



A Patient Level Pooled Analysis of NeuroProtection with the TriGuard Embolic DEFLECTION Device Compared to Unprotected Transcatheter Aortic Valve Replacement

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☐ **I do not have any potential conflict of interest**

☒ **X I have the following potential conflicts of interest to report:**

Honorarium:

Institutional grant/research support: Keystone Heart

Consultant:

Employment in industry:

Owner of a healthcare company:

Stockholder of a healthcare company:

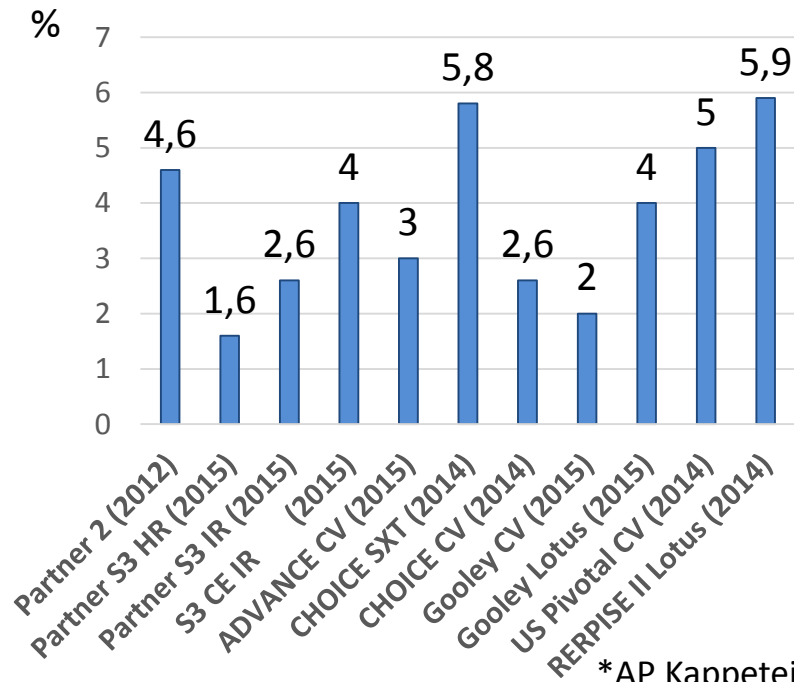
Other(s):

Clinical Stroke after TAVR

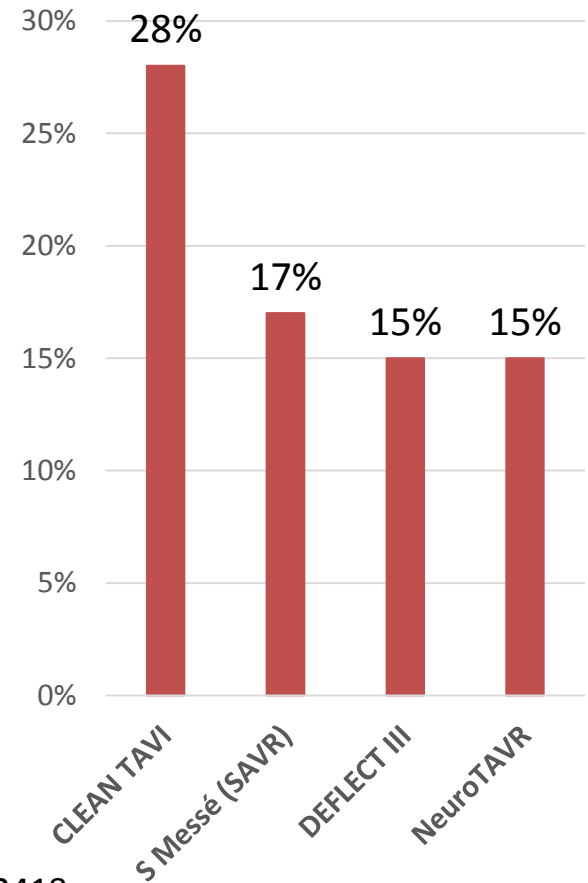
- 1.5-6% at 30 days in recent RCTs
- Confer 3- to 9-fold increased risk of mortality

- Neurologist identified deficits with + Brain MRI lesions
- Stroke range is 15-28%

30-day stroke rates in recent RCTs



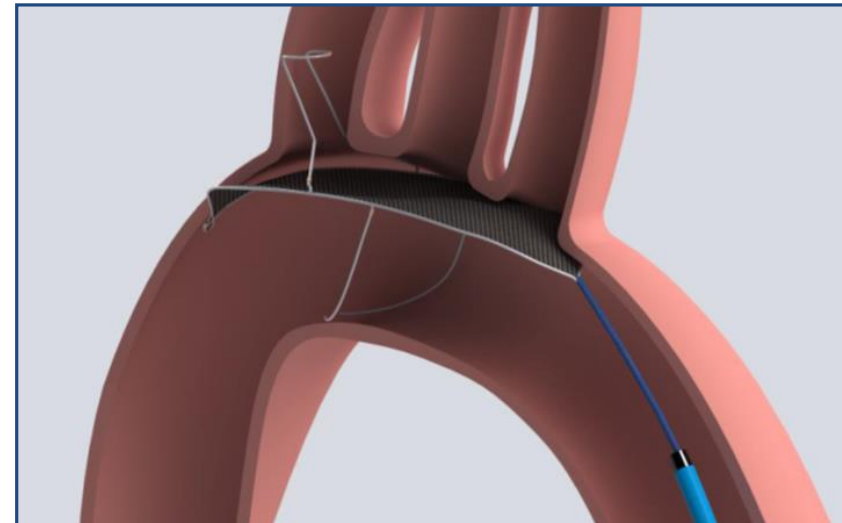
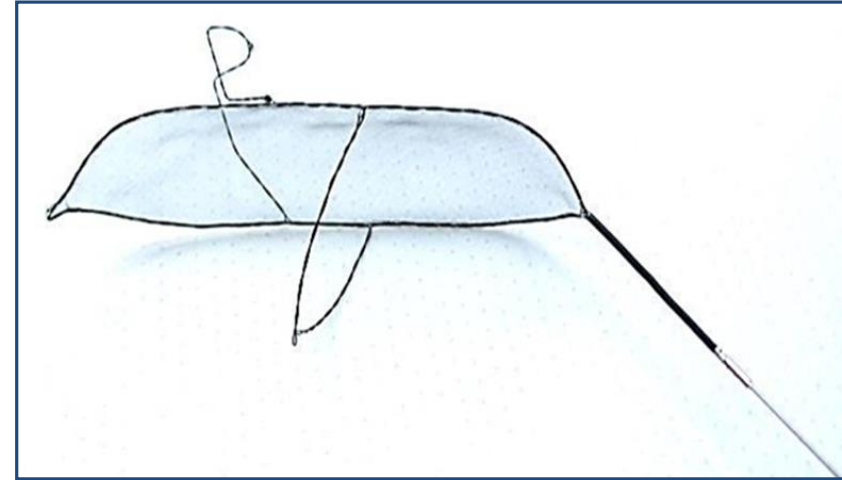
Stroke is under-reported in trials



*AP Kappetein et al. EHJ (2012) 33, 2403–2418;

**Sacco et al. Stroke. 2013;44:2064-2089

- Single-wire nitinol frame and mesh filter with pore size of $130\mu\text{m}$ designed to deflect cerebral emboli during TAVI while allowing maximal blood flow
- Positioned across all 3 cerebral vessels and maintained by a stabilizer in the innominate
- Delivered via 9 Fr sheath from the femoral artery



Objective and Methods

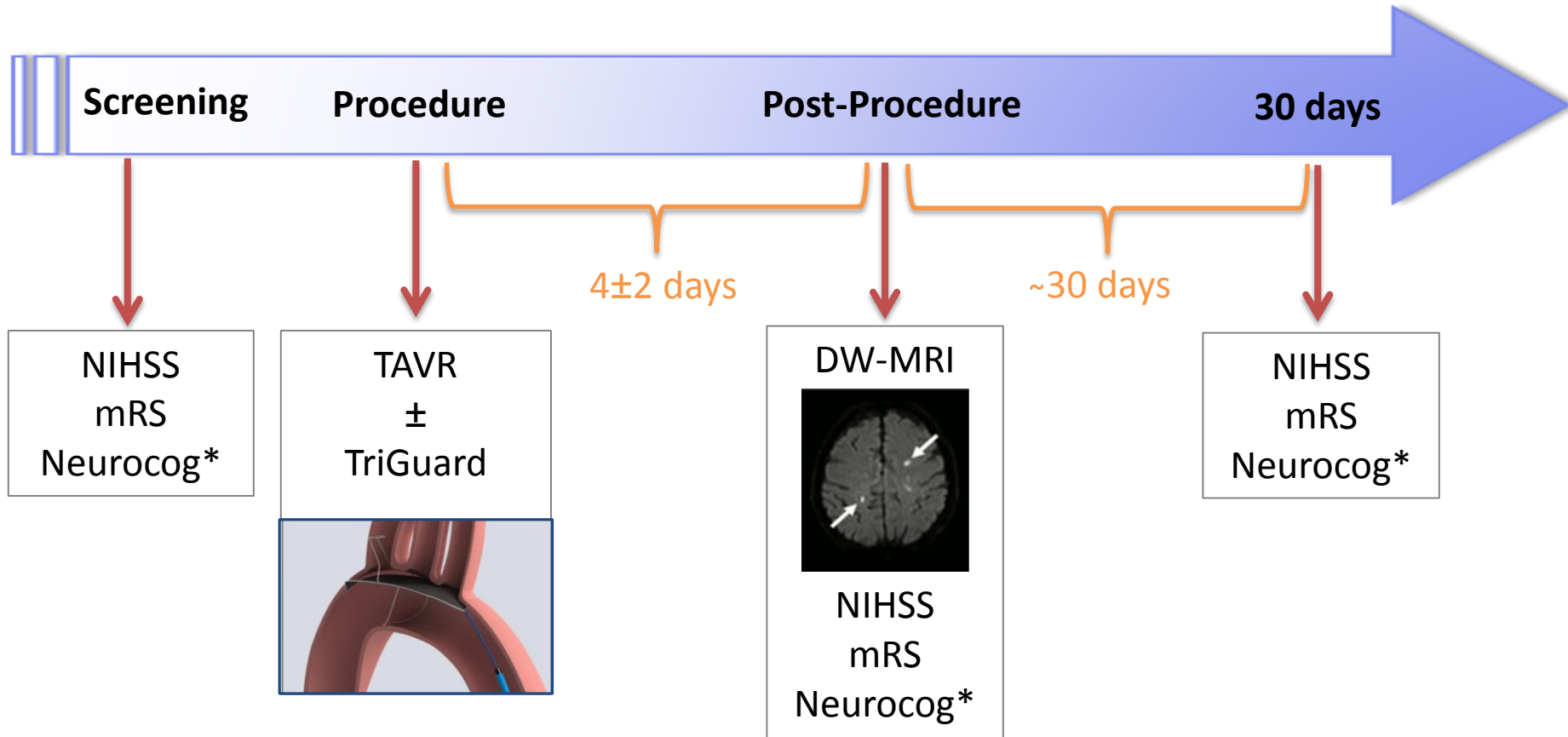
- **Objectives:** To evaluate the safety and efficacy of the TriGuard device as an adjunct to TAVI compared to no protection in an expanded patient level pooled analysis of 3 prospective clinical trials
- **Methods:** A total of 142 patients (TriGuard N=59 vs Controls N=83). This per-treatment analysis includes all TG patients with adjudicated complete cerebral coverage. Trials included:
 - DEFLECT I: A registry of 23 patients with TriGuard
 - DEFLECT III: A randomized trial of 36 patients with TriGuard and 44 Controls
 - NeuroTAVR: A registry of 44 control patients
- **Endpoints:**
 - MACCE: all death, stroke, bleeding, AKI, Vasc Complications
 - Stroke: VARC2 defined * and AHA/ASA defined:**
 - CNS infarction: Number and Volume New MRI lesions
 - Worsening NIHSS and cognitive function (MoCA)

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Procedures & Assessments

All 3 trials used same methodology, definitions, MRI Core Lab and CEC



***Neurocognitive test battery** includes the Montreal Cognitive Assessment (MoCA) and computerized CogState Research Test. Baseline and 30-day evaluations include supplemental Digit Symbol Substitution, Trailmaking, and Word Fluency Tests.

Baseline Demographics

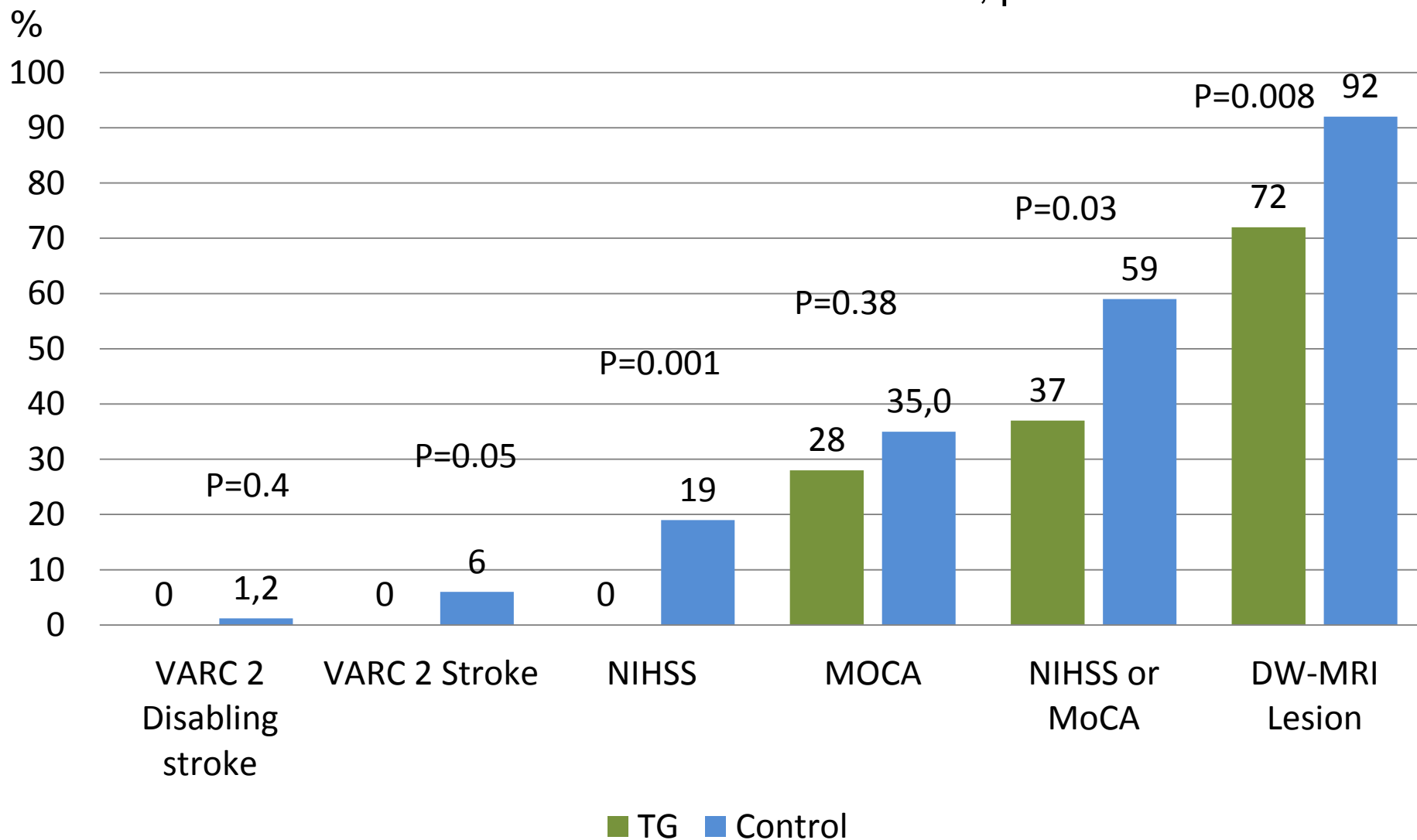
ITT population	TriGuard N=59	Controls N=83	P value
Age (y) ± SD	82.6 ± 6.7	82.8 ± 6.4	0.94
Male	34%	58%	0.005
STS Score	4.7	7.4	0.48
EuroSCORE II	5.3	6.8	0.78
NYHA Class			
III or IV (%)	41.1%	61.0%	0.13
LVEF %	56 ± 12	55 ± 13	0.72
A Fib on admission	22.0%	36%	0.36
CKD	20.3%	21.7%	0.85
COPD	23.7%	32.9%	0.24
O ₂ Dependent	5.6%	2.5%	0.4
Previous stroke/TIA	8.5%	16.9%	0.15
Frailty	11.9%	18.4%	0.42
Porcelain Aorta	5.6%	2.5%	0.41
BAV	73%	82%	0.21

DW-MRI Findings

	TriGuard N=59	Controls N=83	P value
Incidence of CNS Infarction	72%	92%	0.008
Number of Lesions	3 [0-8]	4.5 [2-10]	0.07
Total DWI volume mm ³ [IQR]	101.4 [0-337]	174 [67-575]	0.04
Average DWI volume mm ³ IQR]	25 [0-8]	43 [18-67]	0.07
Total Volume			
None	27.9%	8.3%	0.008
Small (1-50mm ³)	14%	10%	0.54
Medium (>50-150mm ³)	14%	28%	0.08
Large (>150mm ³)	44%	53%	0.36

TriGuard Pooled Analysis: In hospital Results

MACCE: 18.2% TG vs 24.1% Control, $p=0.44$



- Neuroprotection with TriGuard
 - Is safe
 - Associated with reduced Cerebral Infarction :
 - 40% reduction in volume of brain lesions
 - 28% freedom from any cerebral ischemic lesions
 - Associated with reduced stroke:
 - Reduction in VARC defined Stroke ($p=0.05$)
 - Reduction in new neurologic deficits (0% vs 19%, $p=0.001$) post-procedure by systematic NIHSS assessment and brain imaging
- The pivotal REFLECT RCT is designed to confirm our results.