UB NS University at Buffalo Neurosurgery

Jacobs Institute

Perspective of a Neurosurgeon who treats Stroke

Gates Vascular Institute

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Presenting endorsed statement from
American Association of Neurological Surgeons (AANS)
Cerebrovascular Section of AANS & CNS
Society of Neurointerventional Surgery (SNIS)

TOSHIBA STROKE & VASCULAR RESEARCH CENTER

Kaleida Health
Building a healthier future

University at Buffalo
State University of New York

Strokes Post TAVR Multi-Factorial

Embolic material

-Debris released during the procedure

Atrial fibrillation (new onset)

Hypo-perfusion

Hemorrhage

Preventable Strokes During TAVR

Embolic material released during TAVR

- -Atheromatous Material
- -valve tissue
- -calcium
- -thrombus
- -foreign material

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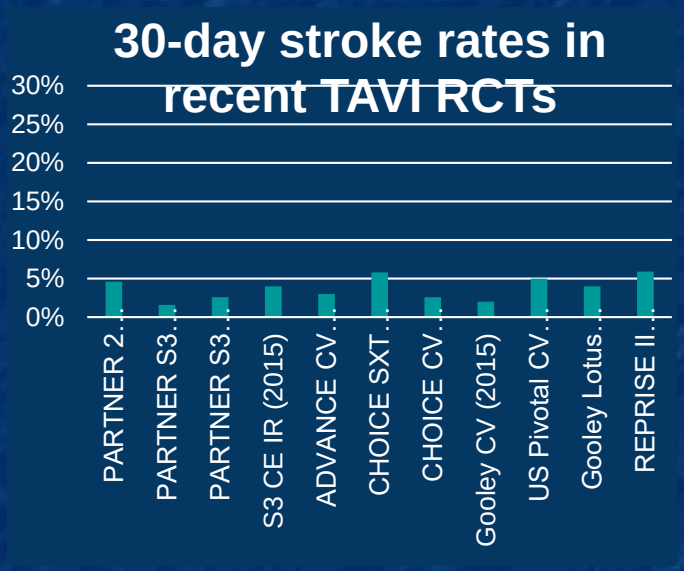
Clinical stroke Post TAVR under-recognized

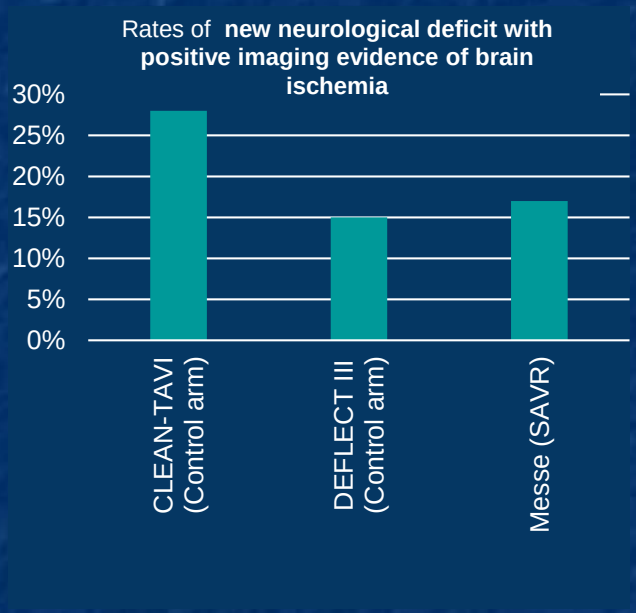
Other Trans Aortic Arch Left Heart Procedures ??

AHA/ASA consensus definition of stroke includes imaging evidence of a CNS infarction with or without acute neurological dysfunction[1]

- Most studies do not use routine MRI imaging post op
- Studies using *discharge* *DETAILED exam by neurologists* report much higher clinical stroke rates[2] (Messé, et al., e.g.)

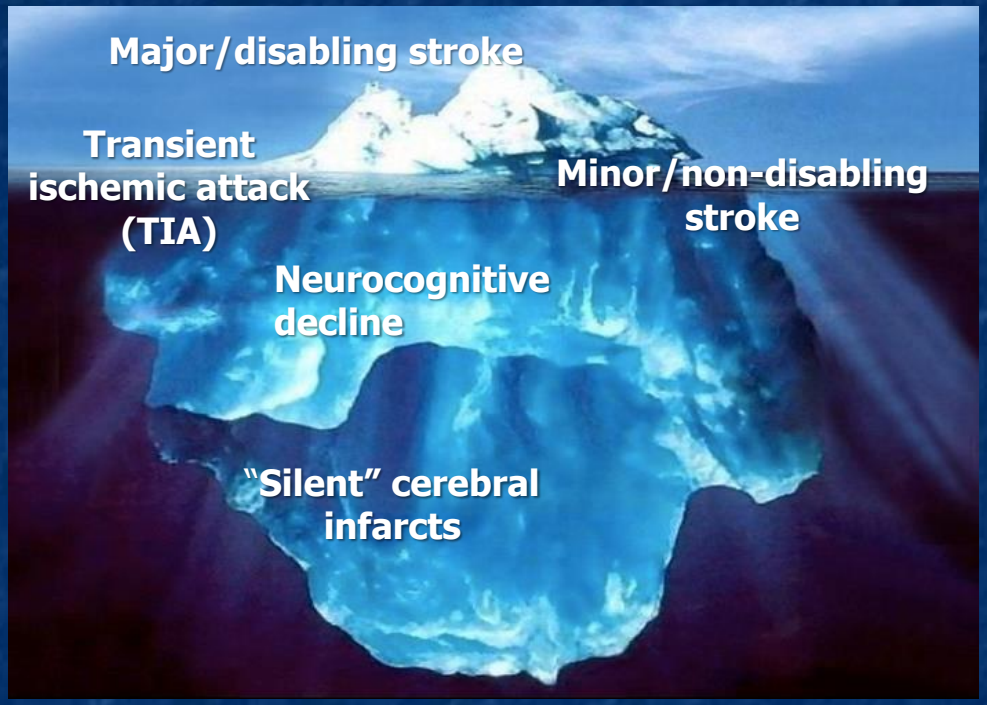


vs.



1. Sacco R, et al., Stroke. 2013;44:2064-2089
2. Messé S, et al., Circulation. 2014;129:2253-2261

Most Ischemic Injury in TAVR Unrecognized



….but can have far-reaching effects

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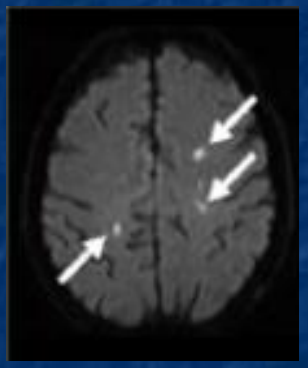
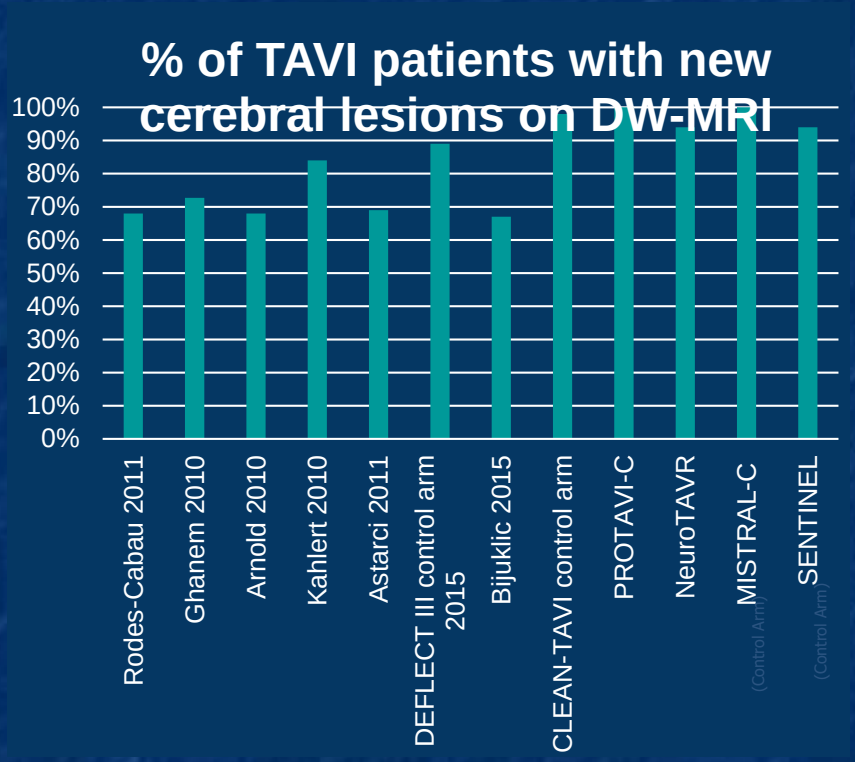
New cerebral lesions found in most patients following TAVR

Mounting evidence MRI lesions associated with delayed problems with cognition



Ghanem et al. JACC 2010

- 68-100% of TAVI patients affected[1-12]
- Most patients have multiple infarcts
- "Silent" infarcts associated with[13-15]
  - 2-4-fold risk of future stroke
  - >3-fold risk of mortality
  - >2-fold risk of dementia
  - Cognitive decline
  - Dementia



1. Rodes-Cabau, et al., JACC 2011; 57(1):18-28
2. Ghanem, et al., JACC 2010; 55(14):1427-32
3. Arnold, et al., JACC:CVI 2010; 3(11):1126 –32
4. Kahlert, et al., Circulation. 2010;121:870-878
5. Astarci, et al., EJCTS 2011; 40:475-9
6. Lansky, et al., EHJ 2015; May 19
7. Bijuklic, et al., JACC: CVI 2015
8. Linke, et al., TCT 2014
9. Vahanian, et al., TCT 2014
10. Lansky, et al., London Valves 2015
11. van Mieghem N, et al. *EuroIntervention* 2016;12:499-507
12. Kapadia, et al., *JACC.* doi:10.1016/j.jacc.2016.10.023.
13. Sacco et al., Stroke 2013
14. Vermeer et al., Stroke 2003
15. Vermeer et al., New Engl J Med 2009

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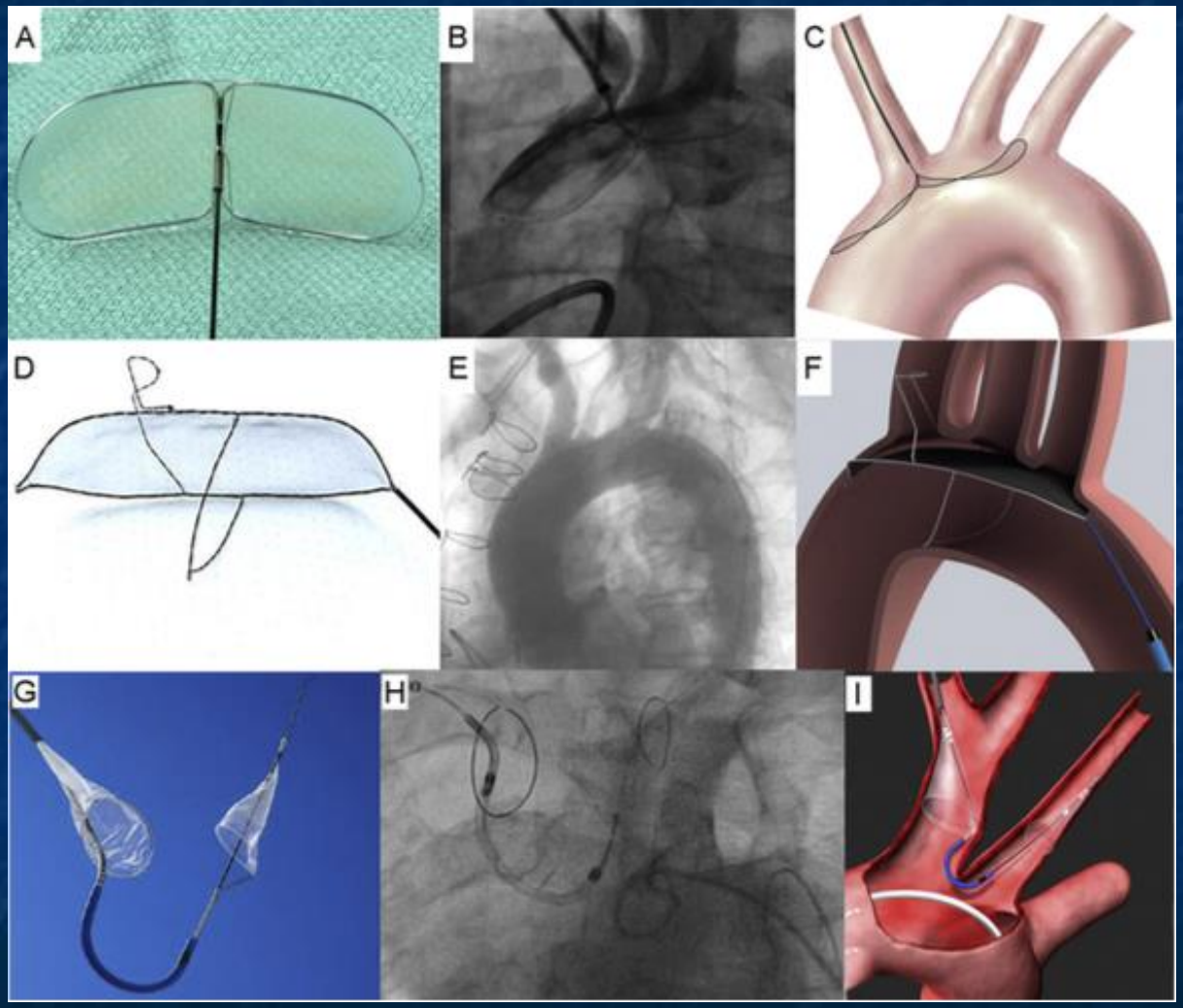
Embolic Protection Filters

Mounting evidence suggests they help



Common Sense

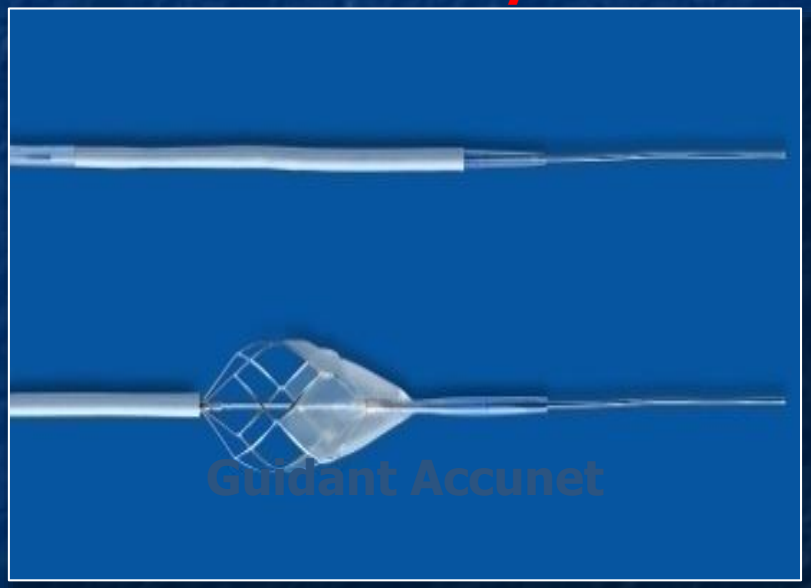
Debris captured in CAS filters 30-60%

Debris captured in TAVR filters 80-99%

Carotid filters captured debris in **57%** of carotid stenting patients in ARCHeR (n=581 patients), including:[1]

- Foam cells, smooth muscle cells, cholesterol, collagen/elastin, platelet/fibrin

EP Mandatory in CAS



1. Gray W, et al. ARCHeR J Vasc Surg 2006;44:258-69

Debris Captured in **99%** of TAVR patients in SENTINEL (n=105 patients), including:[2]

- Arterial wall
- Valve tissue
- Calcification
- Foreign material
- Myocardium
- Organizing and acute thrombus

EP Not Mandatory in TAVR!!???

2. Kapadia S, et al. SENTINEL JACC 2017;69:367–77

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Carotid vs TAVR

Which is which??

CAS

TAVR

TAVR and Stroke

- Subclinical stroke is a serious and under recognized problem
- What are the long-term neurocognitive sequelae to radiographic infarcts on MRI?
- Immediate recognition and restoring flow

Statement Endorsed by

- American Association of Neurological Surgeons (AANS)
- Cerebrovascular Section of AANS and Congress of Neurological Surgeons
- Society of Neurointerventional Surgery (SNIS)

American Association of Neurological Surgeons (AANS) and the Joint Cerebrovascular Section of AANS and Congress of Neurological Surgeons (CNS) and the Society of Neurointerventional Surgery (SNIS) are committed to the prevention, management and recovery from acute ischemic stroke. We are uniquely aware of the inimitable relationship between the brain as an end-organ inherently impacted during therapies carried out in the heart or other antegrade vasculature.

Currently, the endovascular device-based therapeutic options available to treat cerebral infarcts are focused on large vessel occlusions, which are defined arbitrarily as occurring in cerebral arteries with a diameter of greater than 2.5mm. As evidenced by multiple international randomized prospective trials, even in practiced hands the successful extraction of debris in these cases, with a return to a pre-occlusion functional status remains approximately 50%. When treating the smaller strokes with an embolic origin, however, the current standard therapy is I.V. TPA, which has an even more modest success rate depending upon characterization of the debris and the location of the occlusion(s). It should be noted that post-interventional strokes are frequently ineligible for I.V.TPA given systemic use of heparin, fresh arterial puncture or other concurrent invasive procedures.

In instances, such as during transarterial valve replacement (TAVR), where the pathology of the stroke is a 'showering effect' of many small pieces of debris rather than the release of a single large piece of thrombus or calcium, the potential for success is diminished even further. In TAVR procedures, the spectrum of debris is also quite broad ranging from thrombus, arterial, ventricular and valvular tissue to myocardium as well as calcium nodules from the native valves and foreign material from the TAVR catheter. This spectrum of debris besides thrombus is most likely resistant to IV TPA and would otherwise require sophisticated mechanical intervention for removal of tissue. The clinical sequelae include vascular territory ischemia, and subsequent issues of physical, neurological and neurocognitive deficits.

The role of filter-based cerebral protection in the field of TAVR is supported by various studies that demonstrate the safe and effective entrapment and removal from the patient of both micro and macro debris caused by the delivery and deployment of the TAVR system and prosthesis in a heavily calcified aorta and aortic valve. By successfully removing debris before it reaches the brain, this protective technique serves to reduce the incidence of cerebral infarction without significant additional risk or procedure time.

We strongly support developing mechanisms to reduce incident risk of embolic shower to the brain during interventional cardiovascular procedures. We believe that such mechanisms carry the promise of improved neurologic and functional outcomes following these live saving procedures.

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CAS and TAVR Without Embolic Protection