

BHF PROTECT-TAVI Trial Design¹



7635 patients with aortic stenosis in a 1:1 ratio to undergo TAVI with and without Sentinel device

PRIMARY ENDPOINT: Incidence of all stroke at 72-hours after TAVI

EuroSCORE II	CEP Group	Control Group
Low: <4%	44/2124 (2.1)	39/2180 (1.8)
Intermediate: 4 to 8%	15/554 (2.7)	18/529 (3.4) ←
High: >8%	3/215 (1.4)	8/210 (3.8) ←

Outcome	CEP Group (N = 3798)	Control Group (N = 3803)	Treatment Effect	
			Risk Difference (95% CI) [†]	Risk Ratio (95% CI) [†]
Primary outcome	no./total no. (%)		percentage points	
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) [‡]

RESULTS

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No substantial differences in the incidence of all strokes between the two arms **at 72 hours post-TAVI**.

Why?

74% of the total participants are **Low Risk patients** (Median 2,4% EuroSCORE II) **with ~2% Stroke Occurrence**.

EuroSCORE II is not a stroke risk predictor, but stroke incidence increases from 1.8% in low-risk patients to 3.8% in high-risk patients, highlighting the need to identify specific risk factors and carefully select patients for inclusion.

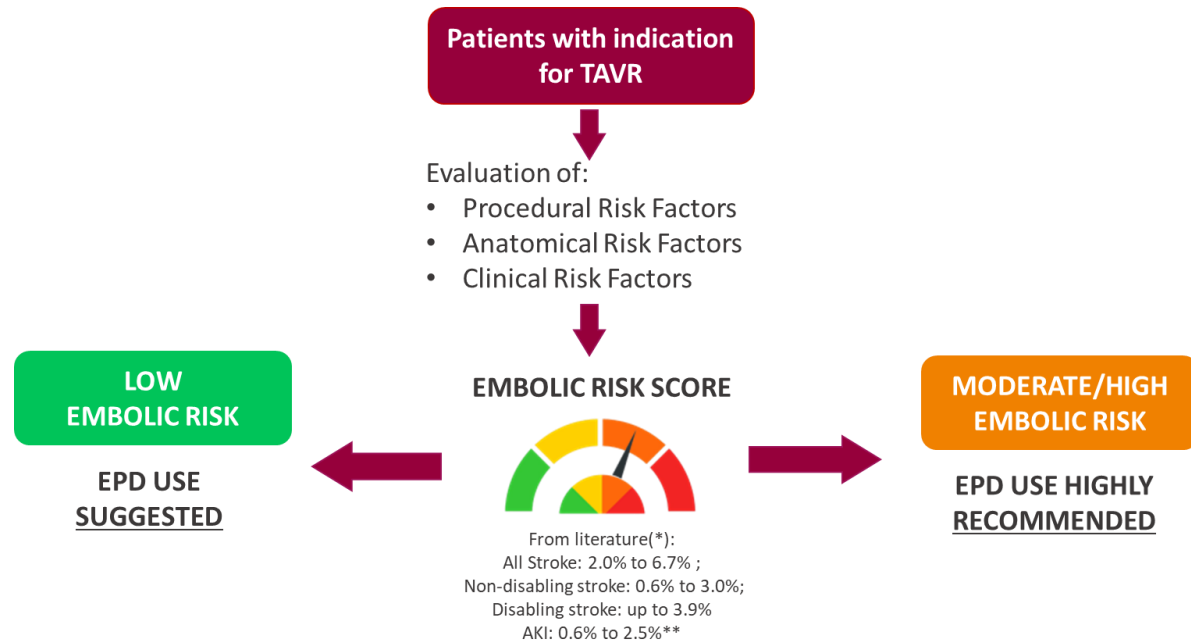


"We need to understand which patients are at higher risk of stroke during TAVR and whether a more stratified approach to delivering therapy to those people is beneficial"
said Kharbanda (BHF PROTECT-TAVI Trial Principal Investigator).

¹ Kharbanda et al. Routine Cerebral Embolic Protection during Transcatheter Aortic-Valve Implantation. *N Engl J Med*

Embolic Risk Factors Calculation

The BHF data highlight the importance of a careful patient selection process to **preliminarily identify individuals at high risk of stroke**.



Aorticlab has been developing a **dedicated tool** to support clinicians in guiding patient selection based on individual stroke risk profiles.

The Renaissance of Embolic Protection

FLOWer provides stroke risk protection for TAVI patients, with particular effectiveness for those who stand to benefit the most from embolic protection.



FLOWer
 WITH CATCH & FLOW TECHNOLOGY



FLOWer is indicated for the protection of all TAVI patients, but proves particularly effective in those with moderate to high embolic risk – **representing ~25% of the overall TAVI population**. In this group, **stroke occurrence exceeds 3.5%**, more than double the rate observed in low-risk patients.