TAVR Versus Surveillance in Patients with Moderate Aortic Stenosis and Heart Failure

A Conversion-Censored Analysis of the TAVR UNLOAD Trial

Philipp von Stein, MD *on behalf of the TAVR UNLOAD investigators*

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Disclosure of Relevant Financial Relationships

I, Philipp von Stein, DO NOT have any financial relationships to disclose.

Background

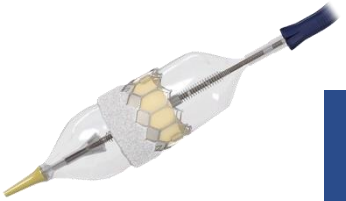
- **Moderate AS** is associated with increased all-cause mortality and heart failure hospitalizations
- Afterload reduction is central in **HFrEF**
- In this context, **TAVR** might be a compelling additional therapy

Study Design

- TAVR UNLOAD was an investigator-initiated, international, open-label, superiority RCT
- Symptomatic HFrEF patients with moderate AS on GDMT
  - Randomized to TAVR or AS surveillance
- TAVR UNLOAD was a neutral but underpowered trial

Van Mieghem et al. *JACC 2025*; 85(9):878-890

Study Flow Diagram



N = 178

N = 89
Allocated to TAVR

N = 89
Allocated to CASS

Clinical AS surveillance and AVR upon progression to severe AS

Van Mieghem et al. *JACC 2025*; 85(9):878-890

Baseline Characteristics

TAVR vs. CASS

	TAVR N = 89	CASS N = 89
Age, years	77 ± 8	78 ± 7
Sex, male	73 (82%)	68 (76%)
STS, %	4.0 ± 2.6	4.8 ± 4.0
NYHA III/IV	54 (61%)	45 (51%)
KCCQ-OSS, points	57 ± 24	55 ± 22
LVEF, %	38 ± 7	38 ± 7

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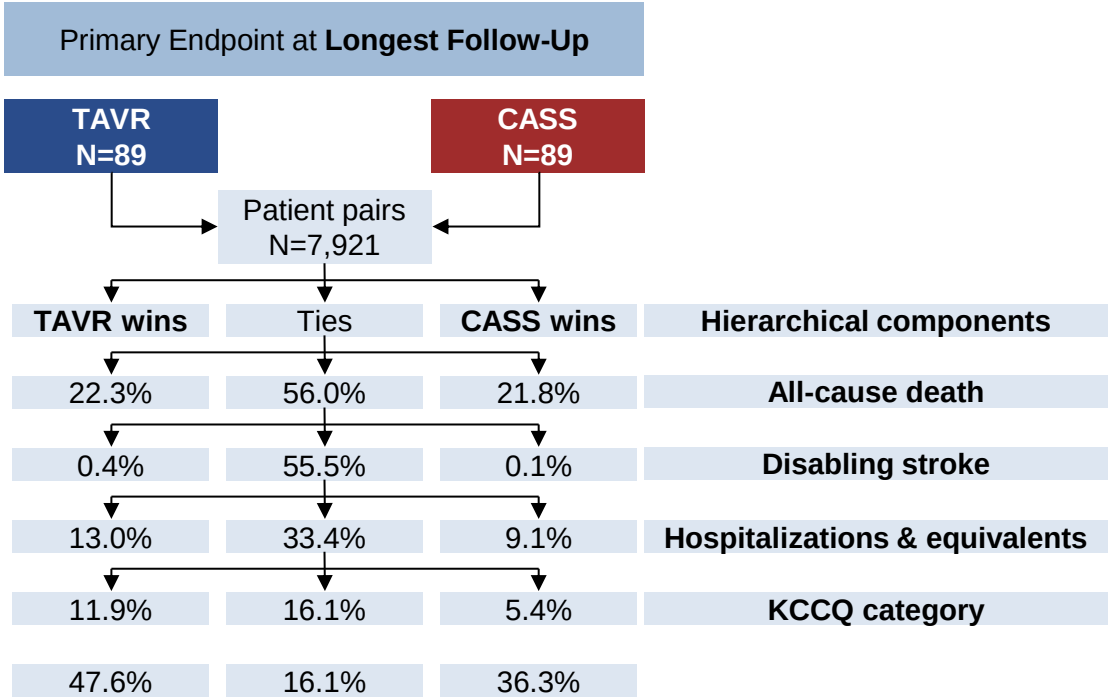
Primary Endpoint — Main Analysis



TAVR wins	Ties	CASS wins	Hierarchical components
22.3%	56.0%	21.8%	**All-cause death**
0.4%	55.5%	0.1%	**Disabling stroke**
13.0%	33.4%	9.1%	**Hospitalizations & equivalents**
11.9%	16.1%	5.4%	**KCCQ category**
47.6%	16.1%	36.3%	

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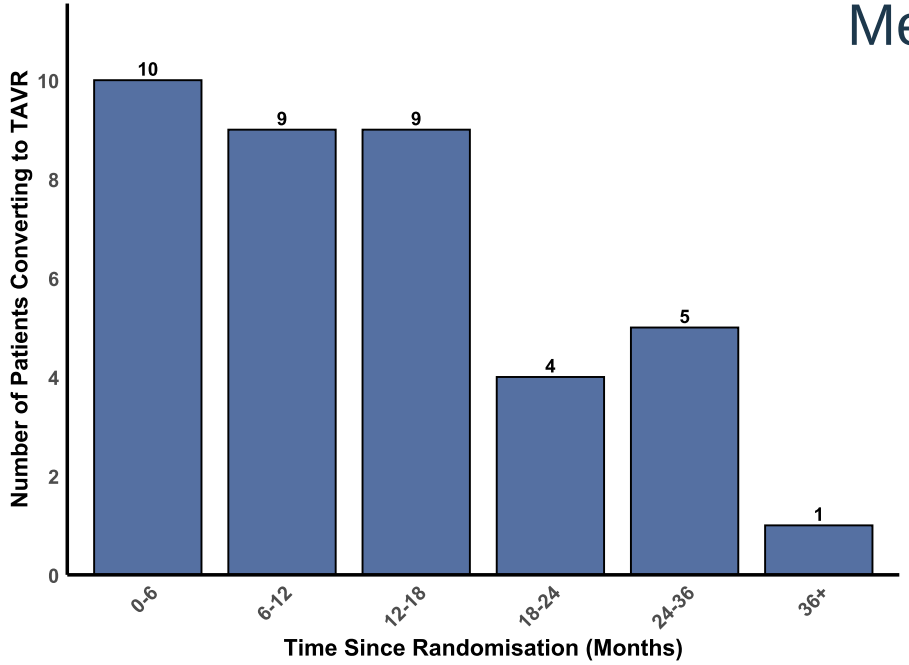
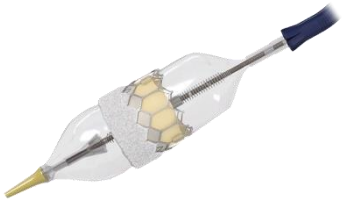
Conversion to TAVR in the CASS arm

N = 89
Allocated to CASS

N = 38 (43%)

Median: 366 days





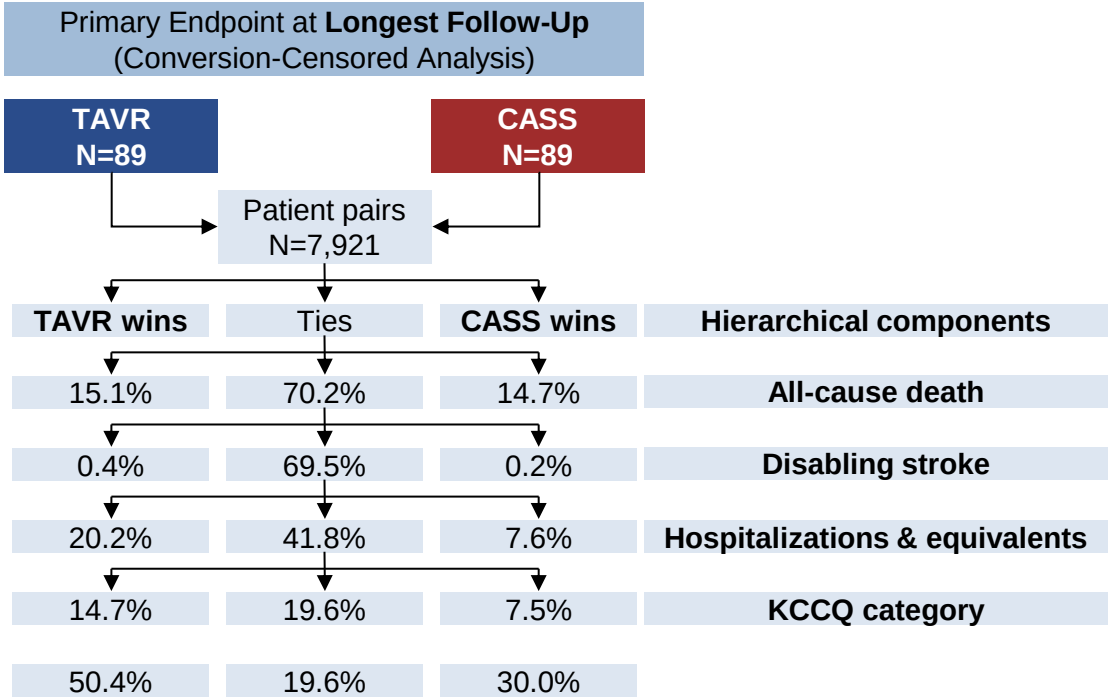
Objective

Evaluate outcomes, with patients randomized to CASS censored (i.e., removed from analysis) at the time of conversion to TAVR and identify predictors.

Study Endpoints

- Hierarchical primary endpoint:
  - All-cause death
  - Disabling stroke
  - Heart failure hospitalizations and equivalents
  - Change in KCCQ-OSS

Primary Endpoint — Conversion-Censored



Multivariable Predictors of Conversion

Adjusted for age, atrial fibrillation, sex, and LVEF

Variable	HR (95% CI)	P-value
Aortic valve mean gradient	**1.09** (1.02-1.16)	**0.015**
Age	**1.05** (0.99-1.10)	0.082
Atrial fibrillation	**2.01** (0.91-4.44)	0.084
Female vs. male	**1.05** (0.48-2.26)	0.906
Left ventricular ejection fraction	**1.00** (0.95-1.06)	0.947

Conclusions

- TAVR was associated with a benefit over AS surveillance in HFrEF patients with moderate AS, when surveillance patients were censored at conversion
- This data supports the hypothesis that patients with moderate AS and HFrEF may derive clinical benefit from TAVR, warranting confirmation in a larger and adequately powered trial
- Close echocardiographic AS surveillance and multimodality imaging are recommended

TAVR UNLOAD Investigators

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Martin B. Leon, MD

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Robert J. Cubeddu, MD

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