TAVR in Moderate Aortic Stenosis: The TAVR-UNLOAD Trial

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Disclosures

Institutional Research Grants

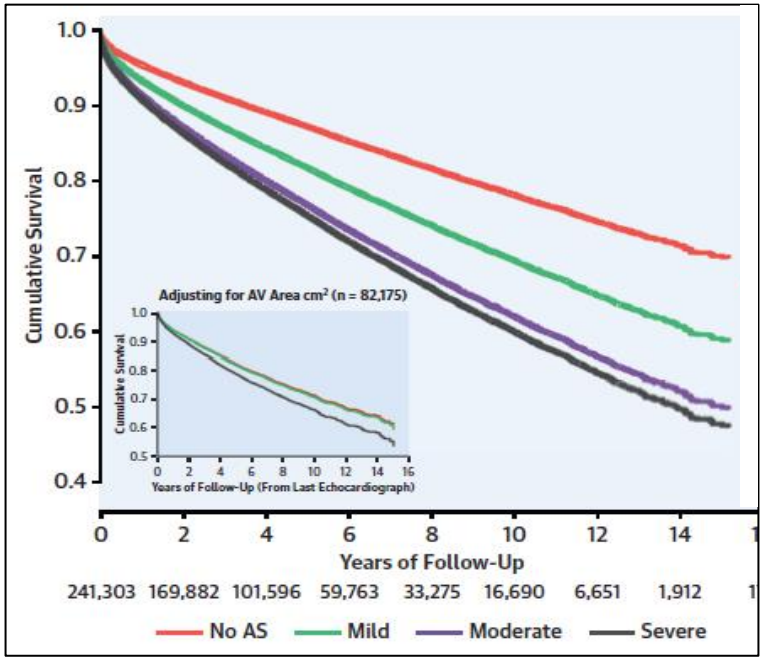
- Edwards Lifesciences
- Boston Scientific
- Corvia
- Philips
- I-Rhythm
- ANCORA
- Abbott Vascular
- Medtronic
- CathWorks
- Zoll/Therox
- JenaValve

Consulting/Speaking/Advisory Boards

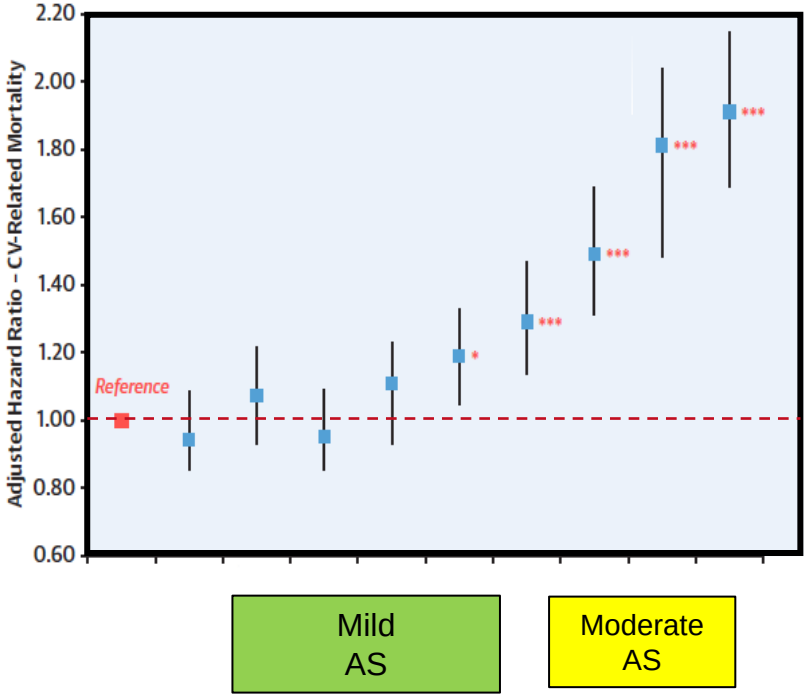
- Medtronic
- Boston Scientific
- Heartbeam
- Edwards Lifesciences
- Abbott Vascular
- Elixir Medical

Is Moderate AS Benign?

Survival by AS Severity



Adjusted HR for CV Death

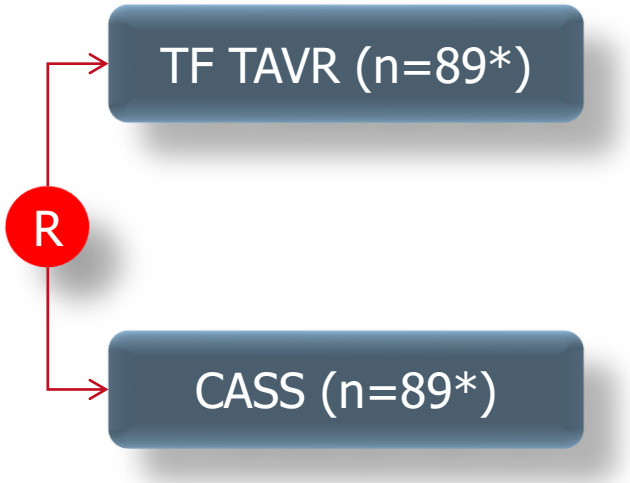


Strange G, et al. JACC 2019; 74:1851-63

TAVR Unload Trial

Symptomatic patients with HFrEF on GDMT and **moderate AS**

- AVA >1.0 and ≤ 1.5 cm^2 by resting echo (or DSE if LFLG suspected); OR
- Indexed AVA ≤0.9 cm2/m2



Clinical AS surveillance and AVR upon progression to severe AS

Primary Endpoint

Hierarchical * occurrence of:

1. All-cause death
2. Disabling stroke
3. Hospitalizations and equivalents
4. Change in KCCQ

1st Key Secondary EP

Time-to-event analysis of composite of:

- All-cause death
- All stroke
- Hospitalizations and equivalents

** Sample size reduced from original 600 pts to 178 due to slow enrollment*
*** With sample size reduction, primary endpoint changed from 1 year to longest f/u*

Baseline Characteristics- Clinical

	TAVR (n=89)	Clinical Surveillance (n=89)
Age, years	77 ± 8	78 ± 7
Sex, female	18%	24%
STS score*	4.0 ± 2.6	4.8 ± 4.0
NYHA class		
II	38%	48%
III	57%	47%
IV	3%	3%
Any HFH during the past 12 months	42%	48%
Coronary artery disease	74%	79%
Pre-existing implantable devices		
ICD	35%	35%
CRT	11%	0%
Atrial fibrillation	46%	46%
KCCQ-OS at baseline	57.1 ± 24.3	54.5 ± 21.8

Van Mieghem NM, et al. JACC 2024; doi: 10.1016/j.jacc.2024.10.070

Baseline Characteristics- Echo

	TAVR (n=89)	Clinical Surveillance (n=89)
AVA (rest), cm^2	1.1 ± 0.2	1.2 ± 0.2
AVA (rest or dobutamine stress), cm^2	1.2 ± 0.2	1.3 ± 0.2
Mean aortic valve gradient, mmHg	19 ± 6	18.5 ± 5.9
LV ejection fraction, %	39 ± 9	39 ± 9
LV end-diastolic volume, mL	180 ± 50	183 ± 57
LV end-diastolic diameter, cm	6.9 ± 7.4	6.3 ± 5.3

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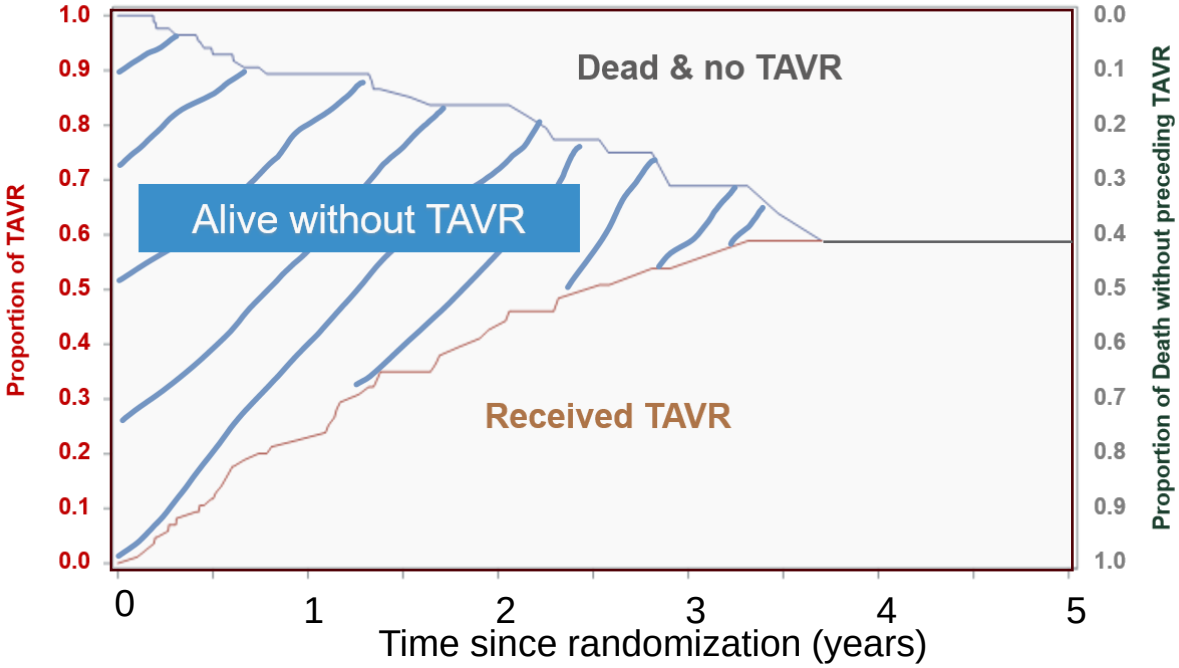
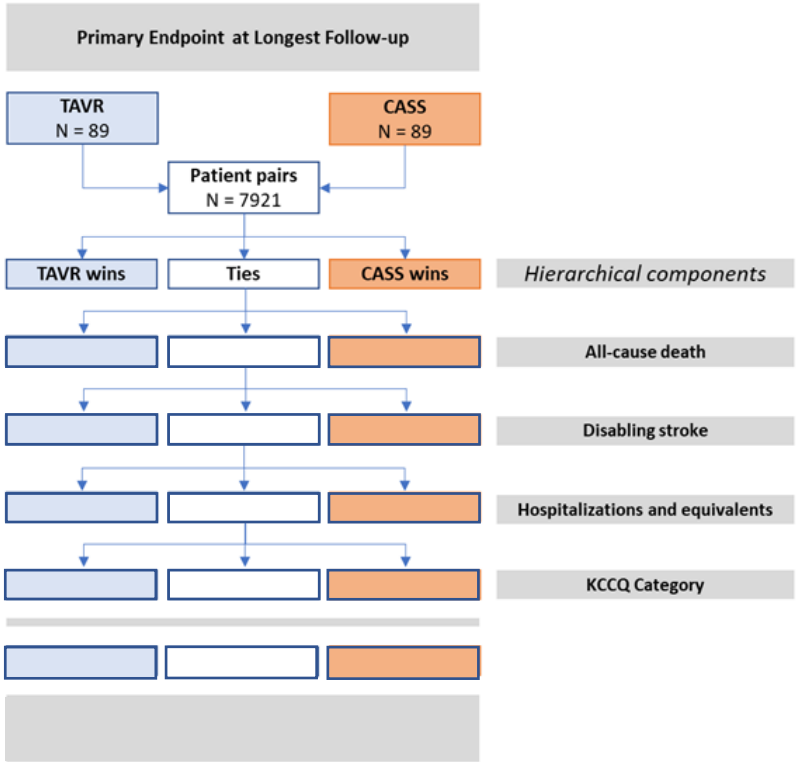
AS-Related Outcomes with Surveillance



- 35 of 89 pts (39%) progressed to severe AS during follow-up (82% in first 2 years)
- 2 patients underwent TAVR for moderate AS
- Half had antecedent HF event prior to conversion
- All treated with TAVR

Primary Endpoint



*Median FU 23 months

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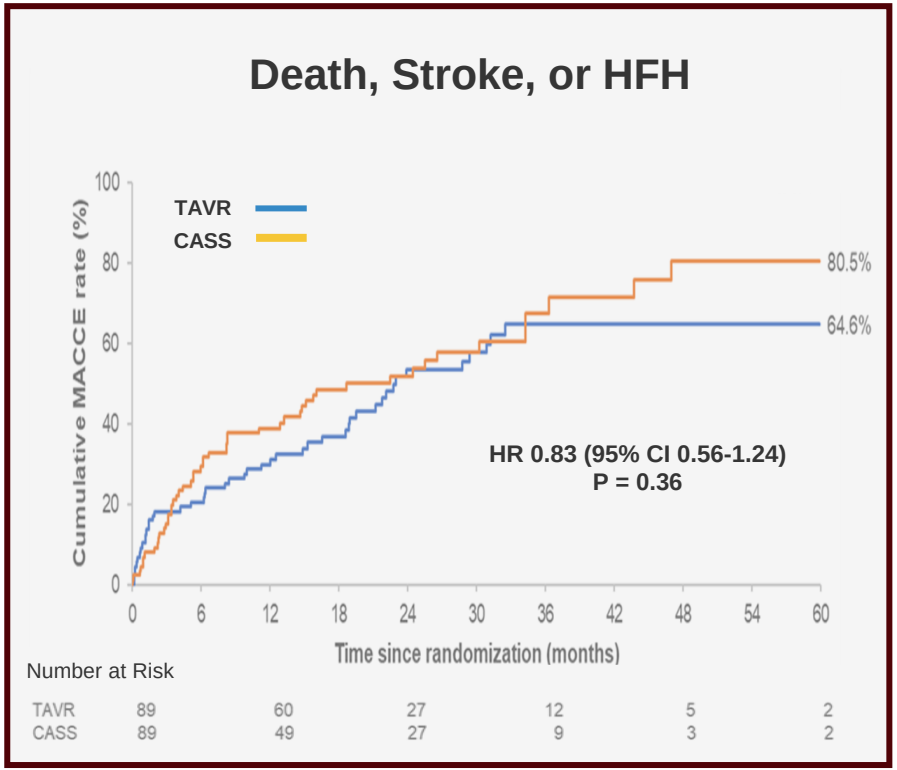
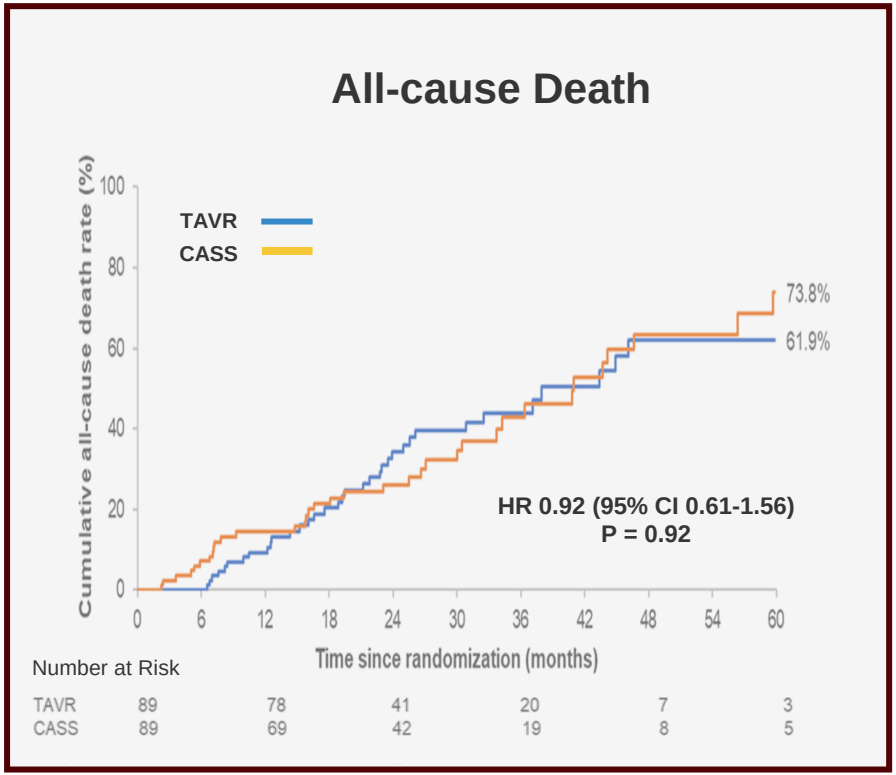
Clinical Outcomes





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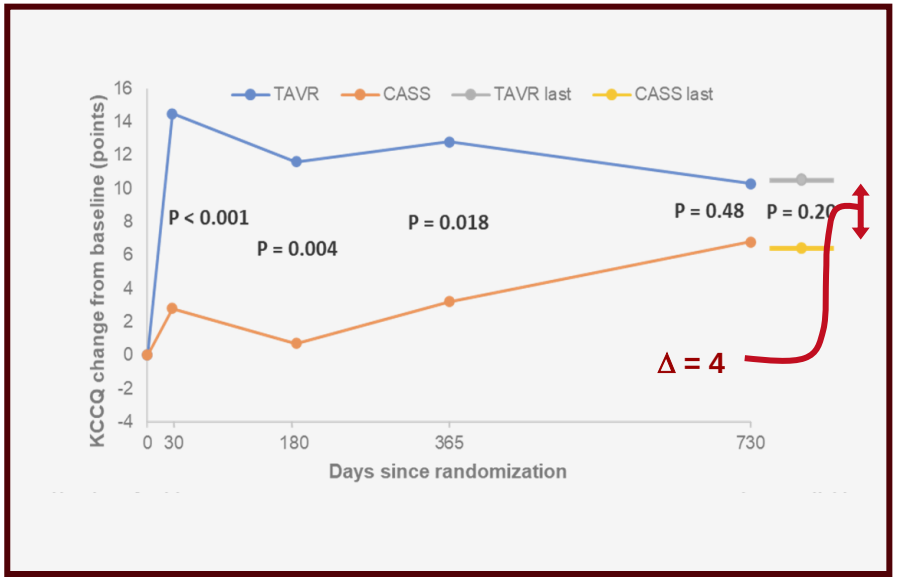
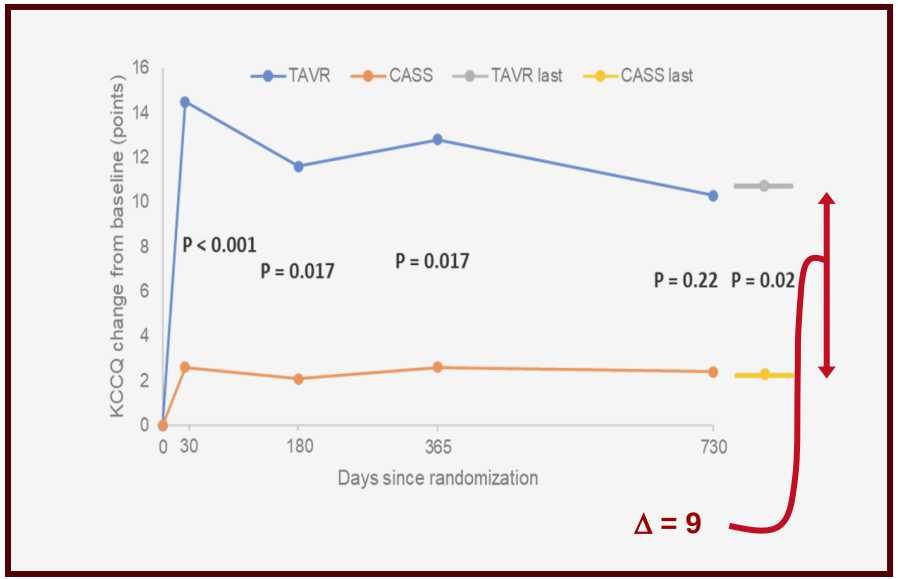
Quality of Life Outcomes

All KCCQ Data



Δ KCCQ = 8 points at 1-year and 4 points at 2-years

KCCQ Censored after TAVR in CASS Group



Δ KCCQ = 10 points at 1-year, 9 points at 2-years

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Summary/Conclusions

- Among patients with HFrEF and moderate AS, TAVR was safe but did not affect the primary hierarchical composite endpoint at a median follow up of 23 months
- Interestingly, TAVR resulted in more wins in the primary hierarchical composite endpoint at one year follow-up-- driven mainly by a clinically meaningful improvement in QOL compared with clinical AS surveillance
- During the trial, 43% of the clinical surveillance group underwent TAVR predominantly because of disease progression to severe AS– a higher rate than expected
- Ongoing clinical trials (PROGRESS, EXPAND) should provide additional insight regarding both clinical and QOL benefits of preemptive TAVR