Final 30-day results of the DEFLECT III trial: a prospective randomised evaluation of the novel embolic protection DEFLECTion device during TAVI

Andreas Baumbach
Bristol Heart Institute
University Hospitals Bristol, UK

For the Deflect Study Group:

J Schofer, D Tchetche, P Stella, C Pietras, H Parise, K Abrams, J Forrest, M Cleman, J Reinöhl, T Cuisset, D Blackman, G Bolotin, S Spitzer, U Kappert, M Gilard, T Modine, D Hildick-Smith, M Haude, P Margolis, A Brickman, S Voros and A Lansky

Potential conflicts of interest

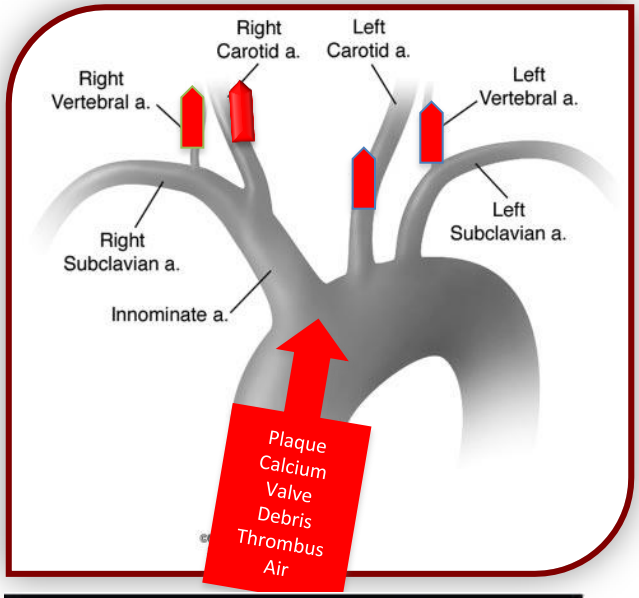
Speaker's name: Andreas Baumbach

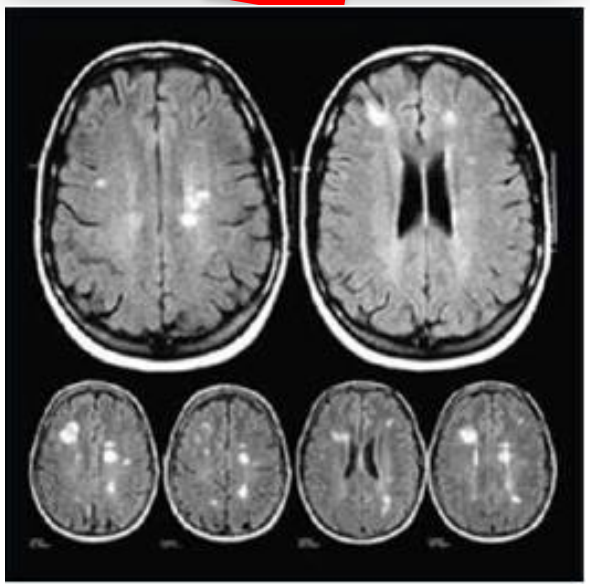
I have the following potential conflicts of interest to report:

Scientific Advisory Board and Research Grants: Keystone Heart

Background

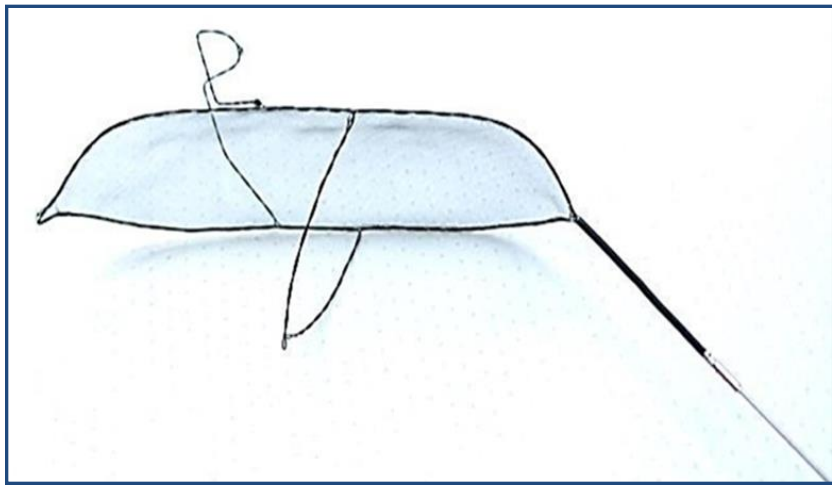
- Stroke is a rare but devastating complication of TAVI
- 50% of events occur periprocedurally
- Clinically ‘silent’ or non-detected strokes are frequent
- New embolic lesions in the brain can be detected in up to 100% of patients following a TAVI procedure
- Embolic events have been linked to neurocognitive decline

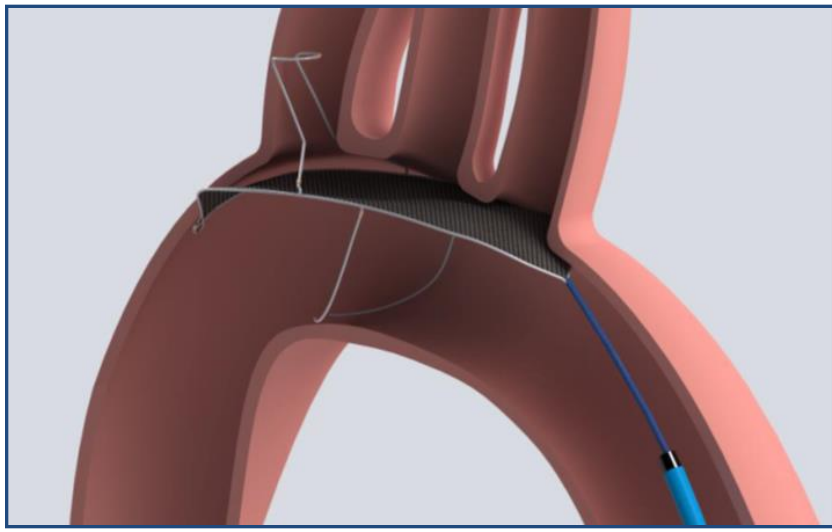




TriGuard Device

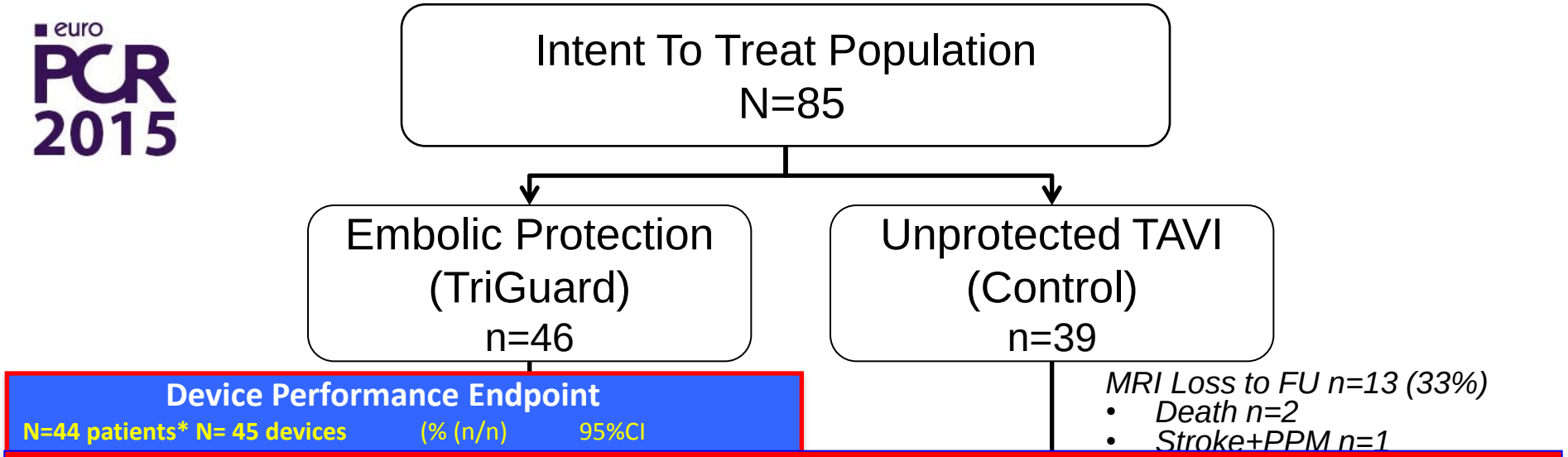
- Single-wire nitinol frame and mesh filter with pore size of 130µm designed to deflect cerebral emboli during TAVI while allowing maximal blood flow
- Positioned across all 3 cerebral vessels and maintained by a stabilizer in the innominate
- Delivered via 9 Fr sheath from the femoral artery





Trial Design and Objectives

- Multicentre (13) randomised controlled trial
- Exploratory trial to benchmark event rates for the design of a definitive clinical trial
- Primary Safety Endpoint: In-hospital mortality, stroke, bleeding, kidney injury 2/3, major vascular complications (VARC2 defined)
- Secondary Device Performance Endpoint
- Secondary Efficacy endpoints: Number and volume of cerebral lesions on DW-MRI and neurological and neurocognitive measures



Device Performance Endpoint

N=44 patients* N= 45 devices (% (n/n) 95%CI

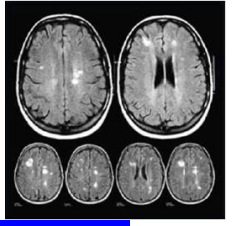
Primary Endpoint: In hospital safety

	TriGuard N:46	Control N:39	
Death:	2.2% (1)	5.1% (2)	p=0.46
Stroke:	4.3% (2)	5.1% (2)	p=0.87
Life threatening bleed:	2.2% (1)	7.7% (3)	p=0.23
AKI (2/3)	2.2% (1)	0%	p=0.91
Major Vascular complication:	17.4% (8)	20.5% (8)	p=0.71

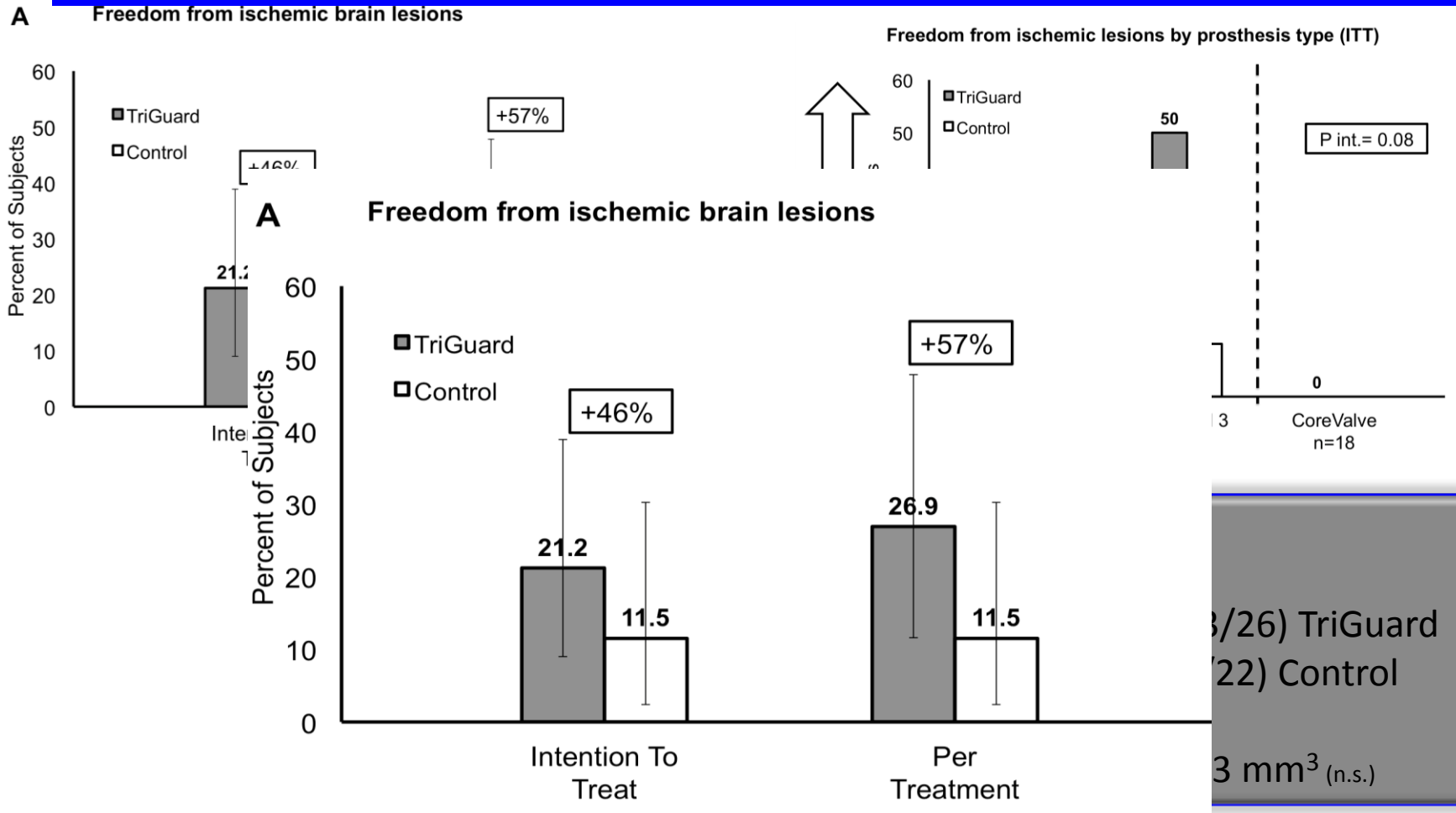
Safety Endpoint 30 Days

	TriGuard N:42	Control N:32	
Death:	2.2% (1)	5.1% (2)	p=0.44
Stroke:	4.3% (2)	5.6%(2)	p=0.83
Life threatening bleed:	4.5% (2)	7.8% (3)	p=0.49
AKI (2/3)	2.2% (1)	0%	p=0.38
Major Vascular complication:	17.4% (8)	20.7% (8)	p=0.69

DW Brain Imaging



Increased rate of pts without any new brain lesion



/26) TriGuard
22) Control

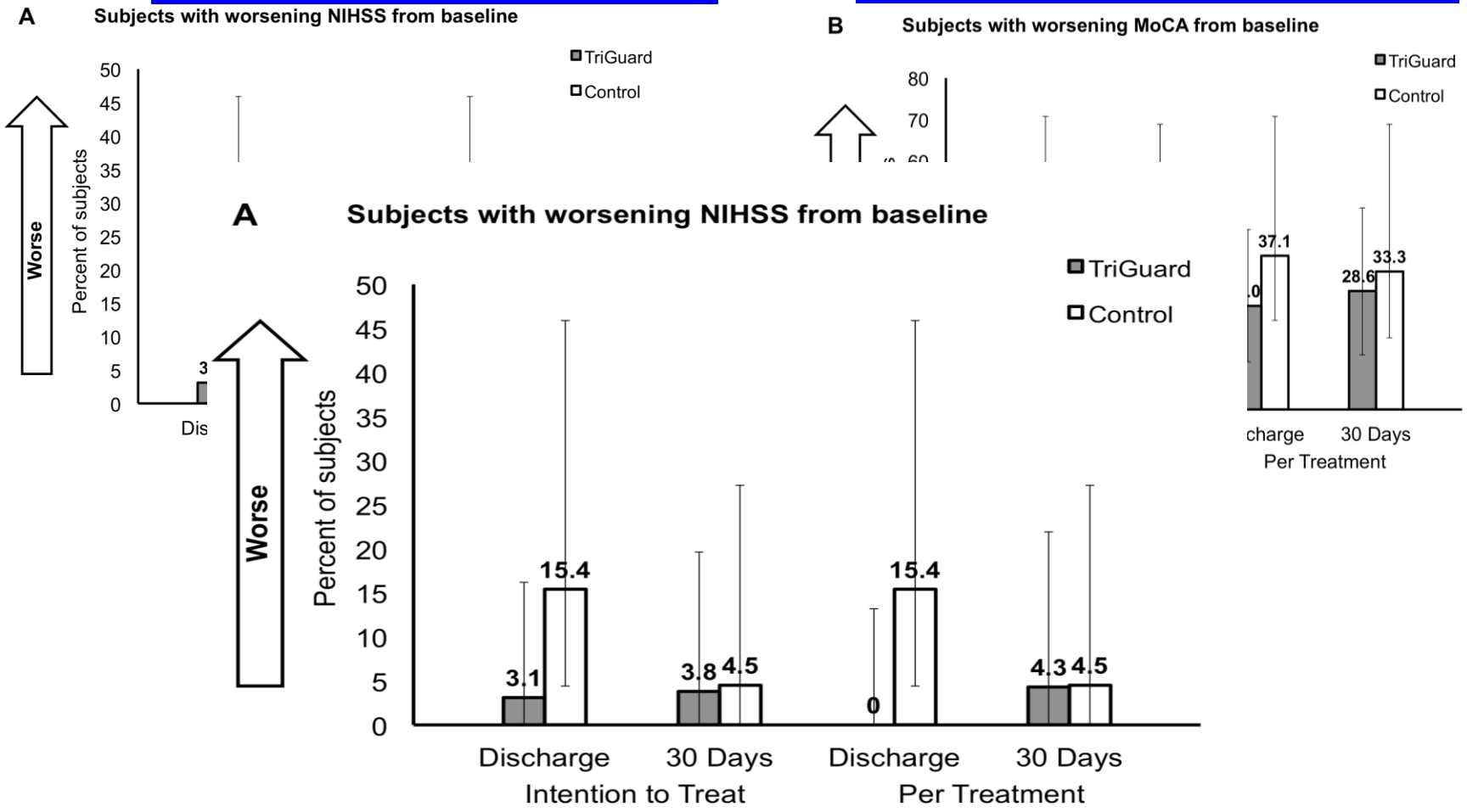
3 mm^3 (n.s.)

mbolic burden
post procedure to 30 days

Results: Neurologic and cognitive

Less new neurological abnormalities with protection

Less reduction of cognitive function with protection



Clinical Implications

- Neuroprotection with TriGuard in DEFLECT III
  - Was safe with complete 3-vessel coverage in 89% of pts
  - Confirms improved DW MRI surrogate measures:
    - > 40% reduction in volume of brain lesions
    - > 45% increased freedom from any cerebral ischemic lesions
  - Provides new evidence of clinical benefit:
    - > 4 fold lower rate of new neurologic deficits (3.1% vs 15.4%) post-procedure by systematic NIHSS assessment
    - 2 fold recovery of cognitive function by MoCA at 30 days
- Neuroprotection is important to reduce the embolic burden in a population with ongoing embolic risk (10% of pts at 30 days)
- The pivotal REFLECT RCT is designed to confirm our results.

Publication today

European Heart Journal
doi:10.1093/eurheartj/ehv191

FASTTRACK to EuroPCR

A prospective randomized evaluation of the TriGuard™ HDH embolic DEFLECTion device during transcatheter aortic valve implantation: results from the DEFLECT III trial


euro
PCR