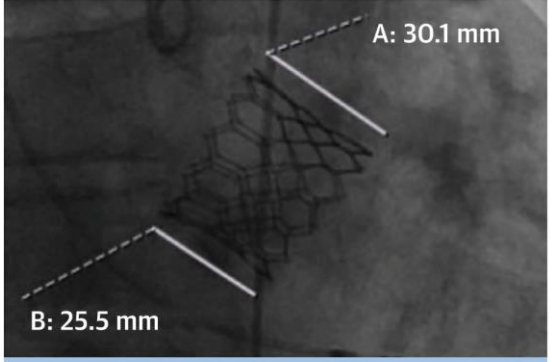
Underexpanded Acurate neo2 Valves Tied to Worse Outcomes: ACURATE IDE

(UPDATED) The explanation for why the valve failed is too little, too late: Boston Scientific ended global sales of the device Wednesday.

by Michael O'Riordan | MAY 28, 2025

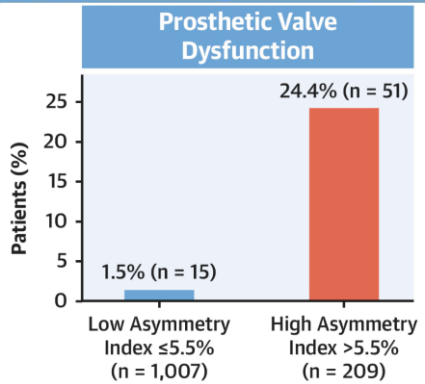


Symmetric TAVR Expansion

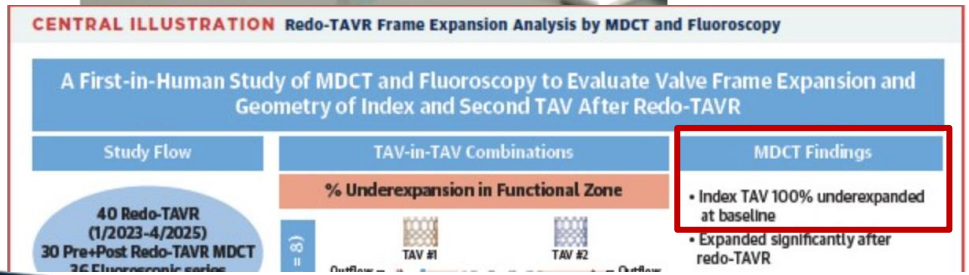


Asymmetric TAVR Expansion

High TAVR asymmetry index was associated with impaired prosthetic valve performance (mean residual gradient ≥20 mm Hg and/or ≥ moderate paravalvular leak) on echocardiography before hospital discharge



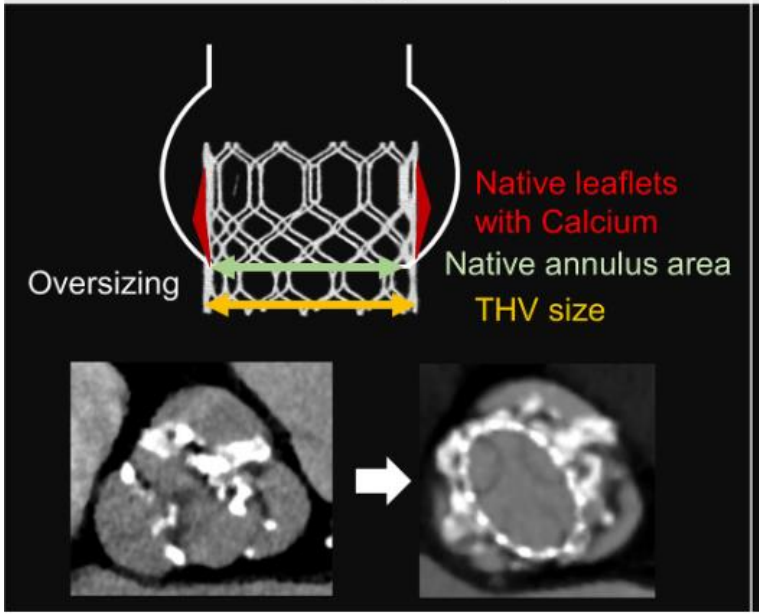
Maznyczka et al. JACC Interv 2024 Sep 9;17(17):2011-2022

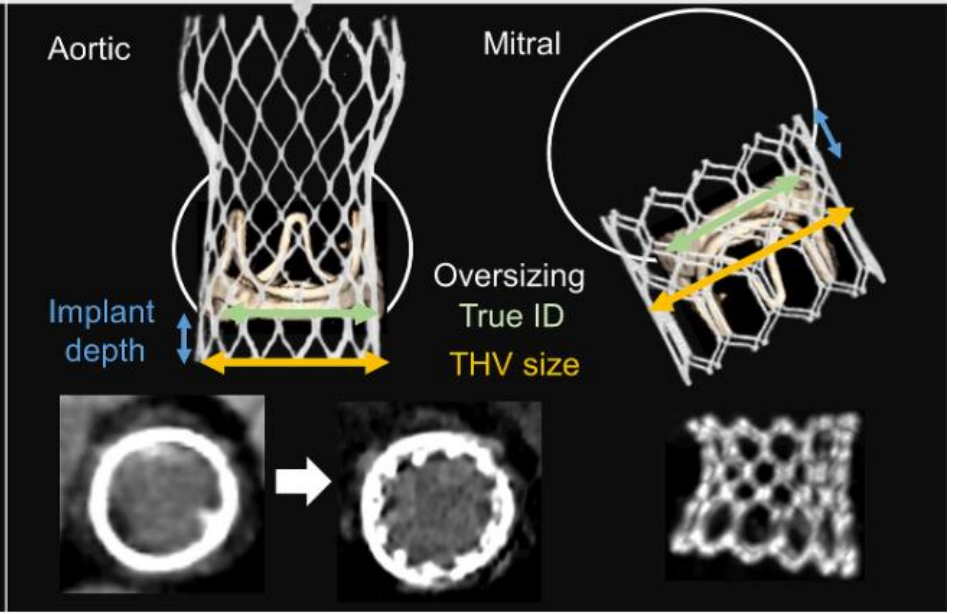


Krishnamoorthy et al. JACC Interv 2025 Aug 25;18(16):1971-85

- Asymmetric prosthetic heart valve expansion occurred in 17% of the population
- TAVR asymmetry index was associated with impaired hemodynamic valve performance
- TAVR asymmetry index was not associated with clinical outcomes

TAVR in Native AS	Valve-in-Valve (Aortic, Mitral)
1. Oversizing 2. Calcium distribution 3. Valve morphology (Bicuspid) 4. Underfilling (BEV)	1. Oversizing 2. Implant depth





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Final Thoughts

- Transcatheter valves durability will require long-term studies with standardized VARC-3 definitions
- HALT relates to stent frame deformation (underexpansion → pinwheeling → leaflet stress → thrombus, fibrosis, thickening)
- It is better to prevent HALT than to treat it. If so, how can we predict or avoid?
  - Should TAVR involve again pre/post-dilation to improve THV frame deformation?
  - Better sizing algorithms (intermediate sizing – MyVal, Braile, X4?)
  - Potential role of AV calcium leaflet modification techniques
  - Screening for HALT in those with frame asymmetry, high Ca^{++} and aggressive oversizing
- Stakes should be higher in asymptomatic severe AS → procedural optimization, proactive HALT screening and THV durability needs to be investigated.
- Such strategies, along with new THV stent and leaflet designs may help to achieve better THV frame expansion, improve achieving laminar flow, minimize leaflet stress and ultimately improve durability.

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Creating a world without heart and vascular disease

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Thank you!