TAVI update 2025

GOOD NEWS / BAD NEWS

IK+E M

2.-4. DUBNA | PRAHA

XXXIV.

WORKSHOP ČESKÉ ASOCIACE INTERVENČNÍ KARDIOLOGIE

	Nemám konflikt zájmů	Mám konflikt zájmů	Specifikace konfliktu (vyjmenujte subjekty, firmy či instituce, se kterými Vaše spolupráce může vést ke konfliktu zájmů)
Zaměstnanecký poměr	X		
Vlastník / akcionář	x		
Konzultant		x	Proctor TAVI výkonů (Edwards, Medtronic)
Přednášková činnost	x		
Člen poradních sborů (advisory boards)	x		
Podpora výzkumu / granty	x		
Jiné honoráře (např. za klinické studie či registry)	x		

TAVI update 2025

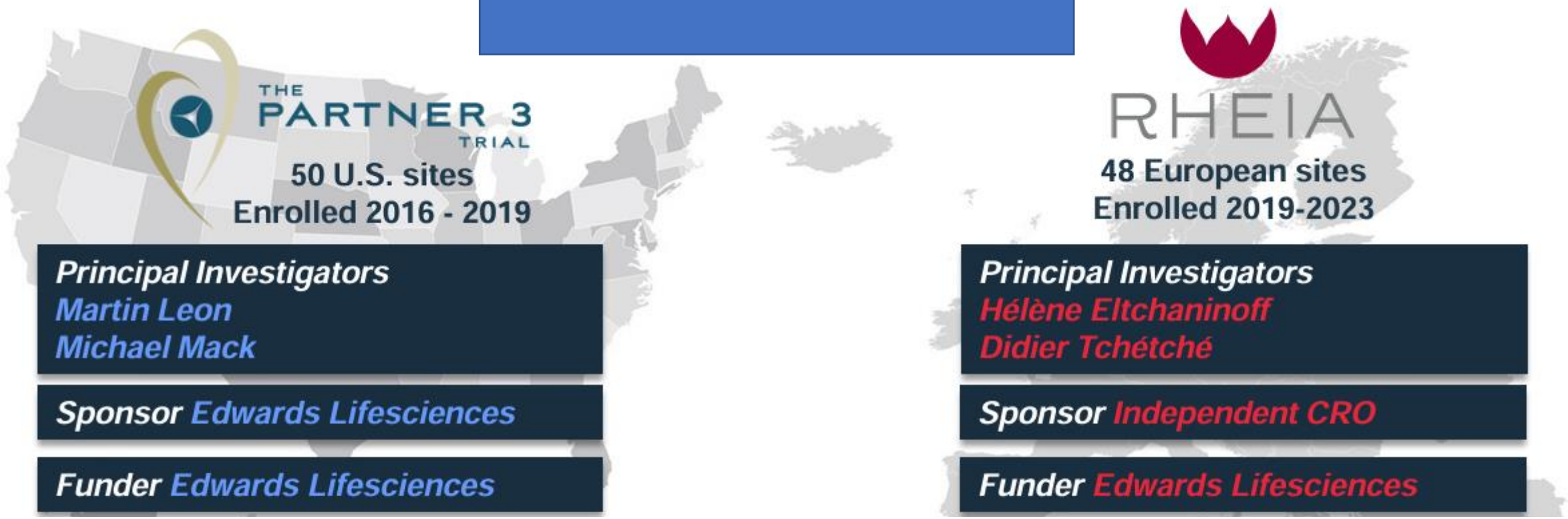
„GOOD NEWS“

- TAVI in Females
- TCW trial
- EARLY TAVR
- AVATAR

„BAD NEWS“

- BHF PROTECT - TAVI
- EVOLVED
- TAVR UNLOAD
- REDO TAVI Registry
- ACCURATE trial

Females and small annuli



Transcatheter vs. Surgical Aortic Valve Replacement in Women: A Pooled Analysis of the RHEIA and PARTNER 3 Trials

Study Design

Women with symptomatic, severe AS in the PARTNER 3 Low Risk and RHEIA RCT

Randomization N=712

TAVR N=376
SAPIEN 3 / SAPIEN 3 Ultra
Balloon-expandable valve

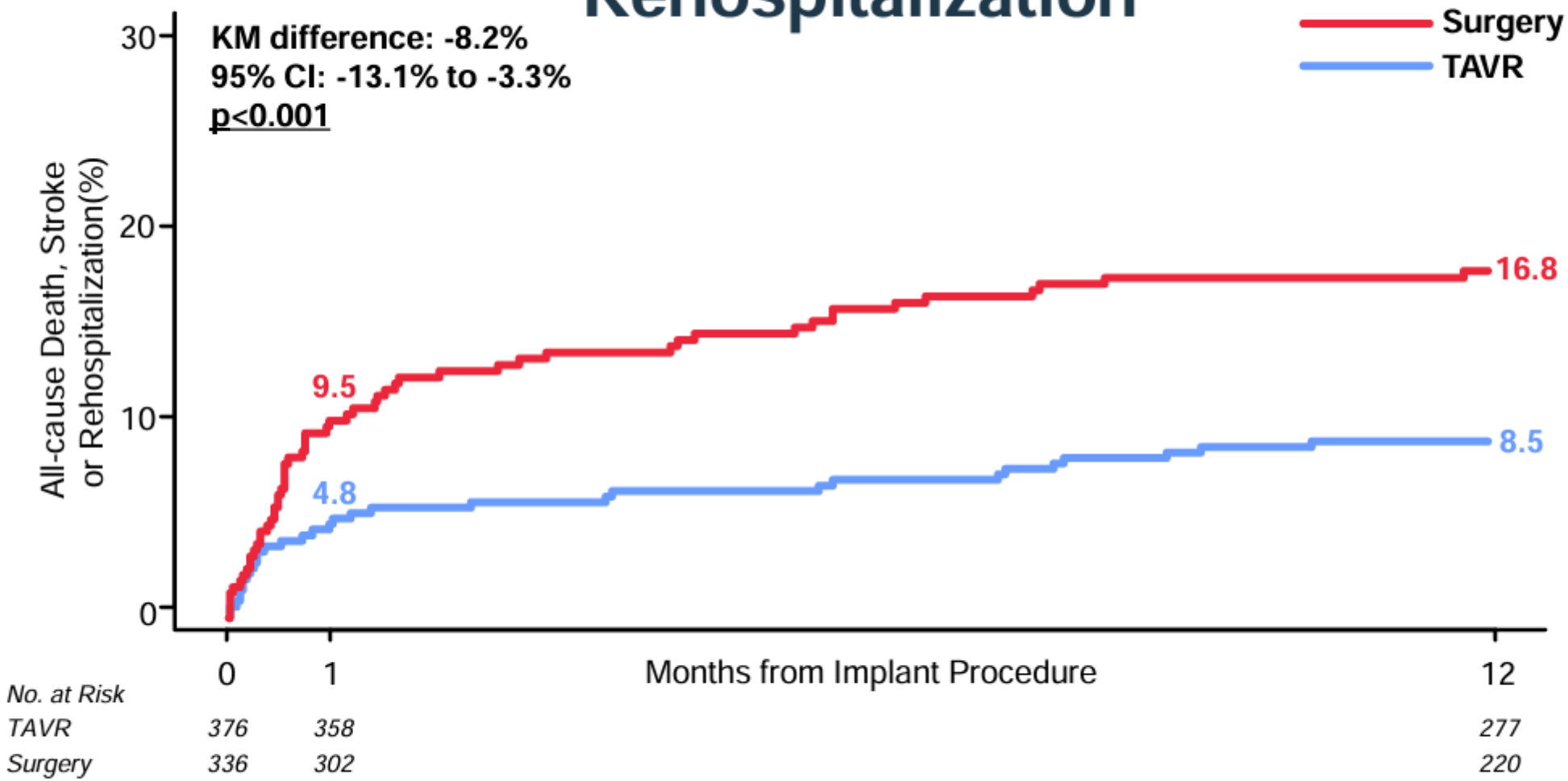
Surgery N=336
Any commercially available surgical valve

Follow-up: 30 days and 1 year

PRIMARY ENDPOINT at 1 Year
Composite of all-cause DEATH, STROKE and REHOSPITALIZATION*

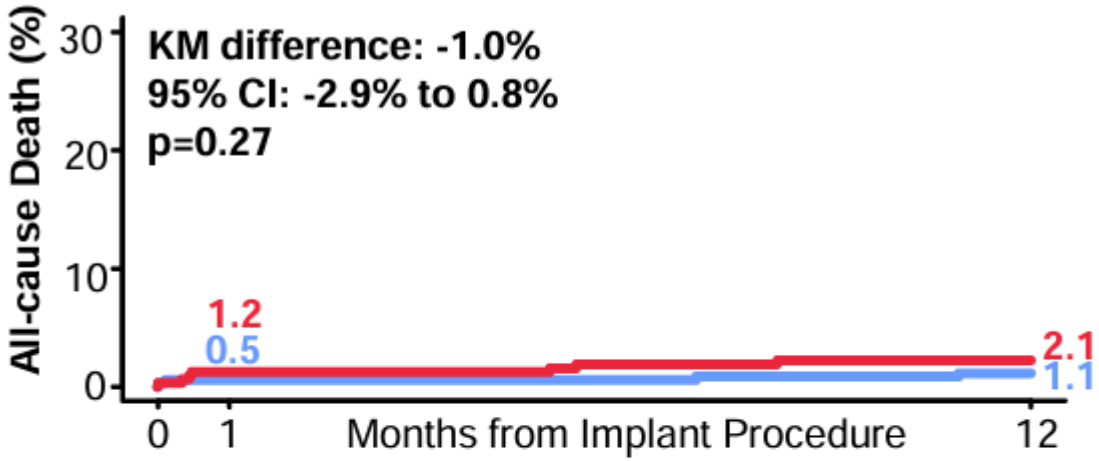
*related to the procedure, the valve, or heart failure.

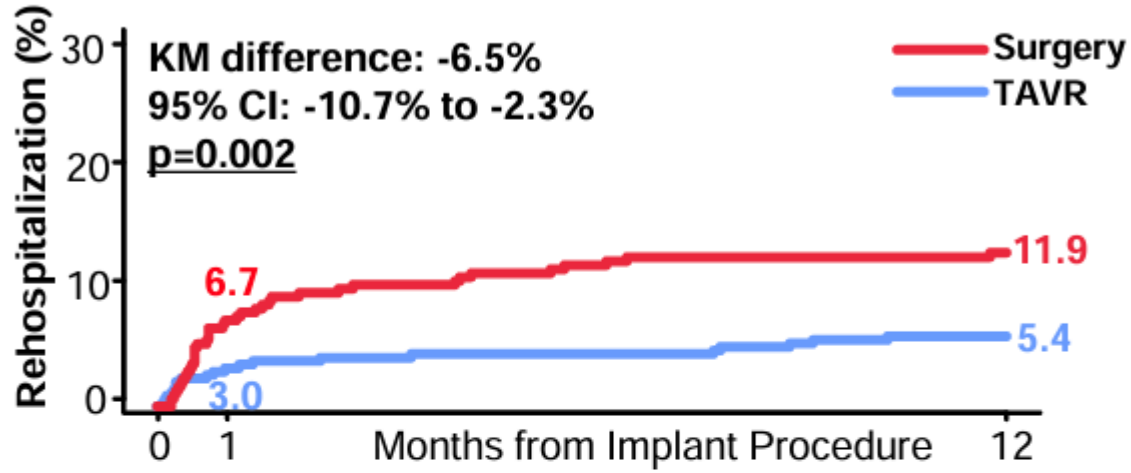
Primary Endpoint: All-cause Death, Stroke or Rehospitalization

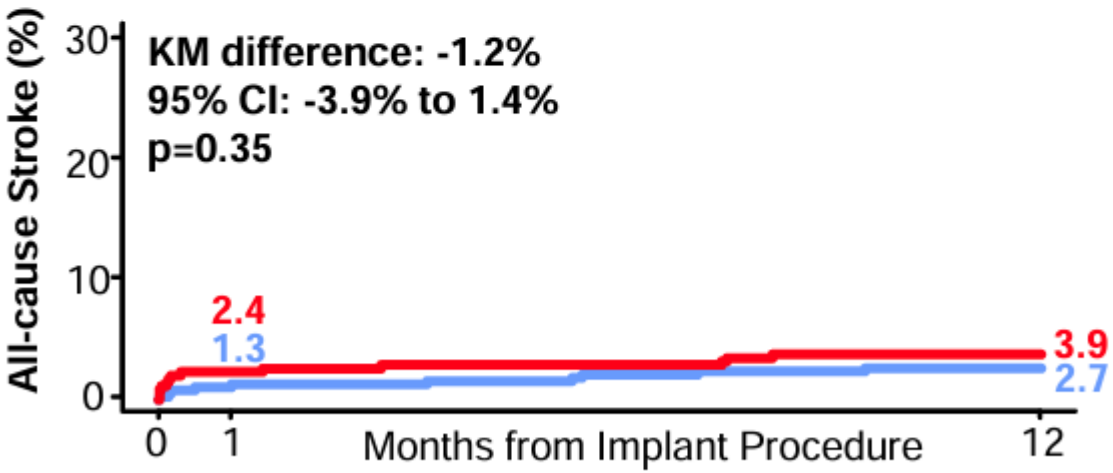


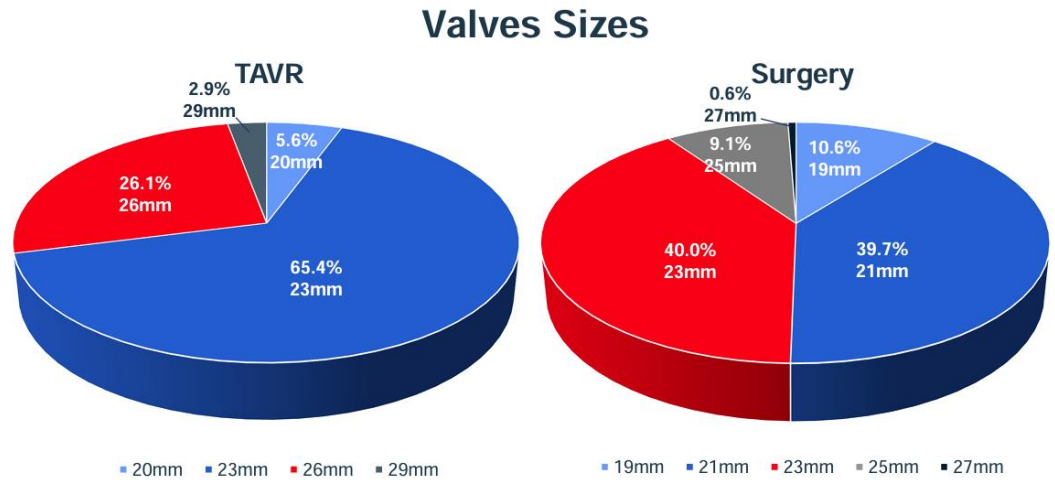
As Treated

Secondary Endpoints





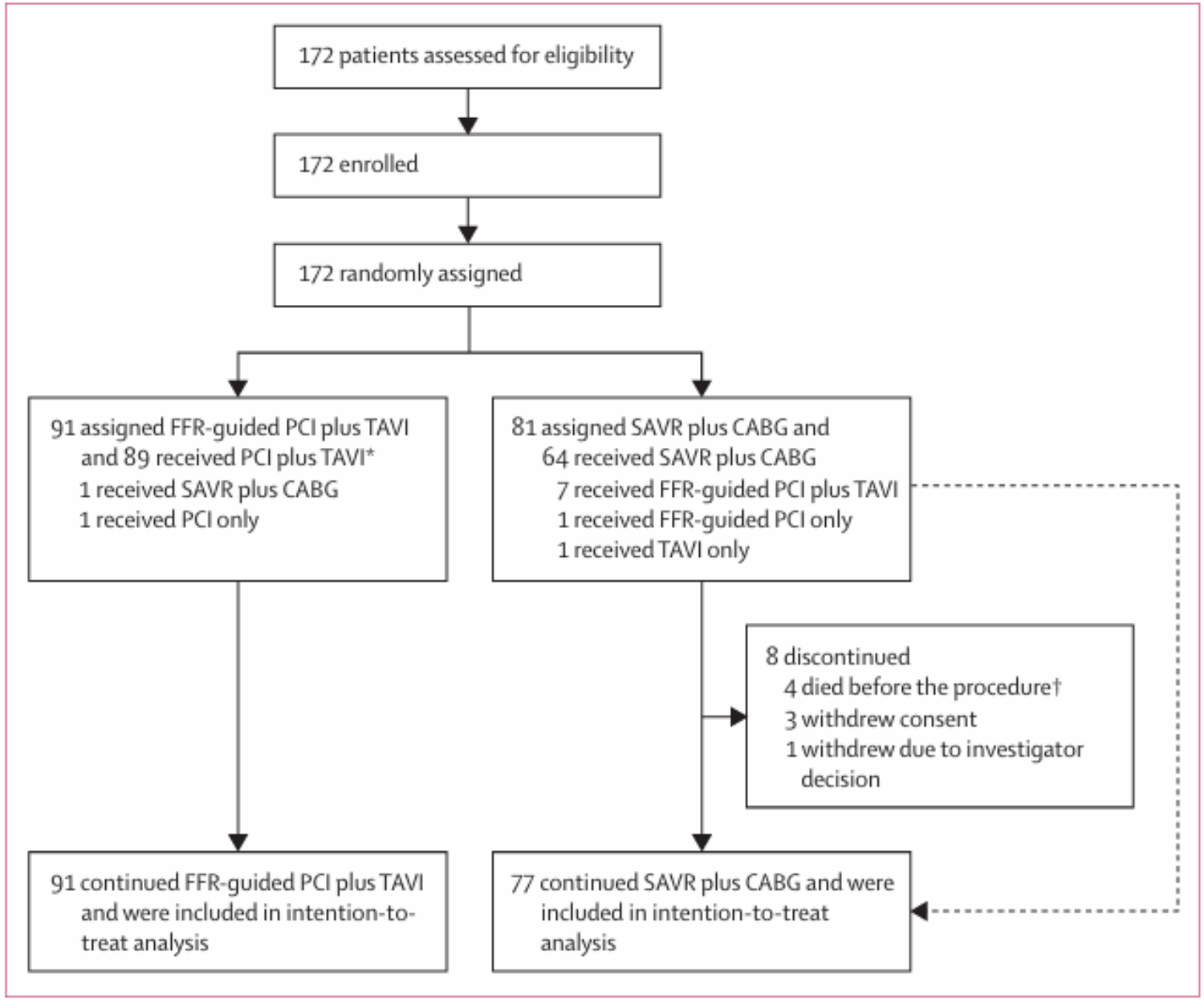




TCW trial

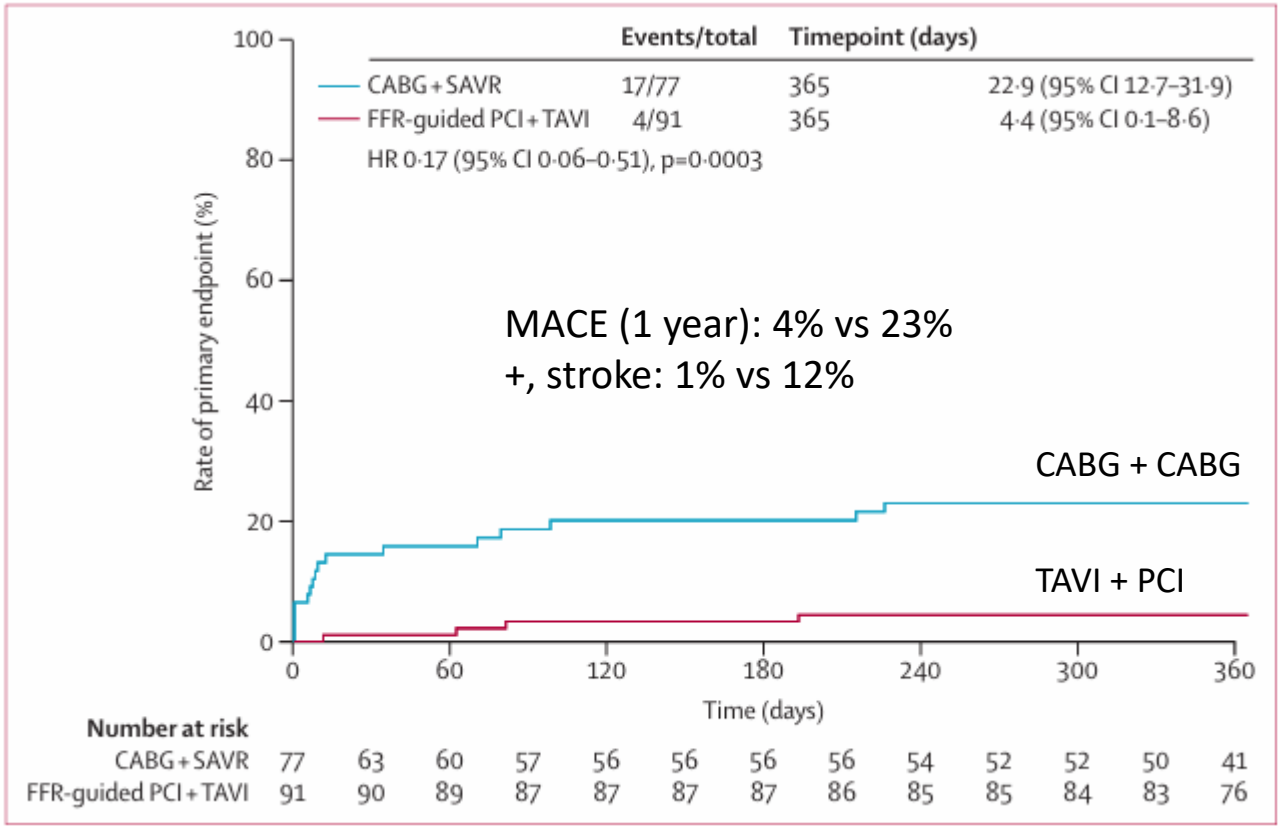
(TransCatheter Valves and Vessels)

TAVI + PCI vs SAVR + CABG



	FFR-guided PCI plus TAVI (n=89)	SAVR plus CABG (n=64)
Lesions per patient	2·2 (1·0)	2·3 (0·8)
FFR-guided revascularisation	73 (82%)	19 (30%)
Lesions treated per patient	1·5 (0·6)	NA
Complete revascularisation	74 (81%)	41 (64%)
Total stent length, mm	53·7 (29·4)	NA
Procedural success	88 (99%)	NA
Femoral access	84 (94%)	NA
Subclavian access	5 (6%)	NA
Conscious sedation	63 (71%)	NA
Successful implantation	89 (100%)	NA
Valve migration or embolisation	0	NA
Device size, mm	29·7 (3·0)	23·5 (2·15)
Device success	89 (100%)	NA
Vessels grafted	NA	1·6 (0·8)
Arterial grafts only	NA	27 (42%)
Arterial and venous grafts	NA	25 (39%)
Venous grafts only	NA	12 (19%)
Biological aortic valve	NA	64 (100%)
Hancock or Hancock Ultra (Medtronic, USA)	NA	10 (16%)
Perimount Magna Ease (Eduard Lifesciences, USA)	NA	41 (64%)
Trifecta (Abbott, USA)	NA	10 (16%)
Parcival (Livanova, UK)	NA	3 (5%)

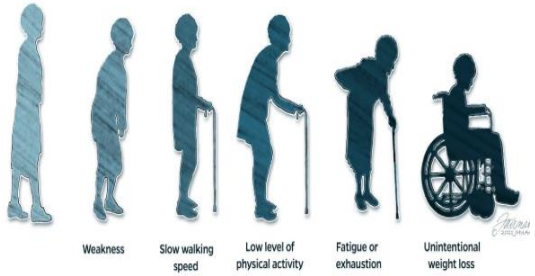
Percutaneous therapy may be best for those in need of both interventions



Medicare database 2018-2022 (17 413 PCI/TAVI or 20 409 CABG/SAVR)

non randomized comparison + real word practice

TAVI/PCI: less bleeding, AKI or in-hospital mortality
SAVR/CABG: long term lower risk of stroke (HR 1,1), mortality (HR 1,09)



SAVR

TAVI

THE EARLY TAVR TRIAL

Study Design

Prospective, multicenter RCT evaluating patients with asymptomatic, severe AS aged ≥ 65 years w/ an STS score ≤ 10% and LVEF ≥ 50%

Asymptomatic Assessment
Confirmed by negative treadmill stress test*

Mean gradient ≥ 40 mmHg or peak jet velocity ≥ 4.0 m/s

Randomization 1:1

Transfemoral-TAVR
(SAPIEN 3 or SAPIEN 3 Ultra THV)

Clinical Surveillance

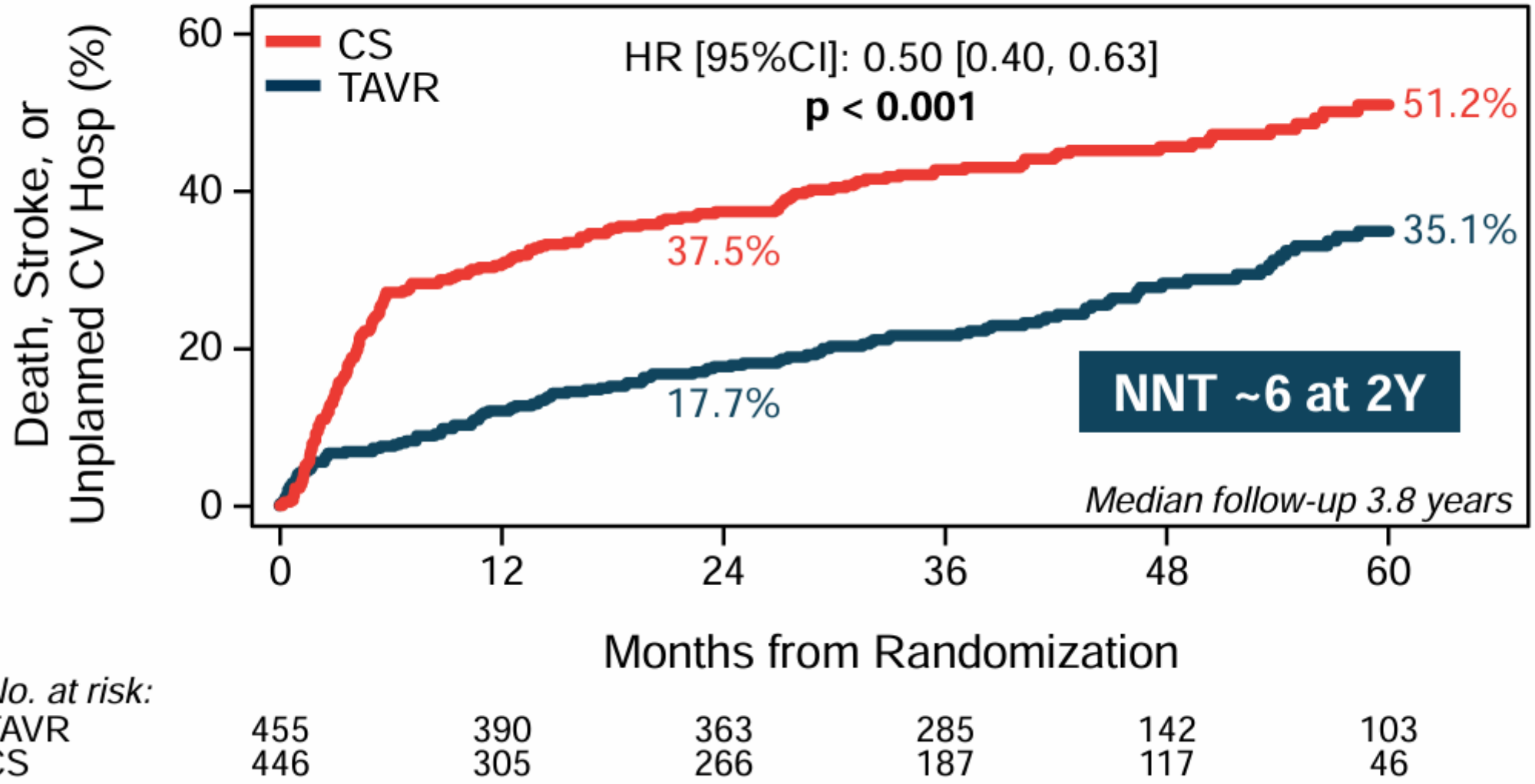
PRIMARY ENDPOINT (Superiority)
Non-hierarchical composite of all-cause death, any stroke, or unplanned CV hospitalization at a minimum follow-up of 2 years

*Confirmed by detailed clinical history alone if patient was unable to perform stress test

THE EARLY TAVR TRIAL

Primary Endpoint

Av. AGE 76y



No. at risk:

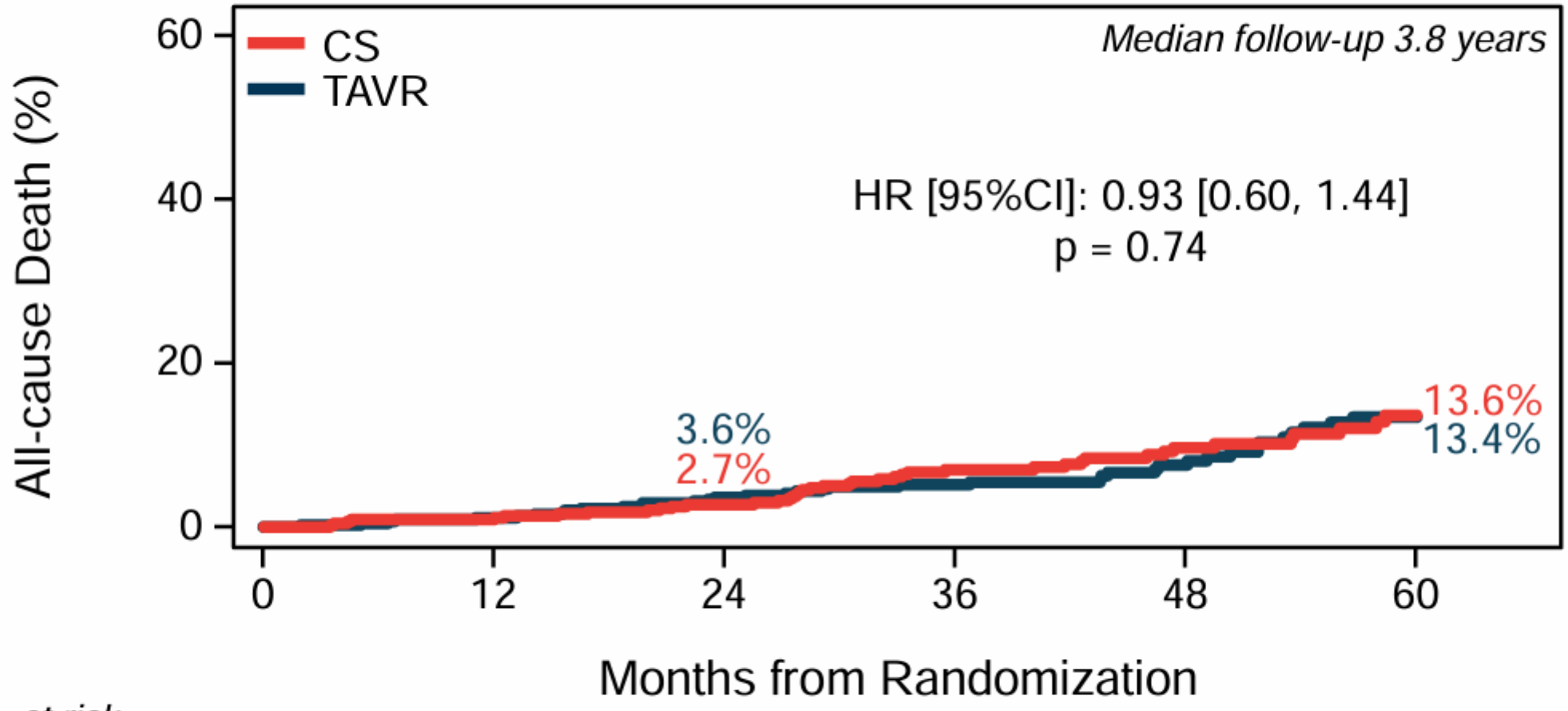
TAVR	455	390	363	285	142	103
CS	446	305	266	187	117	46

Event rates are Kaplan-Meier estimates

Patients had a minimum follow-up of 2 years

THE EARLY TAVR TRIAL

All-cause Death



No. at risk:

TAVR	455	439	425	346	187	136
CS	446	436	418	310	199	95

Event rates are Kaplan-Meier estimates

Patients had a minimum follow-up of 2 years

THE EARLY TAVR TRIAL

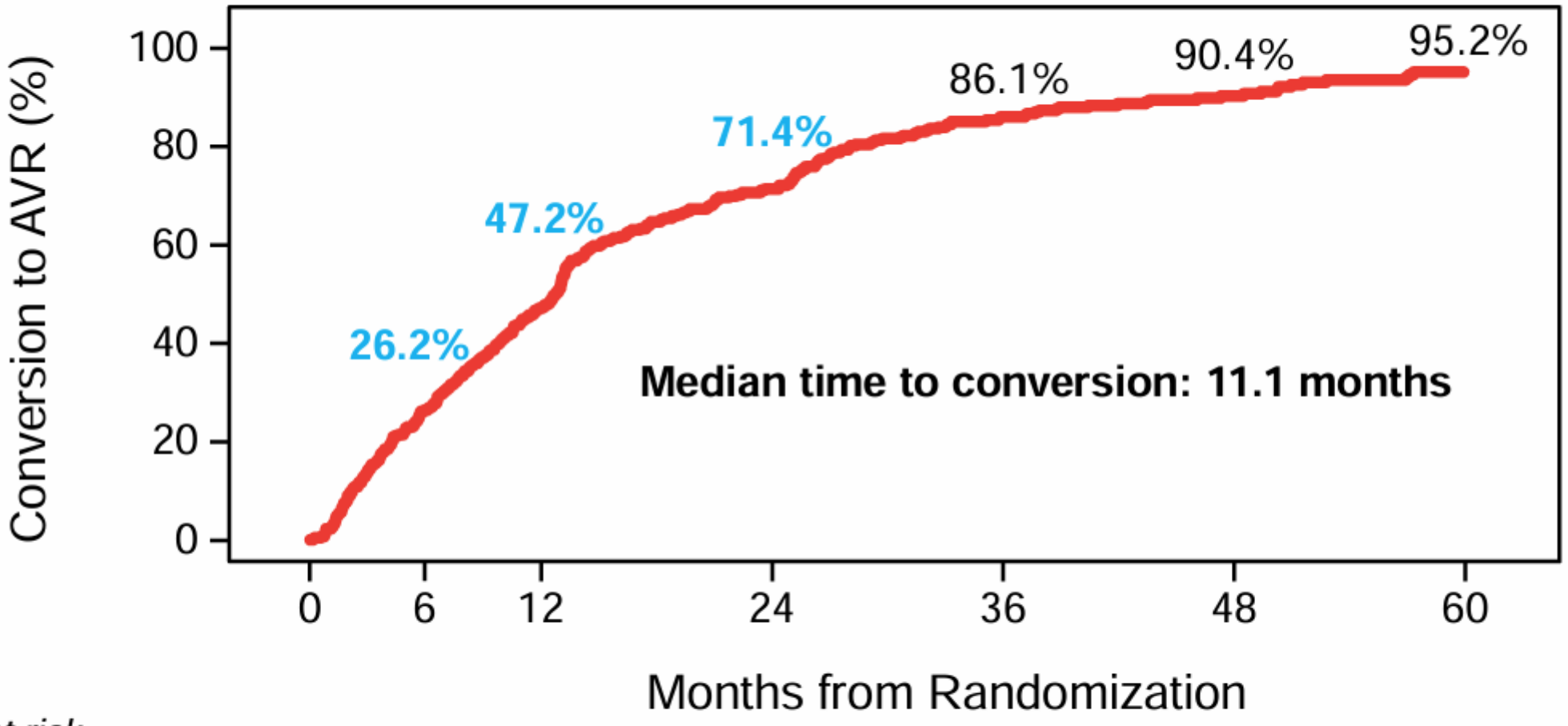
Primary Endpoint Components

Endpoint – % (no. of pts w/ an event)	TAVR (N=455)	CS (N=446)	P-value
Primary Endpoint	**26.8% (122)**	**45.3% (202)**	**<0.001**
All-cause Death	8.4% (38)	9.2% (41)	---
Any Stroke	4.2% (19)	6.7% (30)	---
Unplanned CV Hospitalization	20.9% (95)	41.7% (186)	---

Median follow-up of 3.8 years

THE EARLY TAVR TRIAL

Conversion to TAVI in CS



No. at risk:

Clinical Surveillance	446	326	231	119	45	22	9

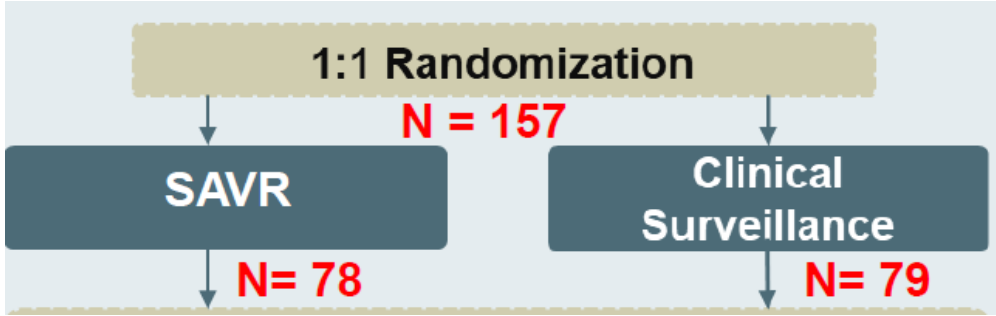
Median follow-up 3.8 years; At the time of analysis, 30 patients were still on study but hadn't converted to AVR

AVATAR

Asymptomatic

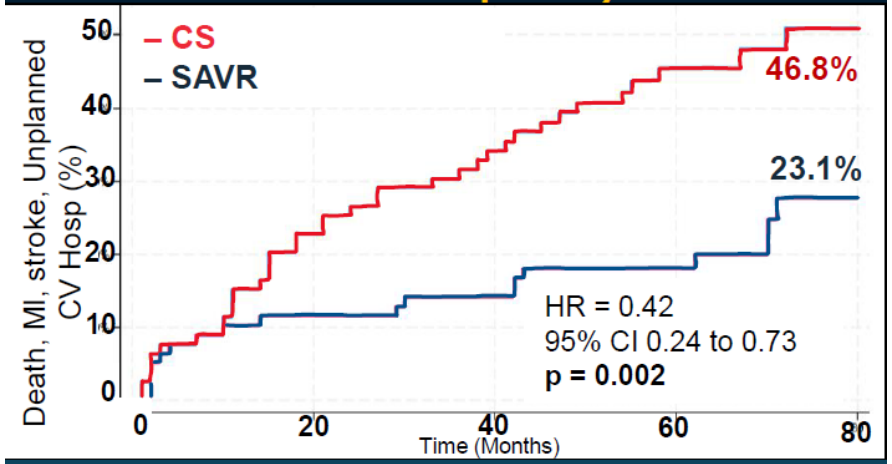
Inclusion/exclusion criteria, treadmill stress test

Key inclusion: > 18 years old, LVEF ≥ 50%, STS risk score < 8%, life expectancy > 3 years



AVATAR

Median follow-up 5.25 years



Endpoint	SAVR (N=78)	CS (N=79)
Primary endpoint	23.1% (18)	46.8% (37)
All-cause Death	16.7% (13)	34.2% (27)
Myocardial Infarction	1.3% (1)	7.6% (6)
Stroke	5.1% (4)	5.1% (4)
HF hospitalization	3.8% (3)	16.4% (13)

AVATAR

Av. Age 69 y

44.3%

Median time to conversion: 15.6 months (IQR 7.4-36.2)

Symptom onset	18 (51.4%)
AS progression	6 (17.1%)
Decrease in LVEF	3 (8.6%)
Combination of factors	8 (22.9%)

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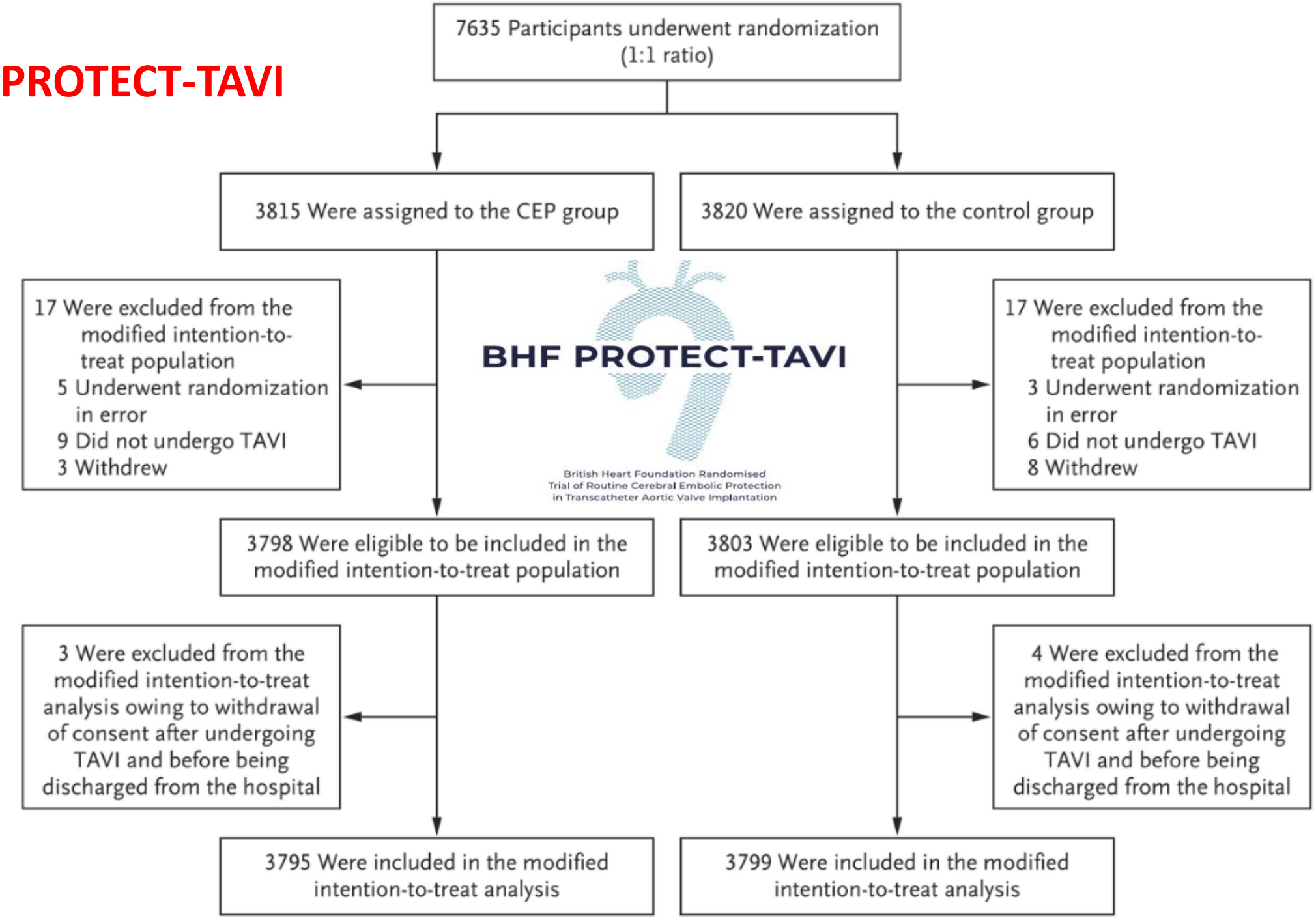
BHF PROTECT-TAVI



BHF PROTECT-TAVI

Outcome	CEP Group (N=3798)	Control Group (N=3803)	Treatment Effect	
			Risk Difference (95% CI)†	Risk Ratio (95% CI)†
	no./total no. (%)		*percentage points*	
Primary outcome				
Stroke within 72 hr after TAVI or before discharge, if sooner	81/3795 (2.1)	82/3799 (2.2)	−0.02 (−0.68 to 0.63)‡	0.99 (0.73 to 1.34)‡
Ischemic stroke	80/3795 (2.1)	82/3799 (2.2)		
Hemorrhagic stroke	1/3795 (<0.1)	0/3799		
Secondary outcomes				
Disabling stroke within 6 to 8 wk after TAVI§¶	47/3795 (1.2)	53/3799 (1.4)	−0.2 (−0.7 to 0.4)	0.89 (0.60 to 1.31)
Ischemic stroke	47/3795 (1.2)	53/3799 (1.4)		
Hemorrhagic stroke	0/3795	0/3799		
Death, stroke, or TIA within 72 hr after TAVI or before discharge, if sooner	126/3795 (3.3)	117/3799 (3.1)	0.2 (−0.6 to 1.0)	1.08 (0.84 to 1.38)
Death	29/3795 (0.8)	26/3799 (0.7)		
Nonfatal stroke	79/3795 (2.1)	78/3799 (2.1)		
TIA	18/3795 (0.5)	13/3799 (0.3)		

NEJM, March 30, 2025

Study Design

Investigator-initiated, international, randomized controlled, open label, superiority trial

TAVR UNLOAD

Symptomatic patients with HFrEF on GDMT & moderate AS

R

TF TAVR (n=89)

CASS (n=89)

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

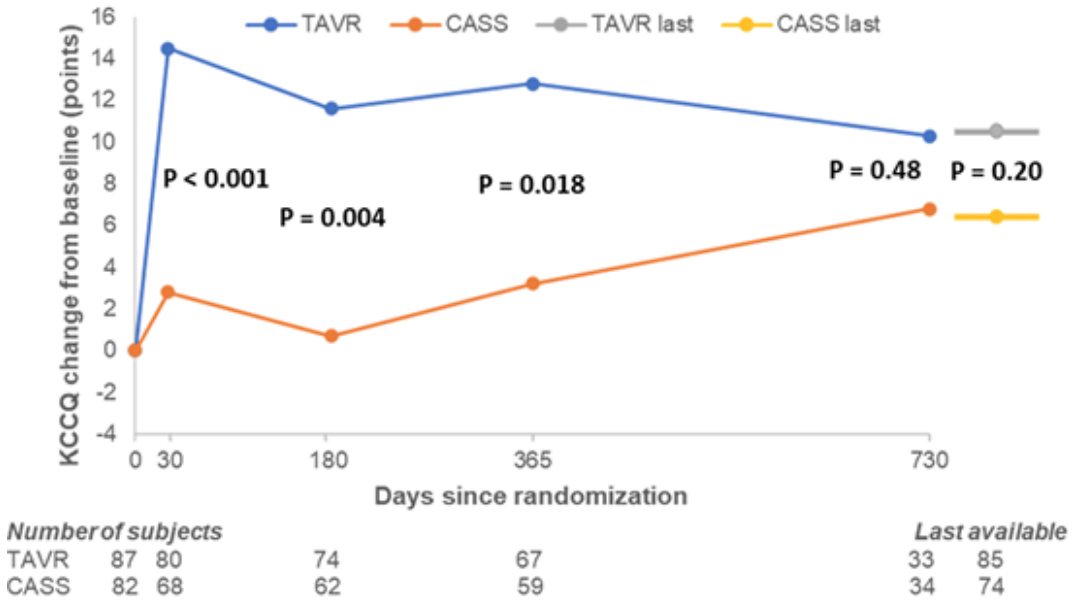
Time-to-event analysis of:

Major adverse cardiac or cerebrovascular events (MACCE) defined as the composite of:

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

* Using Finkelstein Schoenfeld method and presented as a win ratio
** Using Kaplan Meier Method and presented as Kaplan Meier curves

78 y.o., 20% females, 50% AF, 75% CAD, 40 % ICD/CRT, LV EF 40%, moderate AS, NYHA II – 43%, NYHA III – 52%



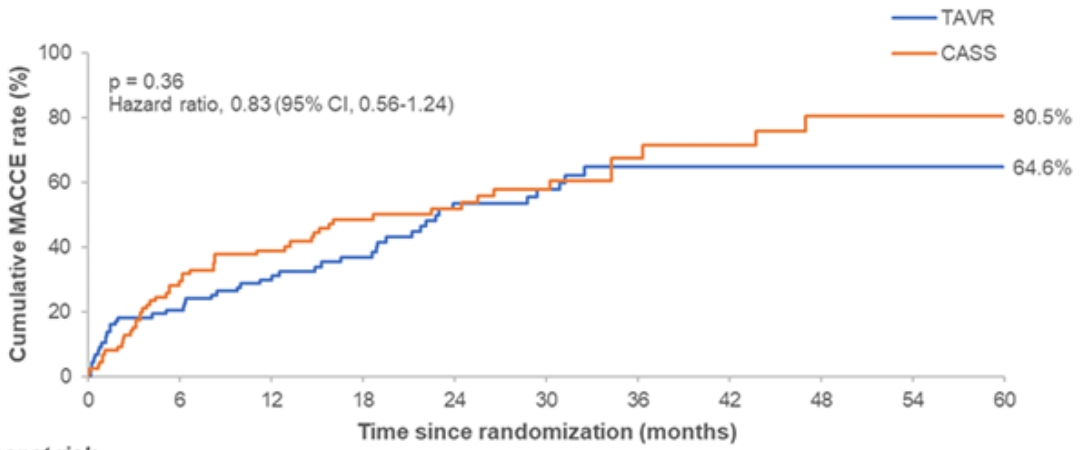
All available KCCQ-OS measurements

➢Progression to severe AS

- ✓ 35/89 patients (39%*)
- ✓ 16 patients in year 1
- ✓ + 13 patients in year 2
- ✓ + 5 patients in year 3
- ✓ + 1 patient in year 4
- ○ All underwent TAVR
- ○ 17 /35 (= 49%) with HF event*

Major Events

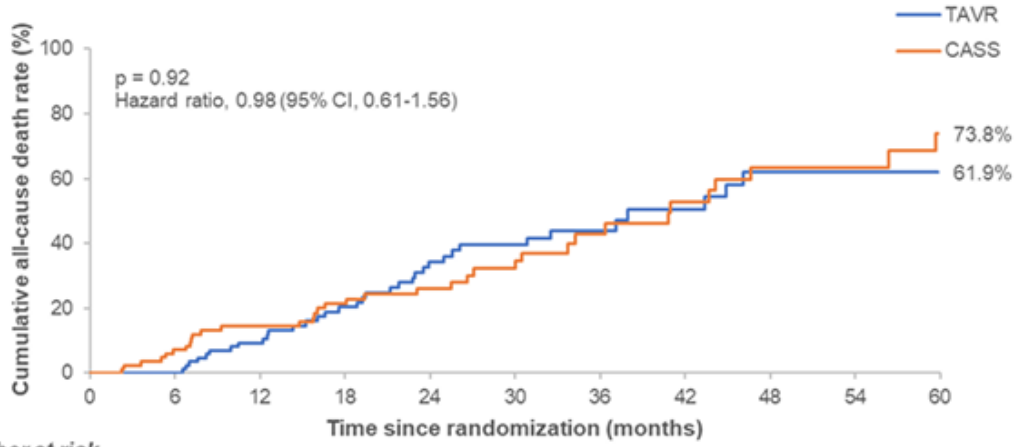
MACCE



Number at risk

TAVR	89	60	27	12	5	2
CASS	89	49	27	9	3	2

All-cause Death



Number at risk

TAVR	89	78	41	20	7	3
CASS	89	69	42	19	8	5

*** MACCE = composite of all-cause death, all stroke, and HF hospitalizations and equivalents**

CONCLUSION

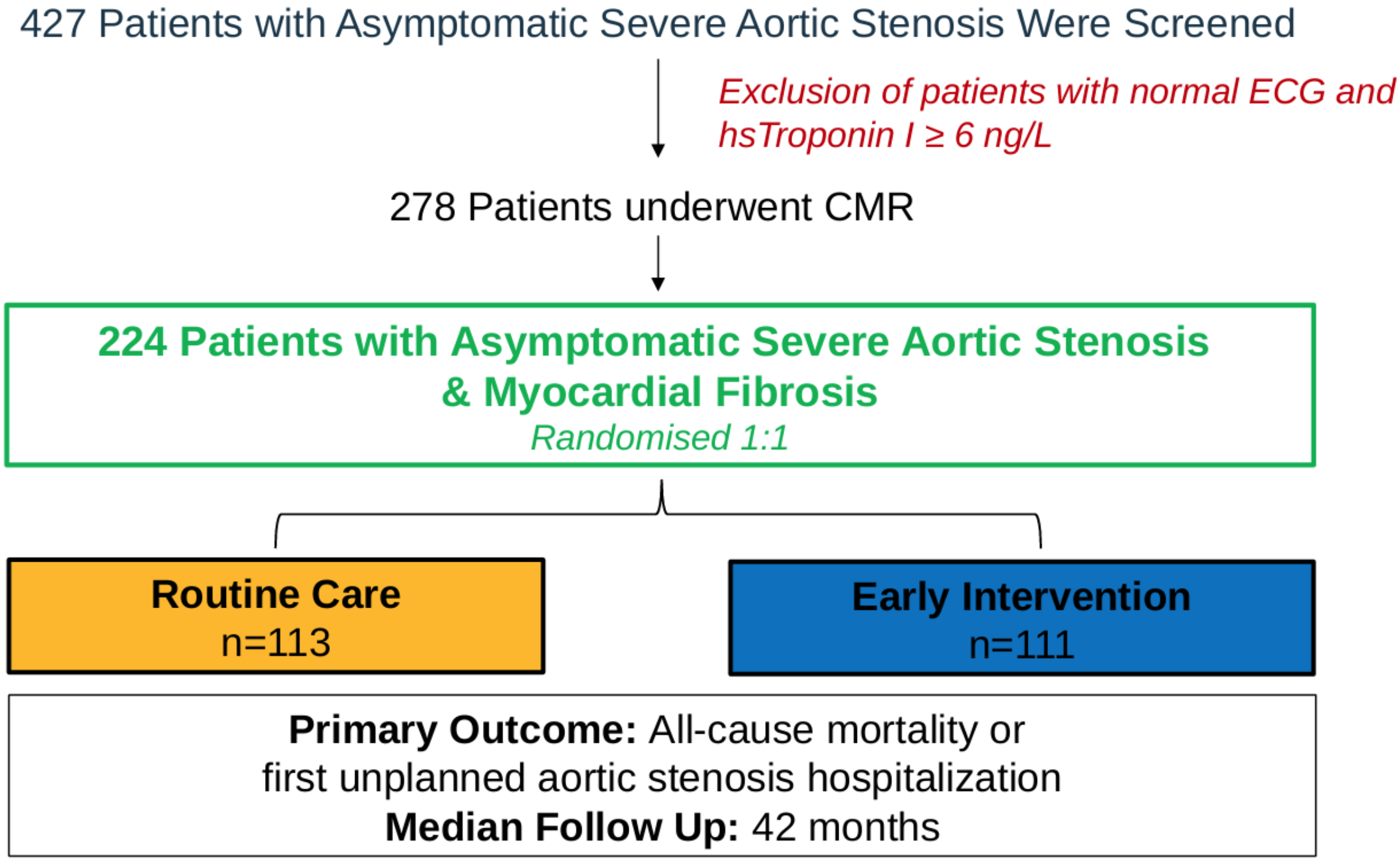
1. TAVR for moderate AS in patients with HFrEF on GDMT was safe but did not affect the primary hierarchical composite endpoint at a median follow up of 23 months
2. TAVR resulted in more wins in the primary hierarchical composite endpoint at one year follow up driven by clinically meaningful improvement in quality of life compared with clinical AS surveillance
3. During the trial, 43% of the clinical AS surveillance group underwent TAVR predominantly because of disease progression to severe AS.
4. The cardiac damage framework may identify a broader patient phenotype with moderate AS that may benefit from upstream TAVR. This concept is under investigation in the PROGRESS and EXPAND TAVR II trials.

EvoLVed

Objective: To investigate whether early aortic valve intervention can improve outcomes in patients with asymptomatic severe aortic stenosis who had myocardial fibrosis

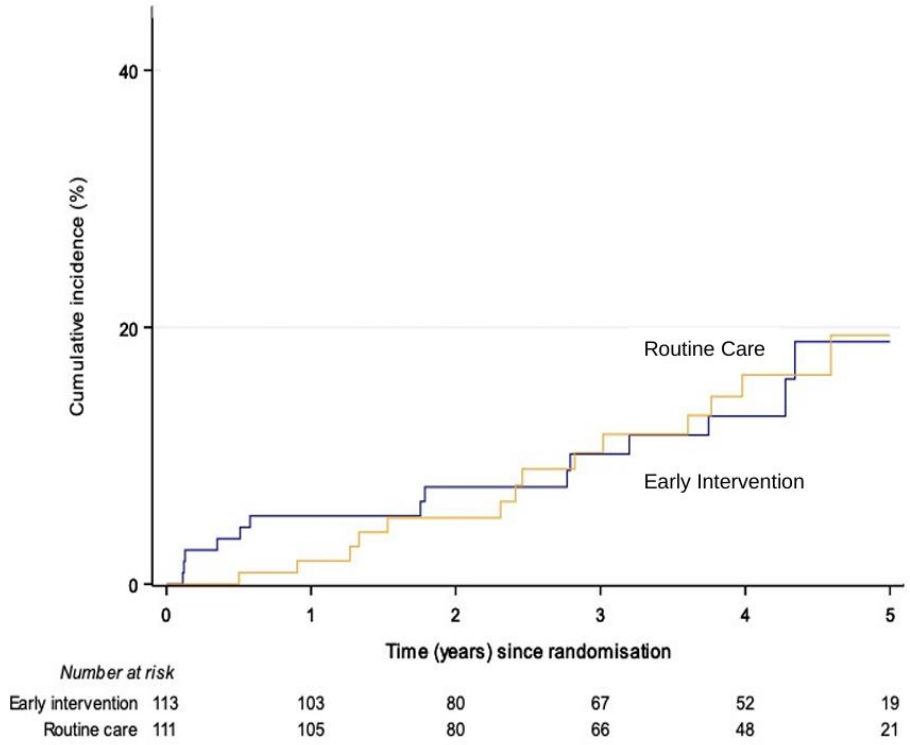
Can at risk Disease Phenotypes Prioritise Earlier Treatment (EVOLVED)

Edinburgh Heart Centre


427 Patients with Asymptomatic Severe Aortic Stenosis Were Screened
Exclusion of patients with normal ECG and hsTroponin I ≥ 6 ng/L
278 Patients underwent CMR
224 Patients with Asymptomatic Severe Aortic Stenosis & Myocardial Fibrosis
Randomised 1:1
Routine Care
n=113
Early Intervention
n=111
Primary Outcome: All-cause mortality or first unplanned aortic stenosis hospitalization
Median Follow Up: 42 months

EvoLVed : negative results

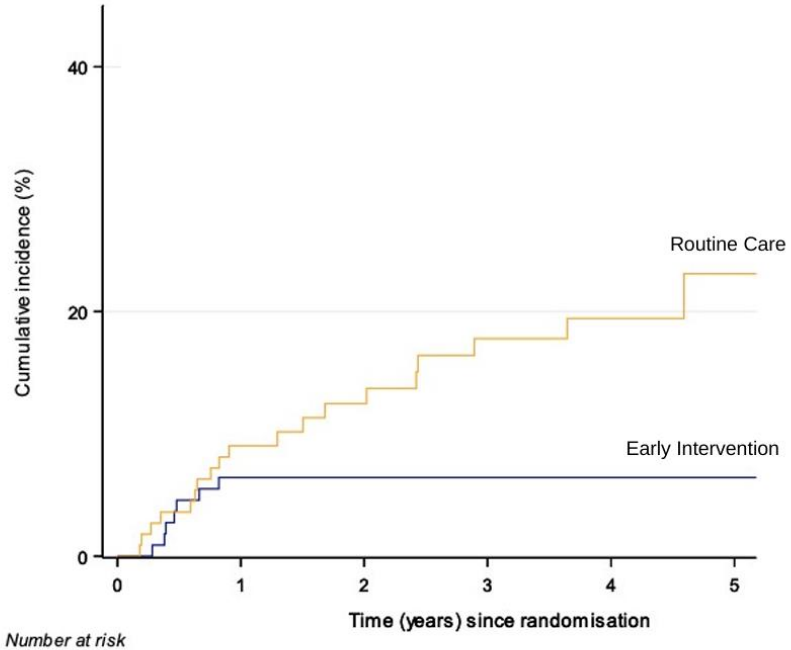
All-cause death



Number at risk

Early intervention	113	103	80	67	52	19
Routine care	111	105	80	66	48	21

Unplanned aortic hospitalizations



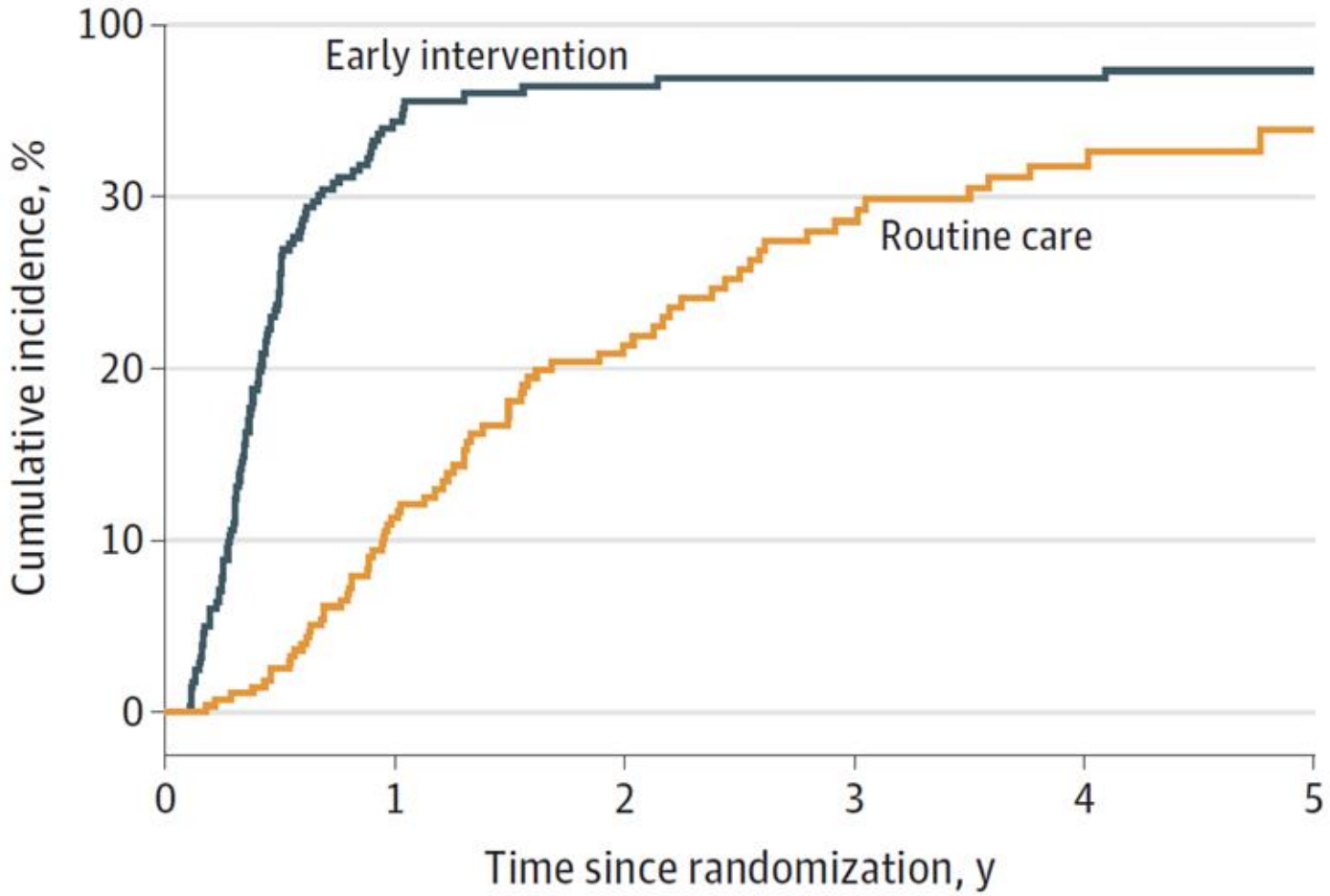
Number at risk

Early intervention	113	97	76	65	51	18
Routine care	111	97	71	57	40	17

Time to Intervention

15-month difference in median time-to-intervention

Median time to intervention
- Early intervention 5 months
- Routine care 20 months



No. of patients at risk						
Early intervention	113	16	8	7	7	6
Routine care	111	77	37	18	12	4

THV in THV:

- Sapien in Sapien:
  - Downsizing 16%, acceptable structural integrity
- Sapien in Evolut:
  - Lowest effective orifice area
  - High position: downsizing in 66% (position in the waist od Evolut) plus highest deformation index
  - Low position: underexpansion in of redo Sapien, exccentricity plus leaflet overhang = worse haemodynamics
- CT planning is mandatory before THV-in-THV
- RedoTAV smartphone app

EXPLANT or REDO TAVI registry

N=503, 2009-2022

Death

In hospital	11,8% vs 2,3%
30-day	14,2% vs 3,5%
1 year	35,5% vs 14,6%

TVT 2022

ACURATE IDE Trial Design

Prospective, multicenter, randomized study
N=1500 patients with symptomatic severe native aortic stenosis indicated for TAVR

Operators pre-specify valve type to be used if randomized to Control

1:1 Randomization

- ACURATE *neo2* N=752
- Mixed Control N=748
  - Evolut N=244
    - CoreValve Evolut R
    - Evolut PRO
    - Evolut PRO+
    - Evolut FX
  - SAPIEN N=504
    - SAPIEN 3
    - SAPIEN 3 Ultra

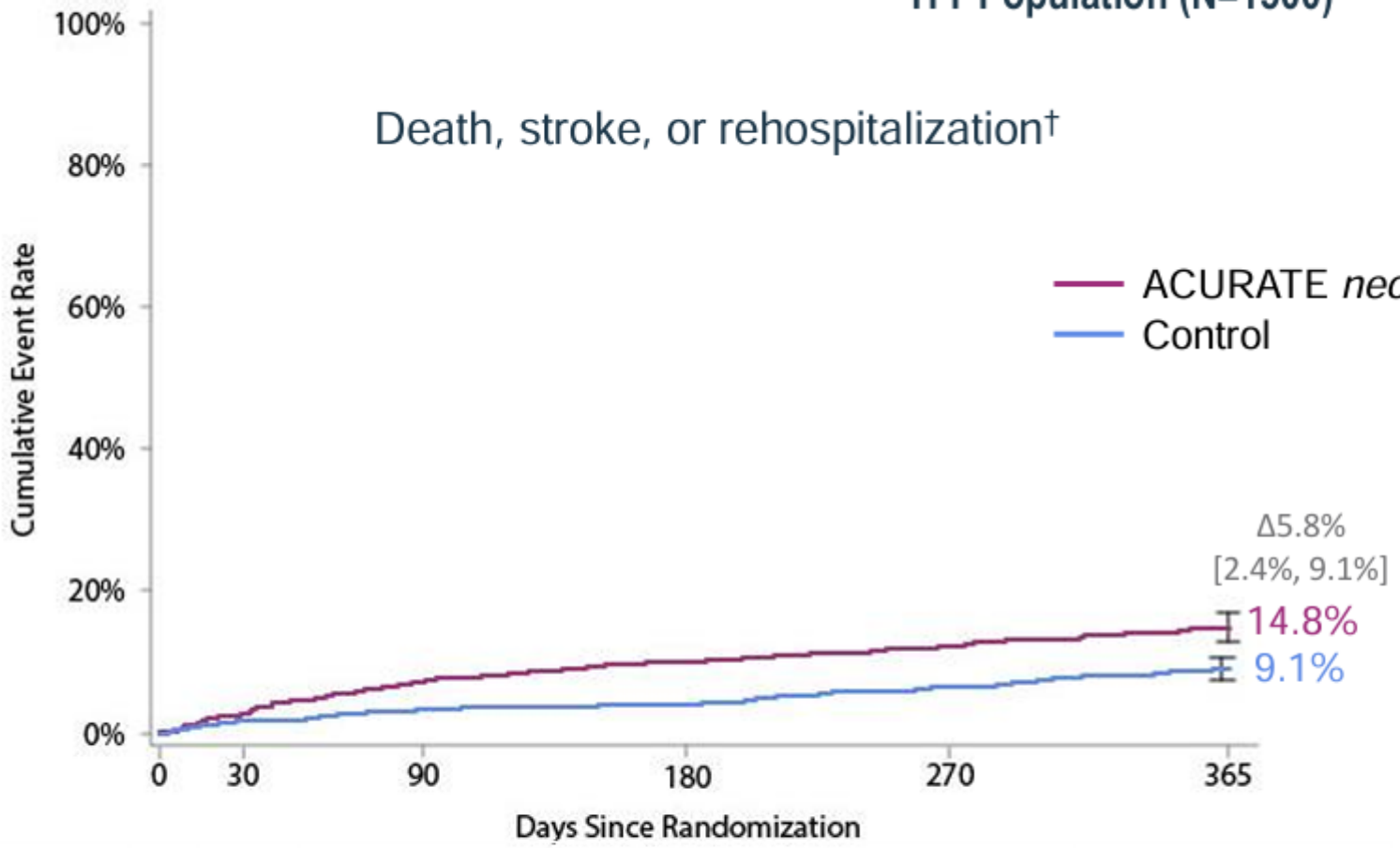
- **Primary Endpoint: Composite of all-cause mortality, stroke or rehospitalization† at 1 year**
- Follow-Up: Discharge/7d post-procedure, 30d, 6mo, 1-10y post-procedure

† Hospitalization for valve-related symptoms or worsening congestive heart failure (NYHA class III or IV); per VARC-2 definition

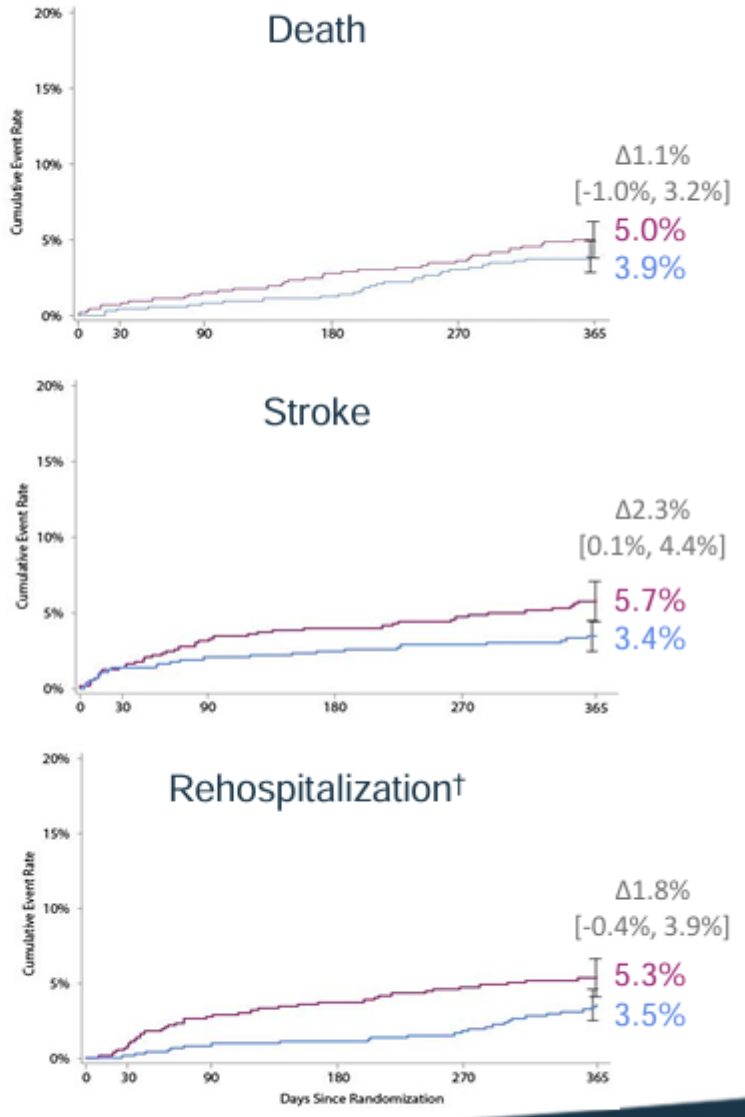
Kaplan-Meier Analysis through 1 Year

ITT Population (N=1500)

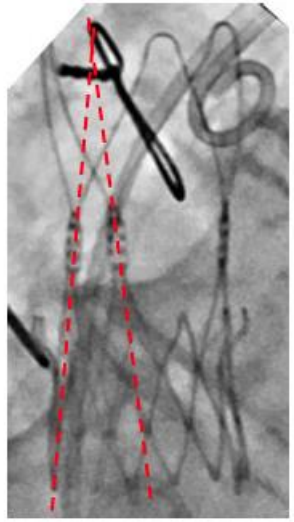
Death, stroke, or rehospitalization†

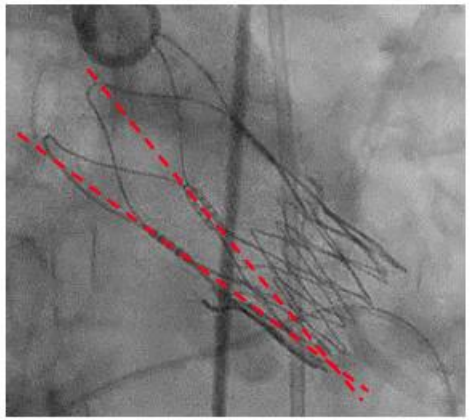


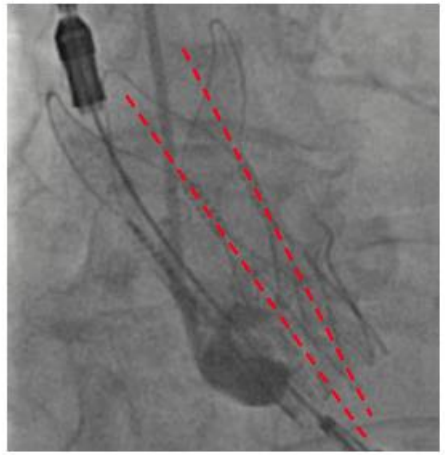
No. at risk						
ACURATE *neo2* (N=752)	752	733	711	676	651	617
Control (N=748)	748	737	723	706	695	654



Note: Control devices include CoreValve Evolut R, Evolut PRO, Evolut PRO+, and Evolut FX and SAPIEN 3, SAPIEN 3 Ultra
† Hospitalization for valve-related symptoms or worsening congestive heart failure (NYHA class III or IV); per VARC-2 definition







Valve frame under-expansion was present in ~20% of ACURATE *neo2* cases

	ACURATE *neo2*		
	Expanded Valve Frame (N=553)	**Under-Expanded Valve Frame (N=150)**	**P-value**
Primary Endpoint: Death, stroke, or rehospitalization†	**12.4% (68)**	**18.8% (28)**	0.050
Individual components			
Death	**3.7% (20)**	**7.4% (11)**	0.054
Stroke	**3.5% (19)**	**11.0% (16)**	<0.001
Rehospitalization†	**5.9% (32)**	**2.7% (4)**	0.131