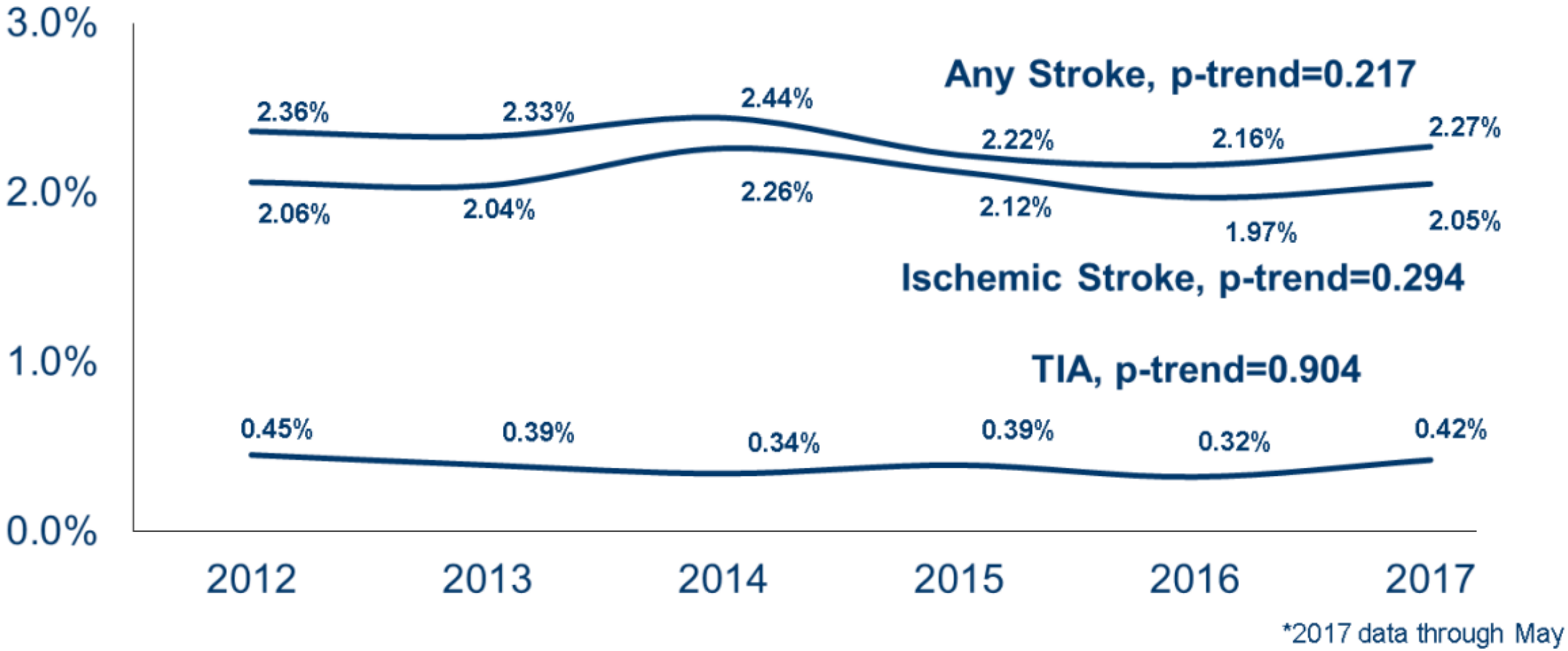
Ischemic stroke complicating TAVI: Predictors, prevention and management

Israel Barbash, MD

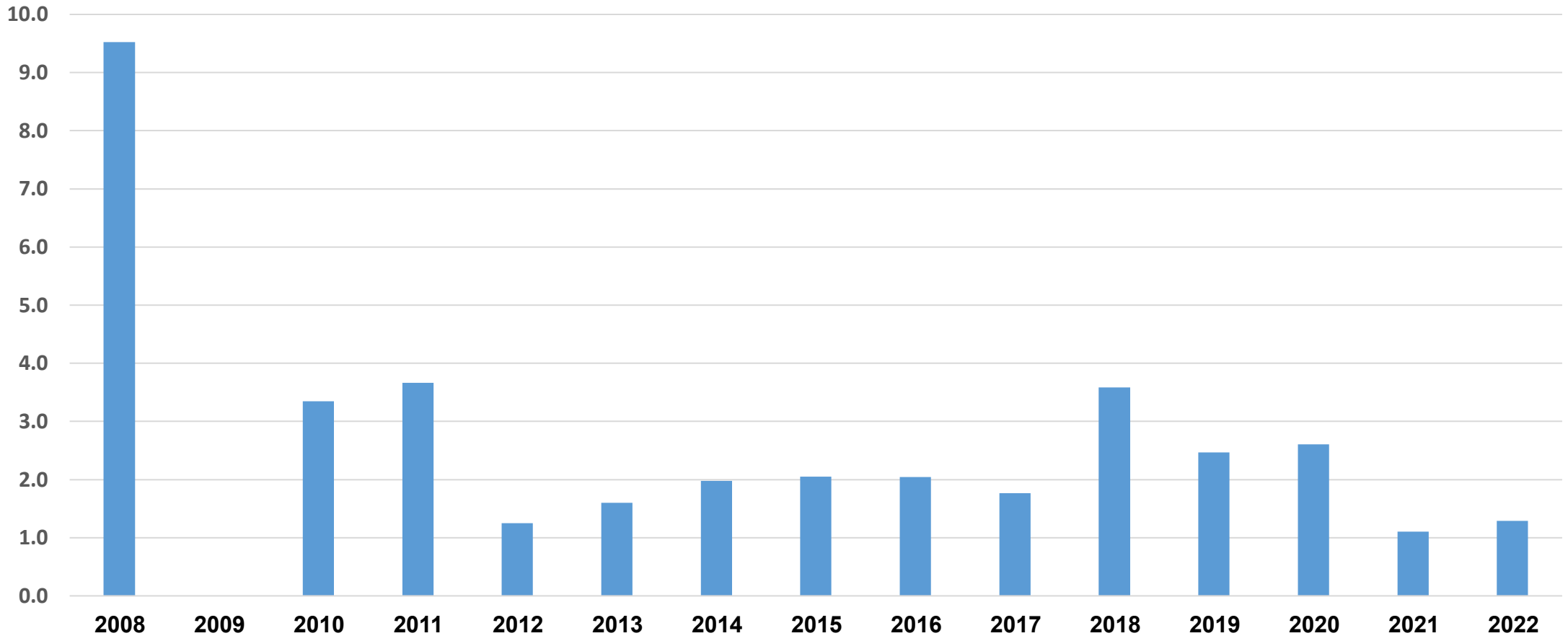
Sheba Medical Center, Israel

Real-life stroke rates remain stable over time



TVT registry, Huded JAMA 2019

In-hospital stroke rates in the Israeli multicenter registry – Stable rates

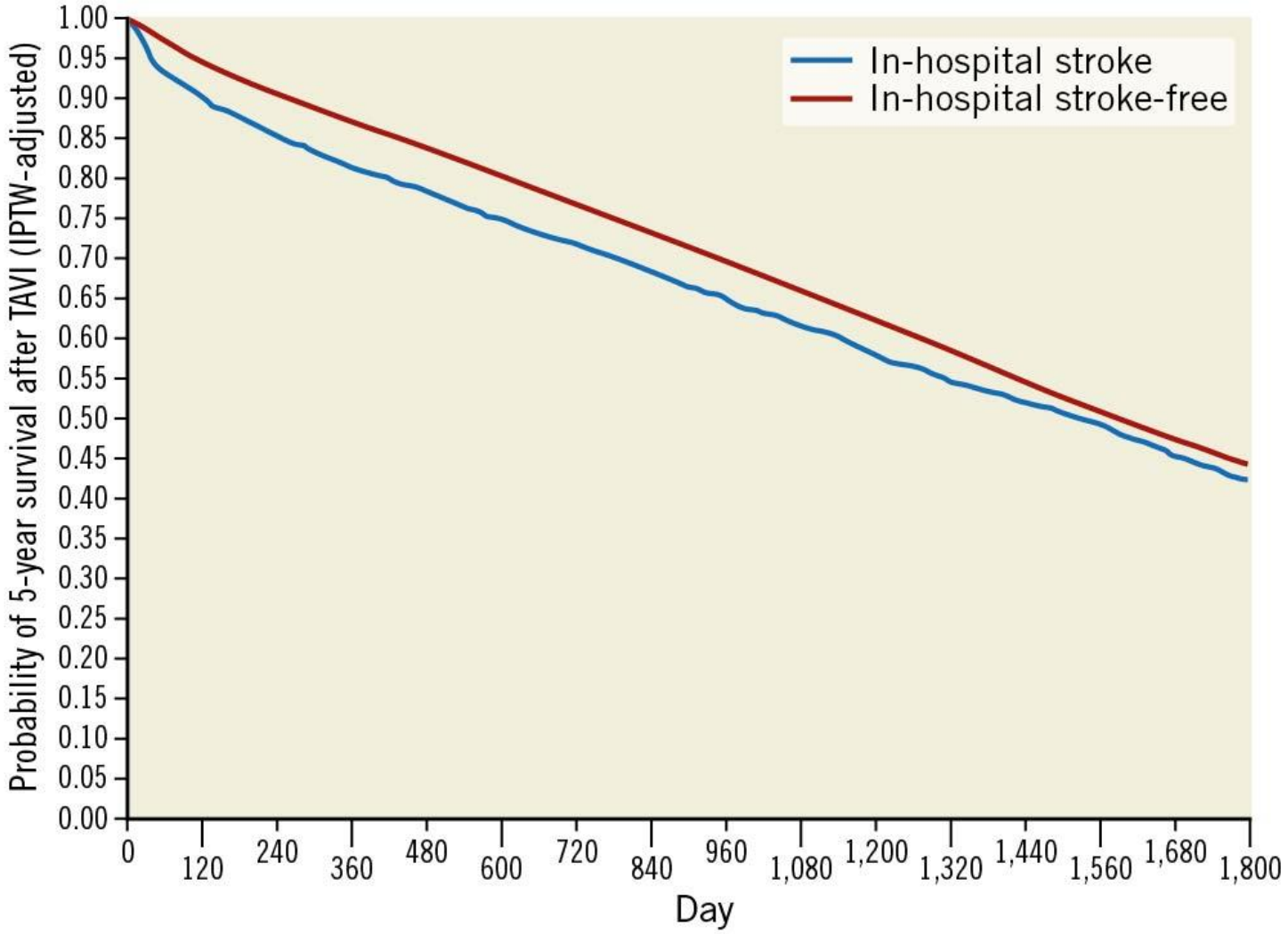


The Tel Aviv Sourasky Medical Center

RABIN MEDICAL CENTER
BEILINSON • HASHARON

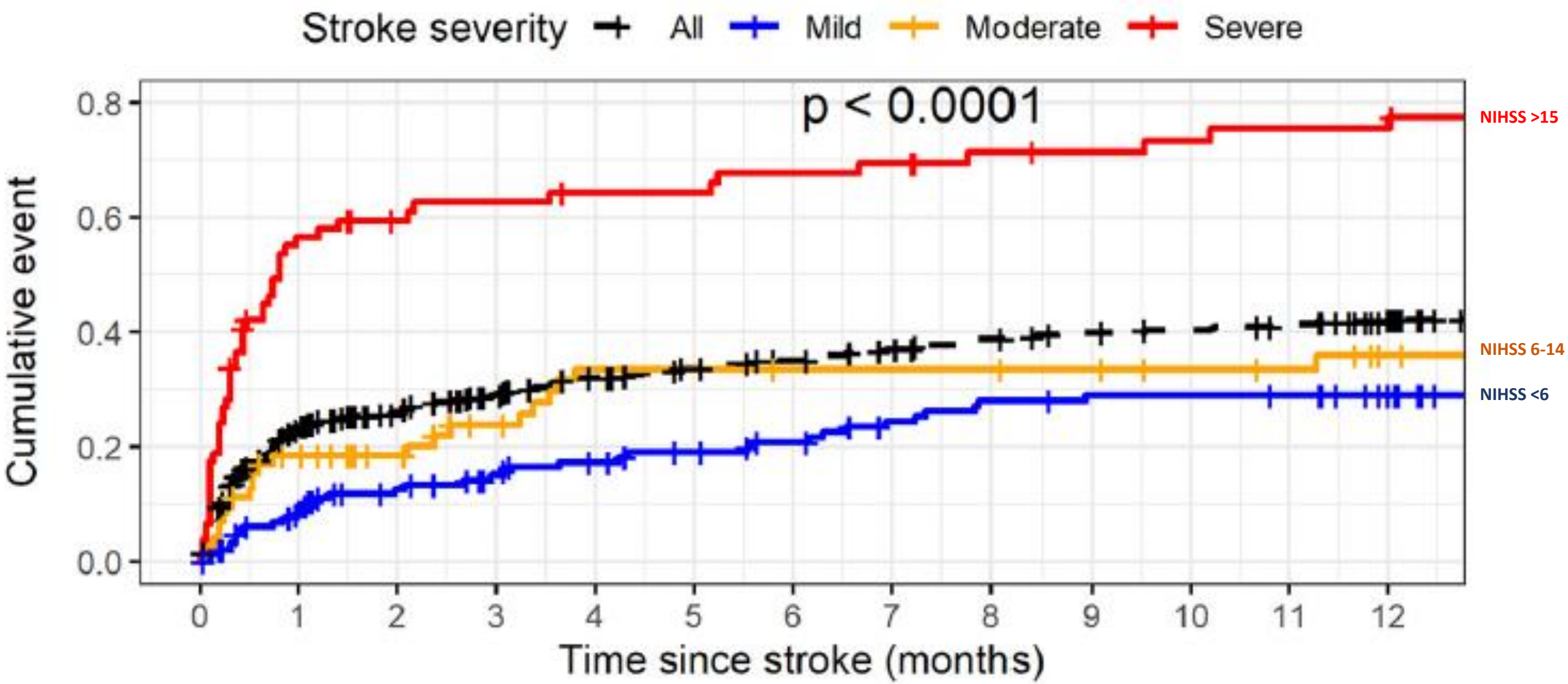
המרכז הרפואי שערי צדק

Procedural stroke is associated with short and intermediate term mortality



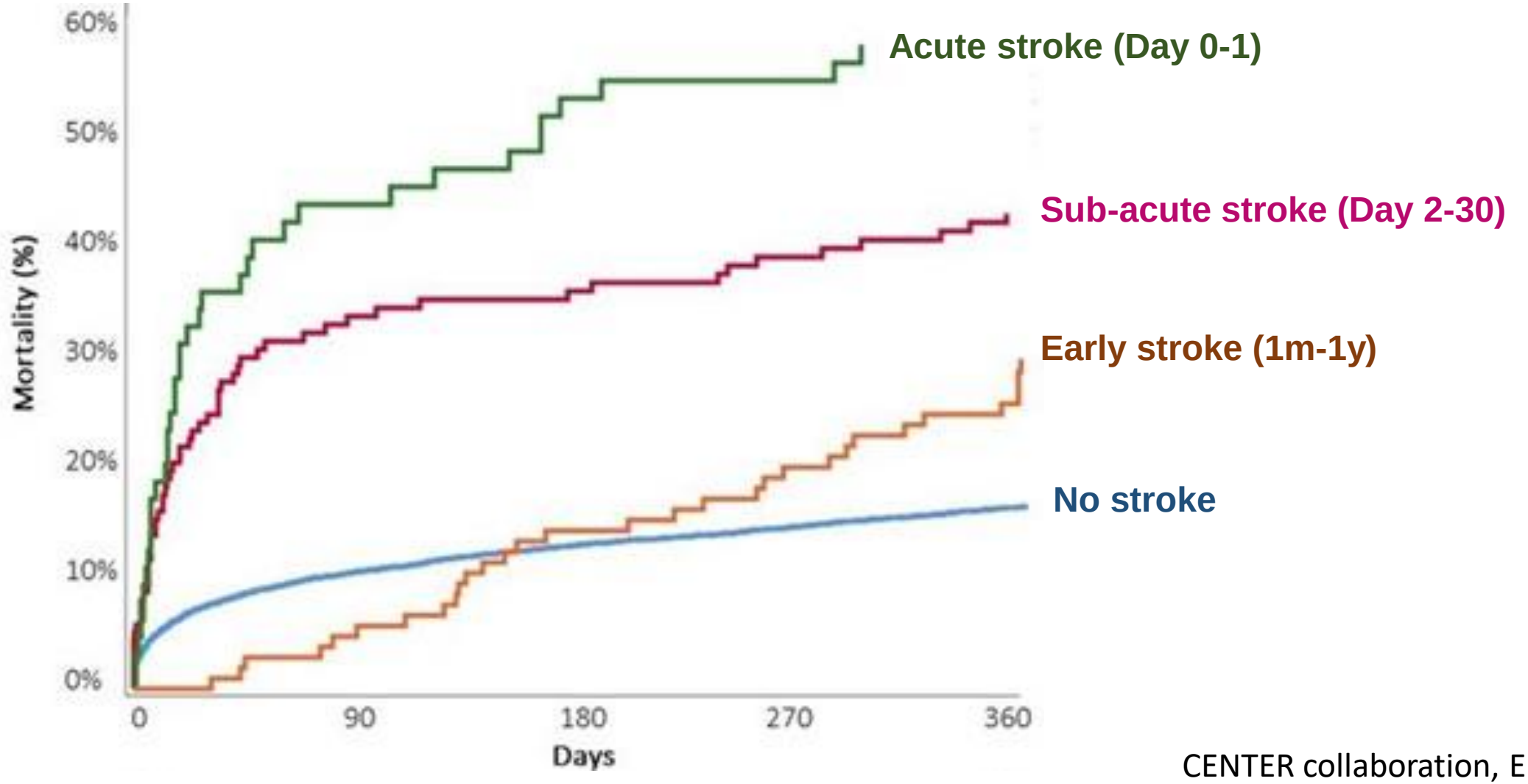
Medicare data, Almarzooq, EuroInt 2022

Not all strokes are the same:
Severe stroke carries higher mortality



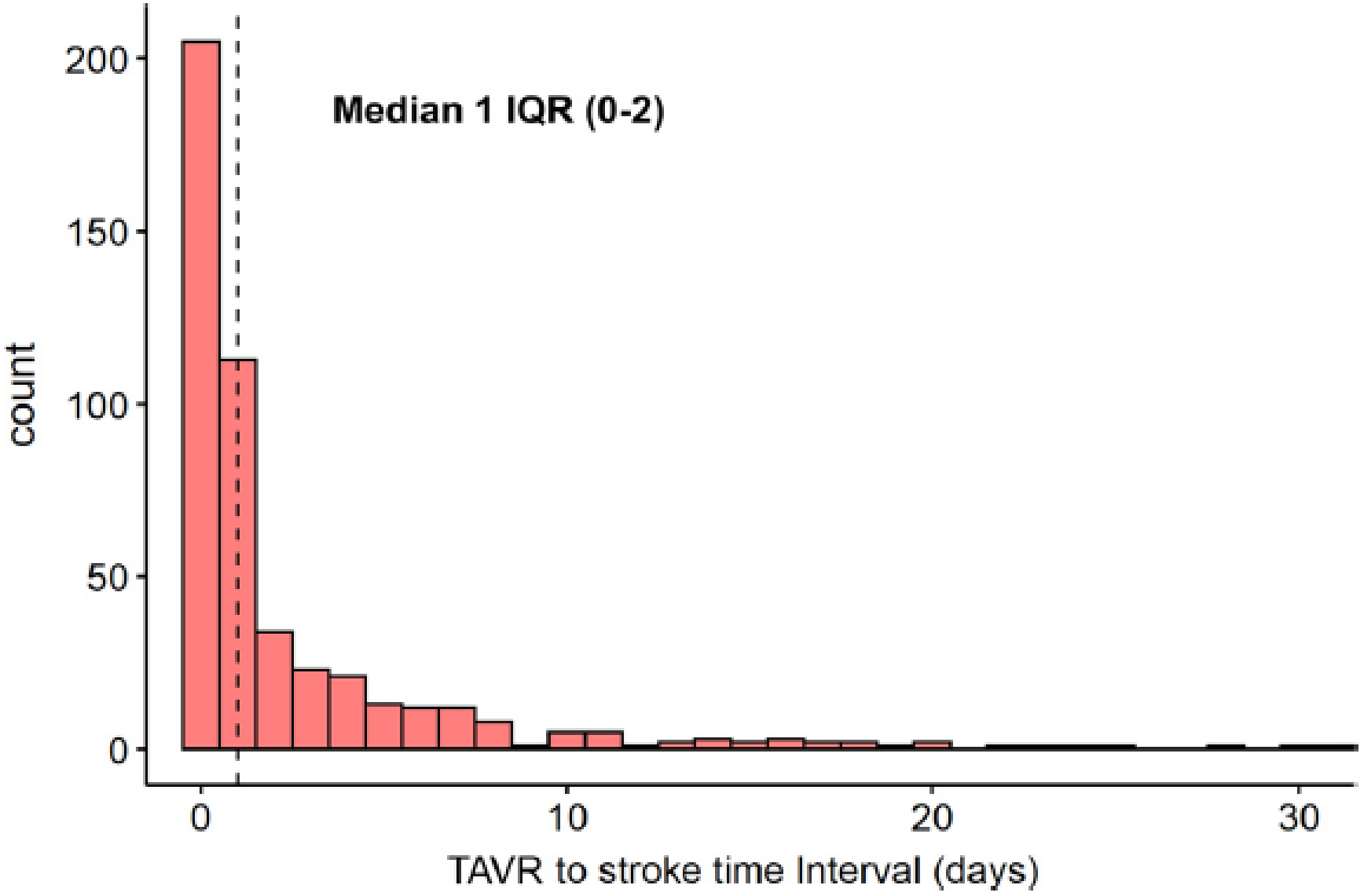
ASTRO JACC Int 2022

Not all strokes are the same:
Acute stroke carries higher mortality



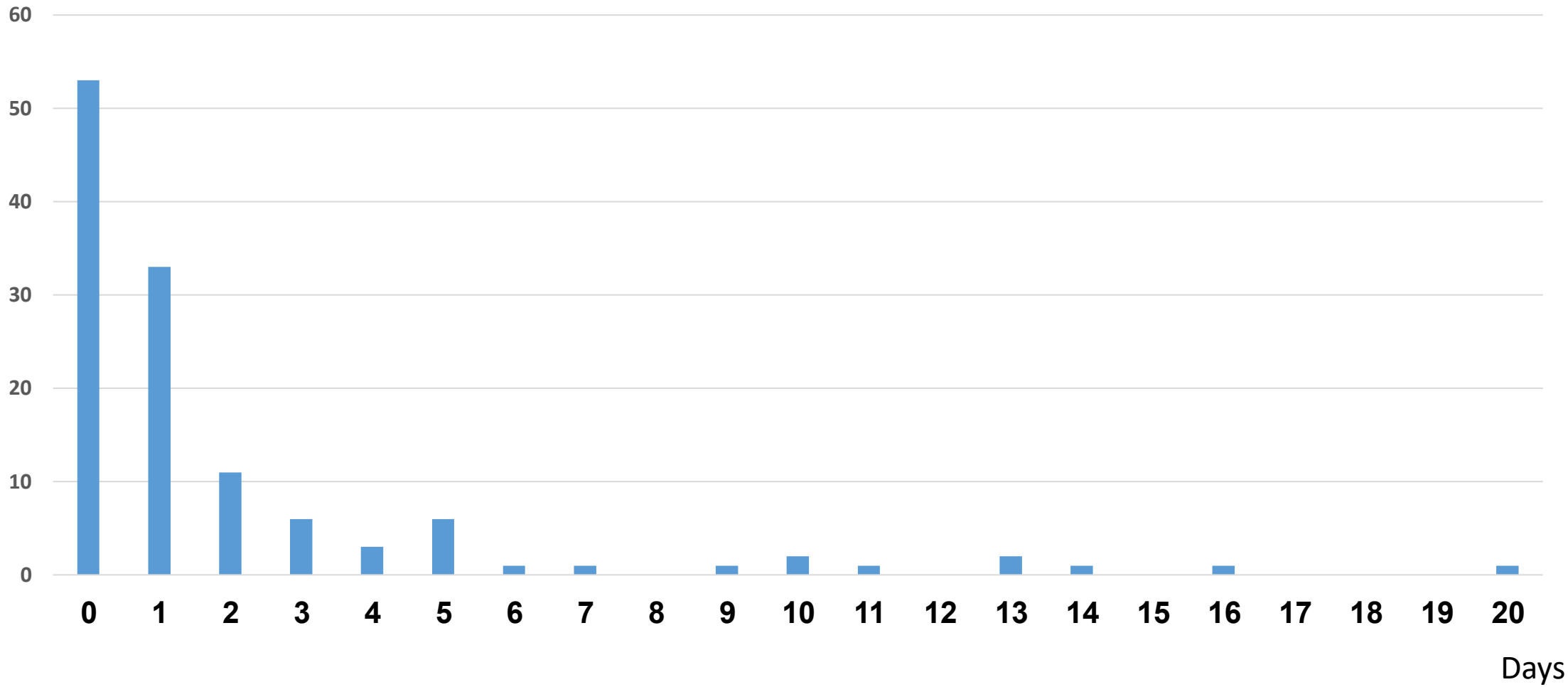
CENTER collaboration, EHJ 2022

The majority of strokes occur within 24 hours of TAVI



ASTRO JACC Int 2022

Timing of stroke in the Israeli multicenter registry

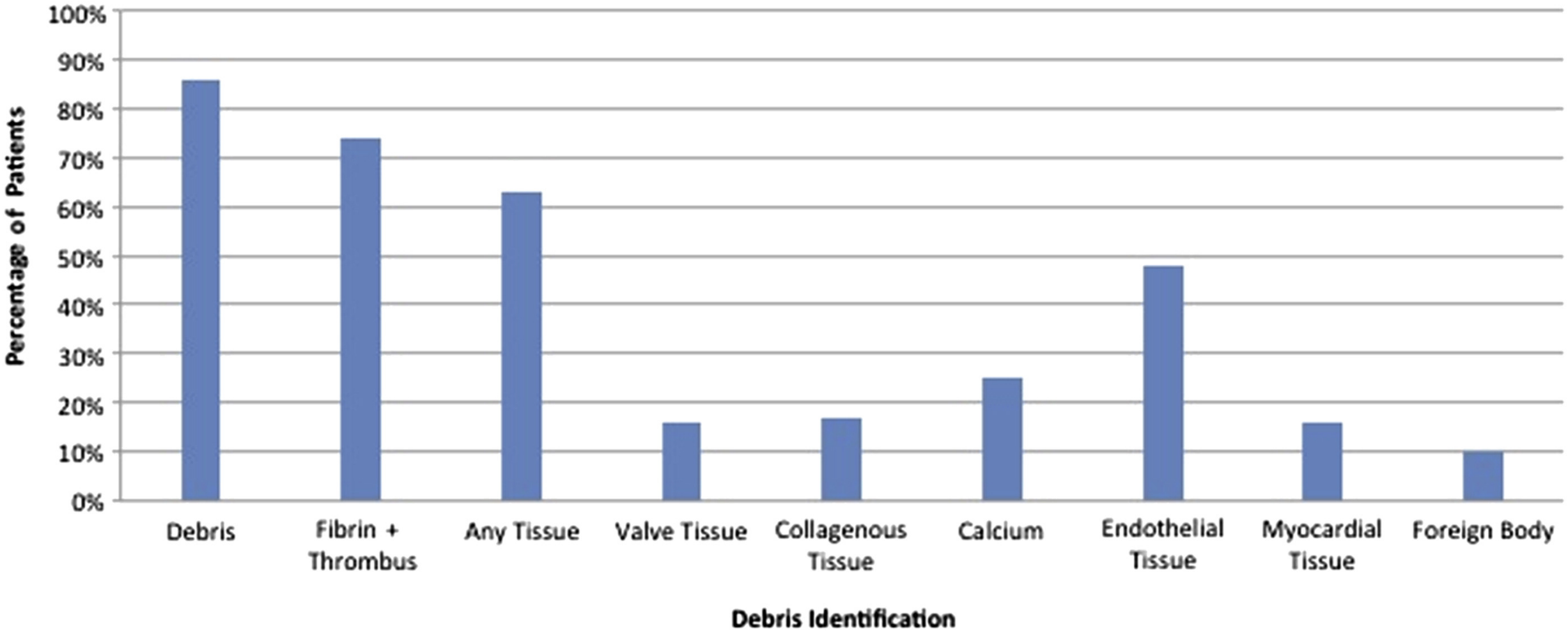


The Tel Aviv Sourasky Medical Center

RABIN MEDICAL CENTER
BEILINSON • HASHARON

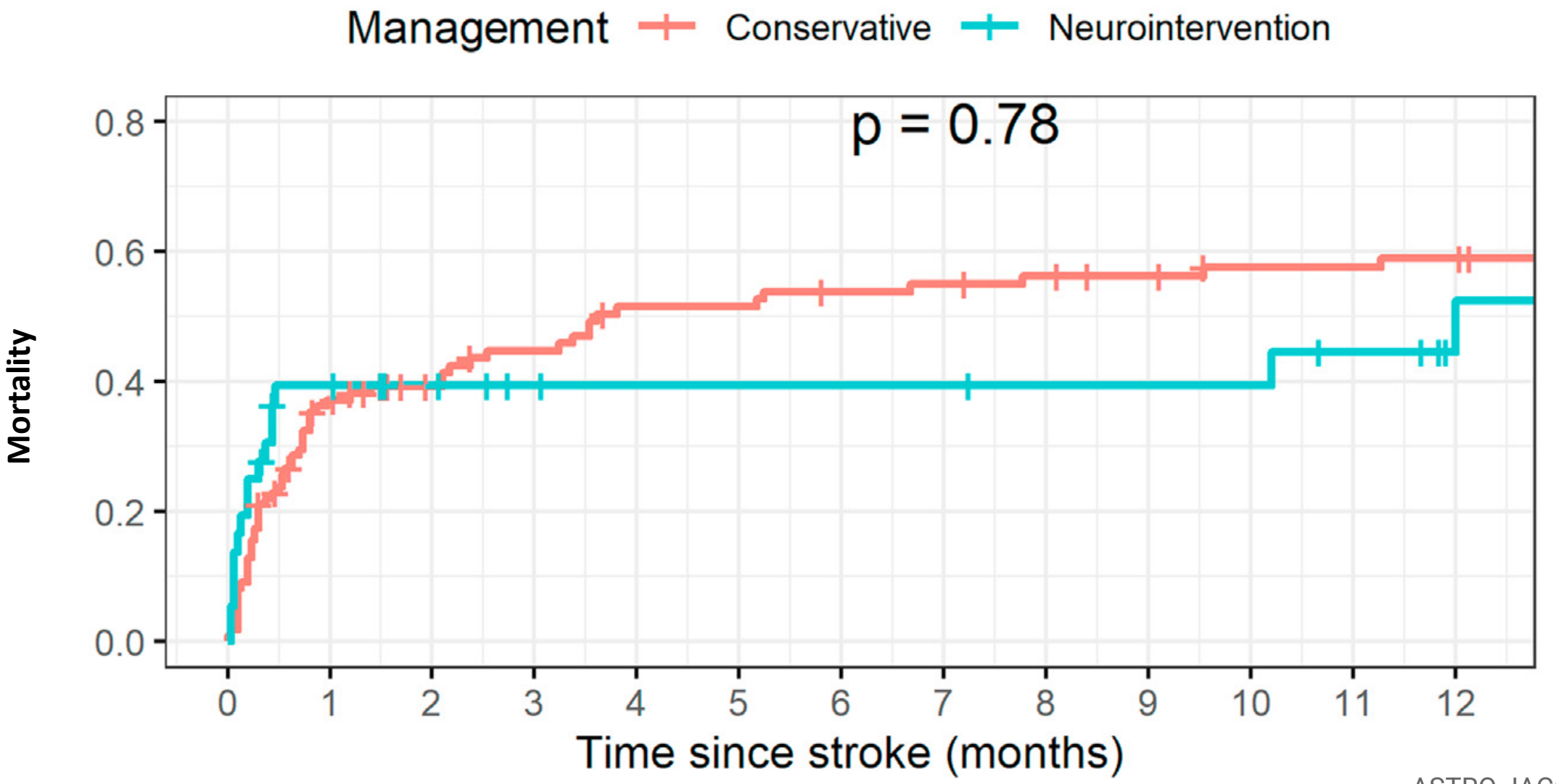
המרכז הרפואי שערי צדק

Pathological assessment shows variable debris content



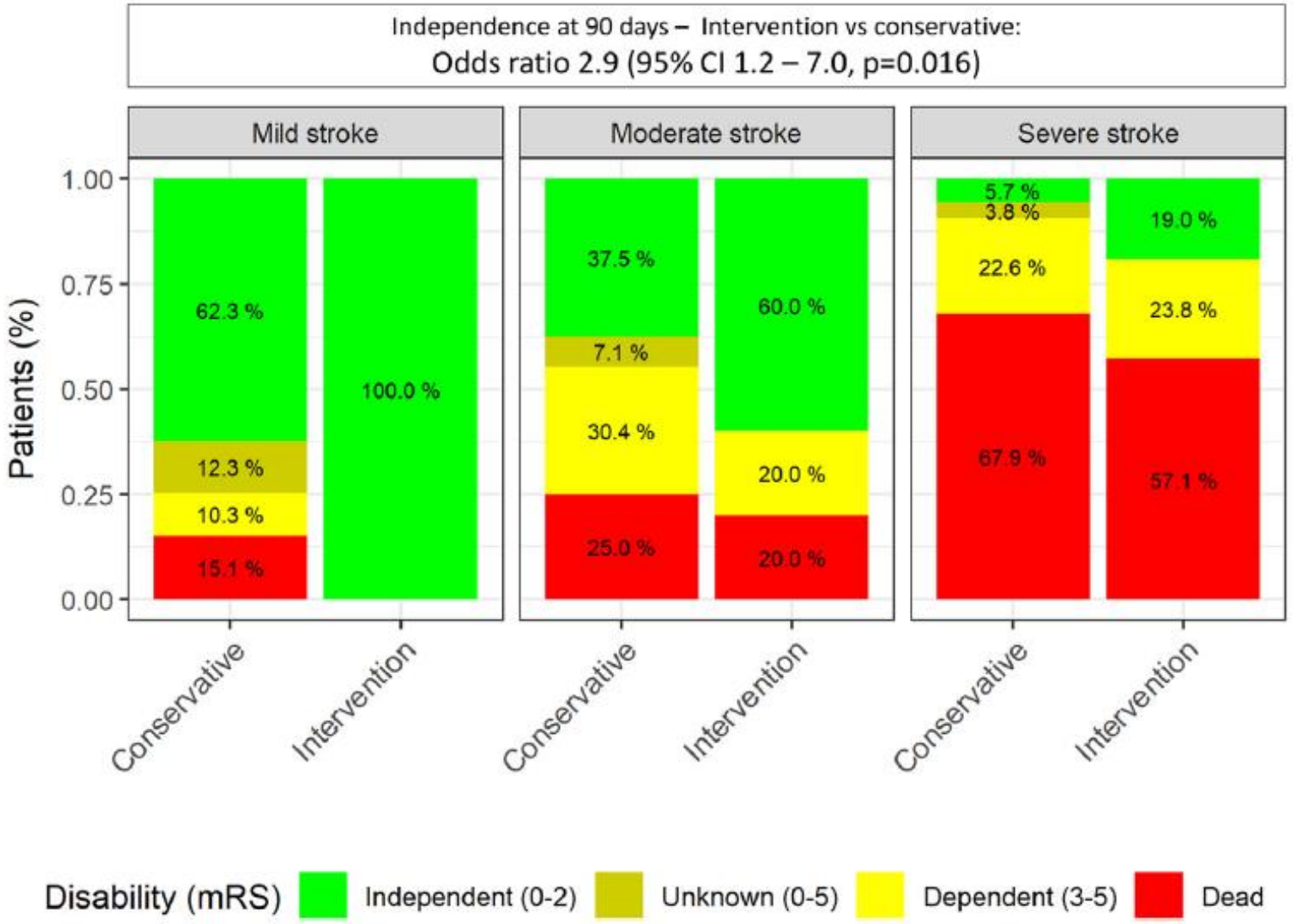
Nicolas M. Van Mieghem JACC Int 2015

Intervention for acute stroke has limited impact on survival



ASTRO JACC Int 2022

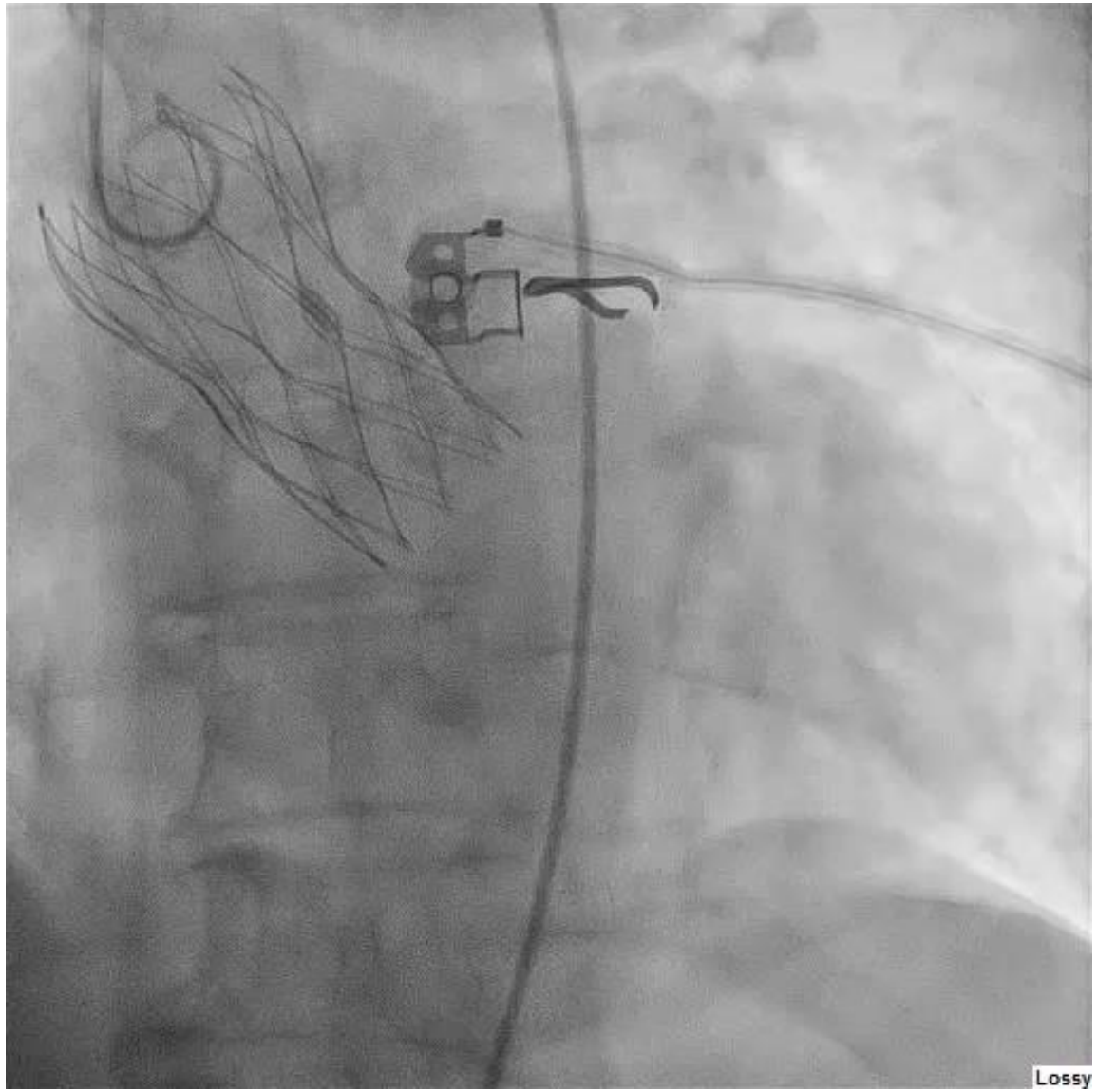
Neuro-intervention is associated with disability-free survival at 90 days



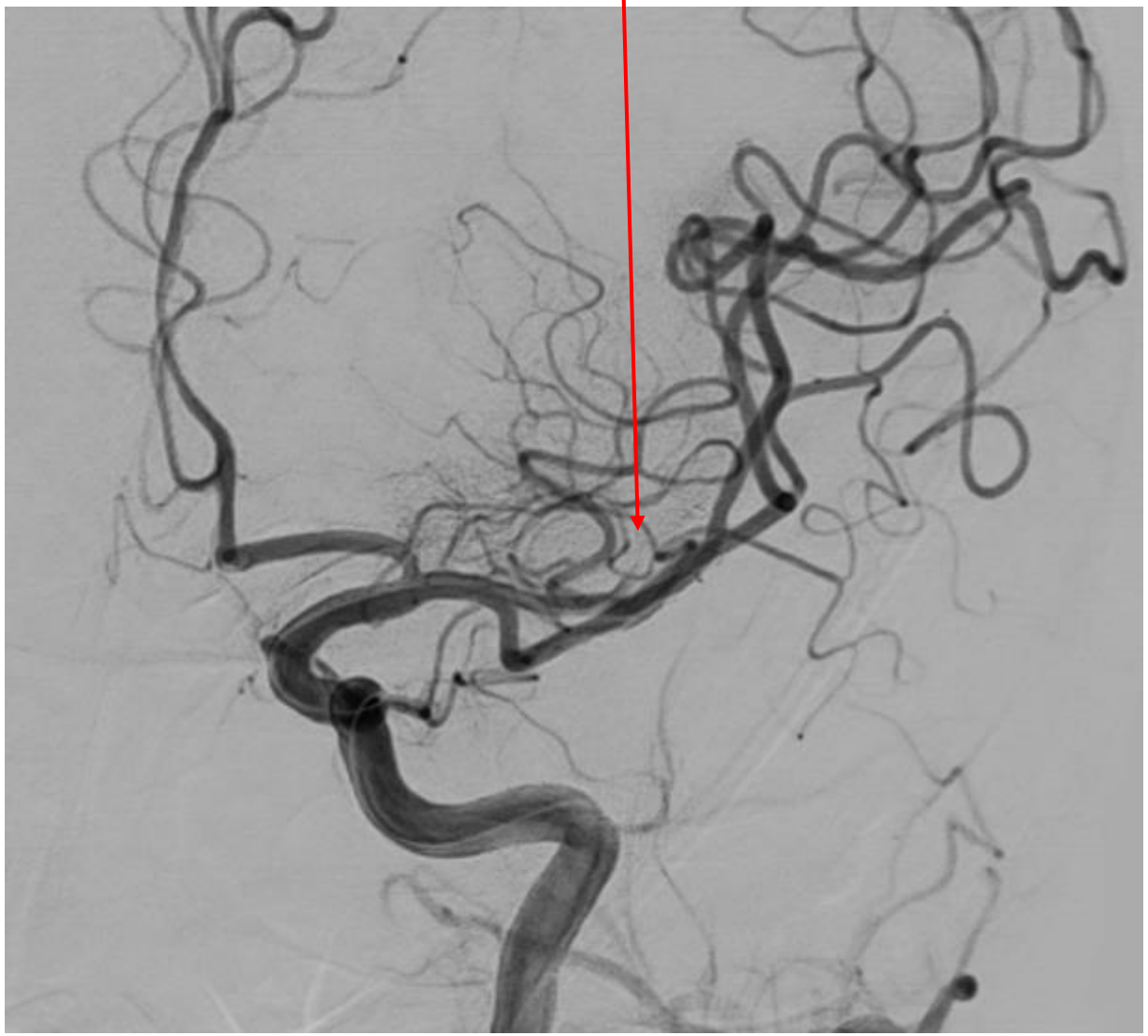
ASTRO JACC Int 2022

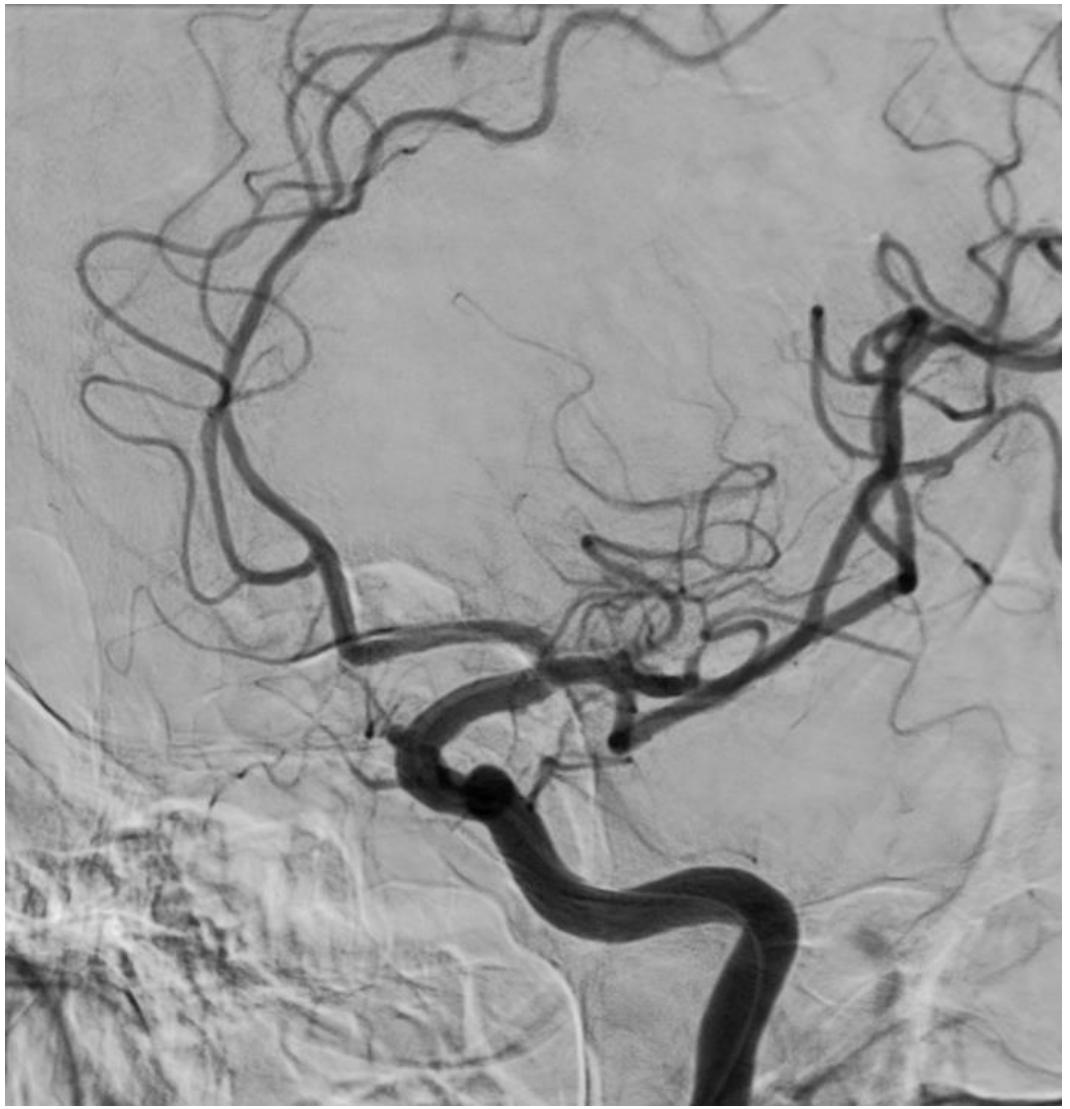
- 79 y/o women
- No significant co-morbidities
- Underwent direct Navitor 23mm Implantation

- During access closure developed aphasia and right hemiplegia



Acute occlusion of LT M2



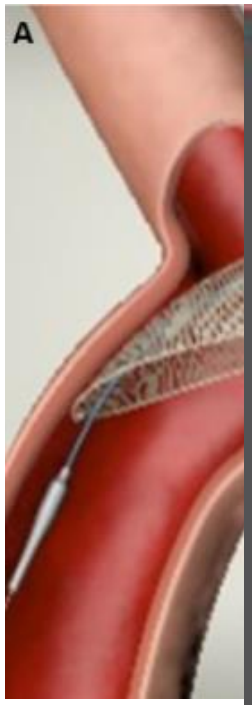


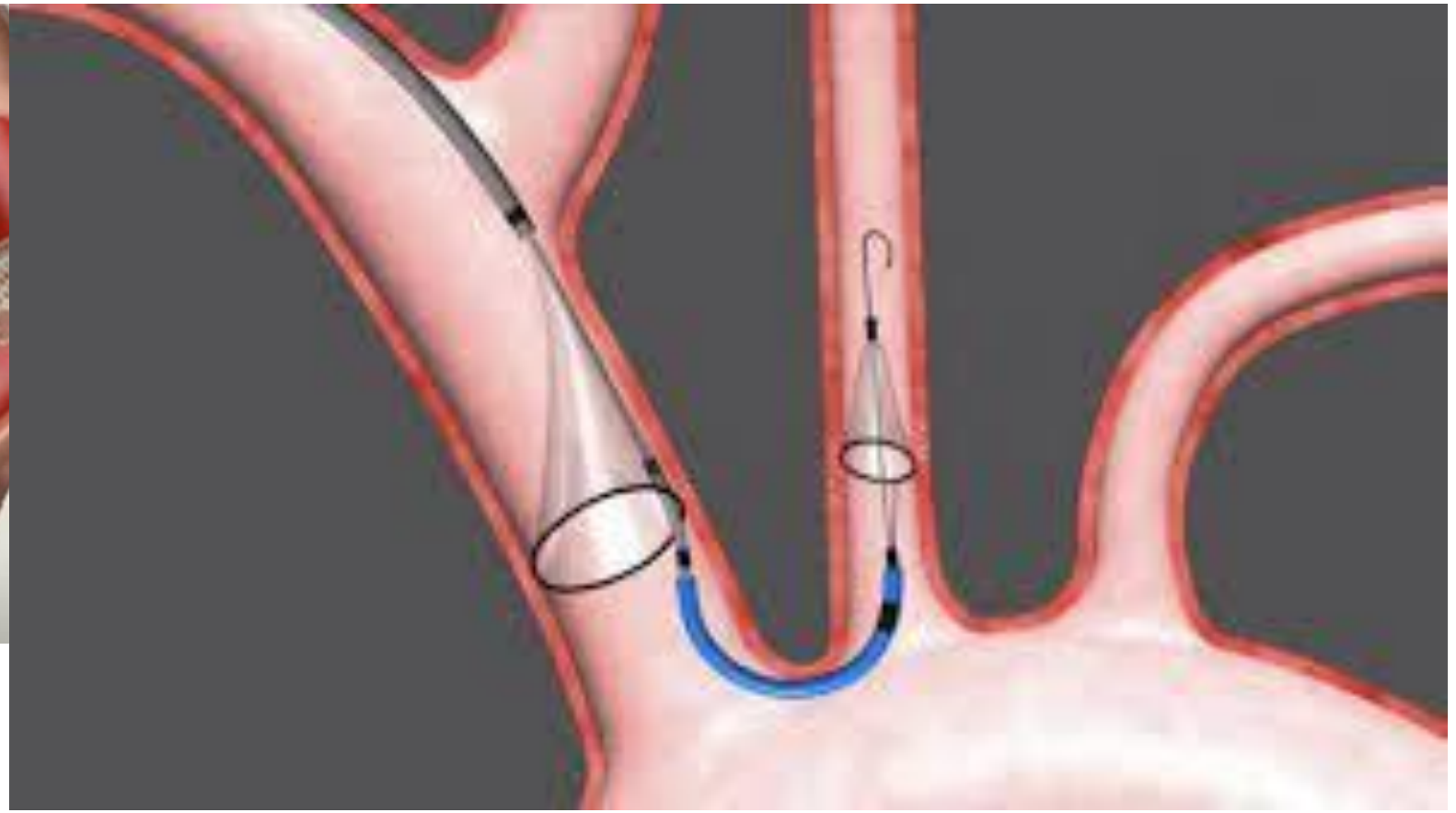
So what can be done to prevent stroke ?

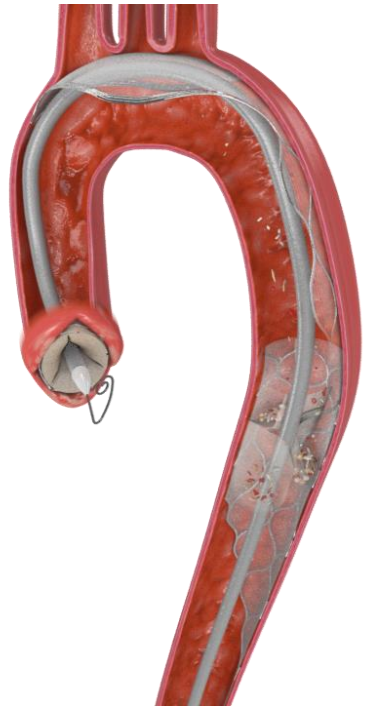
- **Utilization of embolic protection device?**
- **TAVI with uninterrupted OACS ?**
- **Anticoagulation post-TAVI ?**

Cerebral protection devices in TAVI

TriGUARD 3 **Sentinel** **Emboline** **Filterlex**



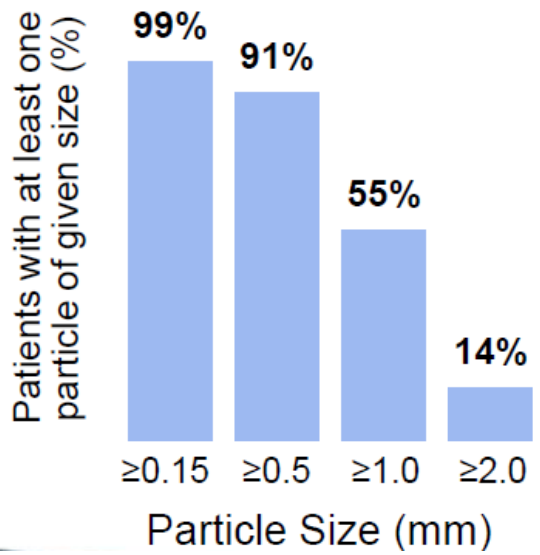




Promising early clinical data

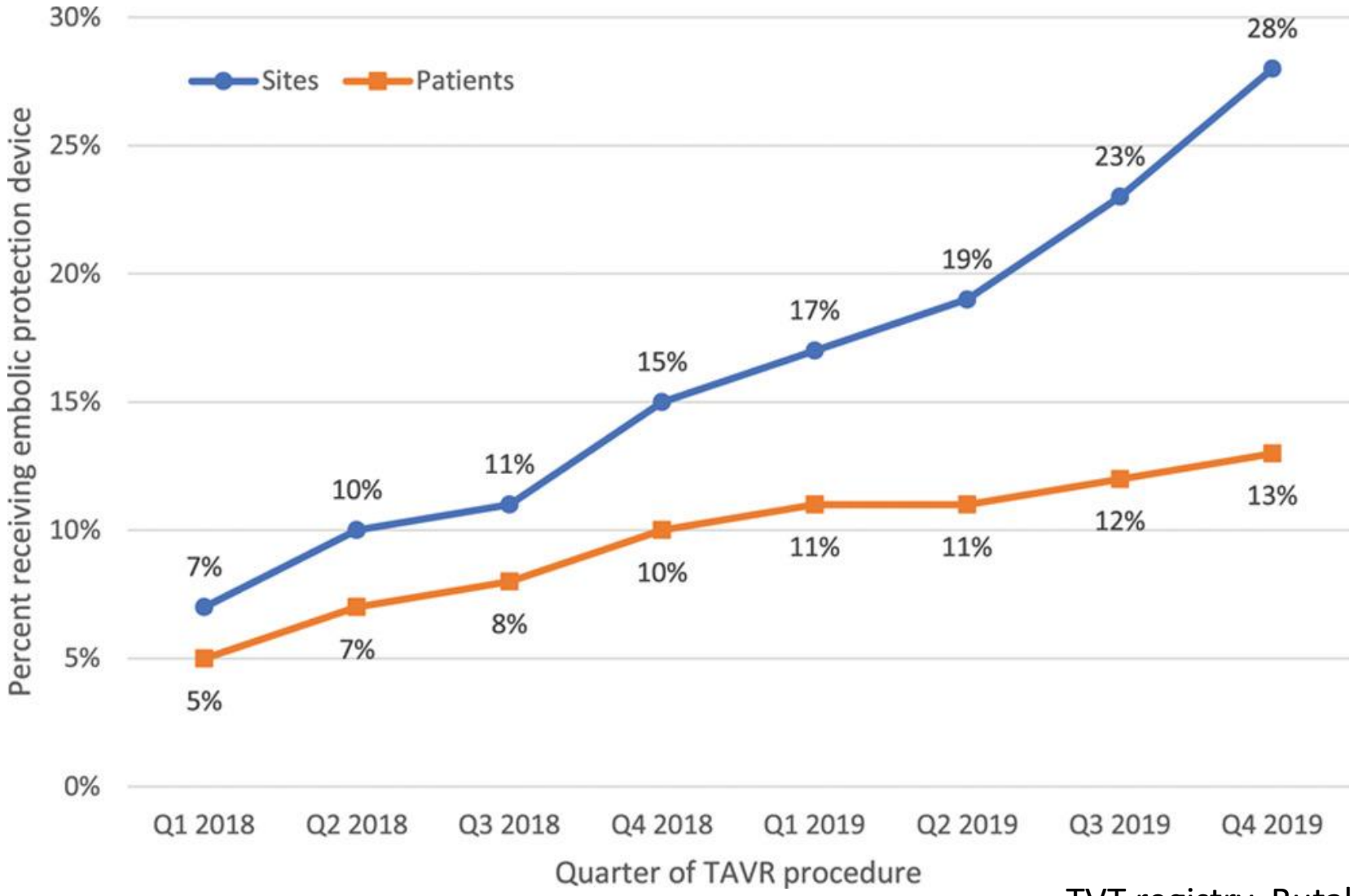
Sentinel IDE Trial[1] : 363 patients randomized 2:1 to TAVR with or without CEP

Captured debris in 99% of patients



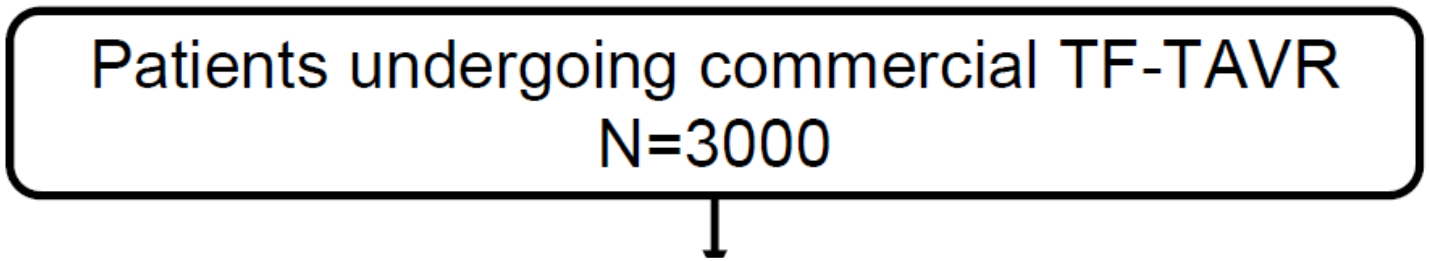
Kapadia JACC 2017

The promise of EPD
Increased utilization in the U.S.



TVT registry, Butala Circulation 2021

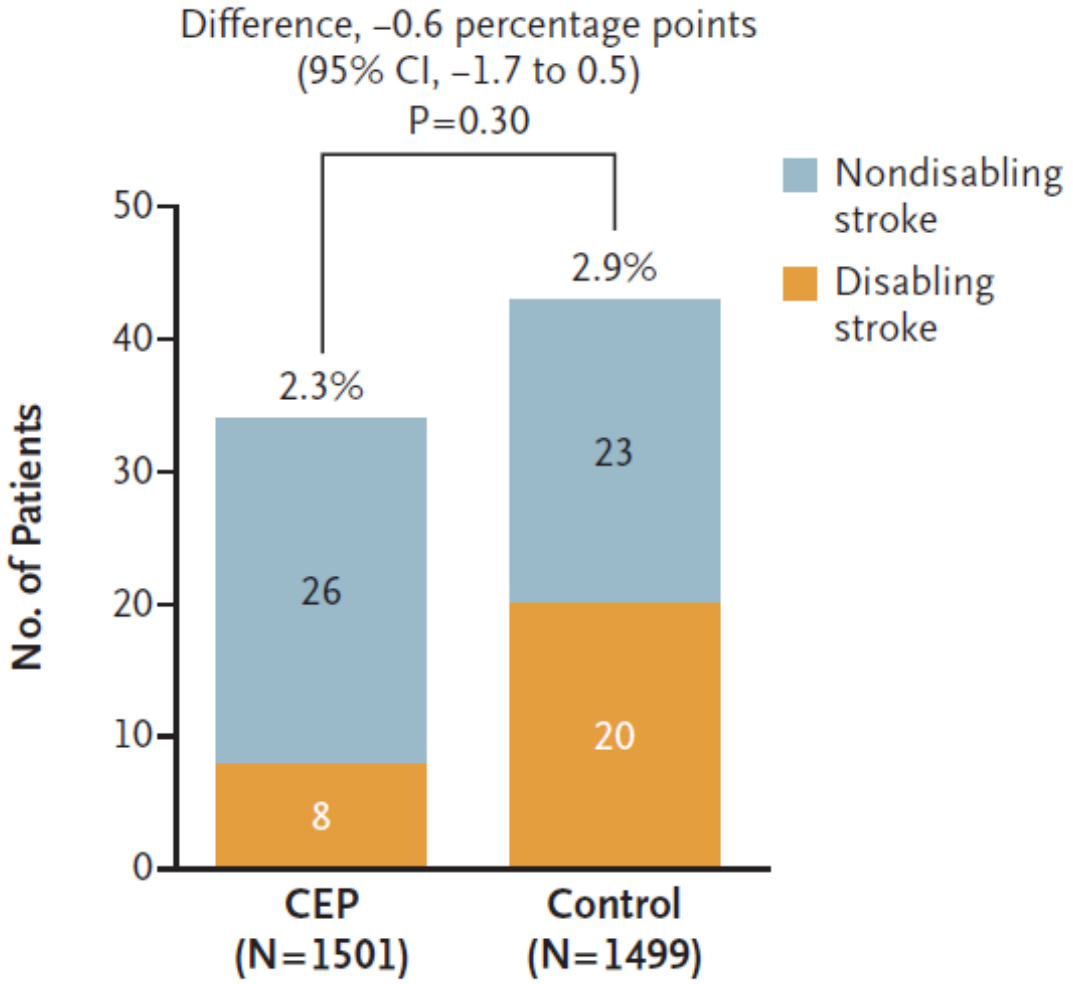
PROTECTED TAVR Study Design



- Patients of all risk categories eligible
- Any commercially available TAVR device

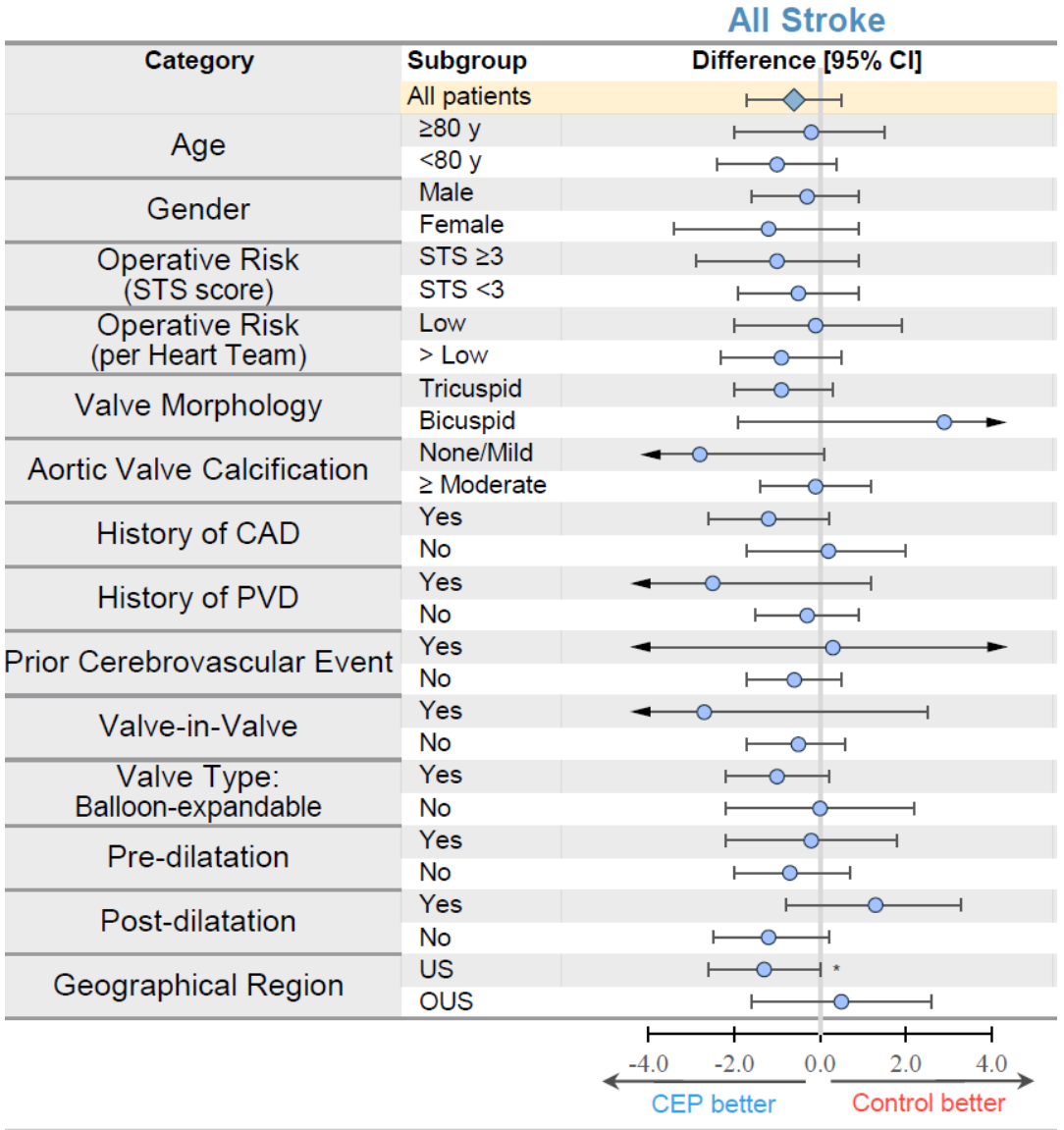
Primary End Point

No change in stroke within 72 Hours after TAVR or before discharge (ITT Population)

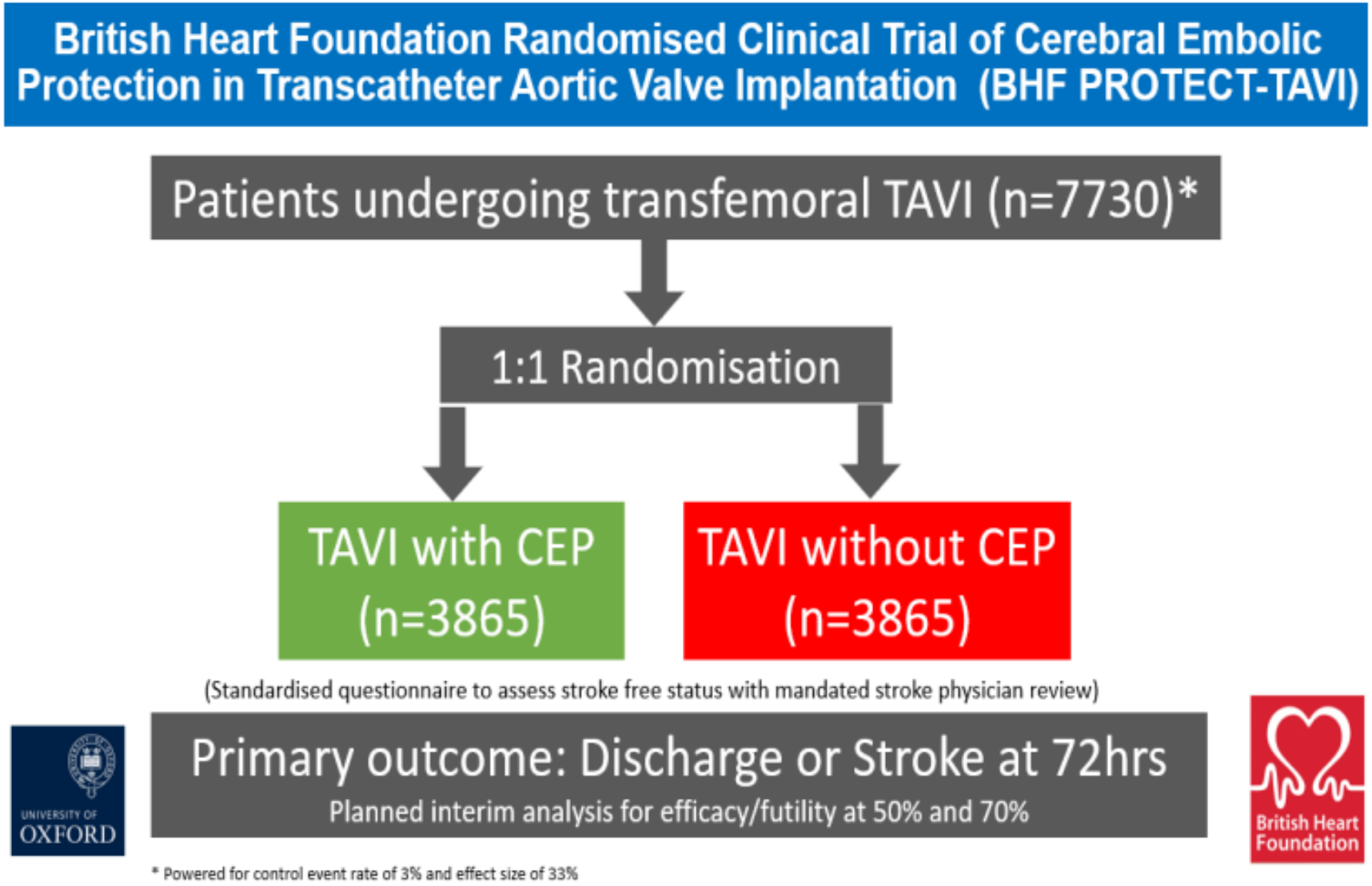


N Engl J Med 2022

No patient subgroup benefits from Sentinel protection during TAVI



BHF PROTECT-TAVI – awaiting results



Identify high risk patients for stroke

Pre-procedural parameters

- Female gender
- Prior atrial fibrillation
- Prior CABG
- Chronic pulmonary disease
- Low body mass index

Procedural parameters

- Acute kidney injury
- Major vascular complication
- Repeated device implantation attempts
- Balloon pre-dilatation
- Balloon post-dilatation

All studies assessed predictors for ANY stroke

Fink et al. Int J Crdiol 2017
Stortecky et al. EuroIntervention 2012
Bosmans et al. JACC 2015

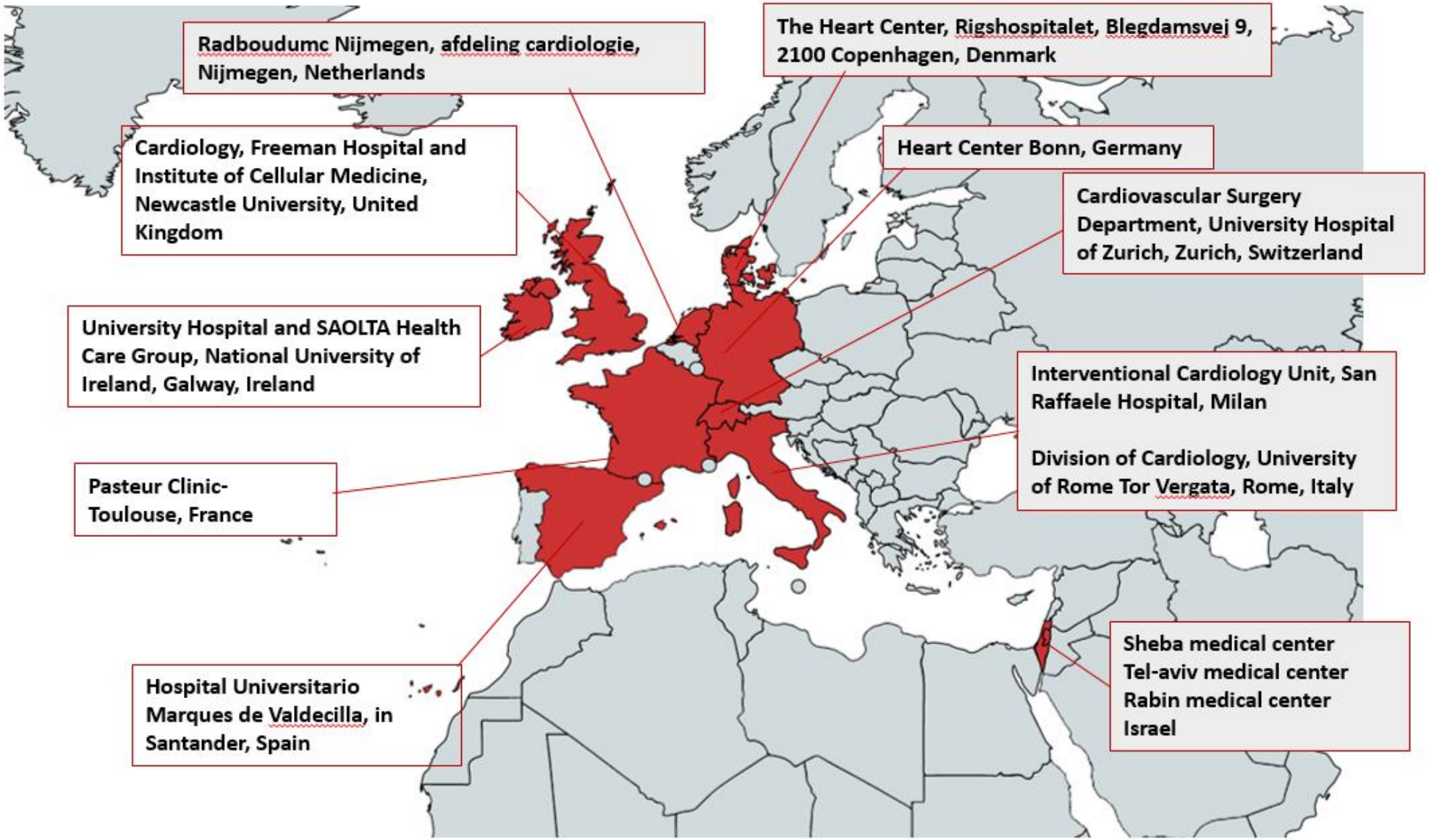
TASK study

Multicenter Transcatheter Aortic valve implantation in-hoSpital stroKe study (TASK study)

- To identify predictors for <u>acute</u> stroke
- To design a simple, clinically relevant, tool to identify high-risk patients for acute stroke after TAVI

Berkovitch et al. J Pers Med. 2022

12 International Sites



TASK score design

Inclusion criteria

- All comers study
- All valve types
- Trans-femoral approach

8,779 Patients

Primary end point

Stroke or TIA within 24 hours of TAVI

127 Acute stroke events

1.4% of all cases

TASK score design

- Utilization of pre-procedural parameters
- Parameters were derived from uni- and multi-variate analysis
- Equivalent power to each TASK score parameter

Baseline characteristics

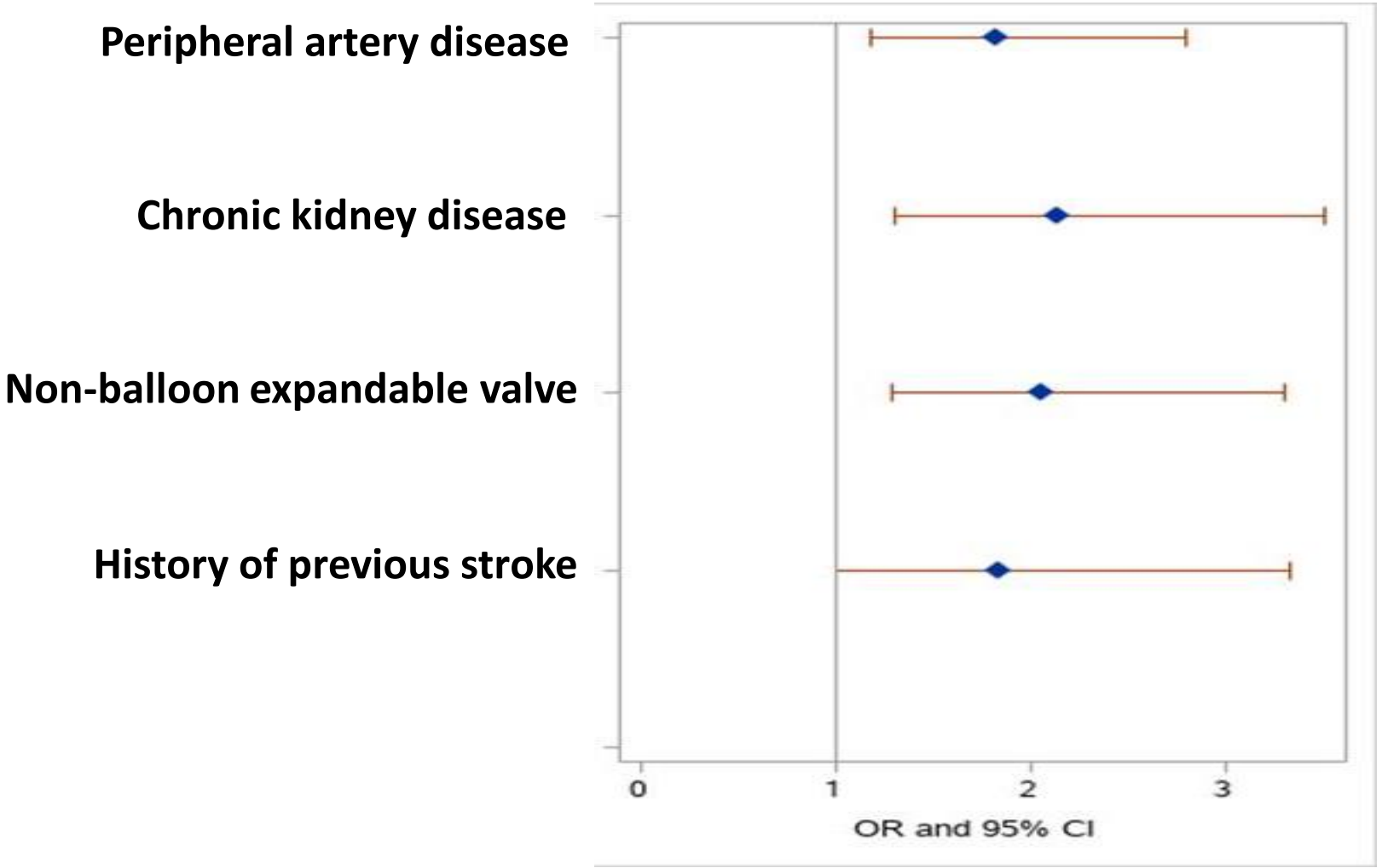
Variable	Acute stroke N=127	No acute stroke N=8652	P value
Age (mean±SD)	82.1±6.8	83.1±6.5	0.12
Female gender	57%	52%	0.27
Low body weight*	52%	40%	0.009
Ischemic heart disease	31%	31%	0.95
Chronic kidney disease**	82%	68%	<0.001
History of stroke	11%	7%	0.1
Atrial fibrillation	29%	32%	0.43
Peripheral vascular disease	29%	19%	0.005
Chronic lung disease	16%	17%	0.92

* Body mass index ≤25 kg/m^2
** Glomerular filtration rate <60 mL/min/1.73m^2

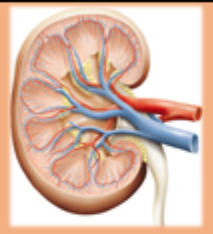
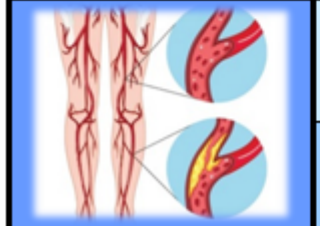
Procedural characteristics

Variable	Acute stroke N=127	No acute stroke N=8652	P value
Conscious sedation	29%	31%	0.67
Self-expandable valve	56%	52%	0.136
Balloon expandable valve	24%	37%	0.005
Mechanical expandable valve	12%	6%	0.001
Balloon pre-dilatation	53%	50%	0.46
Balloon post-dilatation	19%	19%	0.98

Multivariate cox regression analysis for acute stroke

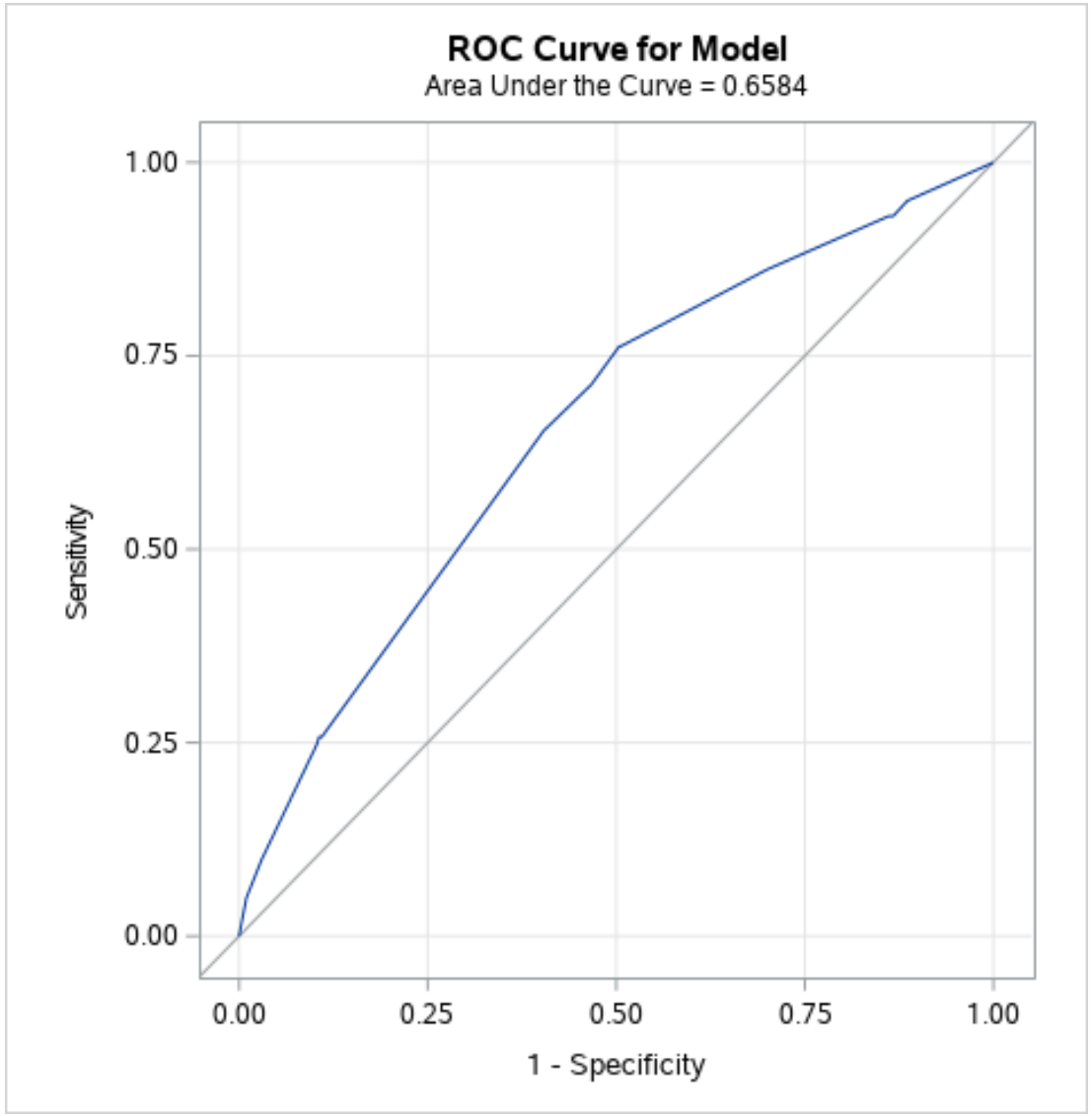


TASK score parameters

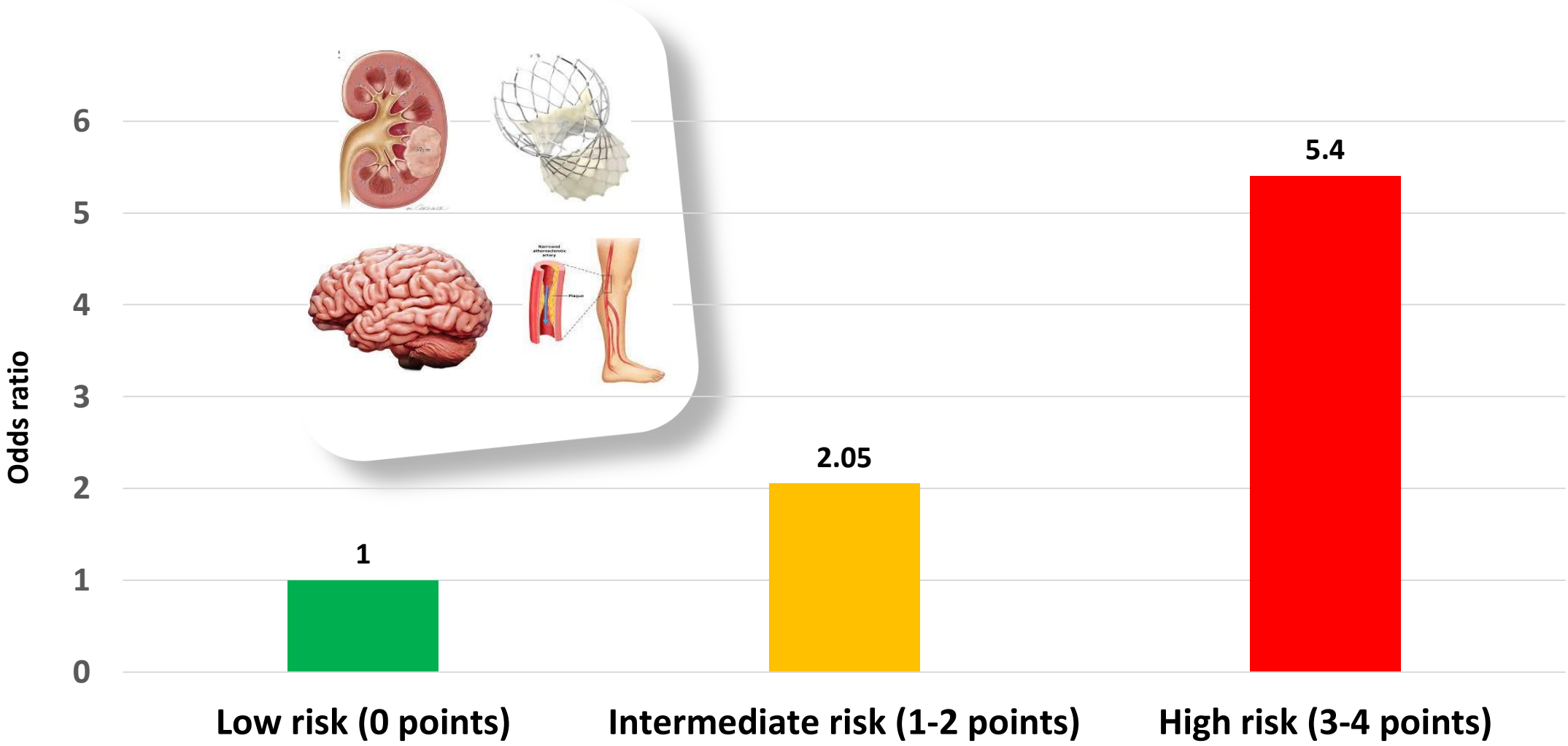
	No history of previous stroke		0 Points
	History of previous stroke		1 Point
	Normal Renal function	GFR≥60	0 Points
	Chronic Kidney disease	GFR<60	1 Point
	Balloon Expandable Valve		0 Point
	Non-Balloon Expandable Valve		1 Point
	No Peripheral vascular disease		0 points
	Peripheral vascular disease		1 Points

TASK points	Acute stroke rate
0	0.7%
1	0.8%
2	2.1%
3	3.4%
4	7.8%

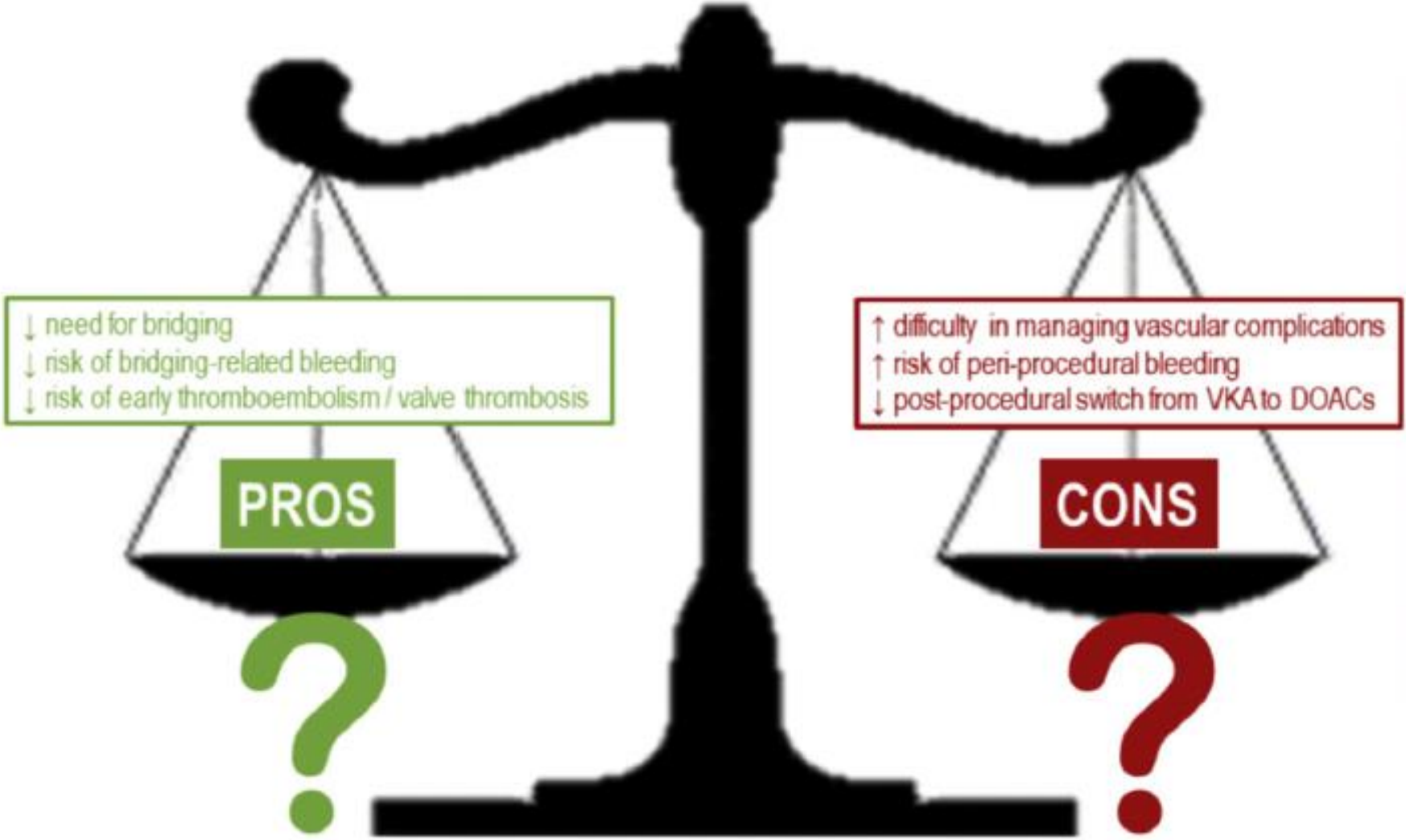
Receiver operator curve



Relative risk of acute stroke according to TASK score

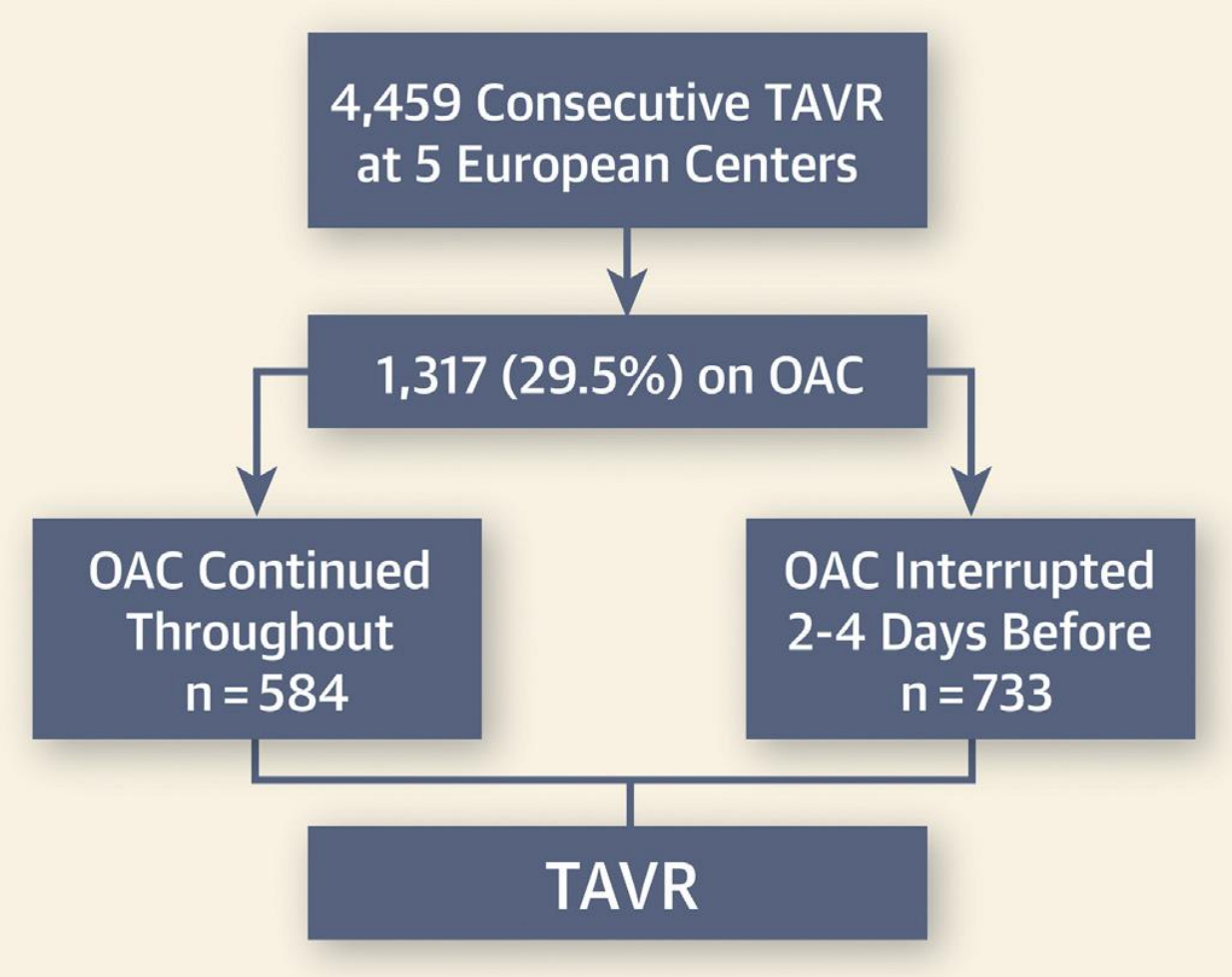


OAC continuation during TAVI
Balancing the risks and benefits



Retrospective assessment of VKA/NOAC continuation during TAVI: Study design

VKA / NOACS ratio
50 / 50 %

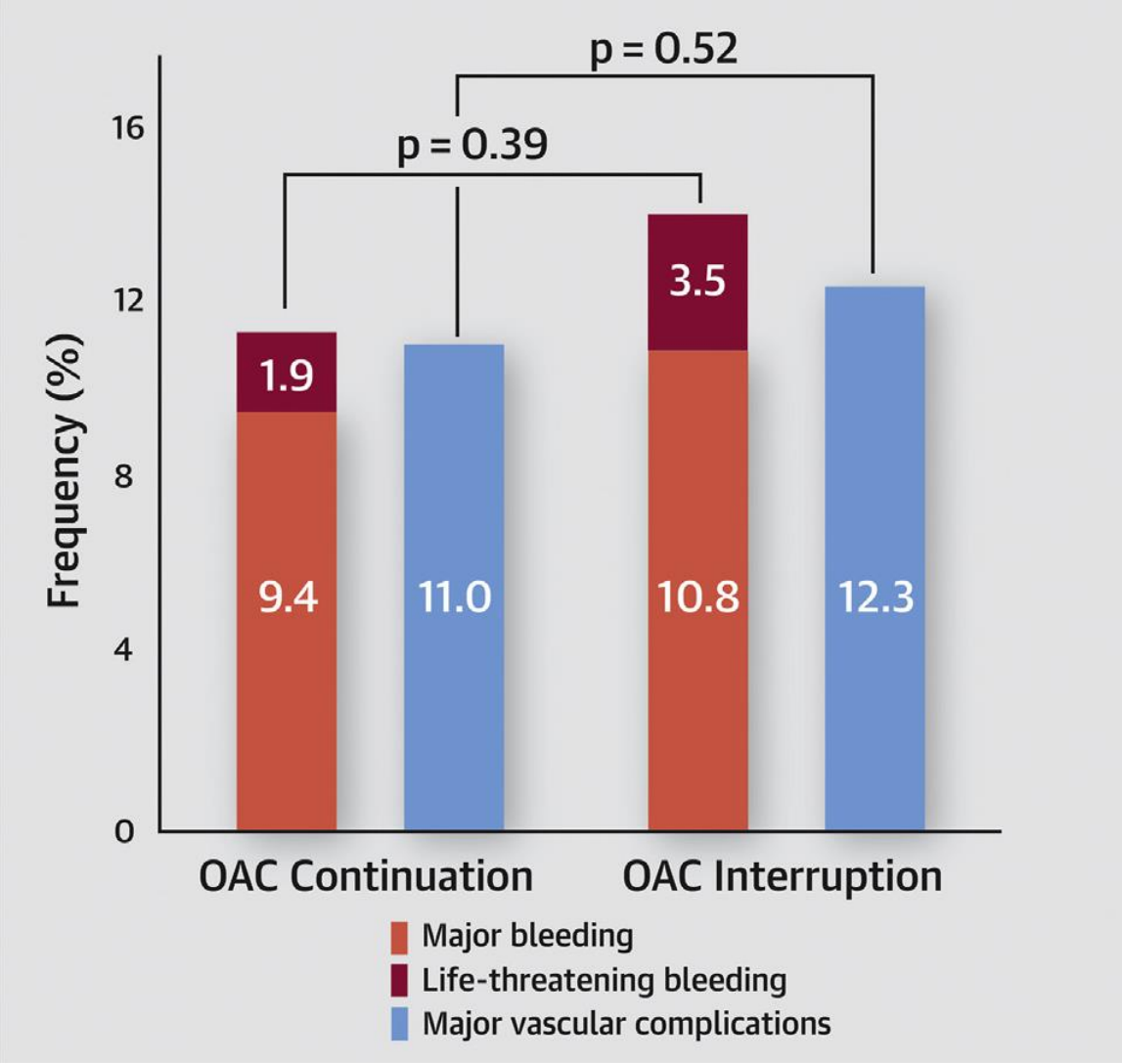


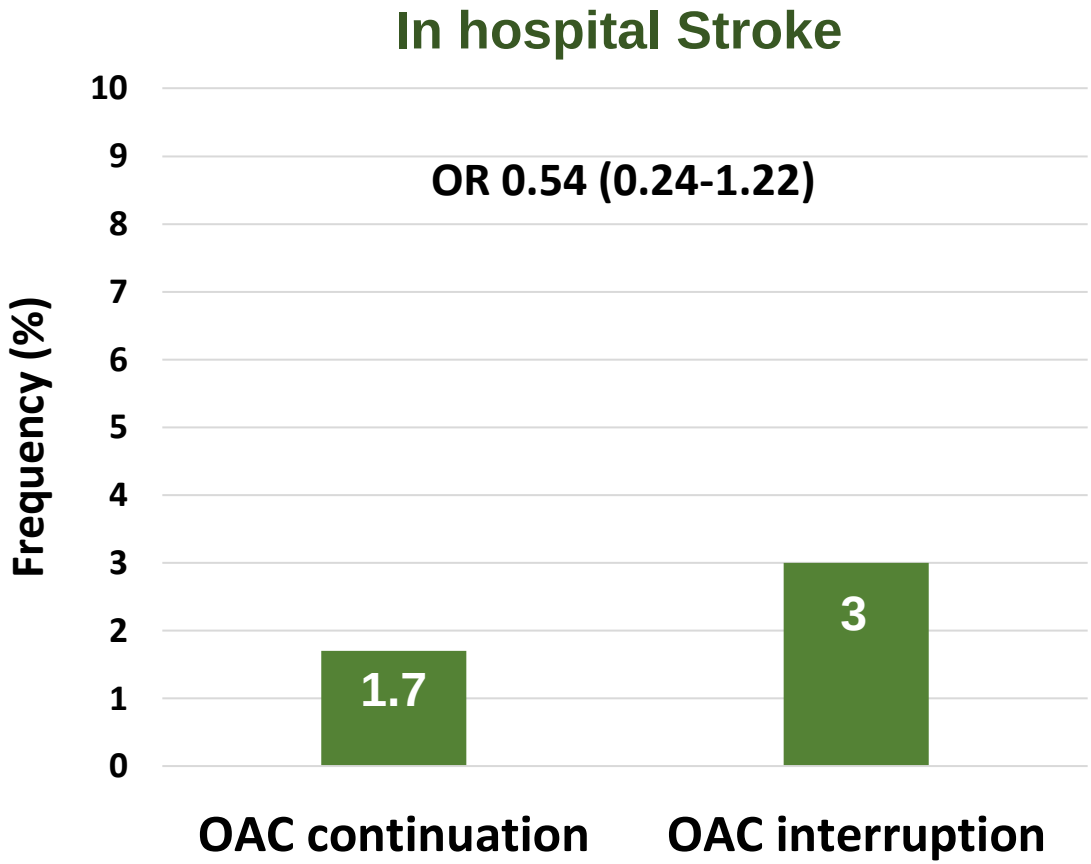
VKA / NOACS ratio
70 / 30 %

Primary safety outcome was major bleeding

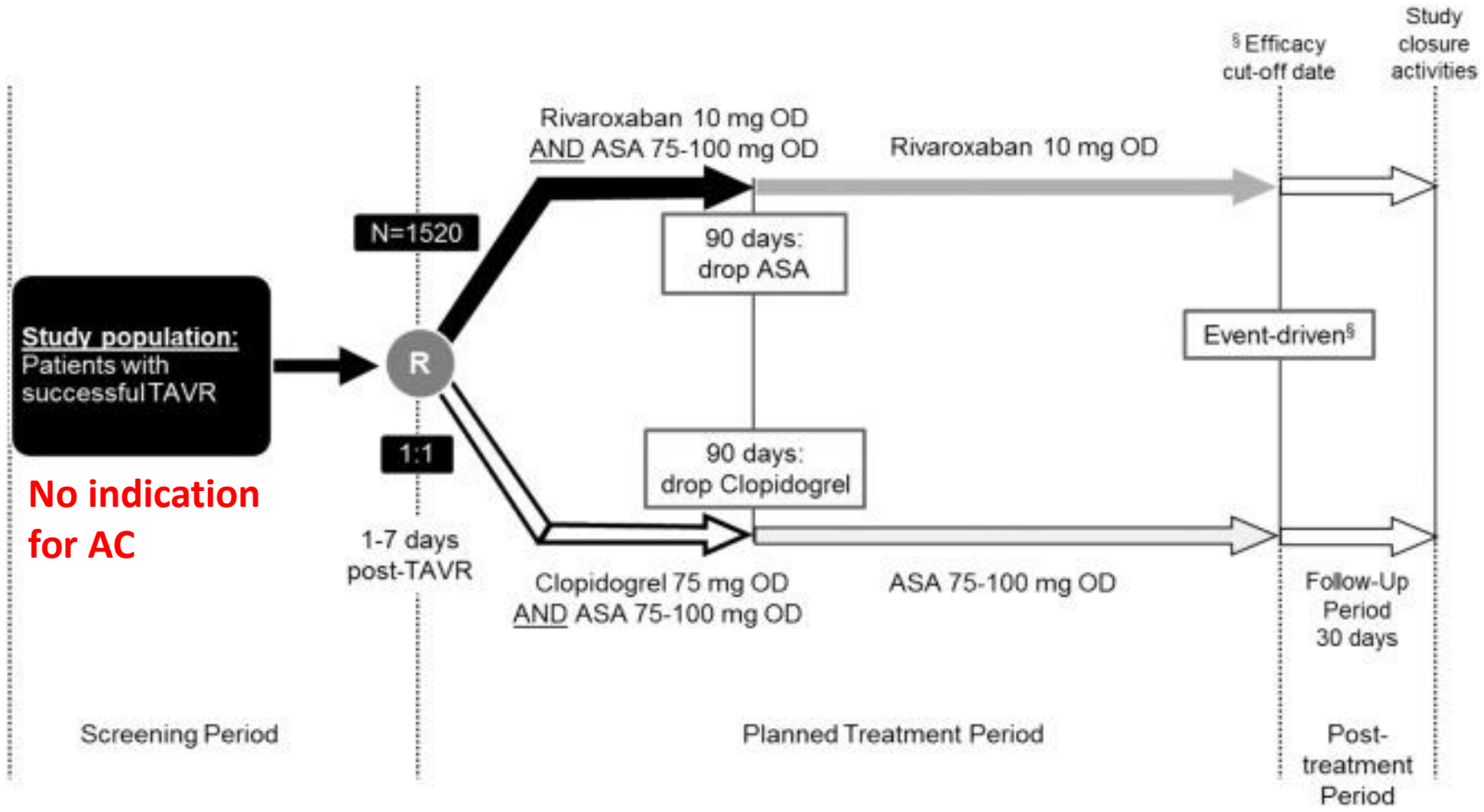
Brinkert JACC Int 2021

VKA / NOACS continuation during TAVI does not increase bleeding



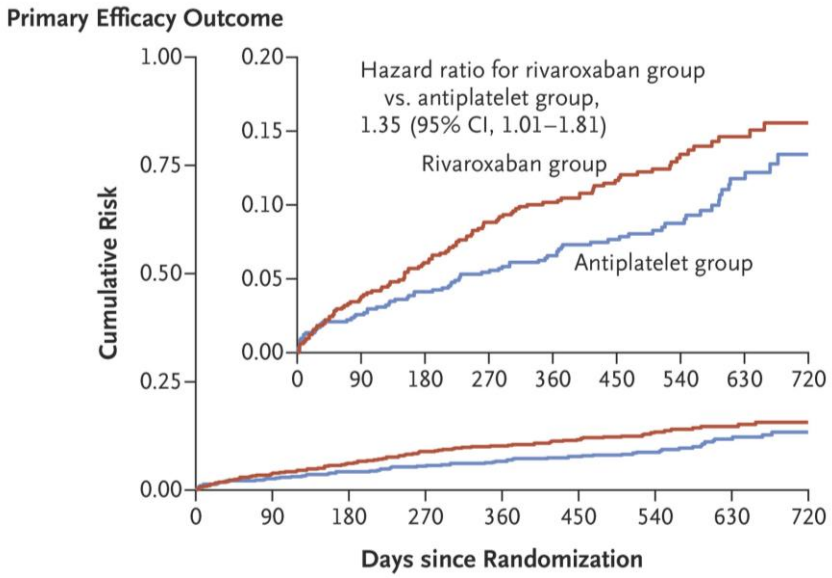


GALILEO trial – Post-TAVI NOACS

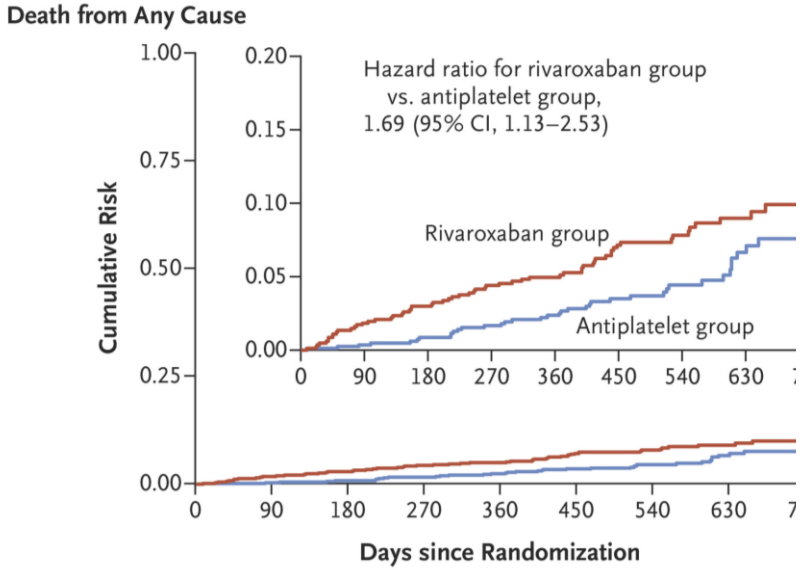


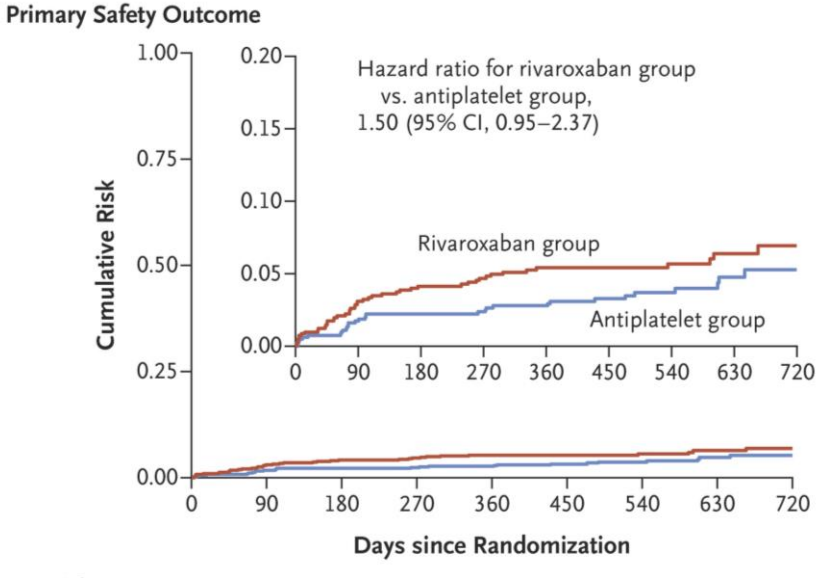
G.D. Dangas and Others
N Engl J Med 2020; 382:120-129

Post-TAVI OAC is harmful



Composite of death, stroke, MI, symptomatic valve thrombosis, PE/DVT, or systemic embolism





Composite VARC life-threatening, disabling, or major bleeding.

Summary

- TAVI-associated strokes are rare, but devastating complication
- Routine use of embolic protection devices is questionable
- A paradigm shift to identify & target high-risk stroke patients may provide means to impact this complication
- OAC continuation during TAVI may prove as a safe approach