



BUENOS AIRES HILTON
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Moderate Aortic Valve Stenosis To Intervene or not to Intervene

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My Conflict of Interest

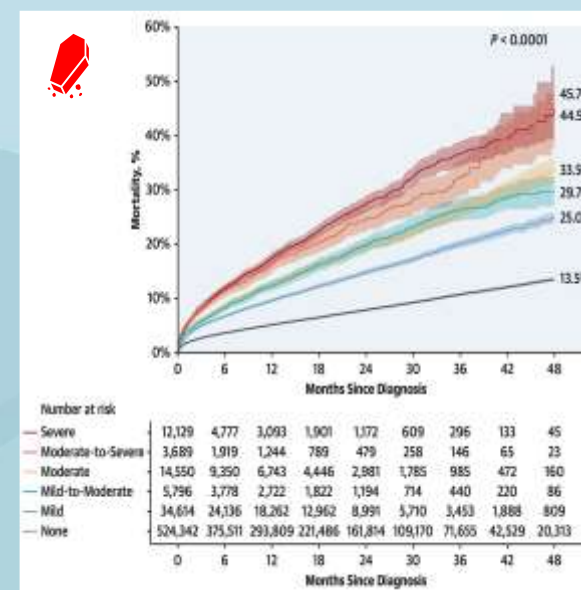
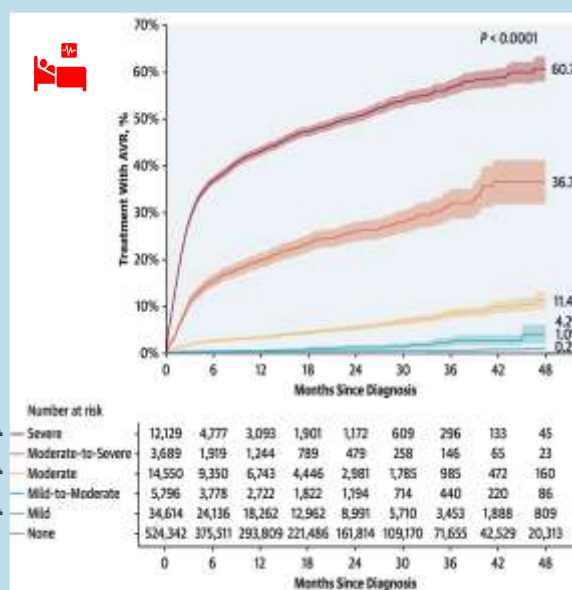
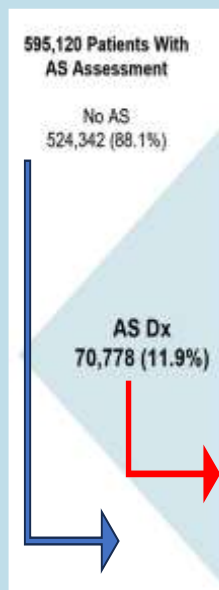
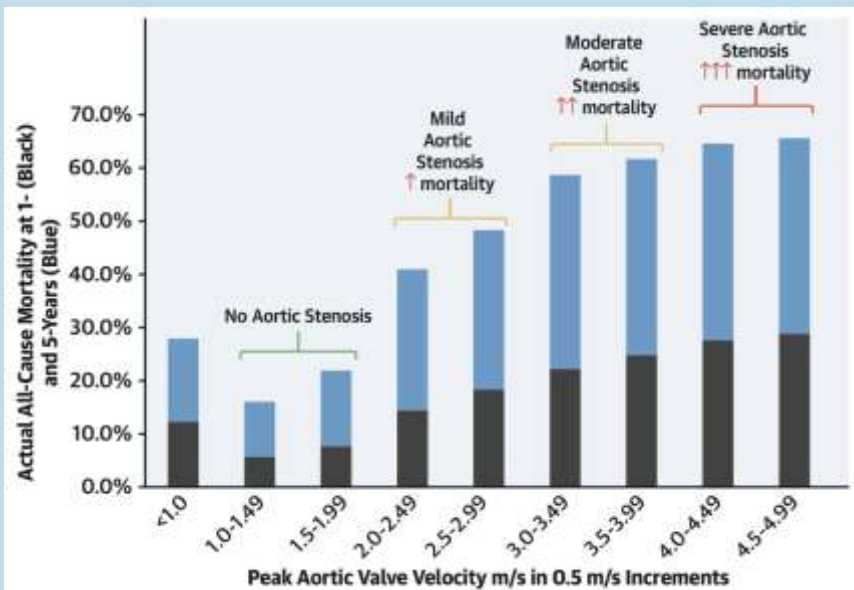
- **Research Grant Support: Abbott, Boston Scientific, Edwards Lifesciences, Medtronic, PulseCath BV, Daiichi Sankyo , Teleflex, Astra Zeneca, HeartFlow**
- **Advisory board: Abbott, Ancora, Boston Scientific, Medtronic, PulseCath BV, Daiichi Sankyo, Abiomed, JenaValve, Anteris, Bolt Medical, Siemens, Pie Medical, Luma Vision, FEops, Materialise**

MODERATE AORTIC STENOSIS – CLINICAL PERSPECTIVE

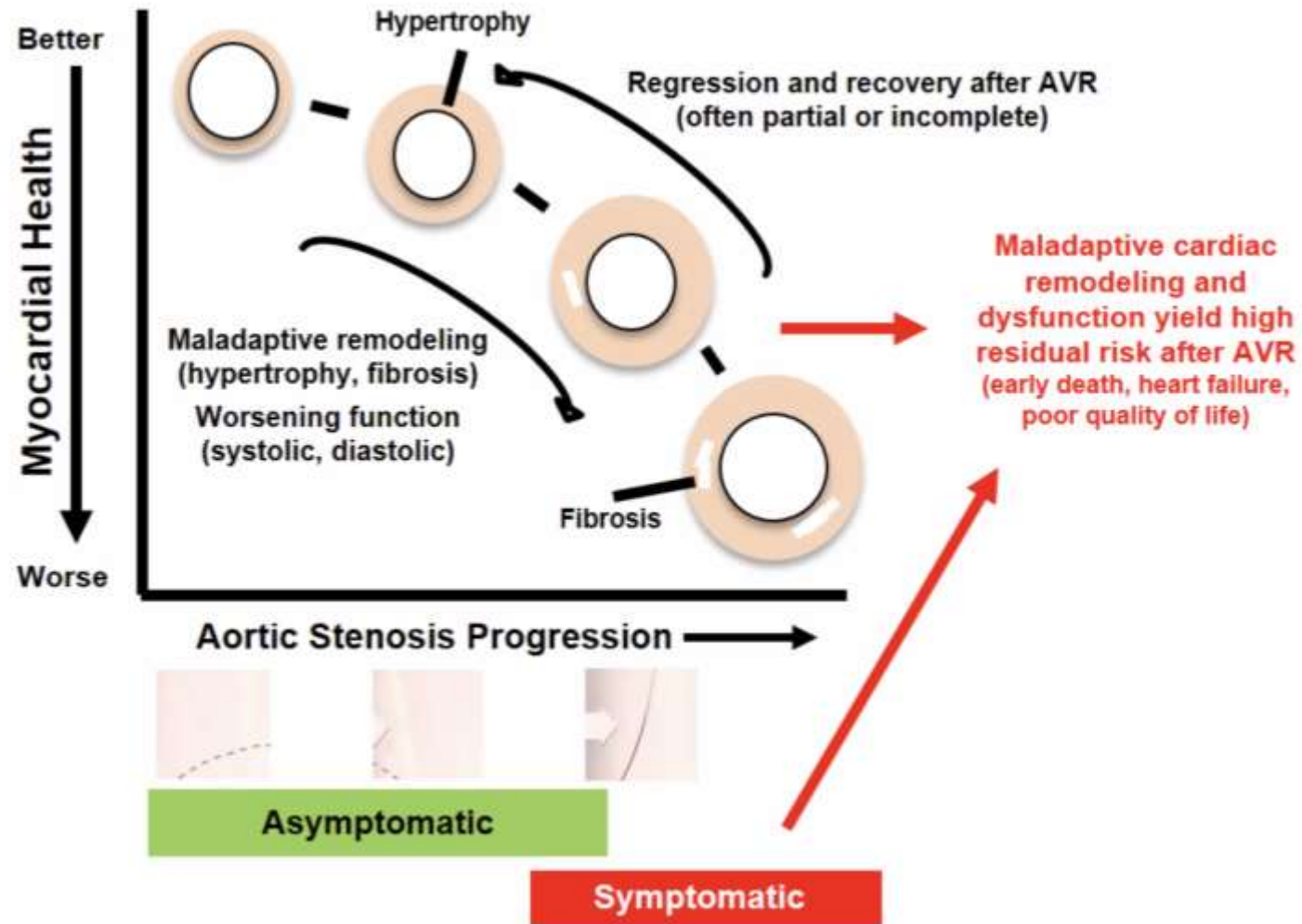


No AS (n = 215,476) Age 60 ± 18 years
Mild AS (n = 16,129) Age 72 ± 14 years
Moderate AS (n = 3,315) Age 74 ± 15 years
Severe AS (n = 6,383) Age 78 ± 15 years

Real-world data set including 1,669,536 echocardiographic reports (1,085,850 patients) from 24 U.S. hospitals (egnite Database)

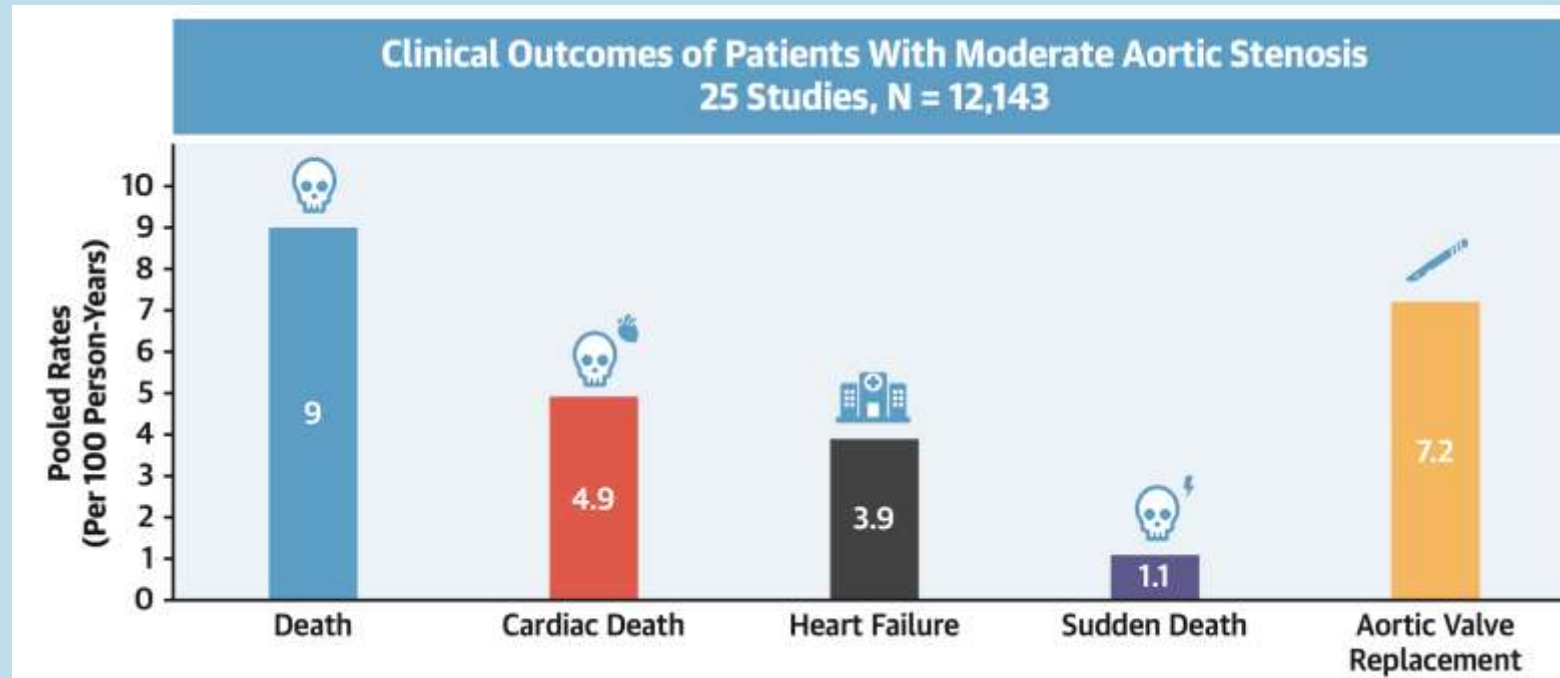


MALADAPTIVE REMODELING & FIBROSIS



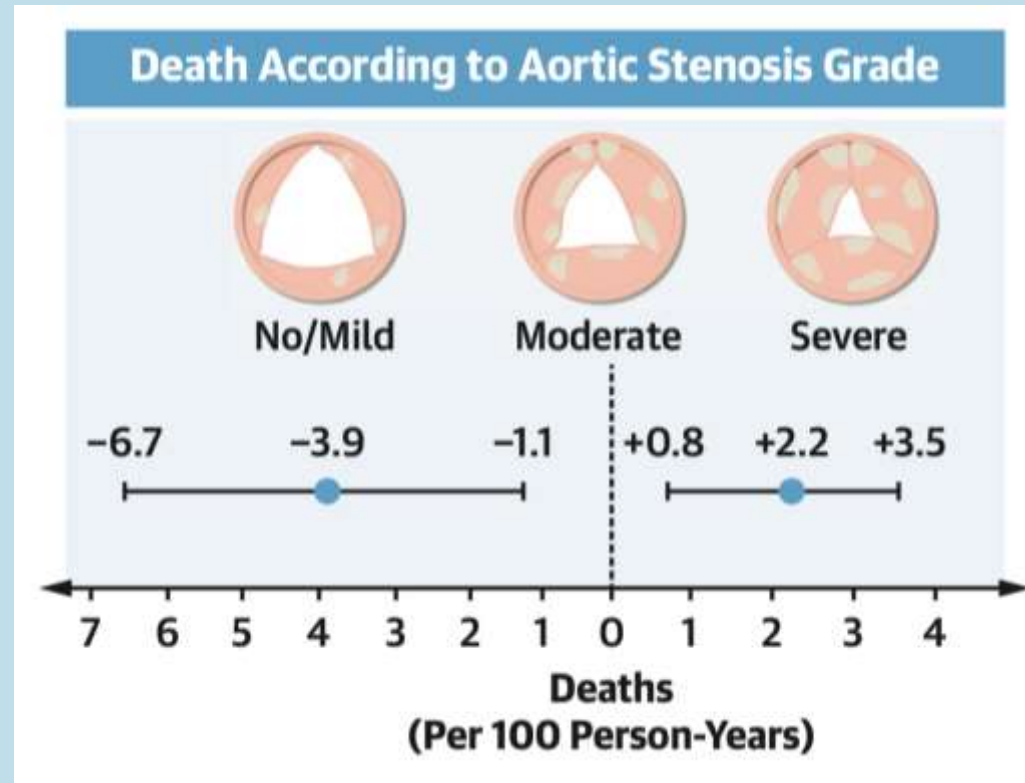
MODERATE AORTIC STENOSIS - IMPACT

- Meta-analysis
- N = 12143
- 25 studies
- Mean FU 3.8 ± 1.7 years
- Mean age 74 years, 40% women

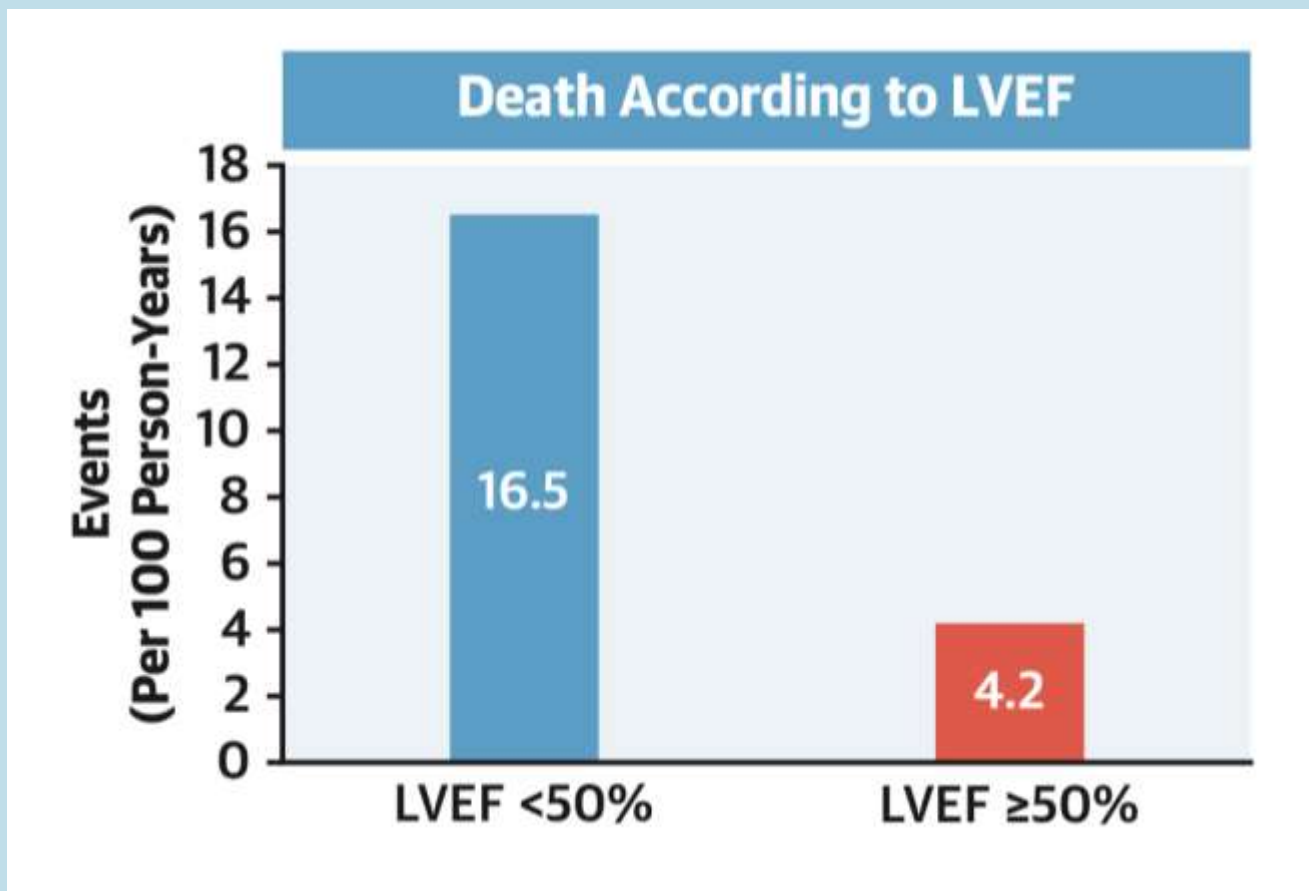


MODERATE AORTIC STENOSIS - PROGNOSIS

- Perspective on all-cause death
- 277041 patients from 8 studies with no/mild AS & 3.7 years FU
- 13848 patients from 11 studies with severe AS & 3.8 years FU

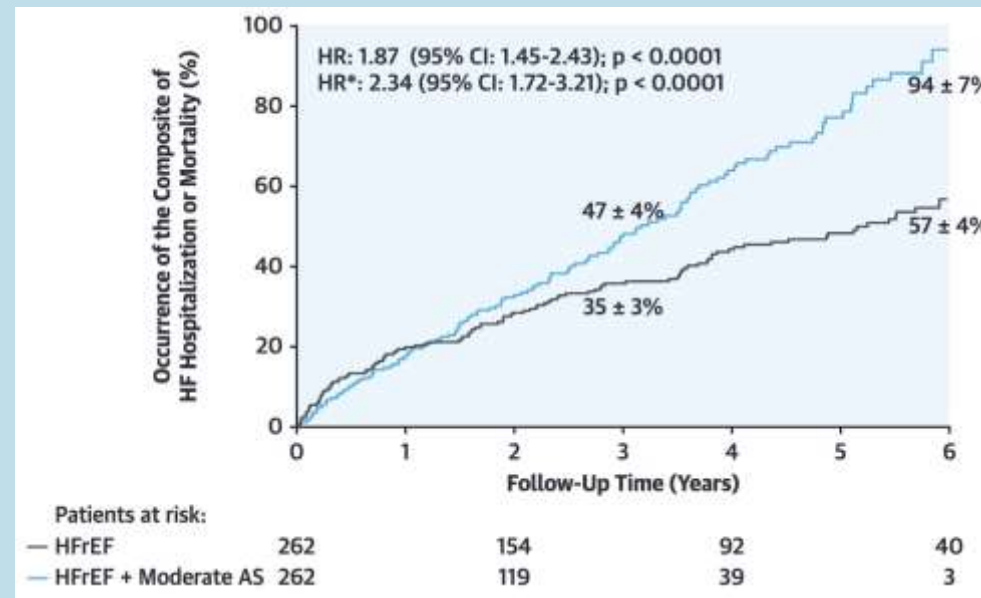
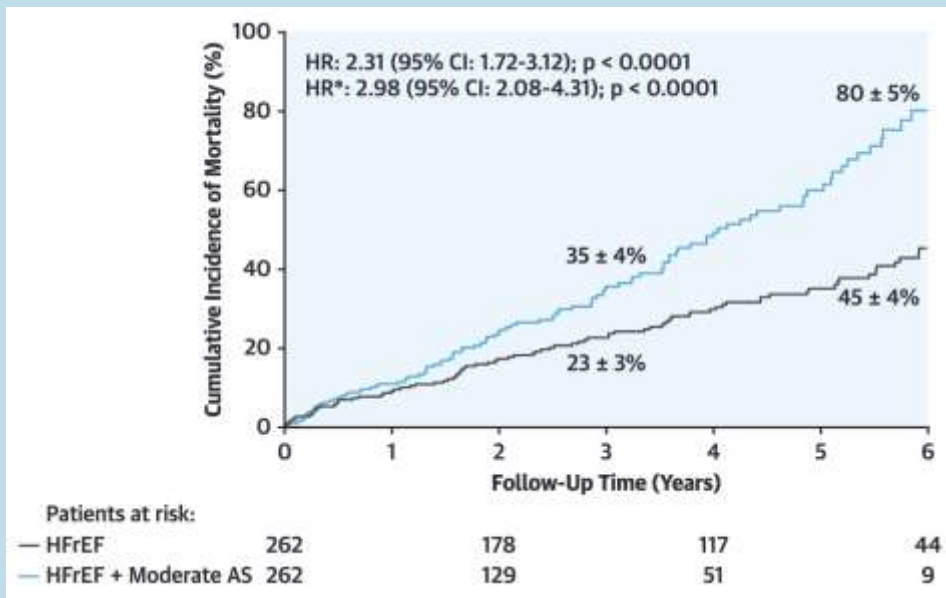


MODERATE AORTIC STENOSIS – IMPACT OF EF

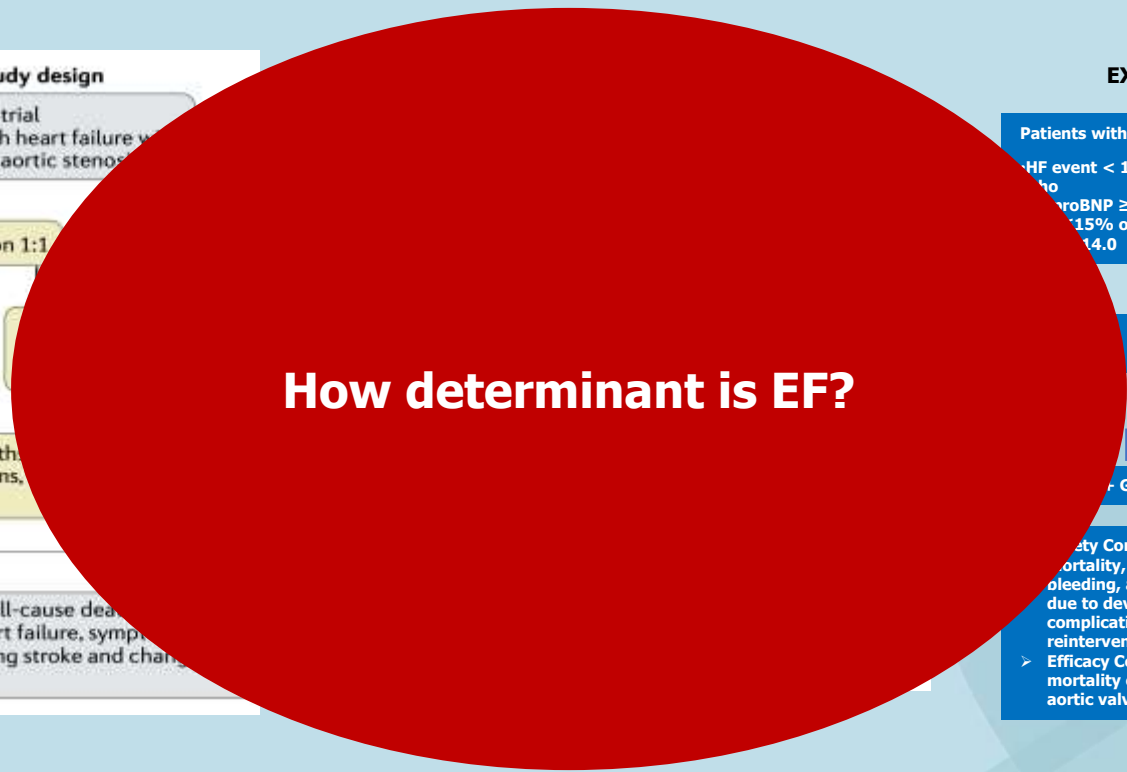
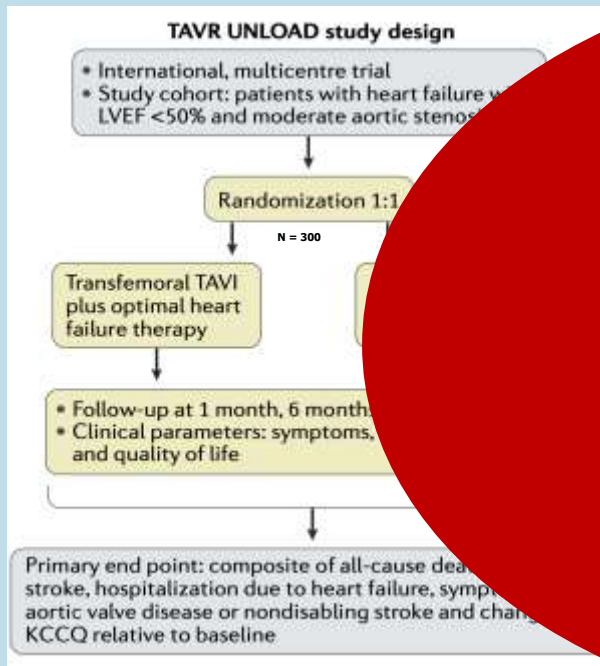


MODERATE AORTIC STENOSIS & HFREF

- ✓ Multicenter Collaboration
- ✓ 262 matched pairs of HFrEF patients + or – moderate AS



TAVI & MODERATE AS → RCT



TAVI & MODERATE AS → RCT

UNLOAD study design

- International multicentre trial
- Study of patients with heart failure with LVEF < 40% and moderate aortic stenosis

Randomization 1:1

Transfemoral TAVI plus optimal heart failure therapy

Optimal heart failure therapy

- Follow-up at 1 month, 6 months, and 2 years
- Clinical parameters: symptoms, echocardiography and quality of life

Primary end point: composite of all-cause mortality, disabling stroke, hospitalization due to heart failure, aortic valve disease or nondisabling stroke and KCCQ relative to baseline

RESULTS @ TCT 2024

PROGRESS study design

Local Health Care Case Review Board & Core Lab Assessments

Moderate aortic stenosis with symptoms or cardiac damage / dysfunction
Anatomy appropriate for transfemoral access

1:1 Randomization (750 patients)

TAVR (SAPIEN 3 Valve Platform)

vs.

Medical Surveillance (valve replacement is allowed for develop severe AS)

Primary Endpoint: All-Cause Mortality, Stroke, and Unplanned Cardiovascular Hospitalization at 2 Years

Follow-up: Annually Through 10 years



Enrollment complete 12/2023

EXPAND TAVR II RCT

Patients with moderate AS, EF > 20%, NYHA ≥ 2 &

- HF event < 1 calendar year prior to qualifying echo
- NT proBNP ≥ 600 pg/ml
- GLT ≤ 15% or
- E/e' ≥ 14.0

1:1 Randomization N = 650

TAVR + GDMT

GDMT



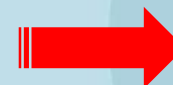
- Safety Composite rate @ 30 days of all-cause mortality, all-stroke, life threatening or fatal bleeding, acute kidney injury, hospitalization due to device or procedure-related complication, or valve dysfunction requiring reintervention.
- Efficacy Composite rate @ 2 years of all-cause mortality or unplanned procedure-related or aortic valve related hospitalization.

TAVI IMMEDIATE EFFECTS ON HEMODYNAMICS

- **18 patients treated with TAVI**
 - ✓ **Moderate AS**
 - ✓ **EF 20 – 50%**

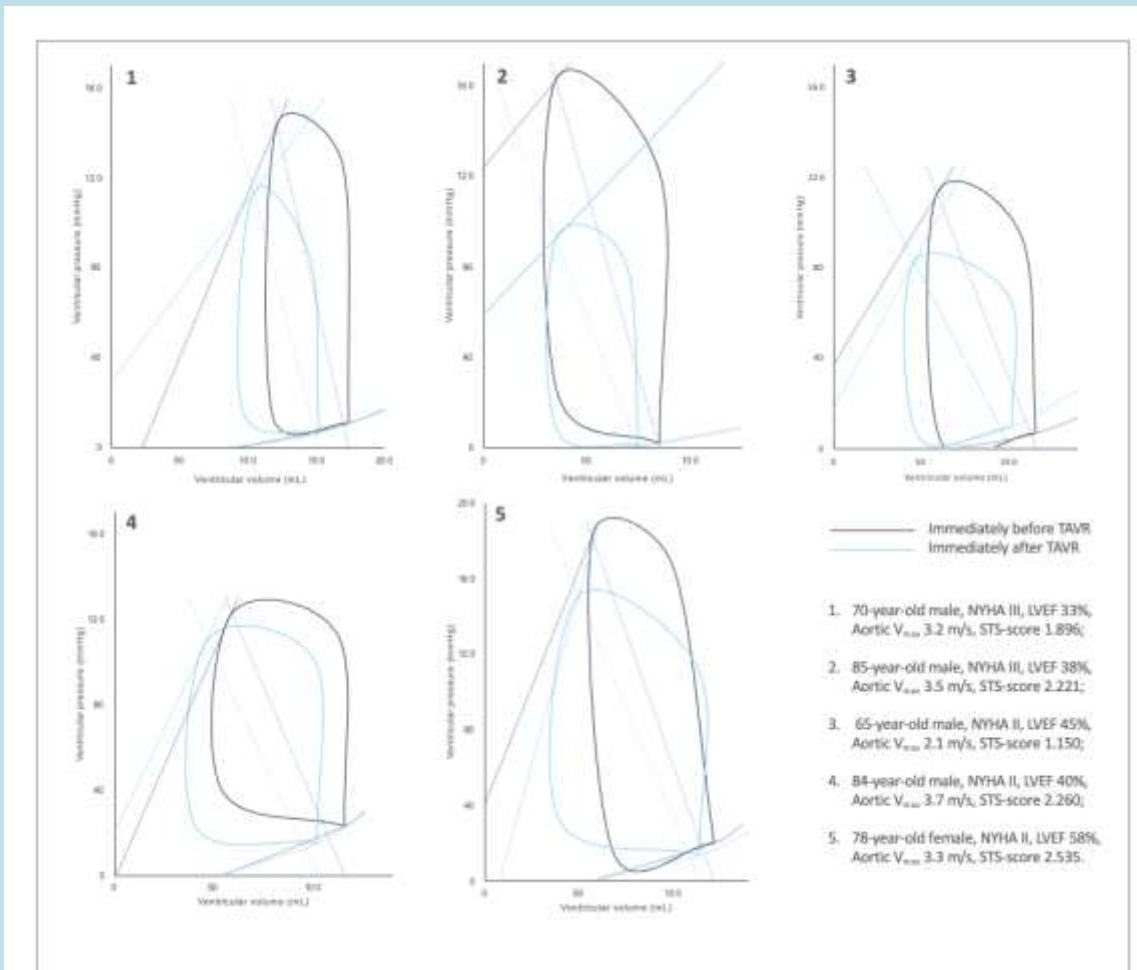
Age (years)	77.4 ± 7.3
Male sex (%)	77.7
LVEF (%)	37.7 ± 12.7
Agatston score, males	1923 ± 737
Agatston score, females	1461 ± 666
AOV annulus area (mm ²)	472.7 ± 55.7
SAPIEN3 size used (mm)	26.7 ± 1.6
Sapien3, 23mm (n)	1
Sapien3, 26mm (n)	12
Sapien3, 29mm (n)	5

Pre procedural TTE measurements	
AOV mean gradient (mmHg)	20.5 ± 6.3
AOV peak gradient (mmHg)	34.4 ± 13.2
AOV Vmax (m/s)	3.0 ± 0.4
AR grade (0-5)	1.9 ± 1.4
Pre procedural invasive measurements	
AOV mean gradient (mmHg)	22.6 ± 8.6
AOV peak gradient (mmHg)	25.5 ± 9.4



Post procedural TTE measurements	
AOV mean gradient (mmHg)	10.3 ± 3.7
AOV peak gradient (mmHg)	16.4 ± 6.8
AOV Vmax (m/s)	2.0 ± 0.4
AR grade (0-5)	0.9 ± 1.3
Post procedural invasive measurements	
AOV mean gradient (mmHg)	4.0 ± 2.4
AOV peak gradient (mmHg)	8.2 ± 4.9

TAVI - IMMEDIATE EFFECTS ON HEMODYNAMICS



- **LV unloading**
 - ✓ ↓ LVEDP & LVESP
 - ✓ ↓ LVEDV & LVESV
- **↑LV-Aorta coupling**
 - ✓ ↑ E_{es}/E_a
- **↓ PVA** ⇒ **↓ Myocardial oxygen consumption**
- **↑ SW/PVA** ⇒ **↑ Metabolic efficiency**

CONCLUSION

Moderate AS \neq Trivial

Moderate AS amplifies HFrEF clinical issues

TAVR UNLOAD terminated enrolment 12/2022 @ N = 178

Follow up complete February 2024

TAVR UNLOAD Data 2024

Guidelines may need to change
